Safety Evaluation Report

Related to the SHINE Medical Technologies, LLC Operating License Application for a Medical Radioisotope Production Facility

Docket No. 50-608

SHINE Medical Technologies, LLC

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Washington, DC 20555-0001

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ABSTRACT

This safety evaluation report (SER) documents the results of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff's technical/safety review of the operating license application submitted by SHINE Medical Technologies, LLC (SHINE, the applicant), as supplemented by the applicant's responses to NRC requests for additional information and as updated on August 31, 2022, for a medical radioisotope production facility in Janesville, Wisconsin. The facility would consist of an irradiation facility (IF) and radioisotope production facility (RPF) for the irradiation and processing of special nuclear material to produce medical radioisotopes, such as molybdenum-99. In turn, the IF would consist of eight subcritical operating assemblies (or irradiation units (IUs)), which would each be licensed as utilization facilities, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.2, "Definitions"; the RPF would consist of hot cell structures and systems, licensed collectively as a production facility, as defined in 10 CFR 50.2. In this SER, the IF and RPF are collectively referred to as the SHINE facility.

The NRC staff's environmental review of the SHINE operating license application is documented in NUREG-2183, Supplement 1, "Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility." A record of decision will be published at a future date concerning the proposed issuance of the operating license.

The NRC's Advisory Committee on Reactor Safeguards (ACRS) independently reviewed those aspects of the application that concern safety and provided the results of its review to the Commission in a report dated December 15, 2022. Appendix D, "Report by the Advisory Committee on Reactor Safeguards," of this SER includes a copy of the report by the ACRS on the SHINE operating license application.

The SHINE operating license application includes a final safety analysis report that describes the SHINE facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole. Based upon the review documented in this SER, the NRC staff finds that: (1) the facility will operate in conformity with the application, as amended, the provisions of the Atomic Energy Act of 1954, as amended, and the rules and regulations of the Commission; (2) there is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public and (ii) that such activities will be conducted in compliance with the Commission's regulations; (3) the applicant is technically and financially qualified to engage in the activities authorized by the operating license in accordance with the Commission's regulations; (4) the applicable provisions of 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements," have been satisfied; and (5) the issuance of the operating license will not be inimical to the common defense and security or to the health and safety of the public.

CONTENTS

The chapter and section layout of this safety evaluation report is consistent with the format of: (1) NUREG-1537, Parts 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors"; (2) interim staff guidance augmenting NUREG-1537, Parts 1 and 2, for licensing radioisotope production facilities and aqueous homogeneous reactors; and (3) the SHINE Medical Technologies, LLC final safety analysis report.

FIGURE

TABLES

APPENDICES

ABBREVIATIONS AND ACRONYMS

°C	degrees Celsius
°F	degrees Fahrenheit
1/M	inverse subcritical neutron multiplication factor
Sccm	standard cubic centimeters per minute
A	ampere
AC	alternating current
ACI	American Concrete Institute
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
ADC	analog to digital converter
AEA	Atomic Energy Act of 1954, as amended
AHR	aqueous homogeneous reactor
AHU	air handling unit
AISC	American Institute of Steel Construction
AL	analytic limit
ALARA	as low as is reasonably achievable
ALI	Annual Limits on Intake
ALOHA	Areal Locations of Hazardous Atmospheres
ANS	American Nuclear Society
ANSI	American National Standards Institute
AOA	area of applicability
APF	assigned protection factor
APL	actuation and priority logic
ARF	airborne release fraction
Ar-41	Argon-41
ASAI	application specific action item
ASCE	American Society of Civil Engineers
ASME	American Society of Mechanical Engineers
ASOS	automated surface observing station
ASTM	American Society for Testing and Materials
BE	best estimate
BF3	boron trifluoride
BOD	board of directors
BVSC	Boiler and Pressure Vessel Code
CAAS	criticality accident and alarm system
CAM	continuous air monitoring
CAMS	continuous air monitoring system
CC1	cooling channel 1
CC2	cooling channel 2
CC3	cooling channel 3
CCDI	control console and display instrument
CCF	common cause failure
CDA	critical digital asset
CDBEM	carbon delay bed effluent monitor
CEO	chief executive officer

CEUS-SSC	Central and Eastern United States - Seismic Source Characterization
CFD	computational fluid dynamics
CFR	*Code of Federal Regulations*
Cfs	cubic feet per second
cm	centimeter(s)
CM	communications modules
COO	Chief Operating Officer
COOP	Cooperative Observer Network
COV	coefficient of variation
CP	construction permit
CSP	criticality safety program
D3	diversity and defense-in-depth
DAC	derived air concentration
DBA	design basis accident
DBE	design basis earthquake
DC	direct current
DCP	double contingency principle
DF	design feature
DID	defense-in-depth
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
EAL	emergency action level
ED	emergency director
EIM	equipment interface module
EIS	environmental impact statement
EMI/RFI	electromagnetic interference/radio-frequency interference
EPA	U.S. Environmental Protection Agency
EPIP	emergency plan implementing procedure
EPRI	Electric Power Research Institute
EPZ	emergency planning zone
ERO	emergency response organization
ESC	emergency support center
ESF	engineered safety feature
ESFAS	engineered safety feature actuation system
FA	fire area
FAA	Federal Aviation Administration
FAT	factory acceptance test
FCHS	facility chilled water system
FCR	facility control room
FCRS	facility chemical reagent system
FDWS	facility demineralized water system
FE	finite element
FEA	finite element analysis
FFIN	failure frequency index number
FHA	fire hazards analysis
FHWS	facility heating water system
ft	foot (feet)
FMEA	failure modes and effects analysis

FMO	fissionable material operation
FNHS	facility nitrogen handling system
FOCD	foreign ownership, control, or domination
FPGA	field programmable gate array
FPP	Fire Protection Program
FPS	fire protection system
FPWS	facility potable water system
FQ	financial qualification
FR	*Federal Register*
FSAR	final safety analysis report
FSDS	facility sanitary drain system
FSTR	facility structure
FVZ4	facility ventilation Zone 4
G_{BE}	best-estimate (mean) soil properties
G_{LB}	lower bound soil properties
G_{UB}	upper bound soil properties
GDC	General Design Criterion (Criteria)
GE	General Electric
gpm	gallon(s) per minute
GWCM	gateway communications module
HAZOPS	hazards and operability
HEC-RAS	Hydrologic Engineering Center's River Analysis System
HEPA	high-efficiency particulate air
HFE	human factors engineering
HIPS	highly integrated protection system
HIPS TR	HIPS technical report
HRA	high radiation area
HSI	human system interface
HVAC	heating, ventilation, and air conditioning
HVPS	high voltage power supply
HWM	hardwired module
HW-SM	hardwired submodule
Hz	hertz
H/U	hydrogen-to-uranium
I&C	instrumentation and control
IAEA	International Atomic Energy Agency
IBC	International Building Code
ICA	internal control area
ICBEP	International Criticality Safety Benchmark Evaluation Project
ICBS	irradiation cell biological shield
ICRP	International Commission on Radiological Protection
ID	inventory difference
IDLH	Immediately Dangerous to Life and Health
IE	initiating event
IEC	International Electrotechnical Committee
IEEE	Institute of Electrical and Electronics Engineers
IF	irradiation facility
IFC	International Fire Code

IMR	Issue Management Report
in.	inches
IPX	iodine and xenon purification and packaging
ISA	integrated safety analysis
ISG	interim staff guidance
ISM	input submodule
ISRS	in-structure response spectra
IU	irradiation unit
JFD	joint frequency distribution
k_{eff}	effective neutron multiplication factor
kg/m^2	kilogram(s) per square meter
km	kilometer(s)
kPa	kilopascal(s)
kV	kilovolt(s)
kVA	kilovoltampere(s)
LABS	analytical testing laboratories
LANL	Los Alamos National Laboratory
lb	pound
LB	lower bound
lb/ft^2	pound(s) per square foot
LCO	limiting condition for operation
LED	light emitting diode
LEU	low-enriched uranium
LIP	local intense precipitation
LOOP	loss of off-site power
LPF	leak path factor
LSSS	limiting safety system settings
LWPS	light-water pool system
m	meter(s)
M	subcritical neutron multiplication factor
MATB	material staging building
MAR	material at risk
M&TE	measuring and test equipment
MBA	material balance area
MC&A	material control and accounting
MCC	motor control center
MCNP	Monte Carlo N-Particle computer code
MEI	maximally exposed individual
MEPS	molybdenum extraction and purification system
MeV	million electron volt(s)
mg	milligram(s)
MHA	maximum hypothetical accident
MHS	material handling system
mi	mile(s)
MIB	monitoring and indication bus
MI-CM	monitoring and indication communications module
MIPF	Medical Isotope Production Facility

MIPS	molybdenum isotope product packaging system
MMS	minimum margin of subcriticality
MMI	Modified Mercalli Intensity
MOU	memorandum of understanding
Mo-99	molybdenum-99
mrem	millirem
mrem/hr	millirem per hour
MUPS	light water pool and primary closed loop cooling make-up system
MWS	maintenance work station
N-16	nitrogen-16
N2PS	nitrogen purge system
NAVD	North American Vertical Datum
NCDC	National Climatic Data Center
NCS	nuclear criticality safety
NCSE	nuclear criticality safety evaluation
NCSP	nuclear criticality safety program
NDA	nondestructive assay
NDAS	neutron driver assembly system
NEC	National Electrical Code
NFDS	neutron flux detection system
NFPA	National Fire Protection Association
NGRS	noble gas removal system
NOAA	National Oceanic and Atmospheric Administration
NPSS	normal electrical power supply system
NRC	U.S. Nuclear Regulatory Commission
OBE	operating basis earthquake
OOS	out-of-service
ORNL	Oak Ridge National Laboratory
ORO	offsite response organization
PA	public address
PAG	protective action guide
PCHS	process chilled water system
PCLS	primary closed loop cooling system
PCMP	project configuration management plan
PTDA	partial trip determination actuation
PEC	passive engineered control
PFBS	production facility biological shield
PHA	preliminary hazard analysis
PICS	process integrated control system
PLDP	programmable logic development plan
PLDS	programmable logic design specification
PMF	probable maximum flood
PMP	probable maximum precipitation
PROP/ECI	proprietary and export-controlled information
PSAR	preliminary safety analysis report
PSB	primary system boundary
psi	pound(s) per square inch
PSP	physical security plan

Pu	plutonium
PVVS	process vessel vent system
QA	quality assurance
QAP	quality assurance plan
QAPD	quality assurance program description
QC	quality control
QL-1	Quality Level 1
RAC	review and audit committee
RAI	request for additional information
RAM	radiation area monitoring
RAMS	radiation area monitoring system
RCA	radiologically controlled area
RCI	request for confirmatory information
RCI	Rock Creek Innovations
RDS	radioactive drain system
rem	roentgen equivalent man
REMP	radiological environmental monitoring program
RF	respirable fraction
RG	regulatory guide
RICS	radiological integrated control system
RISM	remote input submodule
RLWI	radioactive liquid waste immobilization
RLWS	radioactive liquid waste storage
RMS	radiation monitoring systems
RO	reverse osmosis
RP	radiation protection
RPCS	radioisotope production facility primary cooling system
RPF	radioisotope production facility
RPM	Radiation Protection Manager
RTF	Radioiodine Test Facility
RV	radiologically ventilation
RVZ	
RVZ1	radiological ventilation system Zone 1
RVZ1e	radiological ventilation zone 1 exhaust (sub)system
RVZ1r	radiological ventilation zone 1 recirculating (sub)system
RVZ2	radiological ventilation system Zone 2
RVZ2e	radiological ventilation zone 2 exhaust (sub)system
RVZ2s	radiological ventilation zone 2 supply (sub)system
RVZ3	radiological ventilation system Zone 3
RWP	radiation work permit
SAC	specific administrative control
SASS	subcritical assembly support structure
SASSI	Structural Analysis Software System Interface
SAT	systematic approach to training
SBD	safe-by-design
SBM	scheduling and bypass module
SBVM	scheduling, bypass, and voting module
SCAS	subcritical assembly system

SCALE	Standardized Computer Analysis for Licensing Evaluations
SCL	Saint Charles Lineament
SCS	Soil Conservation Service
SDB	safety data buses
SDG	standby diesel generator
SEI	Structural Engineering Institute
SEID	standard of error for the inventory difference
SER	safety evaluation report
SF_6	sulfur hexafluoride
SFG	safety function group
SFM	safety function module
SGS	standby generator system
SHINE	SHINE Medical Technologies, LLC/SHINE Technologies, LLC
SIL2	Software Integrity Level 2
SIXEP	site ion exchange effluent plant
SL	safety limit
SM	source material
SNM	special nuclear material
SPT	standard penetrometer test
SR	surveillance requirement
SRD	shipper–receiver difference
SRM	stack release monitor
SRM	staff requirements memorandum (NRC)
SRWP	solid radioactive waste packaging
SSA	SHINE safety analysis
SSCs	structures, systems, and components
SSE	safe shutdown earthquake
SSI	soil-structure interaction
SSM	supplemental security measure
SVM	scheduling and voting module
SWRA	Southern Wisconsin Regional Airport
SyDS	system design specification
SyRS	system requirements specification
TDA	trip determination actuation
TEDE	total effective dose equivalent
TID	tamper-indicating device
TLU	total loop uncertainty
TOGS	target solution vessel (TSV) off-gas system
TPS	tritium purification system
TRPS	target solution vessel (TSV) reactivity protection system
TRIAD	Transient Reactivity Integration Accelerator Driven Multiphysics Simulation Software
TS	technical specifications
TSPS	target solution preparation system
TSSS	target solution staging system
TSV	target solution vessel
U-233	uranium-233
U-235	uranium-235
U-238	uranium-238

UB	upper bound
UNCS	uranyl nitrate conversion system
UNP	uranyl nitration preparation
UPSS	uninterruptible power supply system
USGS	U.S. Geological Survey
USL	upper subcritical limit
V&V	verification and validation
VAC	volt(s) – alternating current
VDC	volt(s) – direct current
VHRA	very high radiation area
VPE	vice president of engineering
VTS	vacuum transfer system
yr	year

1.0 THE FACILITY

This chapter of the safety evaluation report (SER) is a general introduction to the SHINE Medical Technologies, LLC (SHINE, the applicant) medical radioisotope production facility and an overview of the topics covered in detail in other chapters of this SER, including areas of review, regulatory requirements and guidance, review procedures, and summary and conclusions on principal safety considerations.

1.1 Introduction

This SER documents the results of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff's technical/safety review of the operating license application submitted by SHINE under section 103 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.) (the Act), and Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," for a medical radioisotope production facility in Janesville, Wisconsin. The facility would consist of an irradiation facility (IF) and radioisotope production facility (RPF) for the irradiation and processing of special nuclear material to produce medical radioisotopes, such as molybdenum-99 (Mo-99). In turn, the IF would consist of eight subcritical operating assemblies (or irradiation units (IUs)), which would each be licensed as utilization facilities, as defined in 10 CFR 50.2, "Definitions"; the RPF would consist of hot cell structures and systems, where the irradiated material is processed to separate medical isotopes and where the resulting material is packaged for shipment to customers, licensed collectively as a production facility, as defined in 10 CFR 50.2. In this SER, the IF and RPF are collectively referred to as the SHINE facility. The staff separately performed an environmental review of the SHINE operating license application, and its evaluation and conclusions are documented in an environmental impact statement published as NUREG-2183, Supplement 1, "Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility- Draft Report for Comment" (Agencywide Documents Access and Management System Accession No. ML22179A346). A record of decision will be published at a future date concerning the proposed issuance of the operating license.

The NRC staff previously issued Construction Permit No. CPMIF-001 for the SHINE facility (ML16041A471), in response to a SHINE construction permit application (ML13088A192, ML15258A431, and ML15259A272). The staff's technical/safety and environmental reviews in support of this issuance are NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility Docket Number 50-608" (ML16229A140), and NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility" (ML15288A046), respectively. The issuance was also supported by Commission Memorandum and Order CLI-16-04, dated February 25, 2016 (ML16056A094), and a Summary Record of Decision (ML16041A470). The NRC noticed the issuance of the construction permit in the *Federal Register* (FR) on March 4, 2016 (81 FR 11600).

The SHINE operating license application was filed by letter dated July 17, 2019 (ML19211C143), as supplemented by letters dated November 14, 2019 (ML19331A832), March 27, 2020 (ML20105A294), August 28, 2020 (ML20255A026), November 13, 2020 (ML20325A026), December 10, 2020 (ML20357A084), December 15, 2020 (ML21011A264); March 23, 2021 (ML21095A241), May 7, 2021 (ML21127A051), June 3, 2021 (ML21154A303), July 2, 2021 (ML21183A125), August 31, 2021 (ML21243A266), September 28, 2021 (ML21271A073), September 29, 2021 (ML21272A340), October 15, 2021 (ML21288A050), October 28, 2021 (ML21301A131), November 3, 2021 (ML21307A306), November 22, 2021 (ML21326A205), December 16, 2021 (ML21350A191), December 30, 2021 (ML21364A055); January 27, 2022 (ML22027A353), January 27, 2022 (ML22027A664), January 27, 2022 (ML22027A669), January 28, 2022 (ML22028A221), February 1, 2022 (ML22032A339), February 28, 2022 (ML22059A017), March 9, 2022 (ML22068A217), March 18, 2022 (ML22077A086), March 25, 2022 (ML22084A030), April 4, 2022 (ML22094A045), April 22, 2022 (ML22112A195), May 23, 2022 (ML22143A814), May 24, 2022 (ML22144A231), June 27, 2022 (ML22178A032), July 7, 2022 (ML22188A193), July 21, 2022 (ML22202A448), July 26, 2022 (ML22207A006), August 31, 2022 (ML22249A148), September 28, 2022 (ML22271A962), October 31, 2022 (ML22304A126), November 14, 2022 (ML22318A178), December 1, 2022 (ML22335A572), and December 22, 2022 (ML2235A193).

The NRC staff noticed the receipt and availability of the application in the *Federal Register* on September 10, 2019 (84 FR 47557) and noticed the opportunity to request a hearing and petition for leave to intervene on the application in the *Federal Register* on January 10, 2020 (85 FR 1340).

1.1.1 Areas of Review

For its technical/safety review of the SHINE operating license application, the NRC staff reviewed the final safety analysis report (FSAR) included in the application against applicable regulatory requirements and using appropriate regulatory guidance and standards, as discussed below. The staff evaluated the sufficiency of the SHINE facility description and of the design bases, the limits on facility operation, and the safety analysis of the structures, systems, and components (SSCs) and of the facility as a whole presented in the FSAR. The staff also reviewed the kinds and quantities of radioactive materials expected to be produced in the operation of the facility and the means for controlling and limiting radioactive effluents and radiation exposures within the limits in 10 CFR Part 20, “Standards for Protection Against Radiation.” In addition, the staff reviewed the proposed technical specifications for the facility, the description and plans for implementation of an operator requalification program, the technical qualifications of SHINE to engage in the proposed activities, and the physical security plan. The staff also reviewed the final analysis and evaluation of the design and performance of SSCs with the objective of assessing the risk to public health and safety resulting from operation of the facility.

For its environmental review of the SHINE operating license application, in accordance with section 102(2) of the National Environmental Policy Act of 1969, as amended (42 U.S.C. § 4332(2)), the NRC staff prepared an environmental impact statement (EIS) based on its independent assessment of the information provided by SHINE and information developed independently by the staff. Specifically, in accordance 10 CFR 51.95, “Postconstruction environmental impact statements,” paragraph (b), the staff prepared a supplement to the EIS prepared in connection with the issuance of the construction permit for the SHINE facility, NUREG-2183, updating the prior EIS and only covering matters that differ from those or that reflect significant new information relative to that discussed in NUREG-2183. Upon acceptance of the SHINE operating license application, the staff commenced its environmental review process by publishing in the *Federal Register* on November 27, 2019 (84 FR 65424) a notice of intent to prepare a supplement to NUREG-2183 and to conduct a scoping process. In preparing this supplement, the staff conducted a public scoping meeting in Janesville, Wisconsin, conducted a site audit, reviewed the SHINE operating license application, including SHINE’s supplemental environmental report, consulted with Federal, State, Tribal, and local agencies, conducted a systematic, interdisciplinary review of the potential impacts of the proposed action on the human environment and reasonable alternatives to SHINE's proposal, and considered the public comments received during scoping and on the draft of the supplement, which was published for public comment on July 8, 2022 (87 FR 40868). The staff's review did not identify any information that presented a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility than those presented in the original EIS. The final EIS, published as NUREG-2183, Supplement 1, meets the requirements of 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

1.1.2 Regulatory Requirements and Guidance

The NRC staff reviewed the SHINE FSAR against the following regulatory requirements, as applicable:

- 10 CFR 50.2, "Definitions."
- 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities."
- 10 CFR 50.33, "Contents of applications; general information."
- 10 CFR 50.34, "Contents of applications; technical information."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.50, "Issuance of licenses and construction permits."
- 10 CFR 50.54, "Conditions of licenses."
- CFR 50.57, "Issuance of operating license."
- 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards."
- 10 CFR Part 50, Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities."
- 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."
- 10 CFR 20.1201, "Occupational dose limits for adults."
- 10 CFR 20.1301, "Dose limits for individual members of the public."

In determining the regulatory guidance and standards to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.

- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society standards) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

1.1.3 Review Procedures

The NRC staff’s review was tailored to the nature of the SHINE operating license application and was informed by NUREG-1537 and the ISG augmenting NUREG-1537, as well as other relevant guidance cited therein, cited in the application, or used based on the staff’s technical judgment. The staff considered the final analysis and evaluation of the design and performance of the SSCs of the SHINE facility, including those SSCs shared by both the IF and RPF, with the objective of assessing the risk to public health and safety resulting from operation of the facility.

The NRC staff’s review was also tailored to the unique and novel technology described in the SHINE operating license application. SHINE proposes to operate an IF and an RPF housed within a single building. The IF consists of eight subcritical operating assemblies, each of which would be licensed as a utilization facility, as defined in 10 CFR 50.2. The RPF consists of structures and systems for the separation of Mo-99 from irradiated target solution, plus hot-cell and glove-box structures for processing of irradiated and un-irradiated low-enriched uranium (LEU) materials, licensed collectively as a production facility, as defined in 10 CFR 50.2.

By letter dated February 26, 2021 (ML21057A340), SHINE stated that it intends to pursue a phased approach to startup of the SHINE facility. SHINE stated that this approach consists of four phases of process equipment installation and operation and described the phases. To incorporate its phased approach to startup, SHINE supplemented its operating license application by letter dated January 27, 2022 (ML22027A353,) as supplemented by letters dated May 23, 2022 (ML22143A814), August 31, 2022 (ML22249A148, Enclosure 6 ML22249A143), September 19, 2022 (ML22263A027), and September 20, 2022 (ML22263A344) (hereafter, the SHINE Supplement). The SHINE Supplement describes new or different information from the facility descriptions and analyses provided in the SHINE FSAR resulting from the phased approach to startup. The NRC staff's evaluation of the SHINE Supplement and SHINE's phased approach to startup is discussed separately in appendix A, "Evaluation of the SHINE Medical Technologies, LLC Phased Approach to Startup," of this SER.

1.1.4 Application Availability

Publicly available documents related to the SHINE operating license application may be obtained online in the NRC'S Agencywide Documents Access and Management (ADAMS) Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov.

The current version of the SHINE FSAR, submitted by letter dated August 31, 2022, is publicly available in ADAMS under ML22249A148. Other public documents and correspondence related to the SHINE operating license application may be obtained by searching in ADAMS for the SHINE Docket Number, 50-608, or project number, PROJ0792. Portions of the application or related correspondence containing sensitive information (e.g., proprietary information) are withheld from public disclosure pursuant to 10 CFR 2.390, "Public inspections, exemptions, requests for withholding."

1.1.5 NRC Staff Contact Information

The project manager for this SER was Michael Balazik, Project Manager, Office of Nuclear Reactor Regulation, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Non-Power Production and Utilization Licensing Branch of the U.S. Nuclear Regulatory Commission. Mr. Balazik may be contacted regarding this SER at 301-415-2856 or by email to Michael.Balazik@nrc.gov. Appendix C, "Principal Contributors," of this SER provides a listing of principal contributors, including areas of technical expertise and chapters of authorship.

1.2 Summary and Conclusions on Principal Safety Considerations

The NRC staff reviewed the SHINE FSAR, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. The staff determined, among other things, the sufficiency of the following information in the FSAR:

(1) the general description of the facility;

(2) the design bases, the limits on facility operation, and the safety analysis of the SSCs and of the facility as a whole;

(3) the kinds and quantities of radioactive materials expected to be produced in the operation of the facility and the means for controlling and limiting radioactive effluents and radiation exposures within the limits in 10 CFR Part 20 and as low as is reasonably achievable;

(4) the proposed technical specifications for the facility;

(5) the description and plans for implementation of an operator requalification program;

(6) the technical qualifications of SHINE to engage in the proposed activities;

(7) the physical security plan for the facility;

(8) the final analysis and evaluation of the design and performance of SSCs with respect to assessing the risk to public health and safety resulting from operation of the facility;

(9) the financial qualifications of SHINE to engage in the proposed activities;

(10) the emergency plan for the facility;

(11) the relationship of specific facility design features to the major processes that will be ongoing at the facility, including the building locations of major process components, drawings illustrating the layout of the buildings, and structures within the controlled area boundary; and

(12) the major chemical or mechanical processes involving licensable quantities of radioactive material based, in part, on integrated safety analysis methodology, including the building locations of major process components and brief accounts of the process steps.

Therefore, the applicable regulatory requirements and appropriate regulatory guidance and acceptance criteria are met and the NRC staff makes the following findings:

(1) the facility will operate in conformity with the application, as amended, the provisions of the Act, and the rules and regulations of the Commission;

(2) there is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public and (ii) that such activities will be conducted in compliance with the Commission's regulations;

(3) the applicant is technically and financially qualified to engage in the activities authorized by the operating license in accordance with the Commission's regulations;

(4) the applicable provisions of 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements," have been satisfied;

(5) the issuance of the operating license will not be inimical to the common defense and security or to the health and safety of the public; and

(6) required notifications to other agencies or bodies have been duly made.

1.3 General Description

The NRC staff evaluated the sufficiency of the general description of the SHINE facility, as presented in SHINE FSAR section 1.3, "General Description of the Facility," in part, by reviewing the geographical location of the facility; principal characteristics of the site; principal design criteria, operating characteristics, and safety systems; engineered safety features; instrumentation and control and electrical systems; coolant and other auxiliary systems; radioactive waste management provisions; radiation protection; the general arrangement of major structures and equipment; research and development; and novel facility design considerations using the guidance and acceptance criteria from section 1.3, "General Description of the Facility," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The SHINE facility is located on previously undeveloped agricultural property in Rock County, Wisconsin, in the City of Janesville. SHINE developed a new method for producing Mo-99 using accelerator-driven neutron sources to induce fission in LEU within IUs, creating Mo-99 as a byproduct. The IUs would operate in a batch mode with an approximate week-long operating cycle. Each IU consists of a neutron driver assembly, a subcritical assembly system, a light water pool system, a target solution vessel (TSV) off-gas system, and other supporting systems. The RPF would also operate in a batch mode, and consists of the following processes dedicated to the extraction, purification, and packaging of Mo-99 for end users, as well as preparing the target solution for the IUs:

- Target solution preparation system (TSPS)
- Molybdenum extraction and purification system (MEPS)
- Iodine and xenon purification and packaging (IXP)
- Target solution staging system (TSSS)
- Uranium receipt and storage system (URSS)
- Process vessel vent system (PVVS)
- Radioactive liquid waste storage (RLWS)
- Radioactive liquid waste immobilization (RLWI)
- Vacuum transfer system (VTS)
- Molybdenum isotope product packaging system (MIPS)
- Radioactive drain system (RDS)

In order to produce Mo-99, first, the uranyl sulfate target solution is prepared from recycled materials and/or from raw feed materials in the RPF. The target solution is then transferred to the TSVs within the IF. Once the target solution is in a TSV, the subcritical assembly is operated at full power for approximately 5.5 days, at which time the IU is shut down and the irradiated target solution is transferred to the RPF for radioisotope extraction. Following initial extraction, the Mo-99 is purified and packaged for shipment to customers. The remaining target solution is then prepared for further irradiation in the IUs.

As described in greater detail in subsequent chapters of this SER, the design of the SHINE facility includes engineered safety features to mitigate design basis events or accidents; control and protection systems; an uninterruptable electrical power supply; primary cooling; ventilation; equipment and processes related to handling and storage of target solution, byproduct material, and special nuclear material; a tritium purification system; and fire protection systems. SHINE has a radioactive waste management program and a radiation protection program.

1.4 Shared Facilities and Equipment

The NRC staff evaluated the sufficiency of the evaluation of shared facilities and equipment, as presented in SHINE FSAR section 1.4, "Shared Facilities and Equipment," using the guidance and acceptance criteria from section 1.4, "Shared Facilities and Equipment," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, section 1.4, the NRC staff confirmed that all facilities or equipment shared by the SHINE facility are discussed in the FSAR. The staff verified that the applicant discussed in the FSAR how the normal operating use and malfunctions of the facility could affect the other facilities. The staff also assessed the discussion in the FSAR of the effect of the shared facilities on the safety of the facility.

As stated, in part, in SHINE FSAR section 1.4, "[t]he SHINE facility does not share any systems or equipment with facilities not covered by this report." However, the SHINE facility building includes both the IF and RPF, which, while functionally separate, share some common systems.

The NRC staff finds that all facilities or equipment that will be shared by the SHINE facility represent new construction on previously undeveloped agricultural property. The interface between the IF and RPF, including common systems shared between these facilities, has been adequately analyzed in other chapters in the FSAR.

On the basis of its review, the NRC staff has determined that the level of detail provided on shared facilities and equipment satisfies the applicable acceptance criteria of NUREG-1537, Part 2, section 1.4, allowing the staff to make the following relevant findings:

(1) There are no facilities, systems, or equipment shared by the SHINE facility that are not covered in the SHINE FSAR.

(2) While the SHINE IF and RPF share a common building and several common systems (e.g., cooling and electrical systems), the applicant has shown that a malfunction or a loss of function of either of these facilities would not affect the operation of the other. Neither facility would be damaged as a result of a malfunction or a loss of function of the other and both facilities would maintain the capability to be safely shut down or maintained in a safe condition.

(3) Neither normal operation nor a loss of function of the IF or RPF would lead to uncontrolled release of radioactive material from the licensed facility to unrestricted areas, or in the event of release, the exposures are analyzed in SER chapter 13, “Accident Analyses,” and are found to be acceptable.

Therefore, the NRC staff finds that the evaluation of shared facilities and equipment, as described in SHINE FSAR section 1.4, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

1.5 Comparison with Similar Facilities

The NRC staff evaluated the sufficiency of the comparison of the SHINE facility with other similar facilities, as presented in SHINE FSAR section 1.5, “Comparison with Similar Facilities,” using the guidance and acceptance criteria from section 1.5, “Comparison with Similar Facilities,” of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, section 1.5, the NRC staff confirmed that the characteristics of any facilities compared with the SHINE facility were similar and relevant. The staff also verified that the operating history of licensed facilities cited by the applicant demonstrates consistently safe operation, use, and protection of the public.

As stated, in part, in SHINE FSAR section 1.5.1, “the SHINE facility uses new technology for the manufacture of medical isotopes. The [IU], consisting of the neutron driver, subcritical assembly, light water pool, [TSV] off-gas system (TOGS), and other supporting systems, represents new technology. As such, there are no similar facilities that compare to the IUs.”

One basis of the SHINE facility design is that the IUs will not be operated such that their effective neutron multiplication factor (k_{eff}) is greater than or equal to 1.0, the range for which nuclear reactors are designed, analyzed, and licensed to operate safely. Instead, the IUs will only operate in a subcritical range of k_{eff} that is below 1.0. To maintain this margin of subcriticality, the IUs are designed with several features similar to a nuclear reactor except that, by design, the TSVs have insufficient reactivity to sustain a chain reaction (i.e., to reach a k_{eff} of 1.0 or greater).

While the NRC staff agrees that an IU represents new technology, its accelerator and neutron multiplier add sufficient external neutrons to the TSV such that, although the k_{eff} is below 1.0, a fission rate is achieved with a thermal power level comparable to that of non-power reactors typically licensed under 10 CFR Part 50 as utilization facilities.[1] Given this thermal power, IUs also have many safety considerations similar to those of non-power reactors, including the following:

- Provisions for removal of fission heat during operation

[1] The thermal power levels of non-power reactors currently licensed to operate by the NRC range from 5 watts to 20 megawatts. In the past, the NRC has licensed 12 aqueous homogeneous reactors (AHRs) with thermal power levels ranging from 5 watts to 50 kilowatts. An AHR is similar to the SHINE target solution vessel in that both contain fissile material in an aqueous solution; the difference is that the SHINE target solution vessel has insufficient fissile material for a sustained chain reaction (i.e., to reach a k_{eff} of 1.0 or greater).

- Consideration of decay heat generation after shutdown
- Reactivity feedback mechanisms similar to non-power reactors
- Control of fission gas release during operation and subsequent gas management engineering safety features
- Control of radiolytic decomposition of water and generated oxygen and hydrogen gases
- Control of fission product inventory buildup
- Accident scenarios similar to non-power reactors, such as loss of coolant, reactivity additions, and release of fission products

As such, given that the SHINE IUs have similarities to non-power reactors, which are licensed as utilization facilities under 10 CFR Part 50, the NRC determined that it would be appropriate to license the SHINE IUs as utilization facilities under 10 CFR Part 50. Accordingly, on October 17, 2014 (79 FR 62329), the NRC issued a direct final rule, which became effective December 31, 2014, amending the definition of utilization facility in 10 CFR 50.2 to include the SHINE IUs, so that they could be licensed under 10 CFR Part 50. Therefore, this rulemaking allowed the NRC staff to conduct its licensing review of the SHINE IUs following regulations designed for technologies with similar radiological, health, and safety considerations.

The SHINE RPF consists of hot cells used to process irradiated target solution for Mo-99 separation and purification. According to SHINE FSAR section 1.5.1, "[t]he hot cell design is conventional and is similar to the design used in many other facilities."

Regarding Mo-99 extraction, there are currently no NRC-licensed or U.S. Department of Energy facilities that use SHINE's specific process. However, SHINE cites the Site Ion Exchange Effluent Plant (SIXEP) in the United Kingdom, which uses clinoptilolite to remove cesium and strontium from aqueous process streams, as an example of a facility performing a similar process to SHINE's Mo-99 extraction. SIXEP has been in operation since 1985.

With respect to the Mo-99 purification process, SHINE states that its process is similar to the Cintichem process developed in the 1950s and 1960s by Union Carbide. Cintichem, licensed by the NRC, operated until 1990 as a means to purify Mo-99 for use as a medical radioisotope. The primary difference between SHINE's Mo-99 purification process and that of Cintichem is a slight change in process chemistry to accommodate the change in chemical and isotopic composition due to SHINE's use of LEU instead of the highly enriched uranium used by Cintichem.

SHINE likens its tritium purification system to similar processes conducted at the Savannah River Site and Laboratory for Laser Energetics. However, in FSAR section 1.5.2.3, "Tritium Purification System," SHINE states, in part, that "[d]ue to the sensitive and confidential nature of information relating to tritium production and purification, the design and operational details of these systems are not published. A comparison of the SHINE system with existing facilities is therefore not possible."

On the basis of its review, the NRC staff has determined that the level of detail provided on comparisons with similar facilities satisfies the applicable acceptance criteria of NUREG-1537, Part 2, section 1.5, allowing the staff to make the following relevant findings:

(1) SHINE has compared the design bases and safety considerations with similar facilities, as practicable. The history of these facilities demonstrates consistently safe operation that is acceptable to the NRC staff.

(2) Aspects of SHINE's design that are similar to features in other facilities, which have been found acceptable to the NRC, should be expected to perform in a similar manner when constructed to that design.

(3) SHINE is using test data and operational experience in designing components and SHINE cited the actual facilities with similar components, as practicable.

Therefore, the NRC staff finds that the comparisons with similar facilities, as described in SHINE FSAR section 1.5, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

1.6 Summary of Operations

The NRC staff evaluated the sufficiency of the SHINE summary of operations, as presented in SHINE FSAR section 1.6, "Summary of Operations," using the guidance and acceptance criteria from section 1.6, "Summary of Operations," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, section 1.6, the NRC staff verified that proposed operations of the SHINE facility had been summarized.

In FSAR section 1.6, SHINE listed the major operations to be performed in the SHINE facility as follows:

- Target solution preparation from raw feed material (uranium metal)
- Irradiation of target solution
- Mo-99 extraction from irradiated target solution
- Mo-99 purification
- Target solution adjustments
- Solidification of radioactive liquid waste

As described in SHINE FSAR section 1.6, the uranyl sulfate target solution is prepared from raw feed materials. The target solution is then transferred to the target solution hold tank and then the TSVs within the IF. Once the target solution is in a TSV, the associated neutron driver is energized and the IU is operated at power for approximately 5.5 days, at which time the IU is shut down and the irradiated target solution is allowed to decay. The target solution is then transferred to the RPF for processing. Following initial extraction, the Mo-99 is purified and packaged for shipment.

On the basis of its review, the NRC staff has determined that the level of detail provided for the summary of operations satisfies the applicable acceptance criteria of NUREG-1537, Part 2, section 1.6. The staff also determined that the proposed operating conditions and schedules are consistent with the design features of the SHINE facility and have been found acceptable as described in chapters 4, 5, 6, 7 and 12 of this SER. The proposed operations are also consistent with the relevant assumptions in later chapters of the SHINE FSAR, in which any safety implications of the proposed operations are evaluated. In addition, the proposed operating power levels and schedules are in accordance with the proposed license conditions.

Therefore, the NRC staff finds that the summary of operations, as described in SHINE FSAR section 1.6, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

1.7 Compliance with the Nuclear Waste Policy Act of 1982

The Nuclear Waste Policy Act of 1982 provides that the U.S. government is responsible for the permanent disposal of high-level radioactive waste and spent nuclear fuel, but that the cost of disposal should be the responsibility of the generators and owners of such waste and spent fuel. The NRC staff evaluated the sufficiency of SHINE's compliance with the Nuclear Waste Policy Act of 1982, as presented in SHINE FSAR section 1.7, "Compliance with the Nuclear Waste Policy Act of 1982," using the guidance and acceptance criteria from section 1.7, "Compliance with the Nuclear Waste Policy Act of 1982," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 1.7 states that "[t]he SHINE facility does not produce either high-level nuclear wastes or spent nuclear fuel. Therefore, the Nuclear Waste Policy Act of 1982 is not applicable to this facility." As described in FSAR chapter 11, "Radiation Protection Program and Waste Management," SHINE has identified disposition pathways for all of its identified waste streams.

As defined in 10 CFR 72.3, "Definitions," "Spent nuclear fuel or Spent fuel" means, in part, "fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing." Since SHINE will only be removing its target solution from subcritical assemblies, and will not be constructing and operating a nuclear power reactor from which fuel will be removed, the NRC staff determined that the SHINE facility will not produce spent nuclear fuel. Therefore, since SHINE will not be producing spent nuclear fuel or high-level radioactive waste, the Nuclear Waste Policy Act of 1982 is not applicable to the SHINE facility.

As described in the American Medical Isotopes Production Act of 2012 (42 U.S.C. § 2065(f)), radioactive material resulting from the production of medical radioisotopes that has been permanently removed from a reactor or subcritical assembly, and for which there is no further use, is deemed to be low-level radioactive waste if it is acceptable under federal requirements for disposal as low-level radioactive waste. SHINE will be removing radioactive material resulting from the production of medical radioisotopes in a subcritical assembly. As discussed in chapter 11, "Radiation Protection Program and Waste Management," of this SER, SHINE has committed to following applicable federal, state, and local regulations for managing radioactive wastes. Additionally, SHINE has identified licensed waste disposal sites that can take receipt and dispose of the facility's radioactive waste. For these reasons, the NRC staff determined that the SHINE facility will produce low-level radioactive waste and will not produce high-level radioactive waste. Further, based on SHINE's commitments discussed in chapter 11 of this SER, the staff finds that SHINE's plans for handling radioactive waste demonstrate appropriate consideration of regulatory requirements for the types of waste at the facility.

Therefore, the NRC staff finds that SHINE's description of the applicability of the Nuclear Waste Policy Act of 1982 in section 1.7 of the SHINE FSAR is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

1.8 Facility Modifications and History

The NRC staff evaluated the sufficiency of SHINE's descriptions of facility modifications and history, as presented in SHINE FSAR section 1.8, "Facility Modifications and History," using the guidance and acceptance criteria from section 1.8, "Facility Modifications and History," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 1.8 states that "[t]he SHINE facility described in this report is new construction. There are no existing facilities, there have been no modifications, and there is no history to report. Therefore, this section is not applicable to the SHINE facility."

The NRC staff determined that there are no existing facilities, there have been no modifications, and there is no history to report on the SHINE facility. Accordingly, this section is not applicable to this facility.

Therefore, the NRC staff finds that SHINE's description of facility modifications and history, as described in SHINE FSAR section 1.8, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

2.0 SITE CHARACTERISTICS

The principal purpose of this chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) is to discuss whether the SHINE site is suitable for constructing and operating the SHINE facility.

This chapter of the SER describes the technical review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE irradiation facility (IF) and radioisotope production facility (RPF) regarding site characteristics as presented in chapter 2, "Site Characteristics," of the SHINE final safety analysis report (FSAR) and supplemented by the applicant's responses to staff requests for additional information (RAIs).

Chapter 2, "Site Characteristics," of this SER provides an evaluation of the SHINE site as presented in SHINE FSAR sections 2.1, "Geography and Demography," 2.2, "Nearby Industrial, Transportation, and Military Facilities," 2.3, "Meteorology," 2.4, "Hydrology," and 2.5, "Geology, Seismology, and Geotechnical Engineering."

2.1 Areas of Review

SHINE FSAR sections 2.1 through 2.5 provide the bases for the adequacy of the SHINE site for the construction and operation of the SHINE facility and describe the applicable site characteristics, including geography, demography, meteorology, hydrology, geology, seismology, and relation to nearby installations and facilities.

The NRC staff reviewed SHINE FSAR sections 2.1 through 2.5 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the site for the SHINE facility. The staff's review evaluated the geography and demography of the site; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that the issuance of an operating license would not endanger the public health and safety. The staff's review evaluated structures, systems, and components (SSCs) designed to ensure safe operation, performance, and shutdown when subjected to extreme weather, floods, seismic events, missiles (including aircraft impacts), chemical and radiological releases, and loss of offsite power at the site.

2.2 Summary of Application

As stated above, the SHINE facility consists of the IF (itself consisting of eight irradiation units) and the RPF. Both the IF and the RPF are collocated within a single building on the site.

The SHINE site is on previously undeveloped property in the City of Janesville, Rock County, Wisconsin. The SHINE site is on the south side of the City of Janesville corporate boundaries, and the densely populated parts of the city are more than 1 mile (mi) (1.6 kilometers (km)) to the north.

The SHINE site boundaries encompass approximately 91 acres (36.8 hectares) of land. All safety-related SSCs of the SHINE facility are located within a square area located near the center of the property, referred to as the safety-related area. The center point of the safety-related area has the following coordinates: 42° 37' 26.8" north latitude and 89° 1' 29.7" west longitude. The SHINE site boundary corresponds to the property line around the perimeter of the site. The SHINE operating license would define the owner-controlled area as being delineated by the site boundary.

The distance and direction from the center point of the safety-related area to major nearby features are as follows:

- U.S. Highway 51: < 0.1 mi (0.2 km) west
- Southern Wisconsin Regional Airport: 0.4 mi (0.6 km) west
- Union Pacific Railroad: 1.6 mi (2.7 km) northeast
- Rock River: 1.9 mi (3.1 km) west
- Interstate (I-)90/39: 2.1 mi (3.4 km) east

The finished site grade elevation is approximately 825 feet (ft) (251.46 meters (m)) per the North American Vertical Datum of 1988 (NAVD 88). The SHINE site and adjacent ground within a radius of approximately 1 mi (1.6 km) is generally flat. The tallest building on the SHINE site is the main production facility, which at its highest point is approximately 57 ft (17.4 m) above the site grade level. There is a free-standing 67 ft (20.4 m) high exhaust stack adjacent to the main production facility. The distance from a release point to the site boundary in each of the 16 compass directions, calculated from a circle (radius of 70 m (230 ft)) that envelopes the main production facility, is provided in SHINE FSAR table 2.1-2.

The applicant estimated the resident population distribution surrounding the SHINE site within five distance bands. These bands are represented as concentric circles at 0 to 1 km (0 to 0.6 mi), 1 to 2 km (0.6 to 1.2 mi), 2 to 4 km (1.2 to 2.5 mi), 4 to 6 km (2.6 to 3.7 mi), and 6 to 8 km (3.7 to 5.0 mi) from the center point of the safety-related area. The applicant described the population growth rates used in SHINE FSAR section 2.1.2, “Population Distribution.” The resident population distribution within 8 km (5.0 mi) of the SHINE site is presented in SHINE FSAR table 2.1-4 for the years 2019, 2024, and 2051. The area within 8 km (5.0 mi) of the SHINE site supports a 2019 population estimated to be about 53,000 people. SHINE estimated the 2051 population surrounding the SHINE site at about 73,000 people.

The nearest permanent residence is located approximately 0.50 mi (0.80 km) Northwest of the center point of the safety-related area. There are permanent residences in two other directions that are only slightly farther away; a house located approximately 0.54 mi (0.86 km) north-northwest of the center point and a house located approximately 0.59 mi (0.94 km) to the south-southwest.

In addition to the permanent residents around the SHINE site, there are people who enter this area temporarily for activities such as employment, education, recreation, medical care, and lodging. This data is presented in SHINE FSAR Tables 2.1-5 through 2.1-9. To accurately represent the transient population, the weighted average population is estimated for each directional sector and distance, based on the length of time people are expected to stay at the respective facility. SHINE estimated a 2019 total weighted transient population of about 8,600 people (see SHINE FSAR table 2.1-10).

In SHINE FSAR section 2.2, the applicant identified potential hazards from facilities and transportation routes within the 8 km (5 mi) vicinity of the SHINE site and airports within 16.1 km (10 mi) of the SHINE site. The applicant provided detailed descriptions of these facilities and transportation routes for further consideration of hazards evaluation. There are seven industrial facilities, one major highway, four major roads, two natural gas pipelines, one waterway, three railroads, five airports, four heliports, and eleven airways in this area. There are no major military facilities located within 8 km (5 mi) of the SHINE site, although military aircraft do sometimes utilize the Southern Wisconsin Regional Airport (SWRA).

The descriptions of the industrial and transportation facilities within the vicinity of the SHINE facility are presented in SHINE FSAR section 2.2.1.1, "Descriptions." The information and evaluations with respect to air traffic pertaining to airports and airways within the vicinity of the SHINE facility are presented in SHINE FSAR section 2.2.2, "Air Traffic." The city of Janesville and the city of Beloit Comprehensive Plans do not provide details of any projected or future planned industrial growth.

SHINE FSAR section 2.2.2 discusses air traffic located within 10 mi (16 km) of the SHINE facility (distance from the center of the SHINE facility to the nearest edge of the airway). The applicant also described its analysis of aircraft hazards associated with these airways, including approach and holding patterns near the SHINE facility.

SHINE FSAR section 2.2.3, "Analysis of Potential Accidents at Facilities," describes the analysis of postulated accidents and possible effects that could occur at the SHINE facility, including explosions, flammable vapor clouds, toxic chemicals, and fires. The applicant evaluated potential accidents based on the information compiled for the identified facilities in SHINE FSAR section 2.2.1, "Locations and Routes," using the guidance provided in NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Agencywide Documents Access and Management System Accession No. ML042430048) pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The applicant also used applicable guidance in Regulatory Guide (RG) 1.78, Revision 1, "Evaluating the Habitability of a Nuclear Power Plant Control Room During a Postulated Hazardous Chemical Release" (ML013100014), and Regulatory Guide 1.91, Revision 1, "Evaluation of Explosions Postulated to Occur on Transportation Routes Near Nuclear Power Plants" (ML003740286). The applicant performed an analysis of these accidents to determine whether any of them should be considered as design-basis events (DBEs). The DBEs are defined as those accidents that have a probability of occurrence on the order of magnitude of 10^{-6} per year or greater with potential consequences serious enough to affect the safety of the facility to the extent that the guidelines specified in 10 CFR Part 100, "Reactor Site Criteria," could be exceeded. The following accident categories are considered in selecting DBEs: explosions; flammable vapor clouds (delayed ignition); toxic chemicals; aircraft crashes; and fires.

SHINE FSAR section 2.3 describes the general and local climate, including historical averages and extremes of climatic conditions and regional meteorological phenomena. The SHINE site is located in a region with the Köeppen classification, which is a humid continental climate with warm summers, snowy winters, and humid conditions. The climate features a large annual temperature range and frequent short duration temperature changes. Although there are no pronounced dry seasons, most of the annual precipitation falls during the summer. During the autumn, winter, and spring, strong synoptic scale surface cyclones and anticyclones frequently move across the site region. During the summer, synoptic scale cyclones are usually weaker and pass north of the site region. Most air masses that affect the site region are generally of polar origin; however, air masses occasionally originate from arctic regions or the Gulf of Mexico. Air masses originating from the Gulf of Mexico generally do not reach the site region during winter months. There are occasional episodes of extreme heat or high humidity in the summer. The windiest months generally occur during the spring and autumn. The annual average number of days with thunderstorms varies from approximately 45 days at the southwest corner of the state of Wisconsin, to approximately 35 days at the northeast corner of the state. Hail is most frequent in the southwestern and west central portions of the state, and is most common during summer months, peaking in late July. Tornadoes are relatively infrequent. Winter storms that affect the region generally follow one of three tracks: Alberta, Panhandle, or Gulf Coast. During an average winter, the ground is covered with snow about 60 percent of the time. In addition, the applicant also discussed the potential meteorological effects to the SHINE facility and discussed the dispersion analysis of airborne releases, in both restricted and unrestricted areas, from routine releases during normal operations and from postulated releases resulting from accidents.

In SHINE FSAR section 2.3.1, “General and Local Climate,” the applicant provided a description of the general climate of the region and meteorological conditions relevant to the design and operation of the SHINE facility, including:

- Identification of the region with climate representative of the site
- Regional data sources
- Identification and selection for analysis of weather monitoring stations located within the site climate region
- Extreme wind
- Tornadoes and waterspouts
- Water equivalent precipitation extremes
- Hail, snowstorms, and ice storms
- Thunderstorms and lightning
- Snowpack and probable maximum precipitation
- Design dry bulb and wet bulb temperatures
- Extreme dry bulb temperatures
- Restrictive dispersion conditions
- Air quality
- Climate change

In SHINE FSAR section 2.3.2, “Site Meteorology,” the applicant provided a description of local topography, local meteorological data sources, regional and local wind patterns, atmospheric stability, and the development of joint frequency distributions (JFD) for input to dispersion models.

SHINE FSAR section 2.4.1, “Hydrological Description,” identifies the SHINE site surface water, groundwater aquifers, types of onsite groundwater use, sources of recharge, present known withdrawals and likely future withdrawals, flow rates, travel time, gradients, and other properties that affect movement of accidental contaminants in groundwater, groundwater levels beneath the site, seasonal and climatic fluctuations, monitoring and protection requirements, and manmade changes that have the potential to cause long-term changes in the local groundwater regime.

In SHINE FSAR section 2.4.2, “Floods,” the applicant indicated that flooding near the SHINE site is very unlikely to be caused by local intense precipitation or by the Rock River or the unnamed tributary stream overflowing their banks. The applicant described its analysis of the potential flooding from other natural events, including surges, seiches, tsunami, dam failures, flooding caused by landslides, and effects of ice formation on water bodies. The applicant noted that the Rock River and the unnamed tributary stream are subject to flooding throughout the year. The largest potential for flooding occurs during the spring as a result of precipitation and snow melt. Peak flows occur during the winter and are primarily caused by ice jams.

SHINE FSAR section 2.5.1, “Regional Geology,” describes the regional geology within about 200 mi (322 km) of the SHINE site, including regional physiography and geomorphology; tectonic provinces and structures within the basement rocks; bedrock geology, including stratigraphy, lithology, and structure; magnetic and gravity geophysical anomalies; and surficial geology and glacial history. SHINE FSAR section 2.5.2, “Site Geology,” describes the geologic setting, stratigraphy, and structure within about 5 mi (8 km) of the SHINE site. SHINE FSAR section 2.5.3, “Seismicity,” describes the history of recorded and felt earthquakes in southern Wisconsin and northern Illinois. SHINE FSAR section 2.5.4, “Maximum Earthquake Potential,” describes the historical maximum expected moment magnitude from past earthquakes, and frequency of occurrence. SHINE FSAR section 2.5.5, “Vibratory Ground Motion,” presents an evaluation of the earthquake ground shaking expected at the SHINE site. Because most of the regional geological structures are not considered to be seismically capable, the analysis of earthquake ground shaking at the SHINE site is based on interpolation of the national seismic hazard model. The development of an earthquake ground motion design response spectrum follows the procedures set out in the structural codes and standards applicable to Wisconsin. SHINE FSAR section 2.5.6, “Surface Faulting,” describes the surface faults and folds located in the surrounding region. SHINE FSAR section 2.5.7, “Liquefaction Potential,” describes the soil liquefaction potential within the SHINE site.

2.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 2 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the bases and the information provided by SHINE for the adequacy of the SHINE site for the issuance of an operating license.

2.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE site characteristics are as follows:

- Section 50.34, "Contents of applications; technical information," of 10 CFR paragraph (b), "Final safety analysis report," subparagraph (1), which states:

> All current information, such as the results of environmental and meteorological monitoring programs, which has been developed since issuance of the construction permit, relating to site evaluation factors identified in [10 CFR] part 100 ….

The NRC staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power and testing reactors and, therefore, not applicable to the SHINE facility. However, the staff evaluated SHINE's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1 and Part 2.

2.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.

- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, "References," of this SER.

2.4 Review Procedures, Technical Evaluation, and Evaluation Findings

SHINE FSAR chapter 2 discusses the SHINE site characteristics including the geographical, geological, seismological, hydrological, and meteorological characteristics of the site, the vicinity of the site to present and projected population distributions and industrial and transportation facilities, land use, and site activities and controls. The NRC staff's review of the SHINE site considers site characteristics, design and performance of SSCs, radiation protection and waste management programs, and accident analyses.

The NRC staff performed a review of the technical information presented in SHINE FSAR chapter 2, as supplemented, to assess the sufficiency of the SHINE site characteristics for the issuance of an operating license. The sufficiency of the SHINE site characteristics is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 2.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in section 2.5, "Review Findings," of this SER.

2.4.1 Geography and Demography

The NRC staff evaluated the sufficiency of the applicant's description of the SHINE site characteristics regarding geography and demography, as presented in SHINE FSAR section 2.1, using the guidance and acceptance criteria from section 2.1, "Geography and Demography," of NUREG-1537, Parts 1 and 2, and chapter 2, "Site Characteristics," of the ISG augmenting NUREG-1537, Parts 1 and 2.

2.4.1.1 Site Location and Description

The description in SHINE FSAR chapter 2 of the SHINE facility location in the city of Janesville, Rock County, Wisconsin is used to assess the acceptability of the site. The NRC staff's review covers the following specific areas: (1) specification of the SHINE site location with respect to latitude and longitude, political subdivisions, and prominent natural and manmade features of the area; and (2) maps of the SHINE site area showing the boundaries and zones applicable to project area and owner controlled area and the distance and direction from the center point of the safety-related area to major nearby features such as highways, railways, and waterways in close proximity to the SHINE site. The purpose of the review is to ascertain the accuracy of the applicant's description of the SHINE site for use in independent evaluations of the site boundary, owner-controlled area, the surrounding population, and potential manmade hazards due to nearby facilities.

The applicant addressed the SHINE site location and description in SHINE FSAR section 2.1.1, "Site Location and Description," in which the applicant provided site-specific information related to the SHINE site location and description, including political subdivisions, natural and manmade features, population, highways, railways, waterways, and other significant features of the area.

The NRC staff reviewed the information and site maps presented by the applicant in the FSAR. The staff also performed an independent review of information available in the public domain. Based on its review of the information in the FSAR, and independent confirmatory review of prominent, natural, and manmade features of the area as found in publicly available documentation, the staff finds the information provided by the applicant with regard to the SHINE site location and description adequate.

Based on its review, the NRC staff determined that the level of detail provided on site location and description satisfies the applicable acceptance criteria of NUREG-1537, Part 2, section 2.1, allowing the staff to make the following relevant findings:

(1) The information is sufficiently detailed to provide an accurate description of the geography surrounding the facility.

(2) There is reasonable assurance that no geographic features render the site unsuitable for operation of the facility.

Therefore, the NRC staff concludes that the SHINE facility's geography, as described in SHINE FSAR section 2.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

2.4.1.2 Population Distribution

The NRC staff reviewed the data on the population distribution and future population projections in the SHINE site environs as presented in SHINE FSAR section 2.1.2. The staff's review of the applicant's estimates of the present and projected populations surrounding the SHINE site, including transients, found them to be reasonable and acceptable. The staff estimated population growth rates for Rock County and the cities of Janesville and Beloit, based on US Census data for 2000 and 2010. The staff also independently reviewed the county and city population projections data that is available in the public domain and found the growth rates to be comparable to those estimated by the applicant.

Based on its review, the NRC staff determined that the level of detail provided on population distribution satisfies the applicable acceptance criteria of NUREG-1537, Part 2, section 2.1, allowing the staff to make the following relevant findings:

(1) The demographic information is sufficient to allow accurate assessments of the potential radiological impact on the public resulting from the siting and operation of the facility.

(2) There is reasonable assurance that no demographic features render the site unsuitable for operation of the facility.

Therefore, the NRC staff concludes that the SHINE facility's demography, as described in SHINE FSAR section 2.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

2.4.2 Nearby Industrial, Transportation, and Military Facilities

The NRC staff evaluated the sufficiency of the applicant's description of the SHINE site characteristics regarding nearby industrial, transportation, and military facilities, as presented in SHINE FSAR section 2.2, using the guidance and acceptance criteria from section 2.2, "Nearby Industrial, Transportation, and Military Facilities," of NUREG-1537, Parts 1 and 2, and chapter 2, "Site Characteristics," of the ISG augmenting NUREG-1537, Parts 1 and 2.

2.4.2.1 Locations and Routes

The identification of potential hazards in the SHINE site vicinity covering the description of present and future industrial, transportation, and military installations refers to potential external hazards or hazardous materials that are present or may reasonably be expected to be present during the projected lifetime of the SHINE facility. The purpose of the NRC staff's review of this identification is to determine the adequacy of the information in meeting regulatory requirements and to ensure that all facilities and activities within 5 mi (8 km) are considered in the evaluation of potential hazards. The staff's review covers the following specific areas: (1) the locations of, and separation distances to, transportation facilities and routes, including airports and airways, roadways, railways, pipelines, and navigable bodies of water and (2) the presence of military and industrial facilities, such as fixed manufacturing, processing, and storage facilities.

The NRC staff reviewed the SHINE FSAR information in evaluating potential hazards due to industrial, transportation, and military installations in the SHINE site area.

In SHINE FSAR section 2.2.1, the applicant identified the potential hazard facilities within 5 mi (8 km) of the SHINE site for further analysis based on the U.S. Environmental Protection Agency's Envirofacts Database.

Descriptions of the industrial and transportation facilities other than airports and airways identified within 5 mi (8 km) of the SHINE site are presented in SHINE FSAR section 2.2.1.1.

SHINE FSAR table 2.2-1 provides a concise description of each facility, including its primary function and major products produced or stored. The hazardous chemicals potentially transported on highways within 5 mi (8 km) of the SHINE site are presented in SHINE FSAR table 2.2-5. These highways are U.S. Highway 51 (closest approach of 0.22 mi) and I-90/39 (closest approach of 2.1 mi).

There are three railroad lines within 5 mi (8 km) of the SHINE site: Union Pacific line (closest approach of 1.4 mi (2.3 km) east of the site); Canadian Pacific located on west bank of Rock River (closest approach of 2.0 mi (3.2 km) west of the site); and Wisconsin & Southern Railroad Company on the west bank of Rock River (closest approach of 3.7 mi (4.3 km) north of the site). A single railroad tank car has a maximum capacity of 30,000 gallons.

Natural gas distribution pipelines located within 5 mi (8 km) of the SHINE site are presented in SHINE FSAR table 2.2-2. Alliant Energy operates two main natural gas pipelines—one located at approximately 2.6 mi (4.2 km) east of the site at its closest approach and the other located at approximately 2.5 mi (4.5 km) south of the site at its nearest approach. A gas feeder line at 0.3 mi (0.48 km) is located just west of U.S. Highway 51. ANR Natural gas operates a natural gas distribution pipeline approximately 3.6 mi (5.8 km) northeast of the site at its closest approach.

The airports within 10 mi (16 km) of the SHINE site are listed in SHINE FSAR table 2.2-3. There are four airports or heliports within 5 mi (8 km) and six airports or heliports within between 5 and 10 mi (8 and 16 km), of which one has not been in operation since 1991. There are 10 low altitude airways and one jetway located within 10 mi (16 km) of the SHINE site and they are identified in SHINE FSAR table 2.2-4. Considerable industrial growth is not projected in the area based on city comprehensive plans.

As discussed above, the applicant presented the detailed information to establish the identification of facilities that may have a potential for hazards in the SHINE site vicinity. The NRC staff reviewed the information presented by the applicant and determined that the applicant, using the applicable guidance, provided reasonable and appropriate information with respect to the identification of potential hazards in the SHINE site vicinity. The nature and extent of activities involving potentially hazardous materials that are conducted at nearby industrial, military, and transportation facilities that have the potential for adversely affecting SHINE facility safety-related SSCs are identified.

Based on its review of the information in the SHINE FSAR, as well as information obtained independently from the public domain, the NRC staff concludes that the potentially hazardous activities on site and in the vicinity of the SHINE facility have been identified and are reasonable and acceptable.

2.4.2.2 Air Traffic

There are four airports or heliports within 5 mi (8 km) and six airports or heliports within between 5 mi (8 km) and 10 mi (16 km) of the SHINE site. The majority of the airports/heliports have only sporadic activity. SHINE FSAR table 2.2-3 lists the airports within 10 mi (16 km); SHINE FSAR figure 2.2-2 identifies the airports within 10 mi (16 km). There are no military airports or training routes located within 10 mi (16 km) of the SHINE site.

<u>Airways</u>

There are 10 low altitude airways and one jetway located within 10 mi (16 km) of the SHINE site, which are identified in SHINE FSAR table 2.2-4. Since no screening criterion is provided in NUREG-1537, NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: [Light-Water Reactor] Edition,” section 3.5.1.6, Revision 4, “Aircraft Hazards” (ML100331298), guidance is used for the evaluation of aircraft hazards. Three low altitude airways and one jetway located within 10 mi (16 km) of the SHINE site were identified as having an edge of the airway within 2 mi of the SHINE site and the hazards associated with these airways were evaluated in SHINE FSAR section 2.2.2.5.1, “Evaluation of Airways.” Three airports have holding patterns near the SHINE site; however, the distance from the edge of each holding pattern to the site is greater than the 2 mi screening criterion in NUREG-0800, section 3.5.1.6 and, therefore, this hazard screens out.

<u>Evaluation of the Aircraft Hazards</u>

The non-airport crash impact frequency evaluation from airways is determined by using a four-factor formula outlined in the U.S. Department of Energy (DOE) Standard-3014-96, “Accident Analysis for Aircraft Crash into Hazardous Facilities.” The SWRA and three heliports are within 5 mi (8 km) of the SHINE site. A probabilistic hazard analysis was performed by the applicant for the SWRA. The three heliports have sporadic activity, and their evaluation is considered by the applicant to be bounded by the evaluation performed for the SWRA. Therefore, only the SWRA is evaluated for the potential aircraft hazard by the applicant.

The potential impact probabilities for small non-military aircraft, large non-military aircraft, and military aircraft from airports are provided in SHINE FSAR table 2.2-9. Also included are the effects from increased traffic due to potential future air shows. The risk of an aircraft accident is considered acceptable if the frequency of occurrence is less than 1E-6 per year. The calculated crash probability for small non-military aircraft (3.92 E-4 per year) does not meet the acceptance criterion of 1E-6 per year. The combined probability (3.09E-7 per year) of all other aircraft crashes meets the acceptance criterion of 1E-6 per year. Therefore, the safety-related SSCs of the SHINE facility credited to prevent a radiological release in excess of regulatory limits are designed to withstand the impact of a small non-military aircraft, as discussed and addressed in SHINE FSAR section 3.4.2, “Seismic Analysis of Facility Structures.” The NRC staff evaluation of the SHINE safety-related SSCs is discussed in chapter 3, “Design of Structures, Systems, and Components,” of this SER.

2.4.2.3 Analysis of Potential Accidents at Facilities

The NRC staff’s evaluation of potential accidents considers the applicant’s probability analyses of potential accidents involving hazardous materials or activities on the SHINE site and in the vicinity of the SHINE site to confirm that appropriate data and analytical models were used. The review covers the following specific areas: (1) hazards associated with nearby industrial activities, such as manufacturing, processing, or storage facilities and (2) hazards associated with nearby transportation routes (i.e., highways, railways, navigable waters, and pipelines). Each hazard review area includes consideration of the following principal types of hazards:

- Overpressure resulting from explosions or detonations involving materials such as munitions, industrial explosives, or explosive vapor clouds resulting from the atmospheric release of gases (such as propane, hydrogen and natural gas, or any other gas) with a potential for ignition and explosion;

- Missile effects attributable to mechanical impacts, such as aircraft impacts, explosion debris, and impacts from waterborne items such as barges;

- Toxic vapors or gases and their potential for incapacitating control room operators; and

- Thermal effects attributable to fires.

The NRC staff reviewed the information presented by the applicant in SHINE FSAR section 2.2.3 pertaining to potential accidents, and reviewed the applicant’s responses to RAIs, as discussed below. The staff’s review confirmed that the applicant addressed the required information in the FSAR relating to the evaluation of potential accidents.

The NRC staff reviewed SHINE FSAR section 2.2.1, containing information related to industrial, military, and transportation facilities and routes to establish the presence and magnitude of potential external hazards that include the accident categories, such as explosions, flammable vapor clouds (delayed ignition), toxic chemicals, and fires, addressed in SHINE FSAR section 2.2.3.

Explosions

The applicant considered hazards involving potential explosions resulting in blast overpressure as a result of detonation of explosives, munitions, chemicals, liquid fuels, and gaseous fuels that are processed, stored, used, or transported near the SHINE site. The allowable and actual distances of potential hazardous explosive chemicals transported or stored are determined based on using 1 pound per square inch (psi) overpressure as a criterion for adversely affecting SHINE facility operation or preventing safe shutdown of the facility. In accordance with RG 1.91, peak positive incident overpressures below 1 psi are considered to cause no significant damage.

The chemicals stored at nearby facilities and chemicals transported by roadways and railways near the SHINE site are presented in SHINE FSAR table 2.2-15 along with the respective chemical quantity and distance from the SHINE site. These chemicals are evaluated by the applicant and the results are summarized in SHINE FSAR table 2.2-16. The applicant's analysis included 1,258,091 pounds (lb) diesel fuel storage, 440,000 lb ethylene oxide by rail transport, 133,946 lb gasoline storage, 79,968 lb jet fuel storage, 50,000 lb each of diesel fuel, ethylene oxide, gasoline, and propane by truck transport, and 3,300 lb hydrogen by truck transport. The applicant determined either that the minimum safe distance to reach 1 psi overpressure due to potential explosion from each chemical source is less than the actual distance from the source to the center of the SHINE site or that the quantity of each chemical source is less than the quantity of chemical required to produce 1 psi at a chemical source distance from the center of the SHINE site. Based on this analysis, the applicant concluded that potential explosions would not adversely affect the operation of the SHINE facility.

The NRC staff's calculations confirmed the applicant's results with the exception of three chemicals: ethylene oxide, propane, and hydrogen. For an ethylene oxide tanker truck carrying 50,000 lb travelling on U.S. Highway 51 at a distance of 0.22 mi (0.35 km) from the SHINE facility, the staff finds that the minimum safe (standoff) distance exceeds the actual distance of 0.22 mi (0.35 km). Although the staff's analysis found that the minimum safe distance exceeds the actual distance, the staff finds that the applicant's evaluation is acceptable because it is bounded by a potential explosion of a storage tank of 440,000 lb at a distance of 2 mi (3.2 km) from the facility. For propane and hydrogen, the applicant analyzed only an unconfined explosion scenario with a yield factor of 0.03. However, there is vapor in the tank that could explode as a confined vapor with a 100 percent yield factor. The staff's analysis found that this scenario results in a minimum safe distance that exceeds the actual road-way distance of 0.22 mi (0.35 km) for both propane and hydrogen. In response, by letter dated January 29, 2021(ML21029A101), Enclosure 1 (ML21029A103), the applicant clarified its methodology and justified the rationale applied in its analysis. The staff finds the applicant's response reasonable and acceptable.

Flammable Vapor Clouds (Delayed Ignition)

Flammable gases in the liquid or gaseous state can form an unconfined vapor cloud that could drift toward the SHINE facility before ignition occurs, and then could burn or explode when the vapor concentration is within flammable range. For those chemicals with an identified flammability range, an air dispersion model based on the methods and equations in RG 1.78 and NUREG-0570, "Toxic Vapor Concentrations in the Control Room Following a Postulated Accidental Release" (ML063480551), was used to determine the distance that the vapor cloud could travel before the concentration is less than the lower explosive level (LEL). Chemicals listed in SHINE FSAR table 2.2-15 were evaluated by the applicant to ascertain which hazardous chemical materials had the potential to form a flammable vapor cloud or vapor cloud explosion. For those chemicals with an identified flammability range, the Areal Locations of Hazardous Atmospheres (ALOHA) air dispersion model was used to determine the distances where the vapor cloud may exist between the upper explosive level and the LEL, thus presenting the possibility for potential explosion and thermal radiation effects. The chemicals were also evaluated for potential vapor cloud explosion. The ALOHA model was used to model the worst-case accidental vapor cloud explosion, including the standoff distances and overpressure effects at the nearest SHINE safety-related area. The standoff distance was measured as the distance from the spill site to the location where the pressure wave is at 1 psi overpressure consistent with guidance in RG 1.91 that defines the standoff distance. The analyzed effects of flammable vapor clouds and vapor cloud explosions from onsite and offsite sources are summarized in SHINE FSAR table 2.2-17. The applicant determined that the distances to LEL for both ethylene oxide and propane transported by truck on U.S. Highway 51 exceeded the distance from U.S. Highway 51 to the SHINE facility (0.22 mi (0.35 km)). Therefore, the applicant performed probabilistic analyses to determine the number of shipments required to equal the acceptable probability of 1×10^{-6} per year. The applicant determined that the required number of annual ethylene oxide and propane shipments would be 99 and 404, respectively. Based on information collected from end users of these chemicals, the applicant concluded that the actual number of annual shipments of these chemicals on U.S. Highway 51 is much less than the determined maximum number of shipments associated with the probability of 1×10^{-6} and, therefore, that the potential adverse impact on the operation of the SHINE facility is low.

The NRC staff's independent confirmatory calculations also identified the same two chemicals, ethylene oxide and propane, as having a distance to LEL in excess of the actual distance from U.S. Highway 51 to the SHINE site. The staff reviewed the applicant's probabilistic approach in back calculating the number of shipments of each chemical required to meet the acceptance criterion of 1×10^{-6} per year to demonstrate that the actual number of shipments, based on information and transportation data, is far less than the determined maximum acceptable number of shipments. Based on its review of the applicant's information as well as its independent assessment, the staff determined that the information provided in the SHINE FSAR is reasonable and acceptable and satisfies the appropriate guidance.

Toxic Chemicals

The applicant considered the hazards due to potential accidents involving the release of toxic or asphyxiating chemicals from nearby facilities, transportation, and onsite sources that may have a potential for impact on the SHINE site. These hazards include chemicals stored, used, or transported near the SHINE site. The list of toxic chemicals within 5 mi (8 km) that were evaluated by the applicant is presented in SHINE FSAR table 2.2-19. Chemicals transported by truck were modeled as a release of 50,000 lb of the chemical, except for chlorine and sodium bisulfite. Chlorine is shipped in 150-lb cylinders, one-ton containers, cargo tankers of 15-22 tons, and up to 90-ton rail cars. The maximum amount of chlorine at one site is 900 lb. The potential release of chlorine transported on U.S. Highway 51 is from the failure of one 150-lb cylinder. Chlorine releases on I-90/39 were considered for standard size shipment containers (one ton (2,000 lb)) and 22-ton (44,000 lb) cargo tankers. Sodium bisulfite was modeled as a 15,000 lb release (maximum inventory size) for truck transport on U.S. Highway 51. Of the applicant's analysis of chemicals listed in SHINE FSAR table 2.2-19, only four chemicals—ammonia (50,000 lb) from U.S. Highway 51, chlorine (44,000 lb) from I-90/39, propylene oxide (50,000 lb) from I-90/39, and sodium bisulfite (15,000 lb) from U.S. Highway 51—were found to exceed the respective chemical's Immediately Dangerous to Life and Health (IDLH) concentrations at the SHINE site. As such, these four chemicals were identified by the applicant to be a potential hazard to the habitability of the control room. These four chemicals were further evaluated using probabilistic analysis to demonstrate that their release probability meets the acceptable criterion of 1 x 10^{-6} per year or lower. Based on the review of the applicant's probability calculations, the NRC staff considers the estimated release probabilities of these four chemicals reasonable and acceptable.

The NRC staff's independent confirmatory analysis of the toxic chemicals listed in SHINE FSAR table 2.2-19 identified five more toxic chemicals that have the potential to be hazardous to the habitability of the control room, which are: ethylene oxide from U.S. Highway 51, gasoline from U.S. Highway 51, vinylidene chloride from rail (1.6 mi), sodium hypochlorite from I-90/39, and carbon monoxide from a stationary source. The concentration of each of these chemicals exceeds respective IDLH concentrations of chemicals in the control room. Therefore, the staff requested via an RAI that the applicant justify and demonstrate why these five chemicals were excluded from further consideration. By letter dated January 29, 202 (ML21029A101), the applicant addressed these chemicals with a clarified methodology and approach to justify the rationale applied in the analysis. The staff finds the applicant's response reasonable and acceptable.

In SHINE FSAR section 2.2.3.1.3.4, "On-Site Chemicals," the applicant addressed onsite toxic chemicals by stating that they are evaluated in SHINE FSAR section 13b.3, "Analyses of Accidents with Hazardous Chemicals" (SHINE FSAR table 13b.3-2). The applicant also stated that worker exposures are representative of exposures to control room personnel. Based on its review of the analyses and results, the NRC staff determined that the evaluation methodology used is different than what is used in SHINE FSAR section 2.2.3.1.3, "Toxic Chemicals." Using methodology consistent with what is used in SHINE FSAR section 2.2.3.1.3 (i.e., wind speed 1 meter per second (m/s) and F stability; using IDLH concentration limiting value), the staff determined the chemicals ammonia, nitric acid, and sodium hydroxide to be a potential hazard to the habitability of the control room as each of their concentrations exceed their respective chemical IDLH concentrations. By letter dated January 29, 2021, the applicant revised SHINE FSAR section 2.2.3.1.3.4. Bulk chemical storage is provided in the storage building, as described in SHINE FSAR section 9b.7.10, "Facility Chemical Reagent System." The location of the storage building relative to the main production facility is identified in SHINE FSAR figure 1.3-3. The distance from the north side of the storage building to the ventilation air intake for the main production facility is approximately 233 ft (71 m). Chemicals that are stored in bulk in the storage building are identified in SHINE FSAR table 2.2-20. The applicant's analysis determined the limiting quantity of a solution spill that could result in exceeding the toxicity limits in the control room. The limiting quantity of each chemical determined to pose a potential hazard to the habitability of the control room is provided in SHINE FSAR table 2.2-20. The applicant stated that the maximum container size used for the storage of each of these chemicals in the storage building is less than the determined limiting quantities. Therefore, the applicant concluded that these onsite stored chemicals do not pose a threat to control room habitability. The staff finds the applicant's response reasonable and acceptable.

<u>Fires</u>

Fires in adjacent industrial plants, storage facilities, oil and gas pipelines, and from transportation accidents were evaluated by the applicant as events that could lead to high heat fluxes. Three types of fires were analyzed for high heat flux: boiling liquid expansion vapor explosion (BLEVE) fireballs, pool fires, and jet fires. A BLEVE fireball occurs when a tank containing a flammable liquified gas bursts resulting in a flash fire. The energy released causes the flammable gas to ignite causing a large fireball. A BLEVE fireball has a high heat flux, but a short duration. Pool fires occur when a chemical that is liquid at standard conditions spills and catches fire. A jet fire occurs when a pipeline ruptures or a pressurized tank has a hole causing the continuous release of flammable gas.

The applicant considered the tank rupture of a truck containing 50,000 lb (22,679 kg) of liquified propane as the limiting BLEVE fireball on U.S. Highway 51 at a distance of 0.22 mi (0.35 km) from the SHINE facility. The estimated heat flux is 10.8 kilowatts per square meter (kW/m^2) with a fireball duration of 11 seconds (sec). This would cause a temperature rise on a concrete wall surface of 32.4 degrees Fahrenheit (°F). This is not a significant rise compared to the requirements for short and long-term maximum concrete temperature.

The applicant considered the limiting pool fire from a gasoline truck containing 50,000 lb (22,679 kg) on U.S. Highway 51 at a distance of 0.22 mi (0.35 km) from the SHINE facility. The estimated maximum heat flux is 2.92 kW/m^2 lasting for about 53 sec. This would cause a temperature rise on a concrete wall surface of 43.2°F. This is not a significant rise compared to the requirements for short and long-term maximum concrete temperature.

The applicant evaluated the limiting offsite jet fire from the feeder pipeline at 0.28 mi (0.45 km) from the SHINE facility. The applicant used the ALOHA computer program and estimated the maximum heat flux to be 0.011 kW/m^2, which is negligible compared to a typical solar heat flux of 1 kW/m^2. This is well below a heat flux of 5 kW/m^2, which could cause 2^{nd} degree burns in 60 sec and could cause deterioration of plastic casing of electrical cables. As the determined heat flux is negligibly small, it is not considered a threat to the facility.

The applicant evaluated the limiting onsite jet fire from the 3-inch (in.) pipeline that feeds the SHINE facility. The applicant used the ALOHA computer program and estimated the maximum heat flux to be 0.0565 kW/m^2, which is negligible compared to a typical solar heat flux of 1 kW/m^2 and, therefore, is not considered a threat to the facility.

Based on its review of the applicant’s information and its independent confirmatory analysis, the NRC staff determined that the applicant’s evaluation is reasonable and that the applicant’s conclusion of no adverse impact is acceptable.

The NRC staff reviewed the information provided and, for the reasons discussed above, concludes that the applicant provided adequate and reasonable information that establishes that the site characteristics and design parameters are acceptable to meet the applicable regulatory requirements and guidance for the issuance of an operating license.

2.4.3 Meteorology

The NRC staff evaluated the sufficiency of the applicant’s description of the SHINE site characteristics regarding meteorology, as presented in SHINE FSAR section 2.3, using the guidance and acceptance criteria from section 2.3, “Meteorology,” of NUREG-1537, Parts 1 and 2, and chapter 2, “Site Characteristics,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

2.4.3.1 General and Local Climate

SHINE FSAR section 2.3.1 provides a description of the general climate of the region and the meteorological conditions relevant to the design and operation of the SHINE facility.

The NRC staff reviewed SHINE FSAR section 2.3.1 to ensure that the application represents the complete scope of information relating to general and local climatology. The staff's review confirmed that the application addresses the required information relating to the preceding subject matter.

In SHINE FSAR section 2.3.1, the applicant provided information regarding regional climatic conditions and the occurrence of meteorological phenomena (including both averages and extremes) that could potentially affect the operating bases of SSCs for the SHINE facility.

2.4.3.1.1 Regional Climate

The applicant stated that the SHINE site is located in south-central Wisconsin, which has a humid continental climate with warm summers, snowy winters, and humid conditions. The applicant stated that the climate features a large annual temperature range, frequent short duration temperature changes and, although there are no pronounced dry seasons, most of the annual precipitation falls during the summer. During the autumn, winter, and spring, strong synoptic scale surface cyclones and anticyclones frequently move across the SHINE site region. During the summer, synoptic scale cyclones are usually weaker and pass north of the SHINE site region. The applicant stated that most air masses that affect the site region are generally of polar origin; however, air masses occasionally originate from arctic regions or the Gulf of Mexico. The applicant noted that there are occasional episodes of extreme heat or high humidity in the summer and that the windiest months generally occur during the spring and autumn. The annual average number of days with thunderstorms varies from approximately 45 at the southwest corner of the state of Wisconsin, to approximately 35 at the northeast corner of the state. The applicant stated that hail is most frequent in the southwestern and west central portions of the state, and is most common during summer months, peaking in late July. The applicant noted that tornadoes are relatively infrequent and that during an average winter, the ground is covered with 1 in. (2.54 centimeters (cm)) or more of snow about 60 percent of the time.

The applicant provided additional details about the climate region as it relates to the following:

- Regional land use
- The landforms of Wisconsin
- Lake breeze phenomena
- Effects of the local radiation balance and winds
- Mean monthly temperatures
- Monthly mean liquid-equivalent precipitation
- Climatic statistics

- Monthly mean relative humidity
- Mean monthly water equivalent precipitation and snowfall
- Mean numbers of days per month and per year of rain or drizzle, freezing rain or drizzle, snow, and hail or sleet

Identification of the Region with Climate Representative of the Site

The applicant stated that the SHINE site is located in central Rock County, Wisconsin, which is at the south-central edge of the state. It is located near the boundary of two Wisconsin physiographic provinces, the Western Uplands and the Eastern Ridges and Lowlands. It is located in National Oceanic and Atmospheric Administration (NOAA) Cooperative Observer Network (COOP) Climate Division 8 South Central. The applicant summarized the site location as follows:

- Located in south-central Wisconsin, on rural prairie silt-loam soil.
- Located within till plains glacial deposits on the Central Lowland Province of the Interior Plains Division of the United States. It is on the border between the state of Wisconsin Eastern Ridge/Lowland and Western Upland Terrain, and most like the ridge/lowland to the east because the local topography is relatively gently rolling.
- Located outside the zone of influence of Lake Michigan lake breeze circulation systems.
- Located within the zone of influence of Lake Michigan effects on temperature and precipitation, including the following: added local warmth during winter and autumn, cooling during summer and spring, and additional local precipitation during winter, spring, and autumn.

Based on these characteristics, the applicant outlined a perimeter for the geographic region. This climate region of the SHINE site is used to identify regional weather monitoring stations and other local counties that can be used for comparisons in the analysis of local and regional climate.

Regional Data Sources

After identifying the SHINE site climate region, the applicant identified a number of published data sources that provided the meteorological parameters from weather stations in the site climate region that are used in the meteorological analysis in the application. The applicant provided a list of the data sources and described the information provided by each one.

Identification and Selection for Analysis of Weather Monitoring Stations Located within the Site Climate Region

The applicant presented maps of the SHINE site climate region with additional annotations of locations within that region of NOAA automated surface observing station (ASOS) stations and NOAA COOP stations for which NOAA Climatography of the United States No. 20 (Clim-20) publications and digital updates have been published by the National Climatic Data

Center (NCDC). The applicant presented a list of the ASOS and COOP stations that are identified. A subset of the ASOS stations presented is selected for analysis. The criteria used to select that subset of stations are noted. All COOP stations presented are analyzed. Input information for that analysis includes statistics in the NOAA Clim-20 documents and updates for each station, that summarize climatic conditions during the 30-year period 1971 through 2000 and subsequent updates through 2018.

Extreme Wind

The applicant provided the basic wind speed for the SHINE site; the basic wind speed is a statistic that is used for design and operating bases. Basic wind speeds are 50-year recurrence interval nominal design 3-second gust wind speeds (miles per hour (mph)) at 33 ft (10.1 m) above ground for Exposure C category in chapter 6 of American Society of Civil Engineers (ASCE)/Structural Engineering Institute (SEI) 7-05, "Minimum Design Loads for Buildings and Other Structures." The applicant stated that it considered several sources to determine the wind speeds for the SHINE site. The basic wind speed for the SHINE site is 90 mph (40.2 m/s) based on the plot of basic wind speeds in figure 6-1 of ASCE/SEI 7-05. Basic wind speeds reported in Air Force Combat Climatology Center Engineering Weather Data, 1999, for hourly weather stations in the SHINE site climate region are 90 mph (40.2 m/s) for Madison, Wisconsin and 90 mph (40.2 m/s) for DuPage County Airport, West Chicago, Illinois. Based on the consistency of these three values, the applicant selected a basic wind speed value of 90 mph (40.2 m/s) for the SHINE site. That value applies to a recurrence interval of 50 years.

The applicant used the method in section C6.5.5 of ASCE/SEI 7-05 to calculate wind speeds for other recurrence intervals. Based on that method, a 100-year return period value is calculated by multiplying the 50-year return-period value (i.e., 90 mph (40.2 m/s)) by a factor of 1.07. This approach produces a 100-year return-period 3-second gust wind speed for the SHINE site climate region of 96.3 mph (43.0 m/s).

Tornadoes and Waterspouts

The applicant used the NCDC Storm Events Database, 2018 and selected 30 regional counties that are at least partially included within the SHINE site climate region. The applicant used the database to extract statistics on regional tornadoes and waterspouts. These tornado and waterspout statistics, for the 68-year period from May 1950 through November 2018, are presented in SHINE FSAR table 2.3-7. As presented in that table, total tornadoes and waterspouts reported in the 30-county area during the 68-year period are 794 and 3, respectively. The SHINE site is in Rock County. The strongest tornado in that county and for the seven counties adjacent to Rock County was an F4 storm.

International Atomic Energy Agency (IAEA)-TECDOC-403, "Siting of Research Reactors," provides that design tornado information is to be based on the maximum historical intensity within a radius of about 100 km (62 mi) of the site. The applicant stated that for the SHINE site, a 100 km (62 mi) radius partially extends outside of the representative SHINE site climate region included within the 30-county region described above. An F5 intensity tornado was recorded on June 8, 1984, in Iowa County, Wisconsin at the town of Barneveld, which is located approximately 50 mi (80 km) west northwest of the SHINE site (NCDC Storm Data, 1984).

Water Equivalent Precipitation Extremes

The applicant stated that the daily total water equivalent precipitation is measured at the local NOAA COOP monitoring station at Beloit, Wisconsin and several regional COOP stations within the SHINE site climate region. SHINE FSAR table 2.3-10 presents maximum recorded 24-hour and monthly water equivalent precipitation values for the local COOP station at Beloit and the COOP stations located within the SHINE site climate region.

The applicant stated that the regional historic maximum recorded 24-hour liquid-equivalent precipitation from the local Beloit station or for regional stations is 9.62 in. (24.43 cm). The regional historic maximum monthly liquid-equivalent precipitation from records for either the local Beloit station or for regional stations is 18.27 in. (46.41 cm) at Portage, Wisconsin in June 2008. The regional recorded maximum 24-hour snowfall is 21.0 in. (53.34 cm) at Dalton, Wisconsin and the regional recorded maximum monthly snowfall is 50.4 in. (128.0 cm) at Watertown, Wisconsin in January 1979.

Hail, Snowstorms, and Ice Storms

The applicant listed the mean hail or sleet frequencies during winter, spring, summer, autumn, and annual periods for Rockford, Illinois and Madison, Wisconsin in SHINE FSAR table 2.3-11. Mean hail frequencies are less than one day per season at both stations. Hail events that are either severe or large are reported to have occurred in Rock County, Wisconsin on 11 occasions during the period of 1961–1990, or with a frequency of approximately 0.37 occurrences per year (NCDC Climate Atlas of the United States, 2002). The NCDC Storm Events Database through December 31, 2018, lists the largest hailstones that Rock County has experienced as follows: diameter of 3.00 in. (7.62 cm) on one occasion during June 1975.

The applicant stated that the daily total snowfall amounts are measured at the local NOAA COOP monitoring station at Beloit, Wisconsin, as well as at several regional COOP stations within the SHINE site climate region. SHINE FSAR table 2.3-10 lists that the maximum recorded 24-hour snowfall for either the local Beloit station or for regional stations is 21.0 in. (53.34 cm) at Dalton, Wisconsin. The overall historic maximum monthly snowfall from records for either the local Beloit station or for regional stations is 50.4 in. (128.0 cm) at Watertown, Wisconsin.

In SHINE FSAR table 2.3-4, the applicant listed the mean number of days with freezing rain or drizzle at 2 days per year at both Madison, Wisconsin and Rockford, Illinois. The applicant provided in SHINE FSAR table 2.3-12 a summary of 14 ice storms that affected Rock County during the period of 1995–2011.

The applicant stated that: A 50-year return-interval atmospheric ice load due to freezing rain is estimated to be 0.75 in. (1.91 cm) for the SHINE site (ASCE/SEI 7-05) and the estimated concurrent 3-second wind gust is 40 mph (17.9 m/s) and a 500-year return-interval atmospheric ice load due to freezing rain is estimated to be 1.5 in. (3.81 cm) for the SHINE site (ASCE/SEI 7-05) and the estimated concurrent 3-second wind gust is 40 mph (17.9 m/s).

Thunderstorms and Lightning

The applicant listed the mean seasonal thunderstorm frequencies for Rockford, Illinois and Madison, Wisconsin in SHINE FSAR table 2.3-13 from data in NCDC 2018 Local Climatological Data, Annual Summary with Comparative Data, Rockford, Illinois and NCDC 2018 Local

Climatological Data, Annual Summary with Comparative Data, Madison, Wisconsin, respectively.

The applicant calculated the mean frequency of lightning strikes to earth via a method from the Electric Power Research Institute (EPRI), per the U.S. Department of Agriculture, Rural Utilities Service, “Rural Utilities Service Summary of Items of Engineering Interest,” 1998. Based on the average number of thunderstorm days per year at Rockford, Illinois during the 63-year period of 1955–2018 (43.1 days, which is slightly higher than the value of 39.5 days for Madison, Wisconsin), the applicant stated that the frequency of lightning strikes to earth per square mile per year is 13.4 (5.2 strikes per square km per year) for the SHINE site and surrounding area. For comparison, the applicant looked at the National Lightning Safety Institute Vaisala 10-Year Flash Density Map, 2014, which indicates 6 to 12 flashes per square mile per year (2.3 to 4.6 flashes per square kilometer per year) for the SHINE site region. Therefore, the applicant considered the EPRI value to be a reasonable indicator.

Snowpack and Probable Maximum Precipitation

The applicant determined the snow load by using ASCE/SEI 7-05. Figure 7-1 of that standard provides site estimates of the 50-year ground snow load. Based on the location of the SHINE site, the 50-year ground snow load is 30 pounds per square foot (lb/ft^2). As outlined in ASCE/SEI 7-05, section C7.3.3, a factor of 1.22 is used to account for the 100-year recurrence interval. The resulting 100-year ground snow load is 36.6 lb/ft^2 (178.7 kilograms per square meter (kg/m^2)).

The applicant determined the weight of the 48-hour probable maximum precipitation (PMP) for the SHINE site vicinity using U.S. Department of Commerce Hydrometeorological Report No. 51, “Probable Maximum Precipitation Estimates,” 1978. It was derived by multiplying the 48-hour PMP (in inches) from figure 21 of the report by the weight of 1 in. of water (1 in. of water covering one square foot weighs 5.2 lb (2.4 kg)). The estimated 48-hour PMP for the SHINE site is 34 in. (86.4 cm). The resulting estimated weight of the 48-hour PMP for the SHINE site is 176.8 lb/ft^2 (863.2 kg/m^2).

Design Dry Bulb and Wet Bulb Temperatures

The applicant outlined the statistics used to define the design basis dry bulb temperatures (DBTs) and wet bulb temperatures (WBTs) for the SHINE site and its climate area.

Most of the statistics listed are readily available from American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), “ASHRAE Handbook – Fundamentals,” 2017, which includes values for the following stations in the SHINE site climate region: Fond du Lac, Wisconsin; Madison, Wisconsin; Rockford, Illinois; and DuPage County Airport, Illinois. The resulting statistics are listed in SHINE FSAR table 2.3-14.

The applicant stated that statistics for the maximum and minimum DBT with an annual exceedance probability of 5 percent were not available from ASHRAE, 2017. In lieu of values from other sources, values were extracted from published DBT and wet-bulb depression joint-frequency tables in NCDC International Station Meteorological Climate Summary, 1996. Joint-frequency tables are available only for Madison, Wisconsin and Rockford, Illinois. The extracted statistics for Madison and Rockford are listed in SHINE FSAR table 2.3-14.

The applicant outlined the techniques used to calculate the estimated 100-year return maximum and minimum DBT; mean coincident wet bulb temperature (MCWB) coincident with the 100-year return maximum DBT; historic maximum WBT; and estimated 100-year annual maximum return WBT. The resulting values are listed in SHINE FSAR table 2.3-15.

Extreme Dry Bulb Temperatures

The applicant performed an additional review of regional extreme DBTs using NOAA COOP climate monitoring stations in the SHINE site climate region. The locations of these stations are shown in SHINE FSAR figure 2.3-17. The COOP climate monitoring stations do not measure WBT and do not record hourly DBTs. These stations only record maximum and minimum daily DBTs and daily precipitation totals. Therefore, it is not possible to identify WBTs coincident with the extreme DBTs recorded at those stations. SHINE FSAR table 2.3-16 presents extreme DBTs recorded at the climate monitoring stations and also includes the extreme DBTs recorded at the two first-order stations in the SHINE site climate region (i.e., Madison, Wisconsin and Rockford, Illinois).

The applicant stated that the overall extreme DBTs for the SHINE climate region are a maximum of 109°F (42.8 degrees Celsius (°C)) recorded on July 14, 1936, at Marengo in Boone County, Illinois and a minimum of -45°F (-42.8°C) recorded on January 30, 1951, at Baraboo in Sauk County, Wisconsin. Since Marengo is a COOP station, the WBT coincident with the extreme DBT at Marengo (109°F (42.8°C)) is not available.

The applicant outlined the methodology used to estimate a WBT coincident with the overall extreme DBT and listed the estimated MCWB coincident with the overall extreme DBT of 109°F (42.8°C) at Marengo as 79°F (26.1°C).

Restrictive Dispersion Conditions

The applicant stated that major air pollution episodes are typically a result of persistent surface high pressure weather systems that cause light and variable surface winds and stagnant meteorological conditions for four or more consecutive days. The applicant reviewed NOAA estimates of the stagnation frequency, which indicate that, on average, the site location experiences less than 10 days with stagnation per year. When stagnation occurs, stagnation lasts, on average, less than two days.

Air Quality

The applicant stated that the SHINE site is located in Rock County, Wisconsin, which is part of the Rockford-Janesville-Beloit Interstate Air Quality Control Region and that this air quality control region combines agricultural activities with the Beloit-Janesville, Wisconsin and Rockford, Illinois urban-industrial areas. The applicant noted that the Wisconsin portion of the air quality control region, Rock County, is mostly flat to gently rolling farmland and that industry in the region consists of manufacturing, foundry operations, and electrical power plants. The applicant stated that Rock County is currently in attainment for criteria pollutants (ozone, particulate matter, carbon monoxide, nitrogen oxides, sulfur dioxide, and lead). The applicant also discussed whether the surrounding counties are in attainment or non-attainment with regard to local air quality standards.

The applicant stated that the SHINE site is not located within 100 km (62 mi) of a Class I area, which are national parks and wilderness areas that are potentially sensitive to visibility impairment. Thus, a Class I visibility impact analysis is not necessary.

Climate Change

The applicant stated that, generally, projections of climatic changes have been done at global scales and that predictions of changes at a single station or at a relatively small area, such as the SHINE site climate region, are not reliable. The applicant stated that the facility design is most reliably based on a standard approach of projecting conditions via scientifically defensible statistical methods, using historic statistics as input.

The applicant stated that it is nevertheless valid to examine historic records for indications of long-term trends for informational purposes. The applicant examined trends of the following parameters for the climate region within which the SHINE site is located:

a. Values, for six separate 30-year division normal periods, of mean annual dry bulb temperature and mean annual precipitation. Variations of these parameters are identified in the top half of SHINE FSAR table 2.3-18.

b. During six separate single-decade periods of record, extremes at Madison, Wisconsin of hourly dry bulb temperature, one-day liquid-equivalent precipitation, one-day snowfall, and strongest tornadoes. Variations of those historic meteorological parameters are identified in the bottom half of SHINE FSAR table 2.3-18.

The NRC staff reviewed the description of the general climate of the region and meteorological conditions relevant to the design and operation of the SHINE facility presented in SHINE FSAR section 2.3.1. The staff reviewed the data resources and analytical approaches used by the applicant to prepare the information. The staff used the guidance and acceptance criteria described in Section 2.3, "Meteorology," of NUREG-1537, Parts 1 and 2. Based on its review, the staff concludes that the site characteristics associated with meteorology and general and local climatology are acceptable and reasonably representative of the SHINE site.

2.4.3.2 Site Meteorology

SHINE FSAR section 2.3.2 provides data and descriptions necessary to determine the atmospheric dispersion conditions in the vicinity of the SHINE site. This includes local and regional airflow, meteorological measurements used for dispersion estimates, and local topography.

2.4.3.2.1 Topography

The applicant described the topography immediately around the SHINE site as being flat farmland. Within a 10-mile radius of the site, elevations range from approximately 72 ft (21.9 m) below the site elevation of 825 ft (251 m) NAVD 88, to 206 ft (62.8 m) above the site elevation. Most of the land surrounding the SHINE site is used for agriculture, mostly corn and soybean farming.

2.4.3.2.2 Local Data Sources

According to the application, local meteorological data was gathered from the SWRA in Janesville, Wisconsin. Data from the SWRA for the purposes of the application were recorded during the period from January 1, 2005, to December 31, 2010. Since there is no onsite meteorological monitoring system at the SHINE site, the applicant used the SWRA data as a substitute. In a letter dated March 16, 2021 (ML21075A012), the applicant stated that the SWRA observation station is located directly across U.S. Highway 51 from the SHINE site. This is a distance of 0.25 mi (0.4 km) and is the closest source of meteorological data to the site and is shown in SHINE FSAR figure 2.2-1. The applicant also stated that the SHINE site and the SWRA meteorological station are located at approximately the same grade elevation in a relatively open, flat, and rural location and that, therefore, the air dispersion conditions as sampled by the meteorological instruments at the SWRA are expected to be representative of dispersion conditions at the SHINE site. Based on the meteorological data provided to the NRC staff and the description of the SWRA meteorological tower, the staff finds the use of this data acceptable.

2.4.3.2.3 Plans to Access Local Meteorological Data during License Period

The applicant provided a description of the process to access local meteorological data in the event of an accidental radiological release at the SHINE facility. The SHINE facility does not employ an onsite meteorological measurement system and relies on the local weather station at the SWRA, which is located adjacent to the SHINE site. Although there are no acceptance criteria specific to this approach, the NRC staff finds that the applicant has described a process that will result in the ability to get local, reliable, and accurate meteorological data in the event of an accidental radiological release and that, therefore, the approach is acceptable.

2.4.3.2.4 Comparison of Local and Regional Wind Roses

SHINE FSAR figure 2.3-36 provides a depiction of the wind direction and speeds for the SWRA in Janesville, Wisconsin, along with six other regional stations. The Janesville, Wisconsin, wind rose shows a similar wind pattern to the regional sites, with the predominant wind directions coming from the south and west.

2.4.3.2.5 Atmospheric Stability

The applicant used the PAVAN atmospheric dispersion computer model from NUREG/CR-2858, “PAVAN: An Atmospheric-Dispersion Program for Evaluating Design-Basis Accidental Releases of Radioactive Materials from Nuclear Power Stations” (ML12045A149), to estimate the short-term atmospheric dispersion factors, χ/Q values, as discussed in SHINE FSAR chapter 13, “Accident Analysis.” The PAVAN model implements the methodology outlined in Regulatory Guide 1.145, Revision 1, “Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants” (ML003740205).

The PAVAN code estimates χ/Q values for various time-average periods ranging from 2 hours to 30 days. The meteorological input to PAVAN consists of a JFD of hourly values of wind speed and wind direction by atmospheric stability class. The χ/Q values calculated using PAVAN are based on the theoretical assumption that material released to the atmosphere would be normally distributed (Gaussian) about the plume centerline. A straight-line trajectory is assumed between the point of release and all distances for which χ/Q values are calculated.

For each of the 16 downwind direction sectors, PAVAN calculates χ/Q values for each combination of wind speed and atmospheric stability at the appropriate downwind distance. The χ/Q values calculated for each sector are then ordered from greatest to smallest and an associated cumulative frequency distribution is derived based on the frequency distribution of wind speed and stabilities for each sector. The smallest χ/Q value in a distribution would have a corresponding cumulative frequency equal to the wind direction frequency for that particular sector. For each sector, PAVAN determines an upper envelope curve based on the derived data (plotted as χ/Q versus the probability of being exceeded) such that no plotted point is above the curve. From this upper envelope, the χ/Q value that is equaled or exceeded 0.5 percent of the total time is obtained. The maximum 0.5 percent χ/Q value from the 16 sectors becomes the 0-to-2-hour "maximum sector χ/Q value."

Using the same approach, PAVAN also combines all χ/Q values independent of wind direction into a cumulative frequency distribution for the entire site. An upper envelope curve is determined, and the computer program selects the χ/Q value that is equaled or exceeded 5.0 percent of the total time. This is known as the 0-to-2-hour "5 percent overall site χ/Q value." The larger of the two χ/Q values, either the 0.5 percent maximum sector value or the 5 percent overall site value, is selected to represent the χ/Q value for the 0-to-2-hour time interval (note that this resulting χ/Q value is based on 1-hour averaged data but is conservatively assumed to apply for 2 hours).

To determine χ/Q values for longer time periods during an accident scenario (i.e., 0 to 8 hours, 8 to 24 hours, 1 to 4 days, and 4 to 30 days), PAVAN performs a logarithmic interpolation between the 0-to-2-hour χ/Q values and the annual average χ/Q values for each of the 16 sectors and the overall site. For each time period, the highest χ/Q value from among the 16 sectors and the overall site is identified and becomes the short-term site characteristic χ/Q value for that time period.

The meteorological input to PAVAN used by the applicant consisted of a JFD of wind speed, wind direction, and atmospheric stability based on hourly onsite data from January 1, 2005, through December 31, 2010, as described in SHINE FSAR section 2.3.2.5, "Atmospheric Stability." The wind data was obtained from the NOAA meteorological observation station at SWRA in Janesville, Wisconsin located about 0.25 mi from the SHINE site.

The NRC staff independently developed an annual wind rose from the hourly meteorological database provided by the applicant. The wind roses developed by the staff and the wind roses provided by the applicant in SHINE FSAR figures 2.3.2-3 through 2.3.2-54, show high frequencies of winds from the south through the west and northwest (clockwise). As stated above, this is generally consistent with the wind patterns recorded in the SHINE site region.

The wind roses presented in SHINE FSAR figures 2.3-19 through 2.3-36, depict the wind patterns and wind speeds for all 16 wind direction sectors. SHINE FSAR figure 2.3-19 shows that the wind was calm during 16.61 percent of all hours recorded. The NRC staff compared the number of calms in the wind rose to the JFDs included in SHINE FSAR tables 2.3-24 through 2.3-29 and determined that the JFDs contained about 1 percent more calms than shown in SHINE FSAR figure 2.3-19. The staff considers this difference to be negligible and that it will not have an impact on the atmospheric dispersion modeling results. The staff determined that the wind rose in the application follows the guidance provided in table 3 of Regulatory Guide 1.23, Revision 1, "Meteorological Monitoring Programs for Nuclear Power Plants" (ML070350028), and defines any wind speed below the 0.5 m/s (1.1 mph) threshold as "calm." The JFD tables referenced in SHINE FSAR section 2.3.2.5 provide a summary of the wind speed distribution by stability class. The staff noted and accounted for the different units of measure between the wind roses and the JFD tables in the application.

Based on the above discussion related to the SWRA meteorological data, the NRC staff considers the 2005–2010 meteorological database suitable for input to the PAVAN computer model.

Diffusion Parameters

The applicant chose to implement the diffusion parameter assumptions outlined in RG 1.145 as a function of atmospheric stability for its PAVAN computer model runs. The NRC staff evaluated the applicability of the PAVAN diffusion parameters and concluded that no unique topographic features (such as rough terrain, restricted flow conditions, or coastal or desert areas) preclude the use of the PAVAN model for the SHINE site at the site boundary.

The applicant modeled one ground-level release and did not take credit for building wake effects. Ignoring building wake effects for a ground-level release decreases the amount of atmospheric turbulence assumed to be in the vicinity of the release point, resulting in higher (i.e., more conservative) χ/Q values. A ground-level release is, therefore, acceptable to the NRC staff. Distances to the site boundary for each of the 16 direction sectors is provided in SHINE FSAR table 2.1-1. The staff reviewed the meteorological input, as well as the diffusion parameters, and finds the applicant's use of diffusion parameter assumptions, as outlined in RG 1.145, acceptable.

The applicant included the short-term atmospheric dispersion estimates for the site boundary, resulting from its PAVAN modeling run, in response to NRC staff RAIs. The staff finds these χ/Q values acceptable for use in the SHINE FSAR because they are a conservative estimate of the atmospheric dispersion at the SHINE site.

The NRC staff finds, based on its review of the application and supplemental information provided through the RAI response, that the applicant's analyses of meteorological hazards and atmospheric dispersion are sufficient and acceptable as they followed the applicable local, state, and federal guidelines. The staff concludes that the SHINE site is not located where catastrophic meteorological events are likely, that the applicant considered credible meteorological events in developing the design basis parameters for the facility, and that the applicant provided adequate site characteristics needed to evaluate an uncontrolled release of radioactive materials.

2.4.4 Hydrology

The NRC staff evaluated the sufficiency of the applicant's description of the SHINE site characteristics regarding hydrology, as presented in SHINE FSAR section 2.4, using the guidance and acceptance criteria from section 2.4, "Hydrology," of NUREG-1537, Parts 1 and 2, and chapter 2, "Site Characteristics," of the ISG augmenting NUREG-1537, Parts 1 and 2.

2.4.4.1 Hydrological Description

In SHINE FSAR section 2.4.1, the applicant described the SHINE site surface water bodies related to establishing the design basis flood hazards as well as groundwater properties that would affect the movement of accidental radionuclide contaminations in groundwater.

The applicant stated that the Rock River, which is the main water body near the SHINE site, is located approximately 2 mi west of the site and flows generally north to south from Janesville (located to the north), around the site. The Rock River has a contributing drainage area of approximately 3,340 square miles near the SHINE site. Water surface elevations along the Rock River channel during normal flow conditions are approximately 750 ft at NAVD 88 near the site.

The applicant stated that an unnamed creek (tributary) is located approximately 1 mi southeast of the SHINE site. This tributary stream flows south and then west to where it meets the Rock River approximately 2 mi southwest of the site. The tributary has a drainage area of approximately 18.4 square miles.

The applicant discussed in the SHINE construction permit (CP) application (ML13088A192, ML15259A272, and ML15258A431), that the central and southeastern portions of Rock County are characterized as a flat glacial outwash plain. The majority of the county's rivers and stream valley surfaces are filled with thick deposits of alluvial sand and gravel. The alluvial sediments and upland plains are the result of glacial activities. Surface soils include silt loam, which are underlain by glacial till or stratified sand and gravel outwash units. These soils then serve as the source of sediments to nearby rivers and streams.

The applicant stated that the SHINE site was originally an agricultural field with a center-pivot irrigation system. The fields were cultivated with corn and soybeans. Generalized surface topography of the area slopes gently to the southwest. Based on the 2012 field measurements by the applicant, the ground surface across the site area slopes gently from the southeast to the northwest.

The NRC staff determined that the hydrologic descriptions in FSAR section 2.4 are adequate to understand the local hydrology and drainage patterns for the SHINE site. This understanding supports the relevant evaluation findings in section 2.4 of NUREG-1537, Part 2.

2.4.4.2 Effect of Local Intense Precipitation

SHINE FSAR section 2.4.2.3, "Effect of Local Intense Precipitation," discusses the effects of the local intense precipitation (LIP) flooding on the safety-related SSCs of the SHINE facility. The applicant revised SHINE FSAR section 2.4 from the CP application to address the changes associated with the facility layout, grading plan, roof drain of the main production facility, onsite and peripheral drains, and LIP scenario and the corresponding LIP flood analysis. The application uses a 100-year precipitation event. The NRC staff focused its review on these revised areas as they relate to the LIP flood analysis.

<u>Site Grade and Facility Layout</u>

The applicant stated that the finished site grade elevation is approximately 825 ft NAVD 88, with the highest point of grade set at 827 ft NAVD 88. According to the applicant, the top of the finished foundation (floor) elevation of the main production facility is at least 4 in. above site grade, which will prevent the LIP flood water from entering the buildings. As described in the application, the main production facility, which is the largest among the facility buildings, has a length (north to south) and a width of 212 ft and 158 ft, respectively. There are many other small storage buildings, pads, and tanks that are located on the east and south side of the main production facility. Proposed drainage features include the onsite drainage system, peripheral drainage channels and ditches, and infiltration ponds.

The NRC staff reviewed each of these components as they are related to the LIP flood analysis. The staff found that the applicant's description of these components is adequate to understand their impact on the LIP flood analysis.

Design Local Intense Precipitation Scenario

The applicant estimated onsite runoff for the 100-year rainfall event. SHINE FSAR table 2.4-7 summarizes the applicant's 100-year point rainfall value and intensities for different durations (up to 6 hours). The applicant's 100-year, 5-minute rainfall estimate is 8 inches per hour or 0.67 in. in total. These rainfall estimates are based on the Madison, Wisconsin intensity-duration-frequency curve from the Wisconsin Department of Transportation, "Facilities Development Manual," 1979 (WDOT, 1979). The applicant also used the 100-year, 24-hour rainfall value of 6 in. using the data provided by the Rock County Storm Water Management Ordinance, 2004. This 24-hour rainfall was used in estimating offsite runoff used to design the peripheral drainage channel and evaluating the capacity of the existing channel.

The NRC staff compared the applicant-provided rainfall values to those provided by the NOAA Atlas 14, 2020. The staff obtained, from the NOAA website, a 100-year, 5-minute rainfall at the SHINE site of 0.9 in., with 90 percent confidence intervals ranging from 0.7 in. to 1.18 in. The staff also estimated the 100-year, 24-hour rainfall depth of 6.59 in., with 90 percent confidence intervals ranging from 5.05 in. to 8.37 in. As a result, the staff determined that the applicant-provided design LIP rainfall values are within the range of the site-specific Atlas 14 values. Therefore, the staff concludes that the applicant's LIP rainfall values are acceptable for use in the LIP flood analysis.

Flooding from Onsite Drainage Area

As described in SHINE FSAR section 2.4.2.3, the drainage system is designed to carry runoff from rooftops and adjacent areas, ultimately reaching the peripheral ditches. The SHINE facility is surrounded by berms with interior ditches along the berms. SHINE FSAR figure 1.3-2 shows that the roof of the main production facility has two continuous downslopes from the mild east-side slope to the steep west side slope. Therefore, the roof runoff flows only to the west of the building.

The application states that stormwater from the onsite boundary is directed to the stormwater management system (marked by green lines in SHINE FSAR figure 2.4-11). The entire onsite basin is divided into six drainage subbasins (SHINE FSAR figure 2.4-12). The onsite drain system is designed so that the runoff generated from each subbasin is collected to a lower point and diverted to a trench drain through inlet. There are six inlets located on the east, south, and west sides of the main production facility.

As described in the application, the trench flow is eventually drained into two infiltration cells (ponds) on the southwest corner of the site boundary. The main purpose of these infiltration cells is to control total suspended solids in water. Infiltration cell #1 collects onsite drain water which in turn flows via a spillway to infiltration cell #2. The spillway has a top elevation of 810 ft NAVD 88. The applicant stated that the infiltration cells will not pose a site flooding concern because the spillway was designed to have the peak water surface elevation of 810 ft NAVD 88 plus overflow margin.

The applicant stated that the peak LIP runoff in each subbasin was calculated using the Rational Dekalb method. This method estimates the peak flow rate as a function of runoff coefficient, rainfall intensity, and subbasin area. The applicant described that the onsite ground is graded in such a way that any runoff exceeding the inlet capacity would flow offsite or to another inlet. The applicant used a 100-year, 5-minute frequency rainfall event. The NRC staff confirmed that the onsite runoff estimates are acceptable as they follow the guidelines provided by the State of Wisconsin (WDOT, 1979).

With the estimated peak runoff rate, the applicant estimated the total runoff volume using a temporal runoff distribution method provided by the State of Wisconsin guidelines (WDOT, 1979). The applicant then calculated the maximum flood level at each inlet point using the stage-volume curve for the low area (so called pond/pit) at the inlet point. The applicant stated that, during a design basis LIP event, the onsite storm water drainage system is conservatively assumed to not be functional so that all runoff would be stored in the pond/pit of each subbasin.

The applicant determined, based on the above runoff analysis, that the maximum depth in all low points from impounded water would be below the ground floor elevations of the main production facility and waste staging and shipping buildings, with margin. The NRC staff determined that the applicant's onsite flood level estimates are acceptable as they follow the applicable state guidelines (WDOT, 1979).

Flooding from Offsite Drainage Area

In its application and March 16, 2021 (ML21075A012), RAI response, the applicant stated that the SHINE site is protected from offsite flooding approaching from the north and northeast by drainage channels on the north and east sides of the facility and on the southeast side of the facility (see SHINE FSAR figure 2.4-11). There is a peripheral channel system located on the north and east sides of the SHINE facility. This channel is intended to direct offsite runoff away from the SHINE facility. Offsite runoff generated from the 91-acre basin that flows from the north towards the site is intended to be captured by the peripheral channel which directs flow to an uncontrolled subbasin on the west side of the site. The applicant designed the peripheral channel to carry offsite flooding caused by a 100-year rainfall event. The upstream bank elevation of the channel is 827 ft NAVD 88. The channel is approximately 1,100 ft long with a 0.8 percent slope. The applicant also stated that the portion of the offsite runoff that flows from the northeast towards the site is captured by the channel southeast of the site that eventually flows to the unnamed tributary approximately 1 mi south of the site. The unnamed tributary flows from east to west to meet the Rock River approximately 2 mi south of the site.

The application states that offsite runoff (in depth) for channel drainage was calculated using the Soil Conservation Service (SCS) methodology provided by the Natural Resources Conservation Service (NRCS), "National Engineering Manual," 1986. The key input parameters to the SCS methodology are 24-hour rainfall depth and potential maximum retention depth, which is estimated as a function of the SCS Curve Number. The applicant estimated peak discharge in cubic feet per second (cfs) as a function of the runoff (in depth), subbasin area, unit peak discharge, and pond adjustment factor. The applicant used the Hydrologic Engineering Center's River Analysis System (HEC-RAS), a hydraulic modeling system, to route flows in each channel.

The applicant stated that the estimated peak runoff flow rate for the peripheral channel basin is 42 cfs. The estimated water surface elevation at the upstream end of the channel reaches a maximum height of 826.3 ft NAVD 88, which is below the channel bank height of 827 ft NAVD 88. The NRC staff determined that the channel has enough capacity to carry offsite runoff as there is approximately 0.7 ft margin for the channel flow to reach the top of the embankment of the channel.

The applicant evaluated runoff from the entire 91-acre basin conservatively, which was in turn used to estimate the maximum water depth in the channel southeast of the site from offsite drainage. The applicant reported the peak runoff flow rate of 197 cfs. The runoff is estimated to reach a water surface elevation of 826 ft NAVD 88 at the upstream end of the channel. The flood level is below its bank elevation of 827 ft NAVD 88. The NRC staff concludes that the applicant's estimation of the offsite runoff and flood levels at this channel are acceptable as they follow the guidelines provided by the NRCS, 1986 and the HEC-RAS.

2.4.4.3 Other Flood Causing Mechanisms

In addition to the LIP flooding discussed in SHINE FSAR section 2.4.2.3, SHINE FSAR sections 2.4.3 through 2.4.9 discuss other flood causing mechanisms, including river or stream flooding, surge and seiche, wave runup, landslide, sediment erosion and deposition, cooling water canal and reservoir flooding, channel diversion, tsunami, dam failure, ice, and their plausible combined events. These discussions are identical to those in the SHINE CP application. Also, SHINE FSAR section 2.4.10, "Groundwater Contamination Considerations," which describes groundwater conditions, was not changed from the CP application. There are no additional requirements related to these sections for the issuance of an operating license. Therefore, the NRC staff determined that the conclusions made in NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility" (ML16229A140), for these eight sections are still sufficient and acceptable without further review.

2.4.4.4 Accidental Releases of Radioactive Liquid Effluents in Ground and Surface Waters

SHINE FSAR section 2.4.11, "Accidental Releases of Radioactive Liquid Effluents in Ground and Surface Waters," discusses the hydrogeologic characteristics of the SHINE site related to potential accidental releases of radionuclide effluents. The specific topics covered by this section include alternate conceptual models, pathways, and travel times that affect radionuclide transports in groundwater. The NRC staff reviewed these topics to the extent that they have been revised since the SHINE CP application.

SHINE FSAR table 2.4-12 presents a summary of parameters used for advective travel times in the saturated zone. The applicant updated the travel times of five radionuclide pathways, including the new pathway to the nearest pre-1988 well "Receptor" (namely RO3286). The applicant also updated table 2.4-12 by updating advective groundwater travel times of each pathway for expected (30 percent porosity) and conservative (10 percent porosity) scenarios. The NRC staff reviewed the applicant's calculations, which used local monitoring information, and found the applicant's estimation of the travel times to be acceptable.

In addition, the applicant stated that liquid effluent is not routinely discharged from the radiologically controlled area (RCA) within the main production facility. The applicant also stated that liquid radioactive wastes generated at the SHINE facility are generally solidified and shipped to a disposal facility, and that radioactive liquid discharges from the SHINE facility to the sanitary sewer are infrequent and made in accordance with 10 CFR 20.2003, "Disposal by release into sanitary sewerage," and 10 CFR 20.2007, "Compliance with environmental and health protection regulations." There are no piped liquid effluent pathways from the RCA to the sanitary sewer. Sampling is used to determine suitability for release. Ramps at the entrances to the RCA limit the release of unplanned water discharges from the RCA, such as from a cooling water system rupture or firefighting hose discharge. Therefore, the applicant concluded that there are no accidental radioactive liquid discharges from the RCA. The NRC staff determined that these statements meet the acceptance criteria in section 2.4 of NUREG-1537, Part 2 for determining whether the SHINE facility is designed to mitigate or prevent an uncontrolled release of radioactive materials in the event of a predicted hydrologic occurrence.

The NRC staff finds, based on the review of the application and supplemental information provided through RAI responses, that the applicant's analyses of hydrologic hazards are sufficient and acceptable as they followed the applicable local, state, and federal guidelines. The staff concludes that the SHINE site is not located where catastrophic hydrologic events are credible, that the applicant considered credible hydrologic events in developing the design basis flood parameters for the facility, and that the applicant provided adequate site characteristics needed to evaluate an uncontrolled release of radioactive materials in the event of a credible hydrologic occurrence.

2.4.5 Geology, Seismology, and Geotechnical Engineering

The NRC staff evaluated the sufficiency of the applicant's description of the SHINE site characteristics regarding geology, seismology, and geotechnical engineering, as presented in SHINE FSAR section 2.5, using the guidance and acceptance criteria from section 2.5, "Geology, Seismology, and Geotechnical Engineering," of NUREG-1537, Parts 1 and 2, and chapter 2, "Site Characteristics," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures in section 2.5 of NUREG-1537, Part 2, the NRC staff confirmed that the information presented in the SHINE FSAR was obtained from sources of adequate credibility and is consistent with other available data, such as data from the U.S. Geological Survey (USGS) or in the FSAR of a nearby nuclear power plant. The staff also evaluated whether there is reasonable assurance that the seismic characteristics of the SHINE site are considered in the design bases of SSCs discussed in SHINE FSAR chapter 3, "Design of Structures, Systems, and Components." In addition, the staff performed a confirmatory Probabilistic Seismic Hazard Analysis (PSHA), described below, using NRC-accepted models and methods.

Section 2.5 of NUREG-1537, Part 1 states, in part, that "the applicant should detail the seismic and geologic characteristics of the site and the region surrounding the site. The degree of detail and extent of the considerations should be commensurate with the potential consequences of seismological disturbance, both to the … facility and to the public from radioactive releases."

In SHINE FSAR section 2.5, the applicant provided descriptions of the regional geologic features, the site-specific geologic features, the historical seismic information, the maximum earthquake potential, how vibratory ground motion was addressed, the surface faults in the region, and the liquefaction potential.

The regulations in 10 CFR Part 100, appendix A, "Seismic and Geologic Siting Criteria for Nuclear Power Plants," define a capable fault as a fault with "[m]ovement at or near the ground surface at least once within the past 35,000 years or movement of a recurring nature within the past 500,000 years." Using this definition of capable fault, SHINE FSAR section 2.5.1.4, “Structural Geology,” provides a discussion of 17 major faults and folds in Wisconsin and the six surrounding states, and based on the lack of evidence for Pleistocene or post-Pleistocene displacement, concludes that only the faults responsible for creating the liquefaction features associated with the Wabash Valley seismic zone are considered capable faults under the definition in 10 CFR Part 100, appendix A. The NRC staff reviewed the information provided by the applicant, as well as information contained in the USGS Quaternary Fault database and in NUREG-2115, “Central and Eastern United States Seismic Source Characterization for Nuclear Facilities” (ML12048A776). The staff’s review of this information confirmed that there are no capable quaternary faults located within approximately 200 mi (320 km) of the SHINE site, except for the Wabash Valley liquefaction features, which are included in the USGS seismic hazard analysis.

The applicant used the 2008 USGS National Seismic Hazard Mapping Project (NSHMP) results for determining the seismic hazard at the SHINE site and establishing the safe shutdown earthquake (SSE) discussed in SHINE FSAR section 3.4.1, “Seismic Input.” The 2008 NSHMP results have been superseded by the 2014 USGS NSHMP results. The NRC staff compared the 2014 results to those from 2008 at peak ground acceleration (PGA) for four recurrence intervals (table 2-1). This comparison shows that the 2014 results are generally lower than those from 2008, which provides additional assurance that the 2008 results form a reasonable basis for determining the SSE ground motion at the SHINE site.

Table 2-1: Comparison of 2008 and 2014 USGS NSHMP results for PGA

PGA Spectral Acceleration (g)		
Return Period (yrs.)	**2008**	**2014**
475	0.0173	0.0176
2475	0.0509	0.0448
4975	0.0799	0.0691
9950	0.1254	0.1085

In addition to reviewing the application and the USGS results, the NRC staff performed a confirmatory PSHA that incorporates at-site information about the subsurface geology to develop uniform hazard spectra at the surface for Seismic Design Classification 3 and 4 (SDC-3 and SDC-4) facilities as defined in ANSI/ANS-2.26-2004, “Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design,” and computed following guidance in ASCE/SEI 43-05, “Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities.” The staff used the seismic source model described in NUREG-2115, the ground motion model described in “EPRI (2004, 2006) Ground-Motion Model (GMM) Review Project,” 2013, and the site-specific dynamic properties described by the applicant in letter dated October 4, 2013 (ML13303A887), Enclosure 2 Attachment 26, “Preliminary Geotechnical Engineering Report (Janesville), Revision 3 (ML13309B618). The staff’s results, presented in figure 2.4.5-1, show that for an SDC-4 facility, the SSE envelopes the site-specific hazard at all frequencies greater than 0.6 hertz with significant margin. Greater margin is demonstrated for an SDC-3 facility.

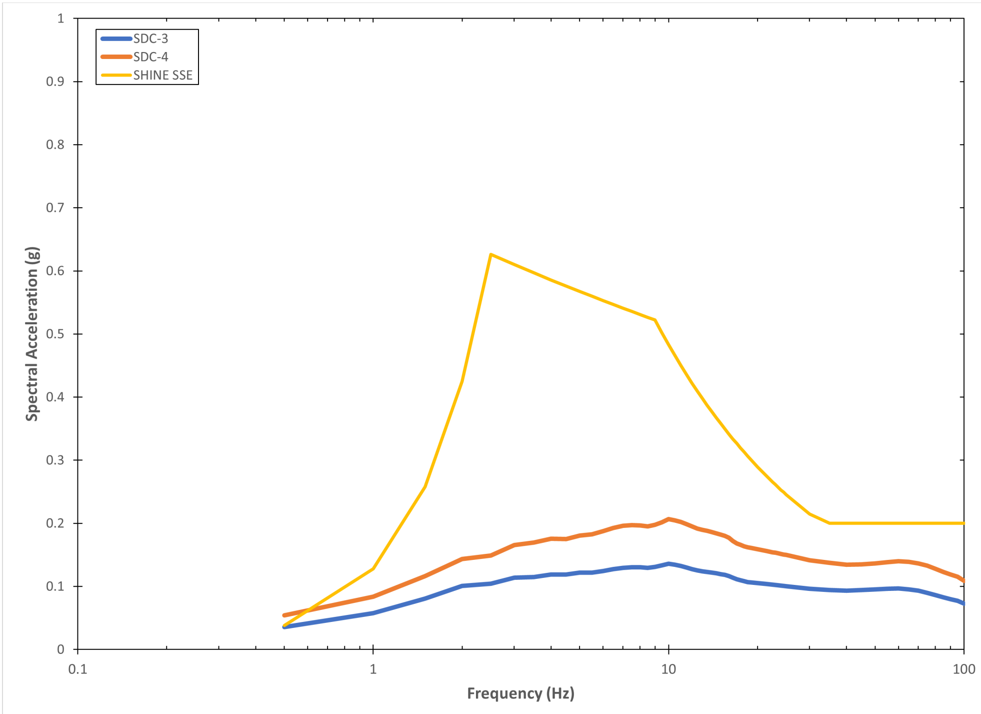

Figure 2-1: Comparison of SSE (yellow) with uniform hazard spectra for SDC-3 and SDC-4 facilities using site-specific subsurface information

Section 2.5.7, “Liquefaction Potential,” of NUREG-1537, Part 1 states, in part, that “[t]he applicant should discuss soil structure.” SHINE FSAR section 2.5.7.1, “Site Soil Conditions,” states that the geotechnical engineering characteristics of the SHINE site were evaluated by field investigations of standard penetrometer test (SPT) blow counts (N-values) measured in 14 boreholes, and laboratory tests including soil grain sizes, soil moisture contents, soluble-sulfate in soil, liquid limits, and plastic limits. The NRC staff reviewed the geotechnical information provided by the applicant in the SHINE FSAR, especially in section 2.5.7.1, section 2.5.7.2, “Groundwater Level,” section 2.5.7.3, “Liquefaction Assessment,” section 3.4.2.6.3.1, “Soil Parameters,” and section 3.4.2.6.4.7, “Soil Pressure,” and related calculations and specifications provided by the applicant and the Preliminary Geotechnical Engineering Report to determine whether the geotechnical engineering features underlying and in the area surrounding the SHINE site are sufficient to provide stable support.

In SHINE FSAR section 2.5.7.3, the applicant stated that there was no potential for liquefaction to occur within the soils underlying the SHINE site based on the results of both the qualitative and quantitative liquefaction analysis. The NRC staff reviewed section 8.4, “Liquefaction Potential and Other Seismically Induced Ground Failures,” and appendix F, “Results of Liquefaction Analysis,” of the Preliminary Geotechnical Engineering Report, which provide detailed analyses of both qualitative and deterministic liquefaction to support the applicant’s conclusion in SHINE FSAR section 2.5.7.3. The staff confirmed that the measured groundwater level elevations range from 58 to 65 ft (17.7 to 19.8 m) below the ground surface and that the relative density of the sandy soils in the upper 100 ft is generally compact to dense. The staff also reviewed the procedure and calculation of liquefaction assessment. The staff verified that the empirical procedure based on the SPT blow counts is in accordance with Regulatory Guide 1.198, “Procedures and Criteria for Assessing Seismic Soil Liquefaction at Nuclear Power Plant Sites” (ML033280143), and that its calculated results of factor of safety against liquefaction range from 2 to 30, and in most cases exceed 3, which is higher than the 1.4 specified in RG 1.198 for soil elements that would suffer relatively minor cyclic pore pressure generation. Based on a review of the subsurface condition and the liquefaction analysis, the staff concludes that no soils underlying the SHINE site are considered to be potentially liquefiable.

In SHINE FSAR section 3.4.2.6.4.7, the applicant stated that static earth pressure consists of at-rest, active, and passive soil pressure loads, which are applied as required to ensure the stability of the building. The NRC staff noted that the coefficients of lateral earth pressure for at-rest, active, and passive soil pressure loads on sub-grade walls of the SHINE facility were estimated in section 7.2.3, "Below Grade Walls," of the Preliminary Geotechnical Engineering Report. The staff performed a confirmatory calculation that confirmed the coefficients of lateral earth pressure. The staff's review of this information confirmed that proper consideration of static, active, and passive lateral soil pressure loads towards the subgrade wall has been given to the structural analysis and design of the SHINE facility.

The NRC staff noted that SHINE FSAR section 3.4.2.6.3.1, provided some soil parameters that were used in soil-structure interaction (SSI) analysis, such as the minimum average shear wave velocity, minimum unit weight, and Poisson's ratio. The staff also noted that backfill materials are used underneath and surrounding safety-related SSCs after excavation. As the properties of backfill materials are important input parameters in structural stability analysis, especially SSI analysis, the staff reviewed section 7.3, "Excavations," of the Preliminary Geotechnical Engineering Report. The staff noted that the Preliminary Geotechnical Engineering Report states that the backfill should be placed in maximum 8-inch-thick loose lifts and compacted to a minimum of 95 percent of the maximum Modified Proctor Dry Density value, which is in line with the requirements of general engineering practice in the industry. Based on its review of the Preliminary Geotechnical Engineering Report, the staff concludes that the soil parameters used in the SSI analysis are reliable and reasonable.

The applicant also provided other parameters in SHINE FSAR section 3.4.2.6.3.1, such as net allowable static bearing pressures at foundation levels. In response to NRC staff RAI 3.4-6, by letter dated December 15, 2020 (ML21011A264), Enclosure 3 (ML21011A240), the applicant provided detailed information on the determination of allowable soil bearing capacity at foundation elevations and allowable total and differential settlements for the specific designed structures, and a comparison of maximum structural foundation responses and soil/foundation capacities. The applicant stated that the allowable soil bearing pressure for the building foundation is at least 6,000 lb/ft^2 (287 kPa). The applicant concluded that the allowable soil bearing pressure is higher than the foundation contact pressures. The applicant provided a brief settlement evaluation that is based on the structural analysis results with soil subgrade reaction springs supporting the foundation. The applicant concluded that differential and total settlements are not beyond maximum allowable values.

To support the review of the applicant's geotechnical evaluation, the NRC staff conducted a regulatory audit (ML21089A334), to seek a detailed geotechnical evaluation to confirm that the allowable soil bearing pressure is higher than the foundation contact pressures, and that the differential and total settlements of foundations will not exceed maximum allowable values. During the audit, the staff reviewed the documents that included the evaluation of ultimate bearing capacity and allowable soil bearing capacity, as well as a calculation package for the structural design of the SHINE facility, including a detailed total settlement analysis and the predicted subgrade modulus of the SHINE site soils for the structural analysis. The staff's review of the analyses and calculations confirmed that the soil property parameters used for the analysis are adequate and conservative. For the applicant's bearing capacity evaluation, the staff noted that the calculation method based on Terzahgi's theory is widely accepted and used by the industry, and that the assumption of foundation sizes used in the calculation is conservative with respect to the bearing capacity. Regarding the applicant's settlement calculation, the staff noted that the total settlement was evaluated by three different recognized methods, including elastic analysis, Burland & Burbidge approximation, and Meyerhoff Settlement estimate.

The NRC staff also conducted a regulatory audit teleconference on March 16, 2021, with the applicant to better understand how the analyses and calculations support the information provided by the applicant in its response to RAI 3.4-6. As a result of this audit, the applicant revised the SHINE FSAR and supplemented its response to RAI 3.4-6 by letter dated April 16, 2021 (ML21106A136). The staff reviewed the information in revised SHINE FSAR section 3.4.2.6.3.1 and noted that the applicant clarified the net allowable static bearing pressure, provided information on the maximum foundation contact pressure predicted through structural response analysis under design load conditions, and verified that the maximum pressure can be enveloped by the allowable soil bearing capacity. The staff also reviewed the supplemented response to RAI 3.4-6 and noted that the applicant included the information in the response that the facility structure is designed to accommodate the potential differential and total settlements of the foundation of the facility structure and, consequently, that there are no allowable settlement limits. Based on its review of the information provided during the audit, the discussion at the audit teleconference, and the review of the revised application materials, the staff concludes that the applicant's evaluation of soil bearing capacity and settlement is adequate. The staff further concludes that the calculated bearing capacities based on conservatively assumed parameters still provide enough safety margin against the bearing demands, thereby ensuring the stability of the foundations and subsurface materials.
Based on its review, the NRC staff determined that the level of detail and analyses provided in SHINE FSAR section 2.5 demonstrate an adequate design basis and satisfy the applicable acceptance criteria of section 2.5 of NUREG-1537, Part 2 allowing the staff to find the following:

(1) The information on the geologic features, the potential seismic activity, and the geotechnical engineering properties including soil parameters, specifications, and foundation and subsurface material stability evaluations at the SHINE site has been provided in sufficient detail and in a form to be integrated acceptably into the design bases for SSCs and operating characteristics of the facility.

(2) The information in the SHINE FSAR indicates that damaging seismic activity at the SHINE site during its projected lifetime is very unlikely. Furthermore, if seismic activity were to occur, any radiological consequences are bounded or analyzed in SHINE FSAR chapter 13.

(3) The SHINE FSAR shows that there is no significant likelihood that the public would be subject to undue radiological risk following seismic activity; therefore, the potential for earthquakes does not make the SHINE site unsuitable for the facility.

Therefore, the NRC staff concludes that the SHINE site's geology, seismology, and geotechnical characteristics, as described in SHINE FSAR section 2.5, as supplemented by the applicant's responses to RAIs, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

2.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE site characteristics, as described in chapter 2 of the SHINE FSAR, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) The information provided by the applicant with regard to the SHINE site location and description is adequate and acceptable.

(2) The applicant's estimates of the present and projected populations surrounding the SHINE site, including transients, are reasonable and acceptable.

(3) The potentially hazardous activities on the SHINE site and in the vicinity of the facility have been identified and are reasonable and acceptable.

(4) The SHINE site characteristics associated with meteorology and general and local climatology are acceptable and reasonably representative of the site region.

(5) The SHINE site is not located where catastrophic meteorological events are likely, the applicant considered credible meteorological events in developing the design basis parameters for the facility, and the applicant provided adequate site characteristics needed to evaluate an uncontrolled release of radioactive materials.

(6) The SHINE site is not located where catastrophic hydrologic events are credible, the applicant considered credible hydrologic events in developing the design basis flood parameters for the facility, and the applicant provided adequate site characteristics needed to evaluate an uncontrolled release of radioactive materials in the event of a credible hydrologic occurrence

(7) No soils underlying the SHINE site are potentially liquefiable, and consideration of static, active, and passive lateral soil pressure loads towards the subgrade wall has been given to the structural analysis and design of the facility.

Based on the above determinations, the NRC staff finds that the SHINE site characteristics are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.0 DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

This chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) reviews the structures, systems, and components (SSCs) considered in the final design of the SHINE facility for its safe operation and for the protection of the public. The U.S. Nuclear Regulatory Commission (NRC, the Commission) staff evaluated these SSCs for their protective functions and related design features to ensure the adequacy of the facility defense-in-depth against uncontrolled release of radioactive material to the environment. The bases for the design criteria for some of the SSCs discussed in this chapter may have been developed in other chapters of the SHINE final safety analysis report (FSAR) and were considered in this chapter's review as deemed necessary.

This chapter of the SER describes the NRC staff's review and evaluation of the final design of the SHINE main production facility structure (FSTR), with its irradiation facility (IF) and radioisotope production facility (RPF), non-radiologically controlled seismic area, relevant non-safety areas, and the nitrogen purge system (N2PS) structure. In addition to the information in SHINE FSAR chapter 3, "Design of Structures, Systems, and Components," this review also includes additional relevant information from other chapters of the FSAR and the applicant's responses to staff requests for additional information (RAIs).

3.1 Areas of Review

SHINE FSAR sections 3.1, "Design Criteria," through 3.6, "Nitrogen Purge System Structure," are the applicable areas for the NRC staff's safety review of the SHINE FSTR, its IF, RPF, and safety and non-safety areas, and the N2PS structure as discussed below.

The NRC staff reviewed SHINE FSAR chapter 3 and other chapters for material and information regarding the final design of SSCs to safely operate the SHINE facility in response to transient and potential accident conditions analyzed in the FSAR. Sections 3.4.2, 3.4.3, and 3.4.5 of this SER specifically discuss the FSTR design features for protection during and/or after meteorological, water, and seismic events. The review considered applicable regulatory requirements and appropriate regulatory guidance and acceptance criteria.

The NRC staff reviewed the description and analysis of the SSCs of the SHINE facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The staff also reviewed the final analysis and evaluation of the design and performance of SSCs with the objective of assessing the risk to public health and safety resulting from the operation of the SHINE facility and the adequacy of the SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents. The staff reviewed whether there is reasonable assurance that the final design is adequate to remain safe during operation and capable of safe shutdown, as defined in SHINE technical specification (TS) 1.3, "Definitions," during environmental events and accident conditions. Special attention was provided to facility design and operating characteristics having unusual or novel design features to ensure that they remain safe and functional so that they can fulfill their intended function during facility operation.

3.2 Summary of Application

SHINE FSAR chapter 3 describes the principal design criteria and design bases of SSCs for the IF and RPF established to ensure facility safety and protection of the public. With the exception of discussions related to IF- or RPF-specific systems, the following summary applies to both the IF and the RPF.

SHINE FSAR section 3.1, "Design Criteria," discusses areas of the SHINE facility and its SSCs subject to this review for its safe operation to ensure that the SSCs within the facility demonstrate adequate protection against the hazards present for the range of normal operations, anticipated transients, and design-basis accidents (including during and/or after meteorological or hydrological events, water impact, abnormal loads, or a design-basis earthquake). This section includes relevant information to demonstrate that the design criteria are based on applicable standards, guides, and codes and to support that the SSCs will function as designed and required by the SHINE safety analyses. It also includes references to where the specifics of the design criteria are discussed in detail.

SHINE FSAR section 3.2, "Meteorological Damage," includes historical data and predictions as specified in SHINE FSAR chapter 2, "Site Characteristics," and discusses the criteria used to design the SHINE facility to withstand the site characteristics of wind, tornado, snow, and ice. The combination of meteorological loads with other loads (i.e., dead loads and earthquake loads) essential for the facility structural analysis is provided in SHINE FSAR section 3.4, "Seismic Damage," and further outlined below.

SHINE FSAR section 3.3, "Water Damage," provides information on the hydrological conditions found at the SHINE facility and discusses the criteria used to design against flooding. The combination of water-related loads with other loads (i.e., dead loads and earthquake loads) essential for the facility structural analysis is provided in SHINE FSAR section 3.4, and further outlined below.

SHINE FSAR section 3.4 includes an outline of the FSTR layout and describes its safety-related SSCs in the IF, RPF, the non-radiologically controlled seismic area, and a non-safety-related area and describes their performance to seismic and abnormal (e.g., aircraft impact) loadings. safety-related and non-safety-related SSCs, which are classified in two seismic categories, Seismic Category I and Seismic Category II, are reviewed. SHINE FSAR section 3.4 includes descriptions of the overall facility, its response to site seismicity, and analyses of potential accidents and hazards internal and external (e.g., damage analysis due to aircraft accidents from the nearby airport) to the FSTR. SHINE FSAR section 3.4 refers to SHINE FSAR chapter 2, which includes several sections on site seismicity, seismic input, and hazards essential to soil-structure interaction (SSI) analysis.

SHINE FSAR section 3.5, "Systems and Components," includes a high-level discussion on the design basis (e.g., separation, isolation, redundancy) and operation (e.g., condition of operation, setpoints, design features) of SHINE SSCs.

SHINE FSAR section 3.6, "Nitrogen Purge System Structure," discusses the N2PS structure and its SSCs. It also describes their design attributes, capacity, and performance associated with meteorological, water, and seismic events.

Additionally, this chapter of the SER includes the NRC staff's review of the SHINE facility safety-related SSCs and those SSCs that are non-safety-related but that perform functions that may impact safety-related SSCs. These SSCs are identified in SHINE FSAR tables 3.1-1 and 3.1-2, “Safety-Related Structures, Systems, and Components,” and “Nonsafety-Related Structures, Systems, and Components,” respectively.

Tables in SHINE FSAR chapter 3 list the applicable design criteria for the SSCs discussed in other FSAR chapters but that are referenced in chapter 3 for consideration as those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public and to control or mitigate the consequences of such accidents.

3.3 <u>Regulatory Requirements and Guidance and Acceptance Criteria</u>

The NRC staff reviewed SHINE FSAR chapter 3 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the principal design criteria and design bases and the information provided by SHINE for the issuance of an operating license.

3.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE principal design criteria and design bases are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34, “Contents of applications; technical information,” paragraph (b), “Final safety analysis report.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR 50.57, “Issuance of operating license.”
- 10 CFR Part 20, “Standards for Protection Against Radiation.”
- 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.”

3.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power

Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

- NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," issued June 2015.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, American Society of Civil Engineers (ASCE) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Following such guidance as well as local building codes and recognized industry practices, as applicable, provides reasonable assurance that any potential damage would not cause unsafe operations, prevent safe shutdown, or allow uncontrolled release of radioactive material. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, "References," of this SER.

In its review, the NRC staff also noted the applicant's voluntary adoption of guidance in specific sections of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [Light-Water Reactor] Edition," including section 3.7.1, "Seismic Design Parameters" (Agencywide Documents Access and Management System Accession No. ML14198A460) and section 3.7.2, "Seismic System Analysis" (ML13198A223) for developing seismic input and performing seismic analysis of the FSTR. The approach taken by SHINE is acceptable because the guidance of NUREG-0800 regarding seismic input and analysis is more stringent than that of NUREG-1537.

3.4 <u>Review Procedures, Technical Evaluation, and Evaluation Findings</u>

The NRC staff performed a review of the technical information presented in SHINE FSAR chapter 3, as supplemented, to assess the sufficiency of the principal design criteria and design bases for the SHINE facility and its safety-related SSCs for the protection of the public and the environment in support of the issuance of an operating license. The sufficiency of the principal design criteria and design bases is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 3.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in section 3.5, "Review Findings," of this SER.

3.4.1 Design Criteria

The NRC staff evaluated the sufficiency of the principal design criteria and design bases, as presented in SHINE FSAR section 3.1, using the guidance and acceptance criteria from section 3.1, “Design Criteria,” of NUREG-1537, Parts 1 and 2, and section 3.1, “Design Criteria,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The principal design criteria for the SHINE facility provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. The design bases identify the specific functions to be performed by an SSC and the specific values or ranges of values chosen for controlling parameters as reference bounds for the design. The principal design criteria for the SHINE facility were established in the preliminary safety analysis (PSAR) as required by 10 CFR 50.34(a)(3). This regulation also required SHINE to provide the design bases and the relation of the design bases to the principal design criteria for the facility.

Subparagraph 50.34(b)(2) of 10 CFR requires a description and analysis of the SSCs of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description must be sufficient to permit understanding of the system designs and their relationship to safety evaluations. Subparagraph 50.34(b)(4) of 10 CFR requires a final analysis and evaluation of the design and performance of SSCs with the objective stated in 10 CFR 50.34(a)(4) and consideration of any pertinent information developed since the submittal of the PSAR.

The NRC staff’s analysis of the SHINE facility SSCs evaluated whether the design bases and principal design criteria for the SHINE systems and subsystems are met and if the FSAR describes how the principal design criteria for the facility are achieved.

SHINE included the discussion of principal design criteria and design bases for SSCs in the applicable FSAR section describing those SSCs. For each SSC, SHINE FSAR tables 3.1-1 and 3.1-2 identify the applicable FSAR section or sections that describe the SSC. Similarly, the NRC staff evaluation, as applicable to the specific principal design criteria and design bases, is included within the chapter of this SER where the staff evaluated those SSCs.

The discussion in this section of the NRC staff’s evaluation discusses the acceptability of SHINE’s chosen principal design criteria identified in SHINE FSAR table 3.1-3, “SHINE Design Criteria,” and of the Nuclear Safety Classification, as described in SHINE FSAR section 3.1, established by SHINE to ensure that the risk of events is highly unlikely or that the consequences are mitigated to acceptable levels.

3.4.1.1 SHINE Facility Design Criteria

Generally, the SHINE facility design criteria adapt 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” Appendix A, “General Design Criteria for Nuclear Power Plants,” for a medical isotope production facility. Since the SHINE facility uses low-enriched uranium in the form of a uranyl sulfate target solution that is irradiated in a subcritical assembly by neutrons produced by a fusion neutron source, many of the general design criteria of 10 CFR Part 50, Appendix A do not apply to it. Additionally, as discussed in chapter 7, “Instrumentation and Control Systems,” of this SER, the application specific action items (ASAIs) specified in the NRC topical report on the highly integrated protection system (HIPS) platform are intended for power reactor applications and, therefore, some of the ASAIs do not apply to the application of the HIPS platform at the SHINE facility for the target solution vessel (TSV) reactivity protection system and engineered safety features actuation system (ESFAS).

The SHINE FSAR lists 39 design criteria for the SHINE facility. The majority of the design criteria have specific application to individual SSCs within the IF's irradiation units (IUs) and the RPF as listed in SHINE FSAR tables 3.1-1 and 3.1-2. The SHINE FSAR further states that Design Criteria 1 through 8 from SHINE FSAR table 3.1-3 are not specifically listed as applicable design criteria in tables 3.1-1 and 3.1-2 but are generally applicable to all SSCs.

Consistent with the guidance in NUREG-1537, the SHINE FSAR includes the following eight generally applicable design criteria:

Design Criterion 1 – Quality standards and records

> Safety-related structures, systems, and components (SSCs) are designed, fabricated, erected, and tested to quality standards commensurate with the safety functions to be performed. Where generally recognized codes and standards are used, they are identified and evaluated to determine their applicability, adequacy, and sufficiency and are supplemented or modified as necessary to ensure a quality product in keeping with the required safety function.
>
> A quality assurance program is established and implemented in order to provide adequate assurance that these SSCs satisfactorily perform their safety functions.
>
> Appropriate records of the design, fabrication, erection and testing of safety-related SSCs are maintained by or under the control of SHINE throughout the life of the facility.

The adequacy of the SHINE quality assurance program is reviewed and found acceptable in section 12.9 of this SER. The SHINE TSs assign the Operations Manager (Level 2) overall responsibility for the development and implementation of appropriate operational controls in accordance with the quality assurance program. Additionally, SHINE TS 5.2.4.1.f requires a biannual audit of the quality assurance program records by an independent review and audit committee and TS 5.4.4 requires that specific facility procedures be developed in accordance with the program. The NRC oversight and inspection program conducts inspections of program records to ensure that required records are maintained and audits were conducted in accordance with the TS requirements.

Design Criterion 2 – Natural phenomena hazards

> The facility structure supports and protects safety-related SSCs and is designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches as necessary to prevent the loss of capability of safety-related SSCs to perform their safety functions.
>
> Safety-related SSCs are designed to withstand the effects of earthquakes without loss of capability to perform their safety functions.

The NRC staff found SHINE's design for natural phenomena hazards acceptable in sections 2.4.3, 2.4.4, 2.4.5, 3.4.2, 3.4.3, and 3.4.4 of this SER. Also, the evaluation of the safety systems against the effects of natural phenomena is documented in sections 7.4.4.2.1 and 7.4.5.2.1 of this SER. Sections 8a.4 and 8b.4 of this SER evaluate the electrical system offsite power service; power distribution system; standby diesel generator and supported loads; distribution equipment; facility grounding system; lightning protection system; cathodic protection system; freeze protection; and cable and raceway components and routing.

Criterion 3 – Fire protection

> Safety-related SSCs are designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.
>
> Noncombustible and heat resistant materials are used wherever practical throughout the facility, particularly in locations such as confinement boundaries and the control room.
>
> Fire detection and suppression systems of appropriate capacity and capability are provided and designed to minimize the adverse effects of fires on safety-related SSCs. Firefighting systems are designed to ensure that their rupture or inadvertent operation does not significantly impair the safety capability of these SSCs.

The NRC staff found SHINE’s design for fire protection acceptable in sections 2.4.2.3, 9a.4.3, and 9b.4.3 of this SER. The staff’s evaluation of fire protection for the safety systems is provided in sections 7.4.4.2.1 and 7.4.5.2.1 of this SER. Additionally, combustible gas management is reviewed and found acceptable in sections 6a.4.2, 13a.4.9, 13a.5.1, and 13b.4.8 of this SER.

Criterion 4 – Environmental and dynamic effects

> Safety-related SSCs are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility.

The NRC staff found SHINE’s design for environmental and dynamic effects acceptable in section 2.4.2 of this SER. The staff also found SHINE’s protection system independence and equipment qualifications acceptable in sections 7.4.4.2.1 and 7.4.5.2.1 of this SER. Additionally, credible facility-specific events related to operations and maintenance, including heavy load drop events, are found acceptable in section 13a.4.12 of this SER. For the RPF, the staff found SHINE’s analyses for mishandling or malfunction of RPF equipment acceptable in section 13b.4.6 of this SER.

Criterion 5 – Sharing of structures, systems, and components

> Safety-related SSCs are not shared between irradiation units unless it can be shown that such sharing will not significantly impair their ability to perform their safety functions.

The NRC staff evaluated the design and performance of the SSCs of the SHINE facility, including those SSCs shared by both the IF and the RPF. The staff found acceptable SHINE’s design with respect to the sharing of SSCs, including the interface between the IF and the RPF and common systems shared between those facilities, as discussed in section 1.4 of this SER. Additionally, although all IUs share the ESFAS and the control room and although each train (Train A, B, and C) of the tritium purification system supplies a specific group of IUs, as discussed in sections 7.4.4.2.1 and 7.4.5.2.1 of this SER, the NRC staff found that the sharing of these systems does not impair the ability to perform the associated safety functions.

Criterion 6 – Control room

> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

The NRC staff found SHINE's control room design acceptable in section 7.4.9.1 of this SER. Additionally, the operator's role to perform required actions is reviewed and found acceptable in section 7.4.9.2 of this SER. The adequacy of specific controls and displays is evaluated in section 7.4.6 of this SER.

Criterion 7 – Chemical protection

> The design provides for adequate protection against chemical risks produced from licensed material, facility conditions that affect the safety of licensed material, and hazardous chemicals produced from licensed material.

The NRC staff found SHINE's evaluation of hazardous materials or activities on the SHINE site and in the vicinity of the SHINE site acceptable in section 2.4.2.3 of this SER. SHINE evaluated onsite toxic chemicals in SHINE FSAR section 13b.3, "Analyses of Accidents with Hazardous Chemicals," and SHINE FSAR table 13b.3-2, "Hazardous Chemical Source Terms and Concentration Levels." The staff found acceptable SHINE's evaluation for adequate protection against chemical risks in section 13b.4.9 of this SER.

Criterion 8 – Emergency capability

> The design provides emergency capability to maintain control of:
>
> 1) licensed material and hazardous chemicals produced from licensed material;
>
> 2) evacuation of on-site personnel; and
>
> 3) on-site emergency facilities and services that facilitate the use of available off-site services.

The NRC staff evaluated SHINE document EMG-01-01, Revision 1, "Emergency Plan," to assess the sufficiency of SHINE's emergency capability. The staff found SHINE's design for emergency capability acceptable in section 12.4.7 of this SER.

The remaining 31 SHINE facility design criteria are specifically assigned to systems and subsystems as detailed in SHINE FSAR tables 3.1-1 and 3.1-2. The NRC staff evaluations of those specific design criteria are provided in the corresponding sections of this SER.

3.4.1.2 SHINE Facility Nuclear Safety Classification

To demonstrate that the principal design criteria are adequate, SHINE FSAR section 3.1 provides that acceptable risk is achieved by ensuring that all postulated events are highly unlikely or by reducing the consequences to less than the SHINE safety criteria. The SHINE safety criteria are listed below followed by the NRC staff's evaluation of their acceptability as constraints to meet NRC regulations and ensure public health and safety.

> SHINE Safety Criterion: An acute worker dose of five rem [roentgen equivalent man] or greater total effective dose equivalent (TEDE).

A dose of 5 rem TEDE is the regulatory occupational dose limit for adults under 10 CFR 20.1201, "Occupational dose limits for adults." It is also the basis for the derived annual limit on intake (ALI) for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rem. SHINE defines the control room operator as the "worker" receptor for calculating radiological consequences.

> SHINE Safety Criterion: An acute dose of 1 rem or greater TEDE to any individual located outside the owner-controlled area.

As discussed in section 13a.4.1 of this SER, no radiological accident dose criterion is set forth in the NRC's regulations or in applicable guidance to assess the risk to public health and safety and control room operators for non-power production or utilization facilities (NPUFs). As a matter of comparison, the NRC staff has used the public dose limits of 10 CFR Part 20 (i.e., 0.1 rem TEDE) as the accident dose criteria to license NPUFs (e.g., Safety Evaluation Report Related to Renewal of the Facility Operating License for the University of Massachusetts Lowell Research Reactor," dated February 2022 (ML21168A054)). For a research reactor, the results of the accident analysis have generally been compared with 10 CFR 20.1001 through 20.2402 consistent with the guidance in chapter 13 of NUREG-1537, Part 2. However, the NRC staff described in the *Federal Register* on March 30, 2017 (82 FR 15643), a proposal to amend the NRC's regulations that govern the license renewal process for non-power reactors, testing facilities, and other production or utilization facilities, licensed under the authority of section 103, section 104a, or section 104c of the Atomic Energy Act, as amended, that are not nuclear power reactors. In this proposed rule, the NRC collectively refers to these facilities as NPUFs, which would include the SHINE facility. The staff stated that it had determined that the 10 CFR Part 20 public dose limit of 0.1 rem TEDE is unduly restrictive to be applied as accident dose criteria for NPUFs not subject to 10 CFR Part 100, "Reactor Site Criteria," which would include the SHINE facility, and proposed, instead, an accident dose criterion of 1 rem. In addition to being consistent with the proposed accident dose criterion in 82 FR 15643, the staff also finds SHINE's accident dose criterion to be acceptable based on the early phase protective action guides (PAGs) established by the U.S. Environmental Protection Agency (EPA), which were published in the EPA document EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents," dated January 2017, to provide reasonable assurance of adequate protection of the public from unnecessary exposure to radiation. The maximum hypothetical accident at the SHINE facility, which would result in a maximum public dose of 0.727 rem, is reviewed and found acceptable in section 13.5.4.7 of this SER.

SHINE Safety Criterion: An intake of 30 milligrams or greater of uranium in a soluble form by any individual located outside the owner-controlled area.

As discussed in the “Introduction to the Interim Staff Guidance,” of the ISG augmenting NUREG-1537, Part 2, the NRC staff has determined that the use of integrated safety analysis methodologies, as described in 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, “Performance requirements,” designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for medical isotope production facilities. As noted in the ISG, this is just one acceptable way of demonstrating the safety of a medical isotope production facility and is not required. Further, the ISG does not require licensees that would not otherwise have to follow the regulations in 10 CFR 70.61 to do so. Under 10 CFR 70.61(b), licensees must use engineered controls, administrative controls, or both to reduce the likelihood of occurrence of each credible high consequence event such that the events are highly unlikely or their consequences are less severe than those described in 10 CFR 70.61(b)(1)-(4). Further, 10 CFR 70.61(b)(3) defines events resulting in an intake of 30 milligrams or greater of uranium in soluble form by any individual located outside the controlled area identified pursuant to 10 CFR 70.61(f) as high consequence events. Finally, 10 CFR 70.61(f) requires licensees to establish a controlled area, as defined in 10 CFR 20.1003, “Definitions,” and notes that licensees must retain the authority to exclude or remove personnel and property from this area.

Although 10 CFR 70.61 does not apply to SHINE, SHINE proposed to adopt the following safety criterion: an intake of 30 milligrams or greater of uranium in a soluble form by any individual located outside the owner-controlled area. As an initial matter, SHINE FSAR section 2.1.1.2, “Boundary and Zone area Maps,” defines an owner-controlled area consistent with the definition of controlled area in 10 CFR 20.1003. Additionally, SHINE retains the authority to exclude or remove personnel and property from this area. Consequently, SHINE proposes to use this criterion from the radiological and chemical consequences and likelihood criteria contained in the performance requirements of 10 CFR 70.61 as a safety criterion.

Consistent with the ISG augmenting NUREG-1537, Part 2, SHINE has chosen to adopt the 30 milligrams or greater soluble uranium criterion from the radiological and chemical consequences and likelihood criteria contained in the performance requirements of 10 CFR 70.61 as a safety criterion. The NRC staff finds this acceptable because, as discussed in the ISG augmenting NUREG-1537, Part 2, doing so presents an acceptable means of demonstrating adequate safety for a medical isotope production facility.

SHINE Safety Criterion: An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could lead to irreversible or other serious, long-lasting health effects to a worker or could cause mild transient health effects to any individual located outside the owner-controlled area.

SHINE FSAR section 13a2 states that the SHINE safety analysis (SSA) applies a methodology based on NUREG-1520 to identify and evaluate credible accident scenarios, including hazardous chemical accidents. The NRC staff evaluated the SSA using the guidance and acceptance criteria from the ISG augmenting NUREG-1537, Parts 1 and 2, which endorses as one acceptable method the use of integrated safety analysis methodologies as described in 10 CFR Part 70 and NUREG-1520. As discussed in section 13a.4.2 of this SER, the staff found SHINE's analysis of radiological consequences as well as chemical consequences for chemical hazards directly associated with NRC licensed radioactive material acceptable.

> SHINE Safety Criterion: Criticality where fissionable material is used, handled, or stored (with the exception of the target solution vessel).

SHINE analyzed inadvertent nuclear criticality in the RPF in SHINE FSAR section 13b.1.2.5. SHINE stated that nuclear criticality safety is achieved through the use of preventative controls throughout the RPF, which reduces the likelihood of a criticality accident to highly unlikely. The NRC staff reviewed this and found SHINE's analysis of inadvertent nuclear criticality in the RPF acceptable in section 6b.4.3 of this SER.

> SHINE Safety Criterion: Loss of capability to reach safe shutdown conditions.

SHINE defines "Safe Shutdown" in proposed TS 1.3 as:

> An IU is in a Safe Shutdown condition if the following performance criteria are achieved and maintained:
>
> A. Target solution is not present:
>
> No target solution is present in the IU
>
> AND
>
> TSV fill valves are closed.
>
> OR
>
> B. Target solution is present:
>
> Target solution is drained from the TSV
>
> AND
>
> Hydrogen is controlled:
>
> Nitrogen purge system (N2PS) is Operable
>
> OR
>
> Target solution hydrogen generation rates are below those requiring preventive controls.

The NRC staff evaluated the specified conditions identified by SHINE for safe shutdown. If target solution is not present within an IU, the IU is stated to be in Mode 0, as defined in proposed TS table 1.3, "IU Modes of Operation." The additional requirement that the TSV fill valves be closed helps ensure that the IU is in a safe shutdown condition. Alternately, the facility is in safe shutdown if target solution is present (but not present in the TSV) and hydrogen is controlled. This implies that the IU is in either Mode 3 (post-irradiation (shutdown)) or Mode 4 (transfer to RPF). Although the hydrogen generation rate of the irradiated target solution is minimized by stopping irradiation activities, hydrogen generation continues in facility tanks containing irradiated target solution or radioactive liquid waste via radiolysis generated by radioactive decay. Control of hydrogen minimizes the risk of reaching a flammable concentration and is assured by either operating the N2PS or when hydrogen generation rates are below levels of concern. The draining of the target solution to the TSV dump tank results in safe shutdown since the target solution is drained to the favorable geometry TSV dump tank. The staff evaluated the subcritical assembly and phenomena that are expected to impact the changes in target solution composition in sections 4a.4.2 and 13a4.1 of this SER and found that the target solution design and its interface with the pressure boundary offer reasonable assurance that the health and safety of the public can be assured during normal operation and that the SHINE safe shutdown safety criterion ensures that the facility is designed to automatically shut down the irradiation process, place the target solution into a safe condition, and stabilize accident conditions without immediate operator actions.

3.4.1.3 Review Findings for SHINE Facility Design Criteria and Nuclear Safety Classification

The NRC staff reviewed the descriptions and discussions of the SHINE facility design criteria and nuclear safety classification, as described in SHINE FSAR section 3.1, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE FSAR, the staff determined that:

- SHINE specified design criteria for each SSC that is assumed in the FSAR to perform an operational or safety function.

- SHINE design criteria include references, where appropriate, to applicable up-to-date standards, guides, and codes. The descriptions of the design are included in the section of the FSAR that corresponds to the specific SSC and generally include the following:

    - Design for the complete range of normal expected operating conditions.

    - Design to cope with anticipated transients and potential accidents, as discussed in Chapter 13, "Accident Analysis" of the FSAR.

    - Design for redundancy, so that any single failure of any active component will not prevent safe shutdown or result in an unsafe condition.

    - Design to facilitate inspection, testing, and maintenance.

    - Design with provisions to avoid or mitigate fires, explosions, and potential man-made or natural conditions.

    - Quality standards commensurate with the safety function and the potential risks.

    - Analysis and designs for meteorological, hydrological, and seismic effects (see sections 3.2, 3.3, and 3.4 of the staff's SER)

    - Design bases necessary to ensure the availability and operability of required SSCs.

The principal design criteria are the criteria that SHINE established to ensure, in part, that the SHINE safety criteria are met. The SHINE safety criteria are the criteria that SHINE established to ensure that the principal safety considerations of the facility are adequately addressed. The

SHINE safety criteria are derived from the performance requirements in 10 CFR 70.61(b) and (c). These are not required to be applicable to SHINE's 10 CFR Part 50 license, but were adopted by SHINE to provide controls, to the extent needed, to reduce the likelihood of occurrence and consequences of events. The SHINE nuclear safety classification states that the components that are relied upon to achieve SHINE's safety criteria are classified as safety-related. The NRC staff finds that the safety-related SSCs identified by SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents to within acceptable limits. Therefore, the staff concludes that the SHINE discussion regarding nuclear safety classification is acceptable.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE facility design criteria and nuclear safety classification are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.4.2 Meteorological Damage

The NRC staff evaluated the sufficiency of the SHINE facility design features to cope with meteorological damage, as presented in SHINE FSAR section 3.2, using the guidance and acceptance criteria from section 3.2, "Meteorological Damage," of NUREG-1537, Parts 1 and 2, and section 3.2 of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 3.2 of NUREG-1537, Part 2, the NRC staff considered the description of the site meteorology to ensure that all SSCs that could suffer meteorological damage are considered, as presented in SHINE FSAR sections 3.2 and 3.6 and other relevant chapters of the FSAR. The design criteria are compatible with local architectural and building codes for similar structures. The design specifications for SSCs are compatible with the functional requirements and capability to maintain their function throughout the predicted meteorological conditions. The methods for determining the wind, tornado, and snow and ice loadings are summarized. In SHINE FSAR section 3.4.2.6.3, "Site Design Parameters," these loads are provided as site design parameters rather than as structural design loads. The combinations of the meteorological loads with other loads (i.e., dead loads and earthquake loads) for the structural analysis are discussed in SHINE FSAR section 3.4.2.6.4, "Design Loads and Loading Combinations."

In its review of SSCs considered for meteorological damage, the NRC staff noted that SHINE FSAR sections 3.2 and 3.4.2.6.3 describe the design criteria, methodology, and parameters used for the main production facility structure. However, based on the staff review of SHINE FSAR section 1.4, "Shared Facilities and Equipment," and audited documents, the staff noted that other structures that may support and protect safety-related SSCs from meteorological damage may have not been properly described in the FSAR. The staff also noted that the FSAR inconsistently used the term "SHINE facility" to either refer to the main production facility structure (alone) or to refer to all of the structures within the SHINE facility, as described in SHINE FSAR section 1.4.

During its evaluation of the applicant's response to NRC staff RAI 3.2-1 (ML21029A101), Enclosure 1 (ML21029A103), the staff noted that SHINE stated that the N2PS structure is the only structure described in SHINE FSAR section 1.4 that is not part of the main production facility structure, and that it performs a safety-related function. Since this structure is not considered part of the main production facility structure, SHINE added section 3.6 to its FSAR to incorporate the design criteria, parameters, and methodology for evaluating meteorological damage that is applicable to the N2PS structure and to describe how that structure is designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, and floods. The staff also noted that the design criteria applicable to the N2PS structure are SHINE Design Criteria 1 through 4, as described in SHINE FSAR table 3.1-3. During its review of SHINE FSAR section 3.6, the staff noted that the N2PS structure is designed to withstand the same potential meteorological damage described in SHINE FSAR section 3.2 for the main production facility structure. Therefore, the staff's evaluation of the main production facility structure also applies to the N2PS structure.

The NRC staff finds the applicant's response, addition of section 3.6 to the SHINE FSAR, and changes to SHINE FSAR table 3.1-1 acceptable because SHINE: (a) confirmed that the N2PS structure is the only structure described in SHINE FSAR section 1.4 that has a safety-related function and is not part of the main production facility structure and (b) provided a description, included in the FSAR, of the design criteria, parameters, and methodology applicable to the N2PS structure.

During its review of the design criteria and parameters considered for coping with meteorological damage, the NRC staff noted that some of the criteria, parameters, and methodology defined in SHINE FSAR sections 3.2 and 3.4 were not sufficiently described to understand how the structures were designed for protection from the meteorological condition. To ensure that the applicable design criteria, parameters, and methodology to cope with meteorological damage are sufficiently described in the FSAR, and to provide reasonable assurance that SSCs would continue to perform necessary operational and safety functions throughout the predicted meteorological conditions, the staff issued RAIs 3.2-2 and 3.2-3 (ML21309A019).

During its evaluation of the applicant's response to NRC staff RAI 3.2-2 (ML21011A264), Enclosure 3 (ML21011A240), the staff noted that SHINE FSAR sections 3.2 and 3.4 were revised to also include the following design criteria/parameters:

(1) the exposure coefficient and other factors used in SHINE FSAR Equation 3.2-1 for the wind loading, including the gust factor and pressure coefficient;

(2) the basic wind speed for Wisconsin, including a description of the applied factor to account for a 100-year recurrence interval;

(3) the values applicable to the site for the tornado rotational speed, translation speed, differential pressure, and rate of differential pressure, including additional discussion of the site's design basis tornado missile spectrum and maximum horizontal speed, used for the tornado loading; and

(4) the values applicable to the site for the factors used in SHINE FSAR Equation 3.2-3 for snow, ice, and rain loading, including the snow load and recurrence interval.

During its evaluation of the applicant's response to NRC staff RAI 3.2-3 (ML21011A264), Enclosure 3 (ML21011A240), the staff noted that SHINE clarified that the methodology and acceptance criteria described in NUREG-0800, section 3.5.3, "Barrier Design Procedures" (ML070570004), were used to transform the tornado generated missile impacts into an effective or equivalent static load on the structures. In its response, SHINE also stated that SHINE FSAR section 3.2.2.2 had been revised to correct the reference to NUREG-0800, section 3.5.3 and to add additional information related to the tornado missiles considered in the analysis.

The NRC staff finds the applicant's response and changes to SHINE FSAR sections 3.2.1, 3.2.2, 3.2.3, and 3.4.2.6.3 acceptable because the additional design criteria provided by the applicant for meteorological damages: (a) are consistent with applicable local building codes, national standards, guidelines, and recognized industry practices and (b) are sufficient to provide reasonable assurance that SSCs would continue to perform necessary operational and safety functions throughout the predicted meteorological conditions. The staff also finds the applicant's response and changes to SHINE FSAR section 3.2.2.2 acceptable because they clarify that the methodology used by SHINE is consistent with NUREG-0800, section 3.5.3, which provides an acceptable methodology and criteria for transforming tornado generated missile impacts into an effective or equivalent static load on the structures.

In its review of the methodology used for determining loading and its design, the NRC staff noted that potential meteorological conditions are considered in the design of the SHINE facility by analyzing the pressure effects of wind loads, tornado loads (including tornado generated missiles), snow loads, ice loads, and rain loads using a 100-year return period, as described in SHINE FSAR sections 3.2 and 3.4.2.6.3. These loads are determined by the methodology and guidelines provided in ASCE Standard 7-05, "Minimum Design Loads for Building and Other Structures," and the NRC Regulatory Guide (RG) 1.76, "Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants" (ML070360253). As stated in SHINE FSAR sections 3.2.3 and 3.4.2.6.3.9, rain loading was not considered to be a potential concern because the SHINE facility is designed with a sloped roof and a building configuration that precludes the accumulation of rainwater. Also, as stated in its previous response to NRC staff RAI 3.2-1 for the construction permit application, by letter dated December 3, 2014 (ML14356A528), Enclosure 2 (ML14357A345), rain-on-snow surcharge load was not considered in the structural analysis because the SHINE facility is located in an area where the ground snow load (as determined from figure 71 of ASCE 7-05) is greater than 20 pounds per square foot. The NRC staff also noted that SHINE FSAR section 3.4.2.6.2 states that the following codes and standards are used for the design of the SHINE facility: (a) American Concrete Institute (ACI) 349-13, "Code Requirements for Nuclear Safety-Related Concrete Structures and Commentary," and (b) ANSI/American Institute of Steel Construction (AISC) N690-12, "Specification for Safety-Related Steel Structures for Nuclear Facilitates." Based on the information provided, the NRC staff finds that the design, methodology, and parameters used are consistent with local applicable architectural and building codes for similar structures and are compatible with the SHINE facility functional requirements and capability to retain function throughout the predicted meteorological conditions.

Based on its review, the NRC staff determined that the level of detail provided on meteorological damage is adequate and supports the applicable acceptance criteria of section 3.2 of NUREG-1537, Part 2. The staff concludes that the design criteria and the design for protection from meteorological damage conditions are based on applicable local building codes, standards, and criteria, which provides assurance that SSCs will continue to perform their safety functions as specified in the SHINE FSAR. Therefore, the SHINE facility design features for coping with meteorological damage meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.4.3 Water Damage

The NRC staff evaluated the sufficiency of the SHINE facility design features to cope with predicted hydrological conditions, as presented in SHINE FSAR section 3.3, using the guidance and acceptance criteria from section 3.3, "Water Damage," of NUREG-1537, Parts 1 and 2, and section 3.3 of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 3.3 of NUREG-1537, Part 2, the NRC staff considered the site description and facility designs to ensure that all safety-related SSCs with the potential for water damage, including damage due to external and internal flood hazards, are considered in the SHINE FSAR. For any such safety-related SSCs, the staff reviewed the design bases to verify that the consequences are addressed and described in detail in the appropriate chapters of the FSAR.

3.4.3.1 Flood Protection from External Sources

SHINE FSAR section 3.3 describes that the design basis precipitation level is at site grade, the design basis flood level is at 50 feet below grade, and the maximum ground water level is at 50 feet below grade. These levels are associated with the local probable maximum precipitation (PMP) and the local probable maximum flood (PMF) and are quantified in SHINE FSAR section 2.4.2.3, "Effect of Local Intense Precipitation," and section 2.4.3, "Probable Maximum Flood on Streams and Rivers."

SHINE FSAR section 2.4.2.3 states that the effect of the local PMP on the areas adjacent to the safety-related structures of the SHINE facility, including the drainage from the roofs of the structures, was evaluated. The maximum water levels due to the PMP were estimated near the safety-related structures of the facility based on the site topographic survey map. A drainage system designed to carry runoff from the site consists of conveying water from roofs, as well as runoff from the site and adjacent areas, to peripheral ditches. The facility is surrounded by berms with interior ditches along the berms and the grade around the structures slopes towards the peripheral ditches. However, during a PMP event, the stormwater drainage system is conservatively assumed to be nonfunctional. During a PMP event, the water level is estimated to be at grade and the top of the finished foundation elevation is at least 4 inches (in.) above grade.

SHINE FSAR section 2.4.3 notes that a local PMF event creates a water level approximately 50 feet below grade. The lowest point of the facility is 29 feet below grade; therefore, flooding would not cause any structural loading in the case of a local PMF event and there is no dynamic force on the structure due to precipitation or flooding. The lateral surcharge pressure on the structures due to the design PMP water level is calculated and does not govern the design of the below grade walls.

In its response to NRC staff RAI 3.2-1 (ML21029A101), Enclosure 1 (ML21029A103), the applicant noted that the N2PS structure performs a safety function and, therefore, added section 3.6 to the SHINE FSAR to discuss the design of this structure. The applicant also noted that the external flooding assumptions (i.e., PMP and PMF water levels) are the same for the N2PS structure as for the main production facility and that the N2PS structure has been designed to ensure that water does not infiltrate the structures and cause damage to safety-related SSCs.

The NRC staff reviewed the information on the site PMP and PMF provided in SHINE FSAR sections 2.4.2.3, 2.4.3, 3.3, and 3.6.2. The staff noted that the design PMP elevation is at plant grade and that the PMF is approximately 50 feet below grade and approximately 21 feet below the lowest point of the facility. In addition, the staff noted that the finished foundation level is at least 4 in. above site grade. Based on its review, the staff finds that there is no dynamic force applied to the structures due to precipitation or flooding, and that a PMP or a PMF event will not cause water to infiltrate the structures and result in damage to safety-related SSCs.

3.4.3.2 Flood Protection from Internal Sources

SHINE FSAR section 3.3.1.1.2, “Flood Protection from Internal Sources,” states that the bounding flood volume in the radiologically controlled area (RCA) is from the fire protection system (FPS). The credible volume of discharge from the FPS is due to a manual fire-fighting flow rate of 500 gallons per minute (1893 liters per minute) for a duration of 30 minutes, in accordance with the guidance in section 5.10 of National Fire Protection Association (NFPA) 801, “Standard for Fire Protection for Facilities Handling Radioactive Materials.” Therefore, the total discharge volume is 15,000 gallons (56,782 liters). The resulting flooded water depth in the RCA from this fire protection discharge is less than 2 in., which bounds the total water available in the process chilled water system (PCHS) and the radioisotope process facility cooling system (RPCS) that could cause internal flooding. The floors of the uranium receipt and storage system/target solution preparation system rooms are elevated to prevent water intrusion in the event of an internal flood and water sensitive safety-related equipment in the RCA is raised 8 in. from the floor. Safety-related functions of systems that are subject to the effects of a discharge of the fire suppression system are appropriately protected by redundancy and separation. SHINE FSAR section 3.3.2 notes that the load from build-up of water due to FPS discharge is supported by slabs on grade except for the mezzanine floor. However, the mezzanine floor includes openings that will ensure that the slab is not significantly loaded and it is designed with a live load value of 250 pounds per square foot.

SHINE FSAR section 3.3.1.1.2 also notes that flood scenarios have been considered for the pipe trenches and vaults. Process piping, vessels, and tanks containing special nuclear material or radioactive liquids are seismically qualified. There is no high-energy piping within these areas and any pipe or tank rupture in the RPF vaults is routed to the radioactive drain system (RDS). The RDS is sized for the maximum postulated pipe or tank failure as described in SHINE FSAR section 9b.7.6. The design of the shield plugs over the pipe trenches and vaults prevents bulk leakage of liquid into the vaults from postulated flooding events within the remainder of the RCA.

The NRC staff reviewed the information provided in SHINE FSAR section 3.3.2 and noted that the loads due to possible water build-up are supported by slabs on grade, which will be able to support the additional water load. The mezzanine floor is not on grade; however, it has been designed to limit the possible water load to less than the design live load of the floor. Therefore, the staff determined that the structures have been properly designed to support any additional loads from water due to FPS discharge. The staff also reviewed SHINE FSAR section 3.3.1.1.2 and noted that the bounding volume of water in the RCA was due to a manual discharge of the FPS. As part of its review of internal flooding, the staff conducted an audit, during which it reviewed calculations associated with postulated flooding depths in the RCA. The staff identified locations in the RCA that appeared to have flooding depths greater than 8 in. To understand how equipment in these areas would be protected from flooding, the staff issued RAI 3.3-1 (ML21309A019). The staff also noted in the audit that manual flood barriers will be used to control flooding.

In its response to NRC staff RAI 3.3-1 (ML21011A264), Enclosure 3 (ML21011A240), the applicant stated that the bounding internal flood volume of 15,000 gallons distributed over the minimum open floor space in the IF results in a maximum flood height of approximately 11.7 in. Therefore, the design was revised to raise the minimum height of water-sensitive, safety-related equipment in the RCA to 12 in. above the floor. The RAI response also describes that the bounding flood scenario in the RPCS room results in a flood height of approximately 22.9 in. In this room, the minimum height for water-sensitive, safety-related equipment is 24 in. above the floor. The RAI response further notes that the manual flood barrier in the RPCS room is not relied on in the safety analysis to keep leakage from leaving the room.

The NRC staff reviewed the information in SHINE FSAR section 3.3.1.1.2 and finds it acceptable because the applicant clearly identified the maximum flood heights in the building and that the minimum heights of water-sensitive, safety-related equipment ensures that the equipment remains above the postulated internal flood levels.

While reviewing the information provided in SHINE FSAR section 3.3.1.1.2, the staff also noted that the uninterruptible electrical power supply system has two redundant and isolated trains to prevent both trains from being damaged by discharge of the FPS.

In its response to NRC staff RAI 3.3-2 (ML21011A264), Enclosure 3 (ML21011A240), the applicant stated that safety-related equipment subject to discharge of the FPS are protected by redundancy and separation, where practicable. Where equipment cannot be effectively separated, fire response plans are established to ensure that redundant trains are not simultaneously damaged from activation of the FPS.

The NRC staff reviewed the information in SHINE FSAR section 3.3.1.1.2 and finds it acceptable because it describes that water-sensitive, safety-related equipment is protected from discharge of the FPS either by redundancy and separation, or with an appropriate fire response plan.

The NRC staff reviewed SHINE FSAR section 3.6, which describes the design of the N2PS structure. The staff reviewed the information provided in SHINE FSAR section 3.6.2 related to water damage of the N2PS structure and noted that there are no water sources internal to the N2PS structure and so there is no risk of internal flooding. Since there are no internal water sources, the staff finds that there is no potential internal flooding hazard that would cause damage to safety-related SSCs in the N2PS structure.

Based on its review, the NRC staff finds that the safety-related SSCs are adequately protected from internal flooding hazards and that the structures are adequately designed to withstand additional loads from postulated internal flooding.

3.4.3.3 Water Damage Evaluation Summary

Based on its review, the NRC staff determined that the level of detail provided on water damage is adequate and supports the applicable acceptance criteria of Section 3.3 of NUREG-1537, Part 2. The staff concludes that the design criteria and the designs would protect against potential water damage and provide reasonable assurance that SSCs would continue to perform their required safety functions, would not cause unsafe facility operation, would not prevent safe shutdown of the facility, and would not cause or allow uncontrolled release of radioactive material. Therefore, the SHINE facility design features for coping with postulated water damage meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.4.4 Seismic Damage

SHINE FSAR section 3.4 describes the general arrangement of the SHINE FSTR, its IF, RPF, the non-radiologically controlled seismic area, and a non-safety-related area. The IF, RPF, and non-radiologically controlled seismic area are within the seismic boundary of the facility and are classified as Seismic Category I SSCs.

The NRC staff evaluated the sufficiency of the FSTR design and its features to cope with potential seismic damage, as presented in SHINE FSAR section 3.4. The staff's review used the guidance and acceptance criteria from section 3.4, "Seismic Damage," of NUREG-1537, Parts 1 and 2, and section 3.4 of the ISG augmenting NUREG-1537, Parts 1 and 2, applicable references listed in SHINE FSAR section 3.7, and, when and where applicable and as deemed necessary, the additional guidance from sections 3.7.1 and 3.7.2 of NUREG-0800. Consistent with the review procedures of section 3.4 of NUREG-1537, Part 2, the staff also considered the site description and facility design to ensure that all safety-related SSCs with a potential for seismic damage were considered.

SHINE described the FSTR as a reinforced concrete box shear wall system on soil. Its major structural elements include the foundation mat, mezzanine floor, roof slab, and shear walls. Steel roof trusses support the concrete roof slab of the IF and RPF. The mezzanine floor is made of reinforced concrete on metal deck. The floor is vertically supported by structural steel beams and columns, and laterally restrained by reinforced concrete partition walls. A large section of the basemat in the RPF is recessed below-grade to accommodate a series of tanks, valve pits, and other mechanical systems. The tanks are separated by cast-in-place reinforced concrete walls and are covered by precast concrete shield plugs. Depending on their function, interior FSTR walls are made of cast-in-place reinforced concrete, reinforced masonry, or gypsum boards mounted to metal studs. Additional details of facility SSCs and equipment that include an exhaust stack, supercells, and below grade reinforced concrete vaults and tanks are also found in other FSAR chapters (e.g., sections 1.2.1, 2.1.1.2, 3.4.2.6.4.1, and 4b.2.2.2 and tables 7.7-2 and 7.7-3).

To ensure that all applicable design criteria, parameters, and methodology to cope with seismic/transient and other abnormal loads are sufficiently addressed in the FSAR, and to obtain reasonable assurance that SSCs would continue to perform their operational and safety functions during seismic events and for abnormal loads, the NRC staff issued RAIs. The staff reviewed SHINE's response to NRC staff RAI 3.4-7 (ML21011A264), Enclosure 3 (ML21011A240), and finds it acceptable because consistent with NUREG-1537, the applicant's design follows the applicable guidance of RGs, NUREGs, local building codes, and national codes and standards that include provisions for materials testing. The staff also finds the applicant's revisions to SHINE FSAR sections 3.4 and 3.7 acceptable because they reflect references to RGs, NUREGs, local building codes, and national codes and standards that are applicable to the facility design.

To further clarify how various FSTR SSCs (e.g., the stack, walls, tanks, vaults, supercells, etc.) are configured and integrated into the seismic design and because of concern that potential future internal rearrangement of FSTR SSCs and relocation of equipment could alter the intent of the original structural design and to ensure that the facility would continue to maintain its defense-in-depth, the NRC staff issued RAIs. The NRC staff reviewed the applicant's response to NRC staff RAI 3.4-8 (ML21011A264), Enclosure 3 (ML21011A240), and finds its discussion of configuration control acceptable because proposed SHINE TS 5.5.4, "Configuration Management," includes an oversight and controls program that addresses changes made to the facility design, to its physical configuration, and to its documentation so that these are in accordance with the 10 CFR 50.59, "Changes, tests and experiments," process.

The NRC staff noted that although SHINE updated its FSAR to include additional FSTR design details such as its size and seismic isolation, other key design information on the FSTR (e.g., its height, thickness of its walls, materials used for its construction) and its SSCs (e.g., anchorage) was still lacking. This level of detail is needed to sufficiently evaluate future changes that may be made to the facility or its reconfiguration consistent with the 10 CFR 50.59 process and to confirm the conservatisms in the FSTR design and that of its SSCs. Therefore, the NRC staff issued RAIs.

The NRC staff reviewed SHINE's response to NRC staff RAI 3.4-18 (ML21208A135), and noted that the applicant expanded upon the FSAR description of the FSTR and clarified that the collapse of the exhaust stack would not endanger the FSTR, its safety-related SSCs, or the N2PS facility, as these are either designed to withstand substantial loads, such as aircraft impacts, or are removed from harm's way. In its RAI response, the applicant also clarified that the collapse of the stack on the non-safety-related portion of the facility or on the Seismic Category II interior partitions, would not affect safety-related SSCs or create a risk exceeding established facility safety criteria. Furthermore, the applicant clarified that supercells are integrated in the FSTR design and that the concrete shield plugs are properly sized and accounted for in the design. The staff finds that the applicant's finalized facility configuration description and statement that safety-related SSCs are qualified to be functional during and after a transient or abnormal loadings is adequate and consistent with the regulatory framework and, therefore, acceptable. The staff also finds that SHINE's revisions to FSAR sections 3.4, 3.7, 9a2.1.1.1, and 4b.2.2.2.1 are adequate as they provide more detailed descriptions of the facility and of its SSCs and, therefore, are acceptable.

3.4.4.1 Seismic Input

SHINE FSAR section 3.4.1, "Seismic Input," provides an overview of the site seismicity and seismic input for the seismic analysis of the facility. It provides information for the peak ground acceleration for the safe shutdown earthquake (SSE), its design response spectra, synthetic time histories for SSI analyses, and critical damping values for structural components. SHINE FSAR 3.4.1.1, "Design Response Spectra," states that the SSE is defined by a maximum ground acceleration of 0.2 g (seismic acceleration, rate of change of velocity per unit time, e.g., feet per second^2 (ft/s^2)) and design response spectra in both vertical and horizontal directions, as per Regulatory Guide 1.60, Revision 2, "Design Response Spectra for Seismic Design of Nuclear Power Plants" (ML13210A432). The ground motion response spectrum (GMRS) is defined as an outcrop motion at a depth of 2.3 meters (m) (7.5 feet (ft)) below the grade, the location of competent materials with a minimum shear wave velocity of 305 meters per second (m/s) (1,000 ft/s) at the site. This approach follows section 3.7.1 of NUREG-0800. The peak ground acceleration (PGA) of 0.2 g for both vertical and horizontal directions is developed for the site and exceeds the designated minimum free-field PGA value of at least 0.1 g to be used, per acceptance criterion 1.A. of section 3.7.1 of NUREG-0800. For these reasons, the NRC staff finds that the design response spectra used for analyzing the FSTR are acceptable.

To ensure that the SHINE FSAR provides sufficient information that conditions due to a seismic event will not pose significant risk to the health and safety of the public and to conclude that the facility design will perform adequately during a design basis seismic event with its SSCs performing the necessary safety functions as described in the application, the NRC staff issued RAIs 3.4-1 and 3.4-2 (ML21309A019). Through its responses to the NRC staff RAIs 3.4-1 and 3.4-2 (ML21011A264), Enclosure 3 (ML21011A240), SHINE supplemented SHINE FSAR section 3.4.1, as noted above, and section 3.4.2, “Seismic Analysis of Facility Structures,” which the staff reviewed and evaluated as noted below.

Synthetic acceleration-time histories are generated enveloping the design response spectra in three mutually orthogonal directions, using the seed recorded time histories from the El Centro earthquake in 1940, for SSI analysis and developing the in-structure response spectra (ISRS). They are shown in figures 3.4-1-1 through 3.4-1-3 of the applicant’s response to RAI 3.4-1. The NRC staff finds this approach to be consistent with acceptance criterion 1.A(ii) of section 3.7.2 of NUREG-0800. Based on this observation, the staff concludes that the approach to generate synthetic acceleration-time histories is acceptable. These artificial time histories are used in site response analysis to develop strain-compatible soil properties and in-profile ground motions for seismic analysis.

Each of the time histories meets the design response spectra consistent with Option 1, “Single Set of Time Histories,” Approach 2 of section 3.7.1 of NUREG-0800 and, therefore, is acceptable. The calculated correlation coefficient between any pairs of the two horizontal and one vertical SSE motions generated, as given in the applicant’s response to RAI 3.4-1, is significantly smaller than the maximum allowable correlation coefficient of 0.16 given in acceptance criterion 1.B, “Design Time Histories,” of Section 3.7.1 of NUREG-0800. This shows that the generated acceleration spectrum in one direction is independent of those in the other two mutually orthogonal directions. Additionally, the duration of the generated pulse is approximately 40 seconds long, as stated in the applicant’s response to RAI 3.4-1 and as provided in figures 3.4-1-1 through 3.4-1-3, which is significantly larger than the 20 seconds as stated in acceptance criterion 1.B.ii.(a) of section 3.7.1 of NUREG-0800. In addition, the NRC staff finds that the duration of the strong motion portion in each orthogonal direction is significantly longer than the minimum 6 seconds given in acceptance criterion 1.B of section 3.7.1 of NUREG-0800. Based on these observations, the staff concludes that the generated SSE design spectra are acceptable to conduct the SSI analysis.

3.4.4.2 Seismic Analysis of Facility Structures

SHINE FSAR section 3.4.2 addresses modeling and analysis of the FSTR performed by the SASSI2010 and SAP2000 finite element analysis (FEA) codes. It includes applied loads to the structure (e.g., dead, live – including meteorological, crane, fluid, soil pressure, and seismic, etc.), discussions of structural response to multidirectional seismic input, structural seismic stability, etc.

SHINE FSAR section 3.4.2.4, “Seismic Analysis Results,” includes seismic loads that have been applied to the structural analysis model and used to develop the ISRS for use in sizing equipment and structural components. As stated in section 3.4.2.1, “Seismic Analysis Methods,” and further confirmed by SHINE in its response to NRC staff RAI 3.4-2, the seismic analysis of the FSTR used SASSI2010 (version 1.0) and SAP2000 (version 17.2) computer programs. The staff’s RAI 3.4-2 questions on seismic analysis methods and soil-structure modeling and SHINE’s public responses are documented in ML21011A264), Enclosure 3 (ML21011A240).

The staff finds the use of SASSI2010 and SAP2000 for estimating the SSI response and for the structural analysis, respectively, of the FSTR acceptable for the following reasons:

(1) The SASSI2010 and SAP2000 codes are commercially available and widely used for analyses in the nuclear industry.

(2) The SASSI2010 software performs a complex frequency response analysis using the input acceleration time histories, consistent with the defined SSE response spectra, to determine the response of the structure and to generate the ISRS, element force and moments, maximum seismic acceleration (zero-period acceleration (ZPA)), and nodal accelerations for different damping values.

(3) SAP2000 (version 17.2) is a finite element (FE) code commercially available and widely used for analyses in the nuclear industry. By using the earthquake-generated forces as static loads, it performs an equivalent static analysis to determine in-plane shear force in a wall (diaphragm), wall overturning, and stability of the FSTR.

The SHAKE2000 program (version 3.5) was used to generate the strain-dependent soil properties. The SHAKE2000 program is commercially available and widely used for analyses in the nuclear industry.

In addition to the information provided on the structure, the SSI analysis also includes detailed information of the soil layers supporting the structure obtained in the site geotechnical investigation, as summarized in SHINE FSAR section 2.5.2.3, “Site Soil Conditions,” and section 2.5.7.1, “Site Soil Conditions.” The NRC staff reviewed and evaluated the applicant’s information on the SSE ground motion response spectra for the SHINE site in section 2.5 of this SER and found it to be acceptable, because it is consistent with the United States Geological Survey (USGS) Hazards Map. However, the staff noted that soil parameters necessary for SSI analysis and foundation assessment were not sufficiently clear to determine soil bearings at specific elevations, settlements, and stability of the FSTR discussed in SHINE FSAR sections 3.4.2.5 and 3.4.2.6.3.1 and, therefore, issued RAIs 3.4-5 and 3.4-6 (ML21309A019). The staff conducted a regulatory audit (ML21089A334), to review the analysis supporting the geotechnical evaluation. As a result of the audit, the applicant revised its FSAR and supplemented its response to RAI 3.4-6. The RAIs and SHINE’s public responses are documented in ML21011A264), Enclosure 3 (ML21011A240) and (ML21106A136). The staff reviewed the applicant’s RAI responses and finds them acceptable because the computed factors of safety against sliding and overturning are greater than the minimum values required, the allowable soil bearing capacity is higher than the maximum foundation contact pressures, and the differential and total settlements are accounted for in the FSTR FEA through the resulting generalized forces, so the facility structure is designed to accommodate the potential differential and total settlements.

Horizontal soil layers in SASSI2010 model the soil column down to an elastic half-space representing the bedrock. Strain-dependent soil properties are determined from geotechnical investigations and free-field site response analysis using the SHAKE2000 program (version 3.5). The free-field site response analysis is performed using the mean or best estimate (BE), the upper bound (UB), and the lower bound (LB) soil properties to represent potential variations of the in-situ soil conditions. The NRC staff finds this approach to be consistent with section 3.7.2 of NUREG-0800 and ASCE 4-16, “Seismic Analysis of Safety-

Related Nuclear Structures" (section 5.1.7, "Uncertainties in SSI Analysis"), to treat potential variation in soil properties and, therefore, it is acceptable.

The UB and LB soil properties are generated from the mean soil properties (BE) assuming a coefficient of variation of 0.5, because the site is well investigated, which the NRC staff acknowledges to have occurred during the site characterization phase. Additionally, this approach is consistent with section 3.7.2 of NUREG-0800 and section 5.1.7 of ASCE 4-16 and, therefore, is acceptable.

The SSI analysis was performed using LB, BE, and UB soil columns with strain-compatible properties and the corresponding SSE earthquake motion. Major structural elements of the FSTR were modeled with appropriate mass and stiffness properties to analyze the SSI effects using SASSI2010, as stated in SHINE FSAR section 3.4.2.2. SHINE FSAR section 3.4.2.2 considers loads as mass equivalents for seismic analysis. This approach is consistent with NRC guidance (i.e., section 3.7.2 of NUREG-0800) and industry standards and, therefore, is acceptable.

The nature of miscellaneous dead weights as equivalent masses and those associated with hydrodynamic and crane masses is further discussed in the applicant's response to NRC staff RAI 3.4-3 (ML21011A264), Enclosure 3 (ML21011A240). The NRC staff's acceptance of the applicant's response is detailed next. The structural model of the FSTR accounts for the self-weight of the structure. In addition, mass equivalent of 25 percent of the floor live loads and 75 percent of the roof design snow loads are included in the model. In addition, following section 3.7.2 of NUREG-0800, a mass equivalent of 50 pounds per square foot floor load is added to represent the dead load from minor equipment, etc. Floor loads and equipment loads, as previously noted, are converted to mass and included in the model along with the self-weight of the structure. Additionally, 100 percent of the hydrodynamic mass of the water in the IU cells and 100 percent of the crane mass are included in the model. The staff finds that the SSI model of the FSTR appropriately accounts for different dead and live loads including loads from major equipment or other major components (e.g., water in IU cells). Because the loads are consistent with acceptance criterion 3.D of section 3.7.2 of NUREG-0800, the staff finds that the applicant has appropriately included all different load types in the SSI model of the FSTR.

In addition, a cracked case is analyzed with BE soil profile and assumed cracked structural components from an SSE, as stated in the applicant's response to NRC staff RAI 3.4-9 (ML21011A264), Enclosure 3 (ML21011A240). The modulus of elasticity of the modeled concrete elements is reduced by 50 percent of its nominal values, based on ASCE/Structural Engineering Institute (SEI) 43-05, "Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities." The NRC staff finds that the reduction of modulus is also consistent with table 3-2, "Effective Stiffness of Reinforced Concrete Element," of ASCE 4-16 and section 3.7.2 of NUREG-0800. Based on this discussion, the staff finds that the applicant has followed the recommended approach for degradation of stiffness of modeled structural components following acceptable national standards for use in the seismic analysis; hence, the degraded modulus value is acceptable. The staff finds that the applicant's modeling approach satisfies acceptance criterion 3.C of section 3.7.2 of NUREG-0800 and, therefore, is acceptable.

Damping values of concrete and steel components of the FSTR for LB, BE, and UB analyses (uncracked cases) are given in table 2 of Regulatory Guide 1.61, Revision 1, "Damping Values for Seismic Design of Nuclear Power Plants" (ML070260029), with the Operating Basis Earthquake (OBE). As no cracking is expected in an OBE excitation, the corresponding damping values excitation (4 percent for concrete and 3 percent for steel) have been used to analyze the uncracked LB, BE, and UB scenarios. In the cracked case, cracking of components is assumed to occur. The cracked case uses increased values for damping (7 percent for concrete and 4 percent for steel), consistent with those given in table 1 of RG 1.61, Revision 1, for an SSE. Based on this discussion, the NRC staff finds that the damping values used for uncracked scenarios are acceptable as they are from RG 1.61, Revision 1, and, therefore, concludes that acceptance criterion 2 of section 3.7.1 of NUREG-0800 is satisfied. In addition, the cracked case uses damping values associated with an SSE excitation contained in RG 1.61, Revision 1. As the damping values used are consistent with RG 1.61, Revision 1 and ASCE/SEI-43-05, the staff concludes that that appropriate structural damping values have been used in conducting the SSI of the FSTR and, therefore, that acceptance criterion 3.C.iv of section 3.7.2 of NUREG-0800 is satisfied as well, in addition to acceptance criterion 2 of section 3.7.1 of NUREG-0800.

Major openings within the walls and slabs are incorporated in the SSI model. Thick shell elements are used to model the concrete walls, slabs, and basemats. Three-dimensional beam elements are used to model the steel structural elements, such as trusses. Thick shell elements are used to model the interior partition walls made of concrete. Interior partition walls made of masonry or gypsum are not explicitly modeled as they are isolated from the lateral load-resisting system; however, their mass is accounted for in the analysis. Beam elements are used to model the steel truss components. These modeling practices are outlined in the applicant's response to RAI 3.4-9. The excavated soil volume is modeled with solid elements in the SSI model to assess the SSI effects as described in the applicant's response to RAI 3.4-2. The vertical dimension of the elements matches the thickness of the corresponding soil layers. The equivalent linear strain-compatible soil properties determined at the site are assigned to these solid elements. The maximum dimension of these elements is small enough to propagate the highest frequency of interest in the model used in the analysis, as stated in the applicant's response to RAI 3.4-9. The FE model is acceptable because it was developed following regulatory guidance (section 3.7.2 of NUREG-0800) and accepted engineering practice.

The SASSI2010 SSI analysis of the FSTR produces acceleration response in three mutually orthogonal directions from the input motion in each direction, for example, acceleration response in X, Y, and Z directions from input motion only in X direction, Y direction, or Z direction. These codirectional response values were calculated at selected nodes (points) located on different structural elements/locations of the FSTR. The selected response spectra locations are as shown in figures 3.4-4-1 through 3.4-4-9 of the applicant's response to NRC staff RAI 3.4-4 (ML21011A264), Enclosure 3 (ML21011A240). Output from the SASSI 2010 SSI analysis includes response spectra accelerations at the 75 standard frequencies between 0.2 hertz (Hz) and 34 Hz, consistent with table 2 of Regulatory Guide 1.122, Revision 1, "Development of Floor Design Response Spectra for Seismic Design of Floor-Supported Equipment or Components" (ML003739367). In addition, output also includes response spectra accelerations at 37 Hz, 40 Hz, 43 Hz, 46 Hz, and 50 Hz frequencies, as given in SHINE FSAR section 3.4.2.4. These spectra are generated at six critical damping ratios: 2 percent, 3 percent, 4 percent, 5 percent, 7 percent, and 10 percent, as stated in the applicant's response to RAI 3.4-4. The ordinate of the calculated response spectrum is at frequencies sufficiently close to produce an accurate response spectrum following RG 1.122, Revision 1. In addition, several high frequencies are included in developing the ISRS. These codirectional responses are combined using the square-root of the sum of the squares method following Regulatory Guide 1.92, Revision 3, "Combining Modal Responses and Spatial Components in Seismic Response Analysis" (ML12220A043), and is consistent with acceptance criterion 5.A of section 3.7.2 of NUREG-0800. Therefore, the NRC staff finds that the method used to develop the ISRS of the FSTR is acceptable.

As stated previously, the ISRS from the SSI analysis for each soil model is calculated at various nodes/locations shown in figures 3.4-4-1 through 3.4-4-9 of the applicant's response to RAI 3.4-4, with figures 3.4-4-3 through 3.4-4-9 withheld from public disclosure as they also contain security-related information. The combined response from the LB, BE, UB, and cracked seismic analysis cases at each node are enveloped to develop the bounding response at that node. The output response spectra are combined into 39 groups, given in table 3.4-4-1 of the applicant's response to RAI 3.4-4. Responses of nodes in each group are enveloped to determine the bounding response spectra at these structural elements/locations. The resulting bounding response spectra are smoothed, and the peaks of the spectra are broadened by ± 15 percent to account for approximations in the modeling techniques and uncertainties in the parameters used in structural analysis. The resulting ISRS plots for each of the 39 groups are shown in figures 3.4-4-10 through 3.4-4-48 of the applicant's response to RAI 3.4-4. The peak acceleration or ZPA for each of the 39 groups is taken from the corresponding ISRS plot at the maximum frequency point and is given in table 3.4-4-2 of the applicant's response to RAI 3.4-4. As the response has been calculated on different structural components and major facility equipment of the FSTR, the NRC staff finds that the analysis is acceptable because it satisfies acceptance criterion 2.B of section 3.7.2 of NUREG-0800. The approach to smoothing and broadening the spectra to account for uncertainty follows RG 1.122, Revision 1, and the staff finds that the approach is consistent with acceptance criterion 5.C of section 3.7.2 of NUREG-0800. Therefore, based on the above discussion, the method used to develop the bounding ISRS is acceptable.

SHINE FSAR section 3.4.2.6, "Structural Analysis of Facility," and section 3.4.2.6.2, "Applicable Codes and Standards," provide a succinct listing of applicable codes and standards used for the structural design of the facility. SHINE FSAR section 3.4.2.6.2 states that the facility concrete design is based on ACI 349-13, and for structural steel design on ANSI/AISC N690-12. Regulatory Guide 1.142, Revision 2, "Safety-Related Concrete Structures for Nuclear Power Plants (Other than Reactor Vessels and Containments") (ML013100274), endorses ACI 349 with certain exceptions and modifications so that defense-in-depth is maintained in the design of nuclear concrete facilities.

During its review of SHINE FSAR section 3.4.2.6.2, the NRC staff noted that there is no information in the FSAR regarding whether the applicant considered the guidance of RG 1.142 to further enhance its ACI 349-13 based concrete design so that the defense-in-depth philosophy included in NUREG-1537 is maintained. Concerned that such modifications and omissions from the structural design may have resulted in an overall nonconservative structural design, the staff issued RAI 3.4-10 (ML21309A019). The staff finds the applicant's response to NRC staff RAI 3.4-10 (ML21011A264), Enclosure 3 (ML21011A240), acceptable because the design of the FSTR concrete box and its structural concrete SSCs to transient and/or abnormal loads: (a) is in accordance with the ACI 349-13 as modified by the RG 1.142, Revision 2, regulatory positions for successive levels of protection to act as direct or indirect barriers against the release of radioactive material to the environment and (b) ensures that failure of a single SSC would not impair protection of the health and safety of the public or from the uncontrolled release of radioactive material to the environment.

SHINE FSAR section 3.4.2.6.2 also states that the FSTR structural steel design follows ANSI/AISC N690-12. The NRC staff noted that the limited information provided in this section was not adequate to demonstrate that the requirements of the steel design code ANSI/AISC N690-12 are met, including those related to fire. The staff was concerned with the potential for fires, particularly those associated with an aircraft impact, to generate elevated temperatures and how this could damage the safety-related structural steel used in the FSTR SSCs and issued RAI 3.4-11 (ML21309A019). The staff's RAI and the applicant's public response to NRC staff RAI 3.4-11 are in ML21011A264), Enclosure 3 (ML21011A240), and are discussed below.

The NRC staff reviewed the applicant's response to RAI 3.4-11 and noted that SHINE clarified that the safety-related FSTR structural steel SSCs (i.e., the mezzanine and roof trusses) are designed in strict accordance with ANSI/AISC N690-12 to applicable loads/loading conditions. SHINE also clarified that it used the stepwise screening approach detailed in U.S. Department of Energy (DOE) Standard DOE-STD-3014-2006, "Accident Analysis for Aircraft Crash into Hazardous Facilities," to programmatically reduce the risk for facility damage and to eliminate the need to further examine consequences of elevated temperatures due to aircraft impact generated fires on the safety-related FSTR structural steel SSCs. The staff finds SHINE's design approach based on national standards and building codes to be consistent with NUREG-1537 and, therefore, it is acceptable. Additional concerns regarding postulated aircraft impact locations on the FSTR external envelope were resolved through RAI 3.4-19, which is discussed below in section 3.4.4.5, "Seismic Envelope Design of External Hazards," of this SER.

To ensure that: (a) the consequences of elevated temperatures to FSTR structural steel would be minimal (if any) from postulated aircraft crash fires, (b) the facility would continue to maintain its defense-in-depth, and (c) the DOE-STD-3014-2006 limits to active fire and/or suppression systems following such events had been considered, the NRC staff also reviewed SHINE FSAR section 9a2.3, "Fire Protection Systems and Programs," and the associated applicant responses to NRC staff RAIs in ML21364A055. In particular, the staff noted that the applicant's response to RAI 9-5 outlines facility passive design features to limit fire consequences. The staff also noted that the facility is designed with protective systems such as 1, 2, or 3 hours of fire-resistant barriers separating individual fire areas consistent with NUREG-1537, Part 1, section 9.3, "Fire Protection Systems and Programs," to prevent the uncontrolled release of radioactive material to the environment, should a fire occur. The applicant's response to RAI 9-5 clarifies the basis for the fire barrier ratings (e.g., analysis, regulatory requirements, assessments of fire area contents, means of egress considerations, equipment separation, area considerations). The staff notes that additional safety measures exist, such as manual firefighting capability from nearby fire brigades including those from the adjacent airport. Based on the above, the staff finds the applicant's response regarding fires in RAI 3.4-11, as supplemented by the applicant's responses to RAIs regarding SHINE FSAR section 9a2.3.1, "Fire Protection Plan and Program," adequate and, therefore, acceptable for its safety determination.

For the review of SHINE FSAR section 3.4.2.6, "Structural Analysis of Facility," consistent with the guidance of NUREG-1537, the NRC staff also reviewed other sections of the FSAR to determine how the effects of irradiated environments could affect the performance of structural materials (i.e., concrete and steel) under normal and overload conditions such as those encountered during earthquakes, aircraft impact, and blast loads. Such reviews included discussions on neutron driver assembly system (NDAS) irradiated structural support beams in SHINE FSAR sections 1.3.3.3 and 4a2.3 and neutron and gamma fluxes in the subcritical assembly in SHINE FSAR section 4a2.5.3.2. The staff reviewed the structural performance of irradiated concrete and structural steel affected by radiation exposure exceeding the threshold limits of NUREG/CR-7171, "A Review of the Effects of Radiation on Microstructure and Properties of Concretes Used in Nuclear Power Plants" (ML13325B077), and ACI 349.3R, "Report on Evaluation and Repair of Existing Nuclear Safety-Related Concrete Structures," in these areas during facility operation and issued RAI 3.4-12 (ML21309A019).

The NRC staff reviewed the applicant's response to NRC staff RAI 3.4-12, Revision 1 (ML21271A073), Enclosure 2 (ML21271A076), and noted that the applicant's analyses indicated that FSTR fluence is below the threshold acceptance limits of NUREG/CR-7171 and those of ACI 349.3R for concrete and its steel embedments, respectively. For gamma heating on concrete, although the analyses indicated an elevated exposure below the TSV, the staff finds its effects on concrete pool acceptable because pool light water surrounding the TSV provides significant shielding, thereby reducing the temperature rise in the general and local concrete areas to below the threshold values allowed in ACI 349.3R.

In its response to RAI 3.4-12, the applicant also determined, based on UB effects of fluence on the austenitic stainless steel used in the subcritical assembly support structure (SASS), that safety-related austenitic stainless steel SASS components in the IU cells, near the TSV and NDAS, also exhibit adequate ductility and strength to resist anticipated transients and abnormal loads. In addition, the NRC staff noted that stainless steel used in the design (see SHINE FSAR sections 4a2.4.1.1 and 4a2.4.1.5) was tested for radiation and corrosion at Oak Ridge National Laboratory. Furthermore, the staff noted that the FSAR states that the surveillance and inspection program ensures that the integrity of the primary system pressure boundary components (PSB) is not degraded below acceptable limits due to radiation. The staff finds the capacity of the aforementioned components adequate to perform their intended functions because their evaluation was based on recognized industry practices, as noted in SHINE FSAR section 4a2.4.1.5. The staff also finds that the FSAR surveillance and inspection measures for the effects of fluence on safety-related austenitic stainless steel SASS components are adequate. Based on the above, staff finds the evaluation and measures taken to ensure that the aforementioned austenitic stainless steel components perform their intended functions during the facility operating life to be consistent with the regulatory framework and, therefore, acceptable.

The NRC staff, in its review of SHINE FSAR section 3.4.2.6.4 noted that this section addresses several loads including dead, live, and earthquake loads. For dead loads, the FSAR includes concrete cover blocks for below grade tanks and trenches. The staff noted that this FSAR section considers the concrete blocks to be live loads, which may indicate that they are not integrated in the facility seismic design. To clarify and resolve the size and anchorage of these blocks, whether the facility incorporates them into its design precast vaults in the RPF, what the "minimum" live loads are, and whether the roof live loads align with those referenced in ASCE 7-05 or International Building Code (IBC) 1607, the staff issued RAIs 3.4-7 and 3.4-8. Earthquake loads in the seismic analysis are addressed in RAI 3.4-4.

Further, in its review of SHINE FSAR section 3.4.2.6.4.6, "Crane Load," the NRC staff noted that crane loading was evaluated in accordance with American Society of Mechanical Engineers (ASME) NOG-1, "Rules for Construction of Overhead and Gantry Cranes (Top Running Bridge, Multiple Girder)." The staff also noted the limited description of how crane loads were defined and subsequently incorporated in the crane systems designs. The staff reviewed the applicant's response to NRC staff RAIs 3.4-13 and 3.4-21 ((ML21011A264), Enclosure 3 (ML21011A240), and (ML21208A135), respectively) and noted the following:

(1) For crane loads and loading conditions, SHINE clarified that the IF and RPF crane systems design loads (seismic, dead, impact, stop, lift capacities) are conservatively calculated deterministically consistent with ASME NOG-1, "Rules for Construction of Overhead and Gantry Cranes." Additionally, SHINE clarified that it used the calculated loads also for the FSTR design but ensured

that for crane loading there was conservatism in the building design consistent overall with ASCE 7-05 or IBC 1607 building codes and requirements. Specifically, SHINE calculated the crane seismic loads as distributed loads based on ISRS peak acceleration, crane mass, and full lift load. For the facility crane runway system horizontal impactive design loads, SHINE used those considered for a design basis earthquake, which are more conservative than those of ASME NOG-1 and those required by the aforementioned building codes. The NRC staff finds these approaches based on local building codes, standards, and recognized industry practices to be consistent with NUREG-1537 and, therefore, acceptable.

(2) For crane runway systems design, SHINE clarified that for the SSI analysis, consistent with ASME NOG-1, it decoupled the IF and RPF crane responses from their runways. SHINE also clarified that all building facility sections, including walls supporting the IF and RPF cranes, are designed with a minimum of 10 percent margin for all loading conditions and modes of failure. It also stated that a minimum 7 percent design margin exists for any of the designed IF and RPF crane runway systems components. SHINE then stated that the conservatism used in the estimated deterministic loads further increases the aforementioned two design margins. It then described how the crane runway systems are attached to the facility external walls to help isolate external impact or base induced shear loads. Although the cranes are not considered to be critical or safety-related equipment, as noted in the applicant's RAI response (see also SHINE FSAR section 9b.7.2.3), nonetheless a failure of their runway systems could potentially affect safety-related SSCs. The NRC staff finds that there is reasonable assurance that such a failure would be highly unlikely because the design of the runways has adequate margins and follows the conservatisms of local building codes, national standards, and recognized industry design practices consistent with NUREG-1537 and, therefore, is acceptable.

Based on the above, the NRC staff finds the revised SHINE FSAR section 9b.7.2.1 clarifying that the IF and RPF cranes are designed to remain in-place and on the runway girder, with or without a load, during and after a seismic event, acceptable.

The NRC staff also reviewed SHINE FSAR section 9b.7.2 and noted that the cranes meet ASME B30.2, "Overhead and Gantry Cranes (Top Running Bridge, Single or Multiple Girder, Top Running Trolley Hoist)," and Crane Manufacturers Association of America, Inc. (CMAA) 70, "Multiple Girder Cranes," service level (class) B requirements. The staff noted that both cranes serve the RCA of the FSTR and are used to move or manipulate radioactive material within the RCA. The staff also noted that CMAA-70 Class B cranes are limited to light service requirements (e.g., repair shops, light assembly operations, light warehousing) and limited in height of lifts. In addition, the staff noted that the RPF crane is a 15-ton ASME NOG-1 Type II, double girder bridge style crane with no single failure-proof features to support its lift during a seismic event. However, there was a limited discussion on the effects of radiation and usage of cranes and crane systems during the operating life of the facility. Therefore, the staff issued RAI 3.4-14 (ML21309A019) regarding the potential detrimental effects of radiation on each crane's structure and increased usage that could affect crane performance, such as dropped lifts on safety-related SSCs and potentially challenge the facility's defense-in-depth and the radiological release limits of 10 CFR Part 20 during facility operating life.

In its response to NRC staff RAI 3.4-14 (ML21011A264), Enclosure 3 (ML21011A240), SHINE clarified that the crane purchase specifications included environmental conditions in their design criteria that account for radiation exposure to 30 years. SHINE also stated that the IF and RPF cranes are constructed consistent with ASME NOG-1 Type I and Type II design requirements for seismic loads, fracture toughness, and radiation hardening, as applicable. SHINE further clarified that load cycle limits are those of CMAA 70-2004 and inspection, testing, and maintenance are in accordance with ASME B30.2 and/or ANSI N14.6-1993, “Radioactive Materials - Special Lifting Devices for Shipping Containers Weighing 10000 Pounds (4500 kg) or More,” as applicable. The NRC staff finds the applicant’s approach for the design of cranes with respect to radiation resistance and usage to be in accordance with national codes and standards consistent with NUREG-1537 and, therefore, it is acceptable.

In its review of SHINE FSAR section 3.4.2.6.4.8, “Fluid Load,” the NRC staff noted the existence and application of hydro loads to critical equipment. Additional details for this fluid loading condition are in SHINE FSAR chapter 4, which details the fluid-structure interaction of water with submerged or semi-submerged equipment containing uranyl sulfate solution within the light water pool during seismic/abnormal loading events. SHINE FSAR chapter 3 references ASCE 4-98, “Seismic Analysis of Safety-Related Nuclear Structures and Commentary,” which provides guidance for hydrostatic and hydrodynamic analysis of equipment or structures loaded with hydrostatic and hydrodynamic pressures/forces, assessments of fluid-structure interaction, and the stability of structures in a fluid (water) basin. Although the applicant referenced this standard, it is not clear to what extent the standard was used for the water (fluid), pool (basin), and equipment interactions, and whether the analyses were extended to include comingling of uranyl sulfate solution into the pool in the event of a breach of the TSV tank containing this solution. Material Data Sheets indicate that uranyl sulfate in its solid form has a specific gravity considerably higher than that of water. Consistent with these data, in this case the calculated hydrodynamic loads and stability analyses would differ from a hydrodynamic analysis using solely water as a fluid load.

To clarify what methodology was used to derive the hydrodynamic loads and their effects on submerged equipment/structures/pool and to identify the echelons of defense considered against the release of uranyl sulfate solution into the pool and the subsequent consequences if such a release were to occur, the NRC staff determined the need for additional information and issued RAI 3.4-15 (ML21309A019).

The NRC staff reviewed the applicant’s response to NRC staff RAI 3.4-15 (ML21011A264), Enclosure 3 (ML21011A240), and noted that SHINE evaluated the IU structure and its light water pool submerged or semi-submerged safety-related equipment to hydrodynamic loads composed of sloshing forces and those attributed to added masses during seismic excitation consistent with applicable national standards (i.e., ASCE 4-98, TID-7024, “Nuclear Reactors and Earthquakes,” ACI 350.3-06, “Seismic Design of Liquid-Containing Concrete Structures and Commentary,” and ANSI/AISC N690-12). In its response, SHINE also clarified the defense-in-depth echelons against the release of uranyl sulfate target solution and associated fission material, including the TSV and the light-water pool as barriers, which are part of the PSB. SHINE further clarified that it did not consider the release of uranyl sulfate solution into the pool to be a postulated event, nonetheless it designed the PSB to withstand seismic/abnormal loadings. Furthermore, SHINE observed that a potential leakage into the pool would insignificantly increase the density of the large body of water in the pool and the associated hydrodynamic loads and their effects on submerged/semi-submerged equipment during a seismic event. The staff finds the applicant’s response to the RAI to be acceptable for the following reasons: (a) the calculation of the hydrodynamic forces was done in accordance with national standards, codes, and recognized industry practice, (b) the PSB was designed to resist transient and abnormal loads and with a defense-in-depth philosophy to contain the release of radioactive material, and (c) the calculated increase in the hydrodynamic forces resulting from an increased water density due to uranyl sulfate solution released into the light water pool was insignificant. The staff also finds the revision to SHINE FSAR sections 3.4.2.6.4.8 and 4a2.2.5 regarding hydrodynamic loading and its effects on the SASS acceptable as the methodologies considered in the analyses are in accordance with national standards, codes, and recognized industry practices consistent with NUREG-1537.

3.4.4.3 Seismic Classification and Qualification

SHINE FSAR section 3.4.3, "Seismic Classification and Qualification," identifies categories of SSCs and presents the seismic qualification of the SHINE facility's systems and equipment. It includes the definition of category I and category II SSCs and details of the methodologies used for their seismic qualification. The NRC staff reviewed the methodologies that the applicant used for seismic qualification of equipment/components achieved with analytical methods (including static analysis, simplified dynamic analysis, or detailed dynamic analysis), testing (e.g., material qualification testing), or a combination of the analytical and testing methods and found them acceptable. These are discussed in section 3.4.4 of this SER.

3.4.4.4 Seismic Instrumentation

SHINE FSAR section 3.4.4, "Seismic Instrumentation," summarizes the seismic instrumentation at the facility. The NRC staff reviewed the summary and noted that SHINE has in place non-safety-related seismic instrumentation to assess the effects of accelerations experienced at the facility following a seismic event so that the facility and its safety-related SSCs continue to operate safely. The measurement of seismic acceleration at the facility using non-safety-related instrumentation is reasonable and acceptable because the NRC's regulations do not require seismic instrumentation for this facility.

3.4.4.5 Seismic Envelope Design of External Hazards

SHINE FSAR section 3.4.5, "Seismic Envelope Design for External Hazards," provides input for an aircraft impact analysis, which is necessary because the SHINE facility is located near the SWRA. It also discusses external facility explosions. SHINE FSAR section 3.4.5.1, "Aircraft Impact Analysis," outlines the effects of global and local small aircraft crashes (impact loadings) on the facility from the nearby SWRA. It states that the Challenger 605 was selected as a "design basis aircraft" for global impact response analysis based on airport operations data. It also states that the analysis used the energy balance method of DOE-STD-3014-2006 while taking into consideration the ductility limits of ACI 349-13 and ANSI/AISC N690-12 for reinforced concrete and steel truss elements, respectively. For local impacts, it states that the Hawker and the Challenger 605 were the two aircraft considered as design basis aircrafts. SHINE FSAR section 3.4.5.1 then references DOE-STD-3014-2006, which provides guidance for functional assessments, screening, and evaluating global, local, and vibration damage to the FSTR and its SSCs. The NRC staff notes that the applicant's statement in SHINE FSAR section 1.2.2, claiming design robustness of the building structure, stems from a postulated aircraft impact analysis based on criteria and guidance of DOE-STD-3014-2006.

In evaluating SHINE FSAR section 3.4.5.1, the NRC staff sought clarifications through its RAIs 3.4-16 (ML21309A019) and 3.4-20 (ML21173A012) on how the two aircrafts were selected, what was the perceived mode of impact, and how potential global and local impact loads, damage estimates, and resulting consequences on the FSTR and its SSCs were assessed.

The NRC staff reviewed SHINE's responses to NRC staff RAIs 3.4-16 and 3.4-20 ((ML21011A264), Enclosure 3 (ML21011A240), and (ML21208A135), respectively) and noted that the selected aircraft for local and global impact analysis was the Challenger 605 aircraft based on SWRA operations data and because it had the heaviest engines of all aircraft frequenting the airport. The staff also noted that SHINE's analyses used national standards and codes to assess the effects of postulated impacts (e.g., DOE-STD-3014-2006 and ACI 349-13, appendix F) on the design of the entire exterior envelope of the FSTR as well as on several of its interior walls that act as barriers to exterior wall openings. Regarding potential skidding of the aircraft on the roof, SHINE stated that while this was not explicitly accounted for in the impact analysis, the seismic qualification of the roof slab bounds the skidding aircraft impact scenario. The staff finds SHINE's approach for the aircraft selection based on airport historical data and the analysis performed that conservatively addresses the entire external facility envelope and internal walls for local and global impacts based on national standards and codes adequate and consistent with the guidance of NUREG-1537 and, therefore, acceptable. The staff accordingly finds the revision to SHINE FSAR section 3.4.5.1 clarifying that the FSTR seismic loading bounds any aircraft impact scenario that produces lateral forces acceptable.

Aside from aircraft impacts on the external facility envelope, the NRC staff also examined potential effects of such impacts on safety-related SSCs attached to the facility envelope. The staff followed-up on the applicant's response to RAI 3.4-11, which stated that there was no safety-related equipment supported from the building in the vicinity of postulated impacts and that the risk to damage and resulting consequences were "deemed small and the results are documented." To better assess SHINE's response, the staff issued RAI 3.4-19 requesting that the applicant provide additional clarifications on the analysis methodology used to evaluate the structural behavior at critical areas of the impacted structure and on the overall robustness and structural integrity of the facility based on the structural response at postulated impact locations.

In its response to NRC staff RAI 3.4-19 (ML21208A135), SHINE clarified that the only components attached to facility exterior walls are the crane runways, with the cranes classified as non-safety-related SSCs. SHINE also clarified that the impact analysis methodology used to evaluate the response of the facility structure is in accordance with DOE-STD-3014-2006 with critical facility areas (e.g., exterior and labyrinth walls, missile barriers, roof, wall corners, etc.) of impacted concrete sections designed to ACI 349-13. The NRC staff finds the applicant's response acceptable because it reaffirmed that there is no safety-related equipment on the facility envelope and that the methodology used to assess the response, robustness, and structural integrity of the facility due to aircraft impacts is based on national standards, building codes, and recognized industry practices consistent with the guidance of NUREG-1537. The NRC staff also finds SHINE's revision to SHINE FSAR section 3.4.5.1 acceptable because it clarifies the reason why punching shear damage was not considered in the analysis.

SHINE FSAR section 3.4.5.2, "Explosion Hazards," discusses external explosions/blast effects on the FSTR and references SHINE FSAR section 2.2.3 for details on the source and derivation of blast overpressures, including the regulatory guidance and software used for the hazards evaluation. The NRC staff had questions concerning the validity of software and uncertainties in the methodologies used for the design of the FSTR with respect to blast effects, and whether the external nitrogen tank in the proximity to the FSTR was designed to code for potential accidental explosions and, therefore, issued RAI 3.4-17.

The NRC staff reviewed the applicant's response to NRC staff RAI 3.4-17 (ML21029A101), Enclosure 1, (ML21029A103), and noted that SHINE followed the methodology described in Regulatory Guide 1.91, Revision 2, "Evaluations of Explosions Postulated to Occur at Nearby Facilities and on Transportation Routes Near Nuclear Power Plants" (ML12170A980), to determine that potential explosions would not have adverse effects on facility operations or prevent a safe shutdown of the facility. SHINE also clarified that potential explosive materials are located at a safe distance from the FSTR and that those that are located closer have an explosion incident rate of 1E-6 per year. SHINE further stated that the externally located liquid nitrogen tanks are designed in accordance with the ASME Boiler and Pressure Vessel Code, Section VIII, Division 1 to prevent their accidental explosion and fragmentation. The staff finds that these approaches based on the guidance in RG 1.91, Revision 2, and national codes are consistent with NUREG-1537 and, therefore, acceptable.

3.4.4.6 Seismic and External Hazards Damage Evaluation Summary

Based on its review, the NRC staff finds that the applicant used acceptable methods to perform the SSI analyses, assess transient and abnormal loads, and evaluate conditions and external hazards that could challenge the defense-in-depth of the facility and its SSCs. Based on its review, the staff determined that the level of detail provided in the SHINE FSAR, as supplemented, regarding damage due to earthquakes, abnormal loads, and internal/external hazards is adequate and supports the final design and satisfies the applicable acceptance criteria of section 3.4 of NUREG-1537, Part 2. The staff concludes that the applicant's design criteria and designs would protect against potential seismic or abnormal loads damages and provide reasonable assurance that SSCs would continue to perform their required safety functions, would not cause unsafe facility operation, would not prevent safe shutdown of the facility, and would not cause or allow the uncontrolled release of radioactive material. Therefore, the staff finds that the SHINE facility design is adequate to cope with postulated seismic or external hazards damages and meets the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.4.5 Systems and Components

The NRC staff evaluated the sufficiency of the SHINE facility design features for systems and components, as presented in SHINE FSAR section 3.5, using the guidance and acceptance criteria from section 3.5, "Systems and Components," of NUREG-1537, Parts 1 and 2, and section 3.5, "Systems and Components," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 3.5 summarizes the design philosophy that SHINE applied to the facility design. The SHINE design philosophy includes defense-in-depth practices, use of engineering controls over administrative controls, physical separation and electrical isolation of safety systems, and system redundancy. The NRC staff considered these design philosophies in its evaluation of the SSCs described in the SHINE FSAR in the corresponding sections of this SER.

3.4.6 Nitrogen Purge System Structure

SHINE FSAR section 3.6 discusses the N2PS structure. It addresses design considerations to avert potential damages due to meteorological, water (flooding), and seismic events. Meteorological and water (flooding) related design considerations are addressed in sections 3.4.2 and 3.4.3 of this SER. Design considerations for seismic damage are discussed below.

The N2PS structure contains a portion of the N2PS system, which is a high-pressure nitrogen gas system. In its response to NRC staff RAI 3.2-1 (ML21029A101), Enclosure 1 (ML21029A103), SHINE explained that the seismic analysis is based on the equivalent static load method and uses the seismic analysis of the FSTR. The seismic loads are calculated using the FSTR grade level in-structure-response spectra with an amplification factor of 1.5.

The NRC staff reviewed the information provided in SHINE FSAR section 3.6.3 related to seismic damage of the N2PS structure and finds it acceptable because the equivalent static load method with an amplification factor of 1.5 provides a conservative seismic response and accounts for possible SSI effects between the FSTR and the N2PS structure. SHINE FSAR section 9b.6.2.3 describes that the N2PS structure, and the associated supports, are designed to withstand Seismic Class I seismic events. Therefore, the staff finds that the N2PS structure and pipe and high-pressure tube supports are seismically qualified.

3.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE design of SSCs, as described in chapter 3 of the SHINE FSAR, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) The SHINE facility adequately protects against potential meteorological, water, and seismic or external hazards damages.

(2) The SHINE facility provides reasonable assurance that its SSCs would continue to perform their required safety functions, would not cause unsafe facility operation, and would not prevent safe shutdown of the facility.

(3) The SHINE facility provides adequate levels for defense-in-depth against uncontrolled release of radioactive material to the environment.

(4) The issuance of an operating license for the SHINE facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE design of SSCs are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4.0 IRRADIATION UNITS AND RADIOISOTOPE PRODUCTION FACILITY DESCRIPTION

The facility description addresses the principal features, operating characteristics, and parameters of the SHINE Medical Technologies, LLC (SHINE, the applicant) facility irradiation units (IUs) (which constitute the irradiation facility (IF)) and radioisotope production facility (RPF). An IU is an accelerator-driven subcritical operating assembly that operates with a significant subcritical neutron multiplication factor (M) and is used for the irradiation of an aqueous uranyl sulfate target solution, resulting in the production of molybdenum-99 (Mo-99) and other fission products. The primary function of the RPF is to extract, purify, package, and ship radioisotopes, including Mo-99.

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation by the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE IUs and RPF as presented in chapter 4, “Irradiation Unit and Radioisotope Production Facility Description,” of the SHINE final safety analysis report (FSAR) and supplemented by the applicant’s responses to staff requests for additional information (RAIs).

4a Irradiation Facility Description

Section 4a, “Irradiation Facility Description,” of this SER provides an evaluation of the final design of SHINE’s IUs as presented in SHINE FSAR section 4a2, “Irradiation Facility Description.”

The facility description addresses the principal features, operating characteristics, and parameters of the IF. The primary function of the IUs and, consequently, the IF is to irradiate the target solution to produce Mo-99.

4a.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 4a2 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE IUs. As part of this review, the staff evaluated descriptions and discussions of the SHINE IF, with special attention to principal safety considerations that were factored into the design and operation of the IUs and the IF. The final design bases of the SHINE IUs and IF were evaluated to ensure that the design bases and functions of the structures, systems, and components (SSCs) are presented in sufficient detail to allow a clear understanding of the facility and to ensure that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the workers and the public. Drawings and diagrams were evaluated to determine if they present a clear and general understanding of the physical facility features and of the processes involved.

Areas of review for this section include the subcritical assemblies, neutron driver assemblies, target solution vessel (TSV) and light water pool, the IF biological shield, nuclear design, thermal-hydraulic design, and gas management system.

4a.2 Summary of Application

The SHINE FSAR includes information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the SSCs of the facility. The SHINE IF includes eight IUs and their supporting systems.

An IU is an accelerator-driven subcritical operating assembly used for the irradiation of an aqueous uranyl sulfate target solution, resulting in the production of Mo-99 and other fission products. The accelerator neutron source uses deuterium-tritium fusion reactions in the accelerator target chamber to produce high energy neutrons. The neutrons are multiplied in the natural uranium neutron multiplier and the uranyl sulphate target solution to significantly increase the number of neutrons produced in the TSV compared to the initial deuterium-tritium neutron source. The resultant fission reactions in the target solution create, among others, the fission product Mo-99.

4a.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 4 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the bases and the information provided by SHINE for the issuance of an operating license.

4a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE IF are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.57, "Issuance of operating license."
- 10 CFR Part 20, "Standards for Protection Against Radiation."

4a.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

4a.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR section 4a2, as supplemented, to assess the sufficiency of the final design and performance of the SHINE IF for the issuance of an operating license. The sufficiency of the final design and performance is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 4a.3, “Regulatory Requirements and Guidance and Acceptance Criteria,” of this SER. The findings of the staff review are described in section 4a.5, “Review Findings,” of this SER.

The SHINE IF consists of up to 8 IUs that irradiate a uranyl sulfate target solution with the goal of producing Mo-99. The target solution uses low-enriched uranium (LEU) with a target enrichment of 19.75 percent. The irradiation of the target solution is driven by a neutron source produced from deuterium-tritium fusion reactions. The deuterium-tritium fusion reactions are driven by an accelerator and the source neutrons pass through a natural uranium multiplier before entering the TSV, which holds target solution in which neutrons are further multiplied. The steady-state maximum fission power level of each IU is 125 kilowatts (kW). Each IU is cooled by a forced convection cooling system during normal operation. After the target solution is irradiated in the TSV in the IU, the solution is transferred to the RPF for the extraction from it of radioisotopes, including the fission product Mo-99.

4a.4.1 Summary Description

The NRC staff evaluated the sufficiency of the summary description of the IU, as presented in SHINE FSAR section 4a2.1, “Summary Description,” using the guidance and acceptance criteria from section 4a2.1, “Summary Description,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The application states that each IU consists of a light water pool which contains the subcritical assembly system (SCAS), the neutron driver assembly system (NDAS), the neutron flux detection system (NFDS), and the TSV dump tank. These are surrounded by a concrete biological shield. The systems supporting the IUs are the tritium purification system (TPS), the TSV off-gas system (TOGS), and the primary closed loop cooling system (PCLS). The atmosphere of the IUs and the TOGS is part of the Radiation Ventilation Zone 1 (RVZ1) exhaust subsystem (RVZ1e). Each IU has five modes of operation. These modes of operation are:

- Mode 0 Solution Removed: No target solution in the SCAS
- Mode 1 Startup: Filling the TSV using a 1/M startup methodology
- Mode 2 Irradiation: Activating the neutron driver and irradiating the target solution
- Mode 3 Post-Irradiation (Shutdown): Target solution is drained to the TSV dump tank
- Mode 4 Transfer to RPF: Target solution is transferred from the TSV dump tank to the RPF

The IU system is designed to be subcritical for all modes of operation. The modes of operation are described in detail in SHINE FSAR section 4a2.6.1, “Normal Operating Conditions,” and the operational state of key components in the different modes is shown in proposed technical specification (TS) table 1.3, “IU Modes of Operation.”

SHINE IUs are similar in size and power to some research and test reactors, but they are subcritical and have features and systems that are different than those found in solid fuel reactors. Although subcritical, SHINE IUs have some features in common with a class of reactors called aqueous homogeneous reactors (AHRs) (Oak Ridge National Laboratory (ORNL), “Fluid Fuel Reactors, Part 1, Aqueous Homogeneous Reactors”). AHRs are critical systems, but they operate at power densities similar to those at which SHINE IUs will operate. Although there are currently no AHRs operating in the United States, there is previous AHR operating experience, including the use of uranyl sulfate as fuel. There has been significant interest in using AHRs for Mo-99 production (International Atomic Energy Agency (IAEA)-TECDOC-1601, “Homogeneous Aqueous Solution Nuclear Reactors for the Production of Mo-99 and Other Short Lived Radioisotopes”). There are several AHRs in operation outside of the United States that are mostly used for criticality studies. The one most similar to a SHINE IU is the ARGUS AHR (Los Alamos National Laboratory (LANL)-UR-18-29657, “The ARGUS Solution Reactor and Molybdenum Production: A Summary Report Based on Open Literature) at the Kurchatov Institute in Russia. The ARGUS AHR has been operating since 1981. It originally used high enriched uranium uranyl sulfate fuel but was converted to LEU uranyl sulfate fuel in 2014. It has a heat exchanger in the aqueous fuel and an off-gas handling system that has a recombiner and a condenser to return water back to the fuel solution, which is similar to the SHINE system.

Based on the information provided in SHINE FSAR section 4a2.1, the NRC staff finds that the summary description of the facility and processes of the SHINE IF meets the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4a.4.2 Subcritical Assembly

The primary components that make up the SCAS are the TSV, the TSV dump tank, and the neutron multiplier, which are both supported and positioned by the subcritical assembly support structure (SASS). The SCAS is submerged in a light water pool (SHINE FSAR section 4a2.4.2) and located directed beneath the NDAS (SHINE FSAR section 4a2.3). The SCAS and the NDAS are the primary components of the IU. The TSV contains the LEU uranyl sulfate target solution in a high source multiplication configuration.

4a.4.2.1 Target Solution

The NRC staff evaluated the sufficiency of the SHINE target solution, as presented in SHINE FSAR section 4a2.2.1, "Target Solution," using the guidance and acceptance criteria from section 4a2.2.1, "Reactor Fuel," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff notes that, while the target solution is not considered reactor fuel, it is similar in nature and behavior to the liquid fuel loading of an AHR and, therefore, the guidance in the ISG augmenting NUREG-1537 can appropriately be applied to its review.

The applicant stated that the SHINE target solution is a uranyl sulfate solution with an enrichment of 19.75 +/- 0.2 percent, which is also stated in proposed TS design feature (DF) 4.3.1. The uranium concentration has been estimated using SHINE's neutronics models of the system. The convention for uranium concentration as specified in the SHINE FSAR is grams of uranium per liter of target solution. Fuel solution of this composition has been used in a number of different research programs, as cited in SHINE FSAR section 4a2.2.1.13. Based on these analyses, the chemical and physical characteristics of the target solution constituents are compatible with one another. Each irradiation cycle has a duration of 5.5 days, with some makeup solution expected to be added to counter process losses. SHINE FSAR section 4a2.6.2 states that no precipitation is anticipated and that maximum burn-up is expected to be a low fraction of the initial uranium concentration. The final SHINE target solution operating parameter range will be determined during startup testing. This will be guided by historical operating data from the operation of uranyl sulfate solution reactor systems. The maximum uranium concentration is specified in proposed TS limiting condition for operation (LCO) 3.8.2.

SHINE FSAR section 4a2.2.1.4 states that the primary system boundary (PSB) components were designed to be compatible with the target solution to avoid corrosion and other unwanted metallurgical effects that could compromise the PSB integrity.

SHINE FSAR section 4a2.2.1.6 states that mixing in the TSV takes place by natural convection. The highest heat generation will occur near the center of the solution, and the surfaces adjacent to cooling flow will be the coolest. Thus, there will be an upward flow through the center of the TSV and a downward flow near the cooled surfaces. Non-uniformities, such as non-uniform void distribution, non-uniform temperatures, and non-uniform power distribution, are not expected to impact operational limits.

SHINE FSAR section 4a2.8, “Gas Management System,” states that off-gas formation is handled by the TOGS. Calculations indicate that plutonium and poison buildup, along with changes in pH, will not have a significant impact on the operation of the IUs. The target solution will also be processed through the molybdenum extraction and purification system (MEPS) after each irradiation cycle. After the extraction of the molybdenum, the target solution will be sent to a holding tank where measurements will determine whether the solution is within target parameters. If the solution’s parameters are outside of the acceptable range, then it is adjusted to bring the parameters back within the acceptable range.

The ISG augmenting NUREG-1537, Part 2, section 4a2.2.1, “Reactor Fuel,” Acceptance Criteria, states, in part, that the “design bases for the fuel should be clearly presented, and the design considerations and functional description should ensure that fuel conforms to the bases.” The NRC staff finds that SHINE FSAR section 4a2.2 illustrates a high-level functional description of each of the components of the target solution system, along with the underlying design basis of each component such that the solution-barrier integrity is maintained. Additionally, all described DFs of the target solution system were supported with appropriate tables, figures, references, and experimental programs.

The ISG augmenting NUREG-1537, Part 2, section 4a2.2.1 states, in part, that a description of the fuel (and solvent) should be given with respect to its chemical and physical properties, along with the relationship of the fuel solution to the environment and fuel barrier. It also states that the phenomena capable of changing the fuel operating composition and structural damage, along with the operating physical forces, should also be described with respect to the integrity of the fuel barrier. SHINE FSAR section 4a2.2.1 describes the physical and chemical characteristics of the target solution (chemistry, uranium loading and enrichment, and radiolytic gas formation) in each of its sub-sections, including the solution’s relationship to the primary barrier. Additional details about the control of the uranium concentration, pH, and the catalyst with regards to precipitation of uranium peroxide was provided by letter dated July 30, 2020 (Agencywide Documents Access and Management System Accession No. ML20220A339), Enclosure 2 (ML20220A341). The NRC staff finds that the SHINE FSAR adequately describes the target solution composition components and addresses the pH of the solution and the bounds of pressure, temperature, uranium concentration, catalyst concentration, and power density that are being applied to the solution.

The ISG augmenting NUREG-1537, Part 2, section 4a2.2.1 also notes that the potential for fission product precipitation should be addressed. SHINE FSAR section 4a2.2.1.6 and table 4a2.2-1 describe the operating limits and catalysts in the target solution that were defined to prevent fission product precipitation at nominal conditions.

The ISG augmenting NUREG-1537, Part 2, section 4a2.2.1 also states that a description of radiolytic gas generation and the management of these gases should be given. This issue is described in SHINE FSAR section 4a2.2.1.5, which discusses radiolysis rates for uranyl sulfate systems during fission. By letter dated June 17, 2020 (ML20188A300), Enclosure 2 (ML20188A302), SHINE provided additional details about radiolysis gas formation and how it is calculated.

The SHINE FSAR addresses each of the nominal phenomena that are expected to impact the changes in target solution composition (burnup and radiolytic gas formation), including target solution makeup addition and fission product precipitation, along with the implications to reactivity control of the system due to these system changes. The applicant also described design information, operational details, setpoints, and means for accomplishing surveillances of the system, to form the basis for TSs.

The NRC staff performed an evaluation of the SHINE target solution relative to the acceptance criteria in the ISG augmenting NUREG-1537, Part 2. The staff found that the target solution design information is sufficiently supported in the SHINE FSAR with adequate functional descriptions, tables, text, and referenced reports. The design limits of the target solution are clearly described such that the safety related implications of these limits, and their relationship to the rest of the facility is also described. The presented design information is described at the level of detail such that it would form the basis for TSs and an operational means to monitor the facility and ensure its safe operation. The staff finds that the target solution design and its interface with the pressure boundary offers reasonable assurance that the health and safety of the public is protected during operation. Therefore, the staff concludes that the target solution design basis meets the applicable regulatory requirements and guidance for the issuance of an operating license.

4a.4.2.2 Reactivity Control Mechanisms

The NRC staff evaluated the sufficiency of the SHINE reactivity control mechanisms, as presented in SHINE FSAR section 4a2.2.2, “Reactivity Control Mechanisms,” using the guidance and acceptance criteria from section 4a2.2.2, “Control Rods,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff notes that while the application does not propose to use control rods, the basis and underlying principles of the guidance in the ISG augmenting NUREG-1537 can still be applied to the SHINE reactivity control mechanisms.

The applicant stated that the IUs are not intended to achieve criticality during normal operation and so no control rods are included in the SHINE design. Reactivity is primarily determined by six variables: uranium concentration in the target solution, uranium enrichment, TSV fill volume, neutron driver source strength, target solution headspace pressure, and temperature of the PCLS. During operation, the last four variables can be manipulated to control reactivity, while the others are not significantly altered during operation. The systems used to monitor reactivity are described in detail in SHINE FSAR chapter 7.

SHINE FSAR section 4a2.2.2 states that the variables that influence reactivity are set by the design and are controlled during operation of the facility. Instrumentation is used to confirm that the neutron flux levels don’t exceed trip setpoints during Mode 1. The target solution uranium concentration, uranium enrichment, and TSV fill volume do not change significantly during irradiation (Mode 2). The target solution concentration is established during solution preparation. The vacuum lift tank transfer system is used to transfer the prepared target solution from the target solution hold tank to the TSV during the 1/M experiment fill procedure that establishes the TSV fill volume. The other variables that influence reactivity are controlled during irradiation. For the TOGS, the gas space pressure above the target solution operates at a value less than the pressure of the atmosphere outside the TOGS. The condensate return lines return water to the target solution to reduce uranium concentration changes due to off-gas formation. The design of the TOGS limits the maximum amount of water holdup in the TOGS. For the PCLS system, the temperature of the cooling water is monitored by the TSV reactivity protection system (TRPS) and the target solution is drained to the TSV dump tank if the PCLS temperature limits are exceeded. The reflector temperatures are kept stable by the large thermal mass of the light water pool.

When an abnormal condition arises that requires the IU to be shut down (e.g., loss of power, high flux, high hydrogen concentration), the control system of the neutron driver assembly will shut down the accelerator and terminate the reaction, and the target solution is drained into a criticality-safe geometry TSV dump tank.

Based on the information provided in the SHINE FSAR, the NRC staff finds that the means for reactivity control are adequately described in the FSAR and meet the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4a.4.2.3 Neutron Moderator and Reflector

The NRC staff evaluated the sufficiency of the solid neutron moderators and reflectors, as presented in SHINE FSAR section 4a2.2.3, “Neutron Moderator and Reflector,” using the guidance and acceptance criteria from section 4a2.2.3, “Solid Neutron Moderator and Neutron Reflector,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The applicant stated that the light water pool, which surrounds the TSV, provides neutron moderation and reflection. Additional information is presented in SHINE FSAR section 4a2.4.2. The neutron multiplier that serves to increase the neutron population in the TSV is described in SHINE FSAR section 4a2.2.6.

4a.4.2.4 Subcritical Multiplication Source

The NRC staff evaluated the sufficiency of the subcritical multiplication source, as presented in SHINE FSAR section 4a2.2.4, “Subcritical Multiplication Source,” using the guidance and acceptance criteria from Section 4a2.2.4, “Neutron Startup Source,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The SHINE subcritical multiplication source is a fixed neutron startup source that is used when the neutron driver is not operating. The startup source provides an adequate and stable population of background neutrons so that neutron multiplication in the subcritical assembly can be accurately and reliably measured while filling the TSV with target solution. Its output is several orders of magnitude less than the neutron driver and is suitable for performing 1/M measurements during Mode 1 startup operations. The subcritical neutron multiplication factor (M) relates the source neutron level to a steady-state neutron level and can be used to predict when criticality will occur. It is defined as 1/(1-k) where k is the multiplicative increase of the neutron population from one generation of neutrons to the next generation. A system is critical when k is equal to 1. When a system is critical, M goes to infinity and 1/M goes to zero.

The startup sources described in the SHINE FSAR, Americium-Beryllium or Plutonium-Beryllium with alpha-neutron reactions, are customarily used as startup sources in nuclear reactors. The physical and operating characteristics of the sources that are specified in this section are: the energy spectrum, the materials from which the sources are constructed, the orientation of the sources, the nuclear reaction and source strength, the radiation environment at which the sources operate, and the procedures used to verify the integrity of the sources prior to startup.

Based on the information provided in the SHINE FSAR, the NRC staff finds that the SHINE subcritical multiplication source is adequately described and meets the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4a.4.2.5 Subcritical Assembly Support Structures

The NRC staff evaluated the sufficiency of the SASS, as presented in SHINE FSAR section 4a2.2.5, “Subcritical Assembly Support Structure,” using the guidance and acceptance criteria from section 4a2.2.5, “Reactor Internals Support Structures,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The applicant stated that the SASS maintains the geometry of the target solution during irradiation. It contains the TSV and supports the TSV dump lines, TSV overflow lines, TOGS piping, and associated instrumentation. The SASS also functions to force coolant through cooling paths to cool the TSV and neutron multiplier. It acts as an additional fission product barrier in the event of a TSV failure. The PCLS is attached to the SASS and operates at a higher pressure than the TSV. This reduces or eliminates leakage of target solution to the SASS in the event of a breach of the PSB. The SASS has a design pressure of 100 pounds per square inch (psi).

The applicant stated that the SASS is designed to conservatively withstand all design basis loads, including thermal, seismic, and hydrodynamic loads imposed by the light water pool during a seismic event. It is also designed to withstand all thermal and hydraulic forces imposed by the coolant loop and target solution during normal and off-normal operating conditions.

The applicant stated that the 304L stainless steel used to construct the SASS was chosen due to its compatibility with the chemical environment and demonstrated performance under the expected neutron flux. The SASS has a 30-year design life. By letter dated January 28, 2022 (ML22028A221), Enclosure 2 (ML22028A224), in response to NRC staff RAIs dated December 23, 2021 (ML21355A360), the applicant provided additional information about the neutron spectrum and corrosion testing relevant to the SASS and the TSV. The applicant also stated that the SASS will be subject to a periodic inspection and surveillance program designed to monitor for corrosion and radiation damage. The neutron spectrum is largely thermalized at the location of the SASS structures and the design data used to assess radiation damage effects is applicable.

In its response to NRC staff RAI 4a-17, SHINE contended that stagnant flow areas are not expected in the area between the SASS inner baffle and the SASS inner wall because this channel is filled with cooling water from the PCLS and, while the PCLS does not force water through this channel, flow is provided via natural convection and radiolysis bubbles. The staff notes that this area between the cooling channel 3 (CC3) and SASS inner wall just above this ring is not expected to be well swept by fluid flow given its long, slender cavity and the lack of a significant thermal driving force in the area. The staff believes that it is possible that this location might have stagnant flow and be subject to off-normal coolant chemistry that could cause corrosion and possible cracking due to weld residual stresses. However, there are several mitigating factors that will decrease this likelihood. First, the relatively low temperature at this location is not normally conducive to promoting excessive corrosion or stress-corrosion cracking. Additionally, the PCLS system has a cleanup system to control water chemistry and remove particulates, which decreases the likelihood that significant off-normal water conditions will exist. Further, this ring and the associated connection between CC3 and the SASS inner wall appears to serve no structural purpose as it is only intended to channel flow into CC3. Therefore, even if significant cracking or other degradation were to occur in this region, the only significant potential consequence is that flow could bypass cooling channels. This situation could degrade the cooling of the TSV and cause an increase in the temperature of the target solution. However, the affected IU would shut down if the target solution temperature exceeds the maximum allowed value of 176 degrees Fahrenheit (°F) specified in proposed TS LCO 3.1.4. Therefore, the staff finds that the design limits used by SHINE for radiation fluence to limit radiation damage are applicable, and that both the design margins and safety systems are adequate to provide effective mitigation if significant flow bypass were to occur.

The applicant stated that the SASS was designed to support the TSV hydrostatic loading during steady-state operation, in addition to the expected dynamic loading that would result from seismic activity. The SASS is also anchored to the surrounding system through supports to the dump tank. The applicant indicated that the design of the SASS was developed to support the safe operation of the TSV during all modes of operation by stating that it is a coherent structure that maintains its safety-related functions during anticipated design-basis stresses. These stresses are the result of expected hydrodynamic loads, temperature gradients, and irradiation. In addition, the SASS and associated piping and connections were designed to accommodate the typical displacements that would occur during normal operation and design basis transients, without degrading their capability to contain the target solution. The applicant addressed the interface design of the SASS with its associated piping and connections. The SASS is supported on top of the dump tank and aligned with the neutron drive with anchorages to the IU floor. The SASS was also developed with standard materials that have been shown by testing and experience to be compatible with the expected fluences, and to also accommodate the lifetime of the TSV without significant degradation.

The NRC staff finds that the SASS conforms to a geometrically sound support structure that maintains its functional shape during normal operation and transients. The staff also finds that the SASS is designed with customary materials that do not degrade significantly during the operational life of the TSV. The staff finds that the SASS is designed to serve as a fission product boundary in the event of a fission product breach by operating at a higher pressure than the TSV. Finally, the staff finds that the SASS can accommodate the expected hydrodynamic loads of the piping that it will encounter during operation.

Based on the information provided in the SHINE FSAR, the NRC staff finds that the SASS design basis meets the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4a.4.2.6 Neutron Multiplier

The NRC staff evaluated the sufficiency of the neutron multiplier, as presented in SHINE FSAR section 4a2.2.6, "Neutron Multiplier." While the ISG augmenting NUREG-1537 does not have a section dedicated to the neutron multiplier, which is unique to the SHINE facility, the staff applied parts of the guidance from section 4a2.2.3, "Solid Neutron Moderator and Neutron Reflector," of the ISG augmenting NUREG-1537 to its review of the neutron multiplier. Those portions of the guidance that are relevant to the structural-mechanical properties of the neutron multiplier, and not its functional properties, were applied. For the functional properties of the neutron multiplier (i.e., the increasing of neutrons for the target solution), the staff assessed whether the applicant provided information that satisfies the requirements of 10 CFR 50.34(b)(2).

The applicant stated that the neutron multiplier is an annulus of aluminum-clad material that moderates and multiplies the fast neutrons from the fusion reactions initiated by the neutron driver. The neutrons are multiplied through fission reactions. The design lifetime is 30 years, but the neutron multiplier can be removed and replaced if damaged. The construction materials for the neutron multiplier are compatible with the chemical and radiation environment. The heat generation rate in the neutron multiplier is expected to be approximately 15 kW during normal operation. The neutron multiplier is cooled by the PCLS and a breach of the aluminum cladding will be detected by the detection of radiation in the PCLS cooling water.

SHINE FSAR section 4a2.2.6 states that the neutron multiplier is designed to operate within the IU environment (i.e., at high temperature and irradiation). The multiplier cladding is thick enough to absorb fission fragments and to accommodate radiation damage, burnup, and heating. The mechanical and nuclear properties are not expected to degrade significantly during the multiplier's 30-year lifetime, and the mechanical/nuclear design bases are clearly presented. The manufacturing/machining process for the multiplier is also clearly described. The possibility of small failures of the mechanical integrity of the multiplier is also considered, with steps taken to accommodate mechanical degradation. For the case of cladding failure, the TSV can be safely shut down and the multiplier replaced. There are engineered features of the system to arrest deflagration with hydrogen produced from the cladding. Additional details were provided by letter dated June 17, 2020, that discuss the generation of hydrogen if the TSV solution were to leak into the cooling water and from water reacting with the natural uranium in the multiplier if there was a breach of the cladding. In both cases, the amount of hydrogen generation is expected to be less than what would be produced by radiolysis during normal operation of the IU. If the cladding were to fail, resulting in the contamination of the PCLS, then radiation monitors would detect the breach and actuate the TRPS trips of the PCLS circulation and IU shutdown. The primary, nuclear function (neutron multiplication properties) does not degrade with burnup.

The NRC staff finds that, per the ISG augmenting NUREG-1537, Part 2 evaluation criteria, the presented design describes a mechanically sound neutron multiplier that will allow for the safe operation of the TSV during the irradiation mode (Mode 2). Additionally, per 10 CFR 50.34(b)(2), the neutronic function of the multiplier will not significantly degrade with operation.

Based on the information provided in the SHINE FSAR, the NRC staff finds that the neutron multiplier design basis meets the applicable regulations and acceptance criteria for the issuance of an operating license.

4a.4.2.7 Conclusion

The NRC staff finds that the target solution and its expected chemical makeup, along with the expected interactions between the target solution and the PSB, are described in detail and are consistent with the historical data described in SHINE FSAR section 4a2.2.1.13. The operating conditions and chemical and physics properties of the target solution are described in detail.

The NRC staff finds that the design of the SASS is composed of appropriate materials known to be compatible with the expected chemical and radiation environment. It is designed to withstand the design-basis loads and provides sufficient cooling to the TSV and neutron multiplier.

The NRC staff finds that the SHINE FSAR contains detailed discussions on all major systems and components. These include the subcritical multiplication source, the neutron multiplier, the light water pool, the behavior of the TSV during a credible deflagration event, and the target solution qualification program.

Based on the above, the NRC staff finds that the description of the subcritical assembly and its components, including operating limits and operating conditions, is adequate. The subcritical assembly and its components are sufficient to ensure the health and safety of the public.

Therefore, the staff concludes that the subcritical assembly and its components meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4a.4.3 Neutron Driver Assembly System

The NRC staff evaluated the sufficiency of the NDAS, as presented in SHINE FSAR section 4a2.3, “Neutron Driver Assembly System.” While the ISG augmenting NUREG-1537 does not have a section dedicated to the NDAS, which is unique to the SHINE facility, the staff assessed whether the applicant provided information that satisfies the requirements of 10 CFR 50.34(b).

The applicant stated that the NDAS is an accelerator-driven system that produces 14.1 MeV neutrons via deuterium-tritium fusion reactions. The neutron driver produces a maximum of 1.5e14 neutrons per second. The high-energy neutrons move from the NDAS target chamber to the natural uranium neutron multiplier and then to the target solution to drive the subcritical fission reactions. The NDAS is situated above the subcritical assembly and mounted to the IU cell wall. It is part of the primary tritium system boundary.

The applicant stated that the operational life expectancy of the NDAS is primarily affected by radiation damage resulting from neutron activation of its components. Approximately 90 percent of the activity resulting from activation will be located beneath the pool surface. It is expected that most NDAS components will not experience significant radiation damage. Complex electronic components will be located outside the IU. The NDAS is a component that is designed to undergo maintenance and replacement of parts over the life of the SHINE facility.

4a.4.3.1 Neutron Driver

SHINE FSAR section 4a2.3.1, “Neutron Driver,” states that the neutron driver is contained within the IU cell and is made up of the accelerator section, the pumping stages, and the target section. The components are shown in SHINE FSAR figure 4a3.3-1. The accelerator section ionizes deuterium gas and accelerates the ions and transports them through a drift tube to the target section. The accelerator section is inside a pressure vessel that contains sulfur hexafluoride gas as an electrical insulator. The pumping stages maintain a high vacuum in the drift tube and return gas that escapes the target chamber back to the target chamber. The target section contains a mixture of deuterium and tritium gas and is where most of the deuterium-tritium fusion reactions occur. It has a water-cooling system.

4a.4.3.2 Neutron Driver Support Equipment

SHINE FSAR section 4a2.3.2, “Neutron Driver Support Equipment,” states that the neutron driver support equipment consists of a high voltage power supply (HVPS), a cooling cabinet, and control cabinets located outside the IU. The HVPS operates at 300 kilovolts and is considered in the facility fire hazard analysis. The cooling cabinet contains components of the cooling system for the NDAS cooling system. The NDAS cooling system is a closed loop system and it transfers heat to the radioisotope process facility cooling system (RPCS) though a heat exchanger. The control cabinets contain electrical power equipment, signal equipment, and control logic equipment. They interface with the normal electrical power supply system for electrical power and the process integrated control system (PICS) for control functions.

4a.4.3.3 Operation Overview

SHINE FSAR section 4a2.3.3, “Operation Overview,” states that the tritium and deuterium gas is supplied to the NDAS by the TPS. When the accelerator is turned on, deuterium ions are accelerated into the target chamber that contains a mixture of deuterium and tritium gas. The deuterium-tritium fusion reactions produce 14.1 MeV neutrons. These high-energy neutrons are multiplied in the natural uranium neutron multiplier and then enter the target solution and drive the subcritical fission reactions. The deuterium and tritium gas is sent back to the TPS for purification after irradiation operations are completed.

4a.4.3.4 Control System

SHINE FSAR section 4a2.3.4, “Control System,” states that the control system is the interface for the NDAS. It provides the means to energize, monitor, and change the state of the NDAS components including shutting down the neutron driver after a safety system trip. A two-key interlock on NDAS operation prevents operation when personnel are present in the IU cell or the neutron driver service cell as specified in TS LCO 3.8.5.

4a.4.3.5 Tritium Design

SHINE FSAR section 4a2.3.5, “Tritium Design,” states that the deuterium and tritium in the NDAS is supplied by the TPS and exhausted to the TPS after operation. The NDAS components containing tritium are maintained at low pressure by a vacuum system so that any leaks would be into the system. The NDAS is designed so that no single failure can result in an uncontrolled release of tritium.

4a.4.3.6 Seismic Design

SHINE FSAR section 4a2.3.6, “Seismic Design,” states that the NDAS components within the IU are classified as Seismic Category II to prevent damage to the IU’s safety-related equipment by components from the neutron driver during and following a design basis seismic event. The NDAS cooling system isolation valves and piping between the isolation valves and the primary confinement boundary are classified as Seismic Category 1 to maintain integrity of the primary confinement boundary during and following a design basis seismic event.

4a.4.3.7 Target Chamber

SHINE FSAR section 4a2.3.7, “Target Chamber,” states that the target chamber is maintained at low pressure and filled with a deuterium and tritium gas mixture. Because reactions between the ion beam and the gas cause most of the ion beam to be stopped before reaching the bottom of the target chamber, increases in target chamber pressure have insignificant effect on neutron yield. Decreases in target chamber pressure result in lower neutron yield. The target chamber pressure is limited by proposed TS LCO 3.8.6 to ensure that the amount of tritium in an IU cell is below the limit described in SHINE FSAR section 13a.2.2.12.1. The target chamber is cooled by the NDAS cooling system. It is surrounded by the subcritical assembly and is, therefore, subject to high neutron flux. The construction materials were chosen to mitigate the effects of corrosion and neutron damage.

4a.4.3.8 Conclusion

The NRC staff finds that the descriptions of the components of the NDAS satisfy the requirements of 10 CFR 50.34(b). The staff finds that the failure of any component of the NDAS would conservatively result in a decrease in fission rate. Additionally, safety related trips from the TRPS system would cause a shutdown of the neutron driver. The staff finds that there is a two-key lockout system that prevents operation of the neutron driver when personnel are present in the IU cell or the neutron driver service cell. Further, the NDAS is designed to prevent an uncontrolled release of tritium from any single failure and to prevent damage to any IU cell safety-related equipment during and after a design basis seismic event. Therefore, the staff concludes that the NDAS and its components meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4a.4.4 Target Solution Vessel and Light Water Pool

The NRC staff evaluated the sufficiency of the TSV and light water pool, as presented in SHINE FSAR section 4a2.4, "Target Solution Vessel and Light Water Pool." While the ISG augmenting NUREG-1537 does not have a section dedicated to the target solution vessel, which is unique to the SHINE facility, the staff assessed whether the applicant provided information that satisfies the requirements of 10 CFR 50.34(b).

The light water pool serves multiple functions, including heat removal and radiological shielding. The TSV is part of the PSB, which comprises the TSV, the TSV dump tank, and the TOGS. The TOGS is described in SHINE FSAR section 4a2.8.

4a.4.4.1 Target Solution Vessel

SHINE FSAR section 4a2.4.1, "Target Solution Vessel," describes the physical characteristics of the TSV, including the physical dimensions of the TSV and supporting structures. SHINE FSAR section 4a2.4.1.1, "Design Considerations," also states that the TSV is designed and fabricated in accordance with the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, section VIII, Division 1. The TSV construction material is 347 stainless steel, and it has high corrosion resistance to the target solution environment, so no significant chemical damage is expected. The TSV will be monitored for corrosion with both visual inspections and corrosion coupons. The TSV is designed to last for the lifetime of the SHINE facility and is not expected to be replaced. Some of the piping is 304L and 316L stainless steel. Research performed at ORNL, LANL, and Argonne National Laboratory (ANL) on TSV construction materials during facility-relevant conditions were used to inform the final TSV design. The TSV penetrations and connections are described in SHINE FSAR section 4a2.4.1.4. Additional details about the penetrations and connections are provided in SHINE's letter dated June 17, 2020, including whether the penetrations are liquid or gas-filled during normal operation.

The applicant stated that the work performed at ANL shows that some fission product compounds are likely to reach solubility limits, but that they will be present in small enough quantities that their cumulative effect on reactivity is expected to be negligible. While SHINE plans to use catalytic agents to prevent the precipitation of uranium from the target solution, no catalytic agents will be used to mitigate the precipitation of fission product compounds.

The applicant stated that a TSV can be emptied into a criticality-safe TSV dump tank via the TSV dump valves. There are two completely independent dump valves, along with independent dump lines and overflow lines. These valves can be opened by the TRPS and fail in the open position. There are redundant flow paths to meet single failure criteria and to satisfy the second specification of proposed TS DF 4.3.2. Proposed TS LCO 3.1.5 requires that the TSV dump valves open within 2 seconds of demand, and that each dump line must drain the TSV from greater than or equal to the minimum target solution fill limit within 183 seconds. Proposed TS Surveillance Requirement (SR) 3.1.5 requires quarterly verification that a TSV drains within 183 seconds when it is greater than or equal to the minimum target solution fill limit. Leakage of the TSV dump valves during operation can be detected and would lead to a shutdown of the IU by the TRPS as specified in the low-high TSV dump tank level setpoint in proposed TS LCO 3.2.3.

The applicant stated that the TSV is designed to be resistant to chemical corrosion and neutron damage. The TSV has a 30-year design life and, as described by letter dated January 28, 2022, it will be subject to a periodic inspection and surveillance program designed to monitor corrosion and radiation damage. Also, by letter dated January 28, 2022, SHINE provided information to show that the high energy neutrons are largely thermalized in the region of the TSV, which confirms that the neutron spectrum is not significantly harder than the irradiation used for determining the neutron radiation damage limits because of the 14.1 MeV neutron source. Therefore, the design data used to assess radiation damage effects is applicable.

In its response to NRC staff RAI 4a-16 by letter dated January 28, 2022, SHINE demonstrated that the supplemental corrosion testing performed at ORNL was conducted over a range of test conditions expected to be representative of both normal operating and off-normal conditions at the SHINE facility as defined in the design basis. These tests evaluated corrosion characteristics over a wide range of electrochemical conditions, examined erosion-corrosion and potential cavitation effects, studied the effects of radiolysis on corrosion, and evaluated the effects of irradiation on key material properties. These tests support the assurance that the design requirements will be maintained over the TSV and SASS operating lifetimes and that the potential effects of material degradation over the design life have been sufficiently evaluated.

In conjunction with the testing performed at ORNL, SHINE described its surveillance and inspection plans in the response to NRC staff RAI 4a-18. SHINE plans to insert corrosion, tensile, and fracture specimens into the TSV at several prescribed elevations and orientations. Nine specimen-withdraw times are planned over the 30-year design life of the TSV. Each withdrawal will remove and evaluate one corrosion coupon, two tensile specimens, and one fracture toughness specimen. The testing of the withdrawn coupons and specimens will allow a direct comparison between corrosion rates and mechanisms occurring within the TSV and allow trending of the mechanical property and fracture toughness behavior as a function of both operating time and irradiation fluence. The first specimen withdrawal will occur early in the life of the facility, at 1 effective full power year, to ensure that accelerated degradation is not occurring. Subsequent withdrawal times will be informed by the prior results to ensure both that property trends can be appropriately monitored, and that sufficient surveillance material will remain for evaluating properties at the end of the design life.

Boroscopic visual inspections of the TSV and SASS structures will also be performed periodically through access ports to examine the inner TSV surfaces that are most likely to experience degradation including weld locations, the liquid level line, piping connections, areas with the expected highest likelihood of chemical damage, areas experiencing the highest radiation fluence, and areas most likely to be subject to pressure pulses. Weld locations and mechanical locations of the SASS will also be visually inspected. As with the surveillance plan, the inspection plan and periodicity will be updated based on the surveillance and inspection findings.

Based on the above, the NRC staff finds that SHINE has an adequate program to monitor TSV radiation and corrosion damage over the life of the facility.

4a.4.4.2 Light Water Pool

SHINE FSAR section 4a2.4.2.1 states that the light water pool associated with each IU is constructed from concrete and lined with stainless steel and is designed to withstand the chemical environment of the target solution. Each pool contains approximately 19,000 gallons of water. The pool and the pool liner are designed as Seismic Category I structures to remain functional after a design basis earthquake. The nominal pool height is 15 feet relative to the bottom of the pool. The pool provides cooling and shielding. The SASS and TSV are located inside the light water pool, with the top of the TSV 5.3 feet (ft) below the water's surface under normal operating conditions. The pool also acts as a neutron moderator and reflector. In the event of a leak of target solution into the pool, the IU cell would be shut down and the light water pool system would pass the contaminated water through an ion exchange bed. If the degree of contamination were to exceed the cleanup capacity of the ion exchange beds, then the contaminated water would be processed by grouting and processing as low level waste. Piping penetrations to the light water pool are either above the minimum pool level or have anti-siphon devices or other means to prevent draining the pool below the minimum level.

SHINE FSAR section 4a2.4.2.2 states that the light water pool provides decay heat removal from the TSV dump tank after the target solution is drained from the TSV. The light water pool also provides about 5.5 kW of heat removal during irradiation of the target solution. The light water pool transfers heat from the PCLS through natural convection heat transfer. The light water pool also provides a heat sink with large thermal capacity for shutdown cooling after a postulated accident.

Proposed TS LCO 3.3.1 specifies that the light water pool minimum level as 14 ft relative to the bottom of the pool to ensure adequate cooling and shielding. The pool level is verified to be above the minimum level before entering Mode 1 (Startup). If the pool level goes below the minimum level during Mode 1 (Startup) or Mode 2 (Irradiation), then the dump valves are opened, and the target solution drains to the TSV dump tank to transition the IU to Mode 3 (Shutdown) and then finally to Mode 0 (Solution Removed).

4a.4.4.3 Conclusion

The NRC staff finds that the descriptions of the TSV and the light water pool satisfy the requirements of 10 CFR 50.34(b). The staff finds that the TSV is conservatively designed to fail to a safe, non-critical geometry and that its components are adequately designed to withstand credible accidents and the normal operating environment. The staff also finds that the light water pool provides cooling to the TSV, biological shielding, and shielding to prevent radiation damage to SSCs in the IUs. Therefore, the staff concludes that the TSV and the light water pool meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4a.4.5 Irradiation Facility Biological Shield

The NRC staff evaluated the sufficiency of the irradiation facility biological shield, as presented in SHINE FSAR section 4a2.5, “Irradiation Facility Biological Shield,” using the guidance and acceptance criteria from section 4a2.4, “Biological Shield,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The applicant stated that the irradiation cell biological shield is designed to protect workers and members of the public from radiation sources in the IF. Shielding is provided through concrete enclosures for the IU cells and the TOGS shielded shell that vary in thickness from approximately 4 to 6 ft. The concrete walls that vary from approximately 0.7 to 1 ft thick and the steel doors that are approximately 3 in. thick act as a shield on the primary cooling room. SHINE FSAR figure 4a2.5-1 shows different section cuts through the biological shield. The dose rates on the external surfaces of the shields are designed to be less than 1 milli-roentgen equivalent man per hour.

The applicant stated that the biological shield is designed to meet the as low as (is) reasonably achievable (ALARA) radiation exposure goals described in chapter 11 of the SHINE FSAR and to meet or exceed the requirements in 10 CFR Part 20. The applicant proposed to use a newer concrete standard, American Concrete Institute (ACI) 349-13, “Code Requirements for Nuclear Safety-Related Concrete Structures and Commentary,” than the one specified in Regulatory Guide (RG) 1.69, Revision 1, “Concrete Radiation Shields and Generic Shield Testing for Nuclear Power Plants” (ML090820425), which is ACI 349-06. The applicant used this standard in a way that is consistent with how ACI 349-06 is used in RG 1.69. The proposed materials and configuration are consistent with NRC staff-endorsed guidance.

To evaluate the effects of concrete degradation due to neutron and gamma radiation, the applicant estimated fluence to the concrete and the corresponding dose at that location with the Monte Carlo N-Particle Transport Code (MCNP) according to NUREG/CR-7171, “A Review of the Effects of Radiation on Microstructure and Properties of Concretes Used in Nuclear Power Plants” (ML13325B077). Fluxes and dose rates were evaluated at various points of the shield structure. As a result of this analysis, the applicant showed that concrete radiation degradation and nuclear heating is not significant over a 30-year operating lifetime. For those locations that accumulate stress concentrations and for which statistically valid flux tallies are difficult (penetrations and interfaces), a shielding program will be put in place and managed as described in SHINE FSAR section 11.1. The shields are constructed according to rigorous standards, such that they remain intact during normal operating conditions and design basis accidents. One unique feature of the SHINE design is the use of 14.1 MeV deuterium-tritium fusion neutrons for the neutron driver. SHINE provided information regarding the adequacy of the shield for these high energy neutrons by letter dated June 17, 2020.

The applicant stated that the radiation fluence to the inside of the shield is well within the allowable standard for the life of the shield. Nuclear heating in concrete can be neglected if energy fluxes are less than 1.0e10 MeV per square centimeter per second or if temperatures are kept lower than 149°F. The energy fluxes in the concrete are below this limit in all areas except for the concrete directly below the TSV dump tank, where there was a calculated maximum energy flux of 6.0e10 MeV per square centimeter per second. However, the light water pool provides adequate cooling of this concrete to keep the temperature of the concrete below 149°F.

The NRC staff finds that SHINE used conservative values for gap sizes in how the plugs fit and that penetration sizes to conservatively account for streaming will ensure that the biological shield design will limit radiation exposure from the IF to workers and the public.

The NRC staff finds that the results of the analyses presented in the SHINE FSAR show that the biological shield meets all regulatory requirements. Therefore, the staff concludes that the biological shield meets the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4a.4.6 Nuclear Design

The NRC staff evaluated the sufficiency of the IF nuclear design, as presented in SHINE FSAR section 4a2.6, "Nuclear Design," using the guidance and acceptance criteria from section 4a2.5, "Nuclear Design," of the ISG augmenting NUREG-1537, Parts 1 and 2.

The IU is comprised of the biological shield, the NDAS, the light water pool system, the SCAS, and the NFDS. The IU's supporting systems include the TOGS, the TPS, and the PCLS. The IF contains eight IUs and each IU is supplied with deuterium and tritium by the TPS. Each of the three TPS trains supports a specified set of IUs. This section evaluates the nuclear parameters and characteristics of the IF to determine whether it can be operated and shut down safely from any operating condition.

4a.4.6.1 Normal Operating Conditions

The NRC staff reviewed the sufficiency of SHINE FSAR section 4a2.6.1, "Normal Operating Conditions," using the guidance and acceptance criteria from section 4a2.5.1, "Normal Operating Conditions," of the ISG augmenting NUREG-1537, Parts 1 and 2. Given that the TSV configuration operates in a sub-critical mode, those criteria that are relevant to a subcritical system with no excess reactivity were adapted for use with SHINE.

SHINE FSAR section 4a2.6.1 describes a subcritical assembly that can operate safely and be shut down and remain shut down through the TRPS and associated TSV dump tank. The design information, as supported by tables and figures, demonstrates that the chemical and physical properties of the target solution are accounted for in the reactivity balance of the system. The physical design configuration is described. The chemical and physical properties of the system are clearly described and supported with associated tables and references. The variables that influence reactivity are identified and calculated; some of these variables are monitored and controlled to be in specified ranges. The NRC staff also reviewed the sections of SHINE FSAR chapter 13 that consider reactivity additions of water due to malfunction of the TOGS or due to failure of the pressure boundary. The means to introduce target solution to the system (through the vacuum transfer system) are actively controlled by the operator, and don't allow the passive addition of extra solution to the TSV.

The applicant also calculated a bounding, worst-case limiting core configuration (during Mode 1 startup), along with the corresponding subcritical multiplication margin. The associated volume margins to criticality were calculated and described in the SHINE FSAR, and additional margins that allow for the return of TOGS condensate to the target solution were also calculated and subtracted from the operating volume. During startup (Mode 1), the subcritical multiplication source allows flux detectors to monitor the reactive increase of the assembly. The target solution chemical and physical state is monitored and controlled prior to startup.

The applicant determined that the limiting case (in terms of margin to criticality) occurs at the point of maximum fill height right before the transition to Mode 2 (i.e., before the start of irradiation), enveloping all other conjectured configurations. Proposed TS limiting safety system setting 2.2.3 sets a source range neutron flux limit; this protects against a sudden increase in reactivity during the fill process.

The application states that all reactivity components of the system were calculated to inform the design, operation, safety features, and protection systems of the SCAS. Changes in reactivity with uranium burnup, plutonium buildup, fission product poisons, radiolytic gas-void formation, TOGS sweep-gas pressure regulation, TOGS condensate return, PCLS water temperature changes, solution temperature changes, neutron multiplier burnup, and neutron multiplier temperature are calculated and accounted for in the target solution startup and irradiation strategy. The target solution chemistry doesn't change significantly with burnup. For this reason, there are no reactivity changes associated with changes in target solution pH or catalyst concentration. There are reactivity changes corresponding to uranium concentration changes (reactivity components are also presented as an equivalent uranium concentration), but this concentration does not substantially change during an irradiation cycle. The reactivity effects of transmutation and fission products are calculated by the applicant. In the case of fission products, the major contributor, plutonium, is managed by extraction through the MEPS. Although the gaseous fission products from solution are extracted through the associated cleanup and safety systems, their bounding reactivity effects are calculated and compared to the other components for both startup and irradiation. The steady-state evolution of core reactivity, and the contribution of each component, is explicitly calculated, with the total batch target solution age being divided into alternating irradiation/shutdown cycles. As the target solution operates subcritical, there are no chemical poisons or mechanical components that are designed to hold down excess reactivity. There is not an associated reactivity change due to the static nature of the mechanical components. There is a holdup of water within the TOGS active gas management system. The volume of this water holdup and its associated reactivity effect are also calculated. The actions of the TOGS have several reactivity effects that were considered by the applicant, specifically, due to the TSV head-space pressure regulation (sweep and purge actions) and the uranium concentration effect of the target solution gaining or losing condensate. The positive reactivity effect resulting from water holdup in TOGS is accounted for when the minimum subcritical volume of the target solution is determined.

The applicant stated that to compensate for uranium burnup and target solution processing at the end of each irradiation cycle, the solution is adjusted before transfer to the TSV. Administrative controls are applied to ensure that the solution temperature, uranium concentration, solution chemistry, pH, catalyst, and solution volume are within acceptable levels prior to transfer to the TSV.

The applicant stated that several drastic core configuration and component scenarios were evaluated in terms of static reactivity changes for the startup and irradiation modes: water flooding of the head-space volume above the target solution; driver target flooding; neutron multiplier flooding (assuming a cladding breach); voiding of PCLS; and a total loss of pool water. The limiting core configuration that would give the highest power densities in terms of uranium concentration, batch size, and fill height was also calculated.

The applicant used the TRIAD [Transient Reactivity Integration Accelerator Driven Multiphysics Simulation Software] code to calculate coupled system behavior by considering the total impact on the target solution with three induced transients. Reactivity effects of void collapse were considered along with peak power change relative to nominal power. The applicant's analysis demonstrated that power changes could be accommodated through natural self-dampening effects of the negative target solution coefficients (temperature and void). Coupled system oscillations are anticipated due to beam variations (normal beam interruptions), the TOGS pressure variations, and the PCLS temperature variations. The transients induced by the NDAS beam interruptions were analyzed by the applicant. To preclude over-cooling (and, in turn, reactivity increase) of the target solution in the TSV that would occur with a temporary NDAS beam interruption, the TRPS limits the time duration over which this beam interruption could occur by opening the HVPS breakers after a time delay, depending upon the source strength. This protection is discussed in SHINE FSAR section 7.4.3.1.4. This limits the amount of the calculated peak power change during the transient such that operational power limits aren't reached. Similarly, the change in fission power due to the TOGS pressure oscillations and the PCLS temperature changes are also calculated. These transients do not go beyond operational limits.

SHINE has an administrative program and engineering DFs that form the bases of TSs, and envelope the normal and transient behavior of the TSV related to uranium concentration, target solution chemistry, NFDS flux setpoints, allowable fill volumes and solution heights, trip setpoints, solution fill rates, and delay times for opening of dump valves. These values inform proposed TS SRs and LCOs.

SHINE developed administrative, procedural, and engineering barriers to prevent the unwanted addition of reactivity during all operational modes. Except for the engineering barriers (which are binned as the natural physics of the negative temperature coefficients and are part of the design), the other barriers were put in place to keep the solution under control for all anticipated operational states and transients.

SHINE FSAR section 4a2.6.1 states that the SCAS operates under three modes that are relevant to nuclear design: Mode 1 (startup); Mode 2 (irradiation); and Mode 3 (post-irradiation). A fourth mode (solution removed) is described in SHINE FSAR chapter 7 and is not discussed in Chapter 4. In each of these three modes, the IU can be shut down by the TRPS, which will trip on high neutron flux and high PCLS temperature. As an additional, administrative control, the operators can manually dump the contents of the TSV to the TSV dump tank, although these measures are not required for safe shutdown or operation. When shutdown, the neutron driver is de-energized and the target solution is held in a criticality-safe geometry TSV dump tank. Proposed TS LCO 3.1.8 specifies the time that the target solution is required to be held in the TSV dump tank before being transferred to the RPF. This hold time depends on the maximum irradiation power level and limits the radionuclide inventory and source term for the RPF accident analysis. There are two completely independent TSV dump valves, along with independent dump lines and overflow lines. The TSV dump valves fail open and can be triggered by the TRPS, PICS, and the operator. SHINE provided additional details describing the drain rate, trip signal delay, and valve opening time by letter dated June 17, 2020.

The applicant stated that the burn-up after the designed amount of exposure of the target solution is minimal. The effect of Xenon and Samarium accumulation is estimated to result in a power reduction of less than 10 percent relative to a system without Xenon and Samarium.

The final design describes the reactivity and reactivity changes of the system during all modes of operation, including reactivity worth of the IU components for each mode of operation, the worth of water held up outside the TSV and the effects of removing that water, and expected changes in reactivity that would occur due to voiding of the cooling system. The system interfaces with the PICS and TRPS to shut down on abnormal conditions (e.g., loss of power, high flux, high hydrogen concentration). The physical and administrative controls that are designed to prevent criticality from occurring are sufficient to protect workers and the public from potential criticality accidents.

The SHINE FSAR states that minor power oscillations during operation are expected due to flow fluctuations and strong void feedback based on AHR operating experience, but that these oscillations would be small and self-limiting due to the low power density and negative void and temperature coefficients. In the case of a TOGS failure, the resulting void collapse would cause a small reactivity increase, but not one large enough to result in criticality.

4a.4.6.2 Target Solution Physics Parameters

SHINE FSAR section 4a2.6.2.1, "Analysis Methods and Code Validation," states that a variety of computer codes are used to calculate nuclear physics parameters. MCNP5 is used to calculate neutron flux, reactivity, dose rates, neutron lifetime, and reaction rates. MCNP5 is publicly available and widely used in the nuclear industry for modeling neutron-nuclear interactions with matter. SCALE [Standardized Computer Analysis for Licensing Evaluations] is a comprehensive modeling and simulation suite for nuclear safety analysis and is capable of performing calculations for reactor physics, criticality safety, and radiation shielding. COUPLE, a module of SCALE, is used to calculate flux-dependent cross-sections and fission yields (COUPLE is not an acronym and references the functionality of the module – it "couples" nuclide decay terms in the master transition matrix with the functional ORIGIN library). Oak Ridge Isotope Generation (ORIGIN), a module of SCALE, is used to generate source term concentrations and activities following various irradiation and decay intervals. By letter dated June 17, 2020, SHINE provided uncertainty analysis for the calculations using these codes. To demonstrate its applicability for uranyl sulfate solution reactors, SHINE compared MCNP5 to a published suite of aqueous solution reactor benchmark cases. From this assessment, the MCNP5 calculated bias and bias uncertainty of system multiplication factor (one-sided tolerance limit) was determined with a standard methodology, NUREG/CR-6698, "Guide for Validation of Nuclear Criticality Safety Calculational Methodology" (ML050250061), and was applied to the analysis of the TSV dump tank and TOGS. MCNP5 was compared to experiments for similar systems to evaluate the applicability of MCNP5 to the solid uranium metal multiplier and found acceptable by the applicant. The SCALE and MCNP5 packages are maintained at Department of Energy facilities under separate configuration management plans.

Using MCNP5, SHINE evaluated all significant contributors to reactivity for the range of solution burnup and for all relevant operational modes. Two-sided tolerance bands at a 95th percentile probability with a 95th percentile confidence limit (95/95) with conservative assumptions were used to quantify the uncertainty of reactivity coefficients and neutron multiplication with respect to uncertainties in state parameters. SHINE established that the total reactivity and power coefficients were sufficiently negative over the range of expected system conditions and that burnup had little effect on power distribution, flux, and reactivity coefficients of the target solution. Kinetics parameters such as neutron lifetime and the effective delayed neutron fraction for both fresh target solution and end of life target solution were also calculated. Reactivity coefficients for the target solution and multiplier were evaluated at different target solution temperatures and uranium concentrations. Uranium concentration, flux density, and power peaking were calculated at both nominal and limiting conditions, along with the corresponding reactivity coefficients.

SHINE stated that the calculations show that target solution void, temperature, and power coefficients will generally be negative for all modes of operation. They are in the range of other operational AHRs and conceptual designs. The temperature and void coefficients for the PCLS are positive, but the applicant's calculations show that this will not result in strong positive feedback because the TSV feedback is dominant. The PCLS is not expected to have significant voiding and the water volume is limited in the narrow TSV cooling paths. The target solution void and temperature coefficients are the most significant because the radiolysis gas and because the majority of the heat is deposited directly into the target solution. Analyses show that the combined reactivity coefficients are sufficiently negative over the anticipated range of operating conditions.

SHINE performed transient analysis with the TRIAD code, which is an extension of a LANL systems code that was developed to model an AHR that is coupled to a neutron-accelerator system (A Generic System Model for a Fissile Solution Fueled Assembly, LA-UR-13-22033, Los Alamos National Laboratory, Kimpland, R., Klein, S., 2013). It is a 1D fluid flow model and has an empirical void transport model. The actual void distribution is determined by a buoyancy driven natural circulation flow pattern that depends on the power void and temperature profiles in the TSV and cannot be mechanistically predicted by the TRIAD code. SHINE performed a group of calculations in which the empirical void transport model was changed over a wide range. The results of the steady state and transient calculations are sensitive to the void transport model. The coefficients can be tuned to improve the fidelity of TRIAD code predictions. By letter dated June 17, 2020, SHINE described the extensions made to the LANL code and explained how TRIAD is validated against the Silene and KEWB (Kinetics Experiments on Water Boilers) experiments.

4a.4.6.3 Operating Limits

SHINE FSAR section 4a2.6.3, "Operating Limits," discusses specific values for operating limits. Void coefficients are negative throughout all operating conditions, and combined reactivity coefficients are sufficiently negative over the anticipated range of operating conditions. The target solution burn-up is minimal in the SCAS. The worth of fission product poisons such as Xenon and Samarium are small compared to the temperature and void defects.

The applicant stated that there are only three initiating events that may result in inadvertent insertions of excess reactivity: (1) excessive cooldown of the TSV; (2) increased pressure in the TSV; and (3) excess volume of target solution. None of these events result in damage to the PSB. These events are described in SHINE FSAR chapter 13, which the NRC staff reviews in chapter 13 of this SER. In the event of a loss of power to an IU, the neutron driver will de-energize and the target solution will be transferred to the criticality-safe TSV dump tank. Each IU has its own TSV dump tank.

4a.4.6.4 Conclusion

The NRC staff finds that SHINE FSAR section 4a2.6 provides an adequate description of the proposed configuration of the SCAS during the three relevant modes of operation. The staff determined that the target solution behavior during operation has been adequately addressed, including gaseous fission product buildup and removal, poisons, and power oscillations. The staff also determined that the reactivity analyses include reactivity values for the in-core components.

The NRC staff finds that SHINE's methodology for calculating the neutron lifetime, effective delayed neutron fraction, and coefficients of reactivity is acceptable. The staff finds that the code predictions for the ratio of neutron production to neutron absorption and leakage, reactivity coefficients, and reactivity worths of target solution changes are bound within an uncertainty band that is determined by code comparisons to experimental benchmarks.

Based on the above, the NRC staff finds that the descriptions of the nuclear design component of the SHINE facility satisfy the requirements of 10 CFR 50.34(b). Therefore, the staff concludes that these descriptions are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4a.4.7 Thermal-Hydraulic Design

The NRC staff evaluated the sufficiency of the thermal-hydraulic design, as presented in SHINE FSAR section 4a2.7, "Thermal Hydraulic Design," using the guidance and acceptance criteria from section 4a2.6, "Thermal-Hydraulic Design," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE provided a description of the systems that are responsible for target solution inventory control, heat removal during irradiation, and shutdown operations for the eight IUs.

4a.4.7.1 Heat Removal Systems

SHINE FSAR section 4a2.7.1 states that the SHINE heat removal systems must have adequate capacity to remove heat during irradiation and shutdown operations. The paths for heat removal from the TSV are the PCLS and the TOGS. The light water pool is also cooled by the piping in the PCLS.

SHINE FSAR section 4a2.7.1.1 states that the PCLS cooling loop circulates water in an upward direction past the TSV heat transfer surfaces using forced convective cooling. Energy can also be deposited into the PCLS coolant by neutron and gamma radiation. The PCLS cooling water removes heat from the TSV and then the PCLS water flows to reject the heat through a heat exchanger in the RPCS.

The SHINE FSAR states that the PCLS cooling loop also removes heat from the light water pool, the neutron multiplier, and the neutron driver tritium target chamber using forced convective flow. The heat loads on the light water pool are energy deposition by neutron and gamma radiation from an operating IU and decay heat loads from the TSV dump tank when it contains irradiated target solution. The PCLS cooling water rejects heat to the RPCS.
During IU operations, the heat deposited in the light water pool is approximately 2 percent of the thermal power.

The SHINE FSAR states that the TOGS operates as a closed loop system in which nitrogen sweep gas is circulated above the top of the TSV liquid level. The gas is circulated through a flow loop that removes iodine from the off-gas, recombines radiolysis generated hydrogen and oxygen to keep them below flammable limits, and condenses water vapor and returns the liquid water to the TSV. Heat from the condensation and recombination processes are transferred through heat exchangers that ultimately reject heat to the RPCS.

4a.4.7.2 Cooling Water Hydraulic Characteristics of the TSV

SHINE FSAR section 4a2.7.3.1 states that the PCLS removes heat from the TSV during irradiation and shut down operations. The PCLS minimum volumetric coolant flow rate is adequate to keep the target solution temperature within allowable limits. The PCLS coolant water enters at 59 – 77°F and a pressure of 138 kilopascals (kPa). The flow rate is adequate to maintain the TSV at a temperature of 120°F during irradiation. The TSV pressure is maintained below the PCLS pressure to prevent leakage out of the TSV in cases where the PSB is breached. In the case of leakage of water from the PCLS into the TSV, the dilution of the target solution will lead to a negative reactivity insertion. If the breach is large enough such that the pressure difference cannot be maintained, then some of the target solution could leak into the PCLS cooling water. The nominal temperature of the target solution in the TSV is 68 – 140°F. The operating conditions in the TSV prevent the plating out of chemicals on the PCLS heat transfer surfaces

The applicant stated that a loss or degradation of the PCLS cooling system would cause an increase in the target solution temperature. If the PCLS coolant temperature or the target solution temperature rises above the allowable limit, the TRPS system will shut down the neutron driver and dump the target solution to the TSV dump tank where it will be cooled by natural convection in the light water pool.

The applicant stated that the light water pool is cooled by the pipes of the PCLS. If the PCLS is not operating, the light water pool has a large heat capacity that can be used to remove decay heat from the TSV dump tank for long periods of time without active cooling. Natural or free convection cooling on the outside of the TSV dump tank is adequate to maintain target solution temperatures within the tank below the 194ºF limit. The heat capacity of the pool is large enough that the pool temperature will remain well below the boiling temperature of water after 90 days of decay heat load at the minimum acceptable pool level for accident conditions.

4a.4.7.3 Target Solution Thermal Power Density Distribution

SHINE FSAR section 4a2.7.4 provides the power density distribution in the target solution. The fission power density has peaks in the axial and radial dimensions due to neutron transport effects. The radiolysis gas generation source is related to the fission power source since the primary mechanism for producing radiolysis gas is the fission fragments colliding with water molecules and causing dissociation of the water molecules. Neutron and gamma radiation can also be a source of radiolysis gas formation. The decay power distribution is not directly related to the fission power distribution since the fission products that are the source of decay power will circulate with the coolant. The thermal power density distribution drives gradients in fluid temperature and void fractions that enhance natural circulation in the target solution.

4a.4.7.4 Thermal-Hydraulic Calculations and Methodology

SHINE FSAR section 4a2.7.5 discusses a correlation-based thermal-hydraulic methodology for safety-related calculations involving fluid flow and convective heat transfer. The applicant stated that the calculations are used to estimate the steady state and transient target solution temperature which is determined by the balance of the heat generation and the heat removal to heat transfer surfaces by natural circulation flows caused by temperature and void fraction gradients. The results of experiments performed at the University of Wisconsin – Madison using electric heaters and bubble injection to simulate the effects of volumetric heating and gas generation were used to determine the expected range of heat transfer coefficients and void fractions. The experiments used magnesium sulfate to simulate the uranyl sulfate target solution. The data collected was used to form the basis of an empirical heat transfer coefficient. The heat transfer correlation has the form of a turbulent free convection correlation with the length scale implicitly embedded in the leading constant multiplied by a void fraction enhancement factor that could account for increased buoyancy driven flow. The enhancement factor is significant which implies that the buoyancy of the voids induces a large recirculating flow. SHINE calculated a void fraction to use in the heat transfer calculations using a bubble nucleation and growth model. A description of assumptions used in the calculation is in SHINE FSAR section 4a2.7.5.5. The heat transfer on the PCLS side of the TSV is single-phase water-cooling flow and the surface temperatures on the PCLS side are below the boiling temperature of the cooling water which eliminates the possibility of exceeding the critical heat flux.

4a.4.7.5 Impact of Operating Conditions on Thermal-Hydraulics

SHINE FSAR section 4a2.7.6 states that the heat removal and recombination capacities of the TOGS will determine the pressure of the gas space and target solution for a fixed TSV power. Feedback effects on the power generation will determine the operating power and pressure where there is a balance between the gas and water vapor generation in the TSV and the heat removal and recombination capacity of the TOGS if steady state operation is possible. It is also possible that the system may operate in an oscillatory mode with operating conditions that vary but stay within safety limits. SHINE provided a stability analysis of the accelerator driven system that was performed by LANL and documented in report LA-UR-14-28684, "Stability of Fissile Solution Systems." The LANL stability analysis showed that the system is stable across the expected range of operation and that any oscillations are damped. Driven and bounded reactivity or source strength oscillations will also result in a bounded response. The target solution is expected to be stable with respect to chemical and physical properties during an irradiation cycle. Void formation in the target solution will be caused by radiolysis gas formation. The effects of the voids on nuclear and heat transfer performance of the system are accounted for in the final design. The void formation enhances the heat transfer in the TSV due to increased natural circulation flows due to buoyancy effects. The natural circulation also helps prevent large non-uniformities in temperature and solution concentration. Target solution pressure, temperature, pH, and solution concentration will be monitored and maintained throughout the cycle. The hydrogen concentration in the cover gas will also be monitored and maintained through the cycle.

4a.4.7.6 Cooling System Design Basis

The thermal-hydraulic design has systems described above that provide heat removal from the TSV. The cooling system design basis and details of the PCLS are provided in chapter 5 of the SHINE FSAR.

SHINE FSAR section 4a2.7.8 states that small amounts of radiolysis gases will be generated in the PCLS coolant since it is exposed to radiation from the TSV. The system is designed so that large pockets of gas will not accumulate and lead to significant void fractions in the region of the TSV.

4a.4.7.7 Bulk Boiling of the Target Solution

SHINE FSAR section 4a2.7.9 states that the temperature of the target solution is monitored. The temperature and flow of the PCLS loop is also monitored to ensure adequate cooling of the TSV. If temperature limits are exceeded, the TRPS system will shut down the neutron driver and dump the target solution to the TSV dump tank. This prevents boiling in the TSV. If boiling were to occur due to unforeseen circumstances, the target solution and off gases will still be confined within the PSB and will not present a radiation hazard.

4a.4.7.8 Conclusion

The NRC staff reviewed the thermal-hydraulic design of the IUs. The staff finds that the thermal-hydraulic design considers the dominant design considerations for heat removal, cover gas control, and target solution control. The staff also reviewed the heat removal system specifications and finds that SHINE has considered all significant heat loads and has provided adequate heat removal capacity and heat transfer area to remove the heat loads and maintain the TSV fluid under normal and abnormal conditions. Adequate heat removal is also provided for decay heat generation in the TSV dump tank. The staff finds that the heat transfer surface temperatures in the PCLS eliminate concerns about critical heat flux. The staff also finds that the TOGS has adequate recombination and condensation capacity to control the cover gas operating conditions and maintain them within normal operating parameters. Based on the above, the staff concludes that the thermal-hydraulic design of the IUs meets the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4a.4.8 Gas Management System

The NRC staff evaluated the sufficiency of the SHINE gas management system, as presented in SHINE FSAR section 4a2.8, using the guidance and acceptance criteria from section 4a2.7, “Gas Management System,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 4a2.8 contains information about the TOGS. Each of the eight IUs has a TOGS. The TOGS removes radiolysis gases and a portion of the iodine in the gas space from the TSV during irradiation operation and during target solution cooldown. The safety function of the TOGS is to provide confinement of target solution and fission products, maintain hydrogen concentrations, and remove a portion of the iodine from the sweep gas.

SHINE FSAR section 4a2.8 states that the TOGS operates by circulating a sweep gas made up of nitrogen and oxygen through the TSV and TSV dump tank at a rate high enough to keep the hydrogen concentration below flammability limits (4 percent lower flammability limit) that can challenge the 65 pounds per square inch absolute (psia) deflagration pressure limit. The PICS controls the TOGS during normal operations. Nitrogen and oxygen can be added to the TOGS to control pressure and minimum oxygen concentration. The maximum operating pressure can be controlled by opening a valve to the vacuum tank. Each TOGS has two separate recombiner loops. There are some asymmetries between the loops. Only one loop provides flow to the TSV dump tank. Additionally, one loop has hydrogen and oxygen sensors and the other has a zeolite bed to capture iodine. Both loops must be operable during irradiation and one needs to operate for a short time after a loss of offsite power to reach a safe shutdown condition. The hydrogen recombiners prevent the concentration of hydrogen from reaching a level where a deflagration or detonation could occur. The water vapor in the sweep gas and from the recombiner is condensed and returned to the TSV. This serves to conserve water in the system since a loss of water will increase the uranium concentration in the solution and, therefore, increase the reactivity of the system. Water holdup in the TOGS is limited to 3 liters. The basis for the estimate of 3 liters and the identification of locations that water can be trapped in the TOGS were provided by letter dated June 17, 2020. Specifically, the TOGS circulates the sweep gas into the TSV dump tank and up through the overflow tubes into the TSV head space to prevent the moist atmosphere in the TSV headspace from flowing down the overflow tubes into the TSV dump tank, which might lead to condensation and loss of water to the TSV dump tank. If excess water does accumulate in the TSV dump tank, it will lead to a shutdown of the IU by the TRPS as specified by the low-high TSV dump tank level setpoint of 3 percent in proposed TS

LCO 3.2.3. Water droplets in the sweep gas are also removed and returned to the TSV to minimize the buildup of fissile material in the TOGS. The TOGS maintains a gas space pressure that is below the IU gas space pressure. The TOGS is designed based on the following TSV operating parameters:

- Gas temperature: The range of temperatures for gas leaving the TSV headspace is based on the sweep gas supply temperature from TOGS and the heat transfer rate between the sweep gas and the target solution at a temperature range of 50°F (10 degrees Celsius (°C)) to 194°F (90°C).

- Gas pressure: -4.5 pounds per square inch gauge (psig) (-31 kPa gauge) to 15 psig (103 kPa gauge).

- Steady state hydrogen production rate: up to approximately 3.8E-2 grams/second.

- Relative humidity: The relative humidity for gas leaving the TSV headspace is based on the evaporation rate of the target solution at a maximum temperature of 194°F (90°C).

SHINE FSAR section 4a2.8.5 states that the TOGS also needs to be adequate to mitigate the design basis accidents analyzed in chapter 13 of the SHINE FSAR. The design pressure for the PSB, and therefore the TOGS, is 100 psi. The design temperature for most TOGS components is 200°F. The hydrogen recombiners, recombiner condensers, and the interconnecting piping have a design temperature of 650°F because the heat from the recombination of hydrogen and oxygen causes elevated temperatures in those TOGS components compared to the temperatures in the other TOGS components and the TSV.

The applicant stated that the construction materials used for the TOGS are compatible with the expected chemical environment and conditions, and that no credible scenarios would result in a loss of confinement because of corrosion. The geometry of the TOGS would preclude criticality even if it were filled with target solution.

The applicant stated that the hydrogen recombiner needs to be capable of preventing a hydrogen deflagration or detonation. Hydrogen and oxygen generation in the TSV is 33 standard liters per minute and consists of 2/3 hydrogen and 1/3 oxygen. The PICS will alert the operator of high hydrogen concentration if it reaches 2.5 percent by volume. This allows the operator to take action before the operating limit of 3 percent. In turn, the 3 percent operating limit provides sufficient margin to hydrogen concentrations (4 percent lower flammability limit) that could result in deflagration pressure exceeding 65 psia should the failure of a single active component occur. SHINE’s analysis shows that this will provide sufficient margin to the lower flammability limit in the event of an abnormal condition such as a TOGS blower failure. The TOGS is designed to withstand system pressures expected during credible TSV power fluctuations.

The TOGS has interfaces with other systems. The TOGS system purges the off-gas to the vacuum transfer system (VTS) which discharges it to the process vessel vent system (PVVS) to prevent a buildup of gaseous fission products. The VTS and the PVVS are part of the RPF. In the PVVS, the off-gas is treated through the PVVS filters, guard beds, and charcoal delay beds, which remove particulates and iodine and delay the release of noble gases to the environment. The pressure safety valves in the TOGS are also connected to the PVVS. The TOGS is shielded to limit personnel exposure to radiation. The system does not release a significant amount of nitrogen oxide or sulfur oxide gas, therefore, no accident scenarios or monitoring for these gases are described in the SHINE FSAR.

By letter dated June 17, 2020, SHINE provided information describing the functionality and design basis functional requirements of the vacuum and pressure relief valve system. The design basis of the vacuum and pressure relief valve system is to keep the TOGS within a pressure range of -4.5 to 15 psig to allow continued functioning of the TOGS blowers. The lower limit is to protect against boiling in the TSV and the upper limit is to protect against an uncontrolled addition of gas from an external source. The relief valve is not needed to protect against exceeding the 100 psi design pressure of the TOGS during a deflagration event.

SHINE FSAR section 4a2.8.7 discusses the TRPS trip inputs related to the operability of the TOGS, which are:

- Low TOGS oxygen concentration
- Low TOGS mainstream flow (Train A)
- Low TOGS mainstream flow (Train B)
- Low TOGS TSV dump tank sweep gas flow
- High TOGS condenser demister outlet temperature (Train A)
- High TOGS condenser demister outlet temperature (Train B)

The SHINE FSAR states that the TRPS inputs are designed to protect against an inoperable TOGS train and loss of cooling to the condenser. If the TOGS becomes inoperable during an off-normal event such as a loss-of-offsite-power (LOOP) event, hydrogen buildup in the system is limited by the nitrogen purge system (N2PS), which injects nitrogen gas into the TSV dump tank to dilute the hydrogen and keep it below 3 percent by volume. During a LOOP event, TOGS Train A is powered by the uninterruptible electrical power supply system for 5 minutes. The N2PS injects nitrogen gas into the TSV dump tank after 3 minutes. The gas mixture is transferred to the PVVS through a high point vent on the TOGS.

The NRC staff finds that the operating condition envelope and design assumptions of the TOGS and the associated analysis are sufficient to provide reasonable assurance of safe operation of the SHINE facility and compliance with all applicable chemical and radiological release criteria. The staff finds that the TOGS and its components are sufficient to ensure the health and safety of the public, consistent with 10 CFR 50.34(b). Therefore, the staff concludes that the TOGS meets the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4a.4.9 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed TSs for the SHINE IUs as described in SHINE FSAR chapter 4.

The proposed TS 2.1, "Safety Limits," safety limit (SL) 2.1.1 states the following:

SL 2.1.1	The combination of differential pressure across the low temperature portion of the PSB and the wall temperature averaged through the thickness shall be within the “Acceptable” region defined by Figure 2.1.1. AND Average wall temperature for the low temperature portion of the PSB shall be ≤ 950 degrees Fahrenheit (°F) for differential pressure ≤ 95 pounds per square inch (psi).
Applicability	This safety limit applies at all times to the differential pressure and the wall temperature of the low temperature section of the PSB. The low temperature portion of the PSB includes all PSB components except the hydrogen recombiner housings, the recombiner condensers, the piping between the recombiners and the recombiner condensers, and the piping between the recombiner condensers and the TSV.

SL 2.1.1 sets differential pressure limits as a function of temperature that apply to the PSB. The limits are shown in TS Figure 2.1.1, “PSB Low Temperature Portion Safety Limit.” The NRC staff determined that the material limits exceed the conditions of the material during normal operation and design basis accidents. Therefore, the staff finds SL 2.1.1 acceptable.

The proposed TS 2.1, SL 2.1.2 states the following:

SL 2.1.2	The differential pressure across the high temperature portion of the PSB shall be ≤ 115 psi and the wall temperature averaged through the thickness shall be ≤ 950°F.
Applicability	This safety limit applies at all times to the differential pressure and the wall temperature of the high temperature portion of the PSB. The high temperature portion of the PSB includes the hydrogen recombiner housings, the recombiner condensers, the piping between the recombiners and the recombiner condensers, and the piping between the recombiner condensers and the TSV.

SL 2.1.2 sets differential pressure and wall temperature limits of the high temperature portion of the PSB. The NRC staff determined that the material limits exceed the conditions of the material during normal operation and design basis accidents. Therefore, the staff finds SL 2.1.2 acceptable.

The proposed TS 2.2, “Limiting Safety System Settings (LSSS),” Table 2.2, “Limiting Safety System Settings,” states, in part, the following:

LSSS	Variable	Setpoint	Applicability
LSSS 2.2.1	High wide range neutron flux	≤ 176% power	Modes 1 and 2
LSSS 2.2.2	High time-averaged power range neutron flux	≤ 85% power; averaged over ≤ 45 seconds	Modes 1 and 2
LSSS 2.2.3	High source range neutron flux	≤ 1.5 times the nominal flux at 95% volume of the critical fill height	Mode 1
LSSS 2.2.4	Low TOGS mainstream flow	[[PROP/ECI]]	Modes 1, 2, 3, and 4
LSSS 2.2.5	Low TOGS dump tank flow	[[PROP/ECI]]	Modes 1, 2, 3, and 4
LSSS 2.2.6	High-high TSV dump tank level	≤ 85%	Modes 1, 2, 3, and 4

LSSS 2.2.1 sets the limit on high wide range neutron flux and limits the power to less than 176 percent of the nominal operating power limit of 125 kW. The NRC staff determined that the setpoint prevents overheating of the target solution, which could lead to boiling in and pressurization of the TSV. Therefore, the staff finds LSSS 2.2.1 acceptable.

LSSS 2.2.2 sets the time-averaged power range neutron flux limit to less than or equal to 85 percent of the nominal operating power limit of 125 kW. The NRC staff determined that the setpoint prevents overheating of the target solution, which could lead to boiling in and pressurization of the TSV. The staff also determined that the setpoint prevents the buildup of hydrogen that could result in a hydrogen deflagration by keeping the hydrogen generation rate below what can be accommodated by the TOGS at the minimum flow specified in LSSS 2.2.4. Therefore, the staff finds LSSS 2.2.2 acceptable.

LSSS 2.2.3 sets a source range neutron flux limit. The NRC staff determined that this setpoint protects against a sudden increase in reactivity during the fill process, which could lead to pressurization of the TSV. Therefore, the staff finds LSSS 2.2.3 acceptable.

LSSS 2.2.4 sets the minimum flow rate for the TOGS mainstream flow. The NRC staff determined that this setpoint prevents the buildup of hydrogen that could result in a hydrogen deflagration that could exceed the PSB pressure safety limit. The setpoint is based on a hydrogen generation rate that conservatively bounds the expected hydrogen generation at the average power specified in LSSS 2.2.2. Therefore, the staff finds LSSS 2.2.4 acceptable.

LSSS 2.2.5 set the minimum flow rate for the TOGS dump tank flow. The NRC staff determined that this setpoint prevents the buildup of hydrogen that could result in a hydrogen deflagration that could exceed the PSB pressure safety limit. The minimum flow is expected to keep the hydrogen concentration below the 4 percent lower flammability limit. Therefore, the staff finds LSSS 2.2.5 acceptable.

LSSS 2.2.6 sets the high-high TSV dump tank level of 85 percent. The NRC staff determined that this setpoint ensures that the target solution height in the TSV dump tank does not obstruct the required TOGS gas flow area to provide adequate hydrogen dilution volume in the TSV dump tank. Therefore, the staff finds LSSS 2.2.6 acceptable.

The proposed TS 3.1, "Irradiation Unit Parameters," LCO 3.1.1 states the following:

LCO 3.1.1	Both TOGS Train A and Train B shall be Operable. A TOGS train is considered Operable if: 1. The blower is Operating, and 2. The recombiner heater is Operating. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3, or 4, according to Table 3.1.1
Action	According to Table 3.1.1
SR 3.1.1	1. Check that both TOGS trains are Operating daily.

The proposed TS Table 3.1.1, "TOGS Actions," states the following:

	Applicability (per IU)	**Condition and Action (per IU)**	**Completion Time**
1.	Mode 1 or 2	If TOGS Train B is not Operable, Place the associated IU in Mode 3.	Immediately
2.	Mode 1 or 2	If TOGS Train A or both trains are not Operable, Place the associated IU in Mode 3 AND Actuate an IU Cell Nitrogen Purge for the associated IU.	Immediately Immediately
3.	Mode 3 or 4	If TOGS Train B is not Operable, Place the associated IU in Mode 0	[[PROP/ECI]]
4.	Mode 3 or 4	If TOGS Train A or both trains are not Operable, Actuate an IU Cell Nitrogen Purge for the associated IU.	Immediately

LCO 3.1.1 requires both TOGS trains to be operable, provides the conditions for a TOGS train to be considered operable, and provides the actions to be taken if a TOGS train is not operable. The TOGS is designed with two recirculation trains per IU. LCO 3.1.1 requires that both the TOGS blower and the TOGS recombiner heater be operating, as defined in TS 1.3, for a single TOGS train to be considered operable. The NRC staff finds that the condition for operation would maintain hydrogen limits and iodine concentrations during startup (i.e., Mode 1), irradiation (i.e., Mode 2), post-irradiation (shutdown) (i.e., Mode 3) and solution transfer to the

RPF (i.e., Mode 4). The staff finds that if TOGS Train B is not operable in Mode 1 or 2, immediately stopping the irradiation process would limit the generation of hydrogen, and the N2PS would not need to be actuated as TOGS Train A would provide hydrogen mitigation of the TSV dump tank. The staff finds that if TOGS Train A or both trains are not operable in Mode 1 or 2, immediately stopping the irradiation process would limit the generation of hydrogen, and the N2PS would provide the hydrogen mitigation of the TSV dump tank that was lost from Train A. The staff finds that if TOGS Train B is not operable in Mode 3 or 4, removing the target solution from the TSV dump tank within the associated completion time would place the target solution in a location within the RPF where hydrogen mitigation is provided by the PVVS and not the TOGS. The staff finds that the completion time allows for the decay of short-lived fission products and that hydrogen mitigation would be provided by TOGS Train A during the completion time. The staff finds that if TOGS Train A or both trains are not operable in Mode 3 or 4, actuating the N2PS would provide the hydrogen mitigation function that was lost from Train A. Based on the above, the staff finds that LCO 3.1.1 is adequate to prevent the buildup of hydrogen to levels that could lead to a deflagration that could challenge the integrity of the PSB. Therefore, the staff finds LCO 3.1.1 acceptable.

SR 3.1.1 requires checking that both TOGS trains are operating daily. The NRC staff determined that this surveillance would ensure that TOGS is performing its intended function during Modes 1, 2, 3, and 4 and, therefore, the staff finds SR 3.1.1 acceptable.
The proposed TS 3.1, LCO 3.1.2 states the following:

LCO 3.1.2	The pressure in the TSV headspace shall be ≥ (-) 4.5 psig and ≤ (+) 0.3 psig. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1 or 2
Action	According to Table 3.1.2
SR 3.1.2	1. Verify TSV headspace pressure is within the limits daily.

The proposed TS Table 3.1.2, “TSV Headspace Pressure Actions,” states the following:

	Condition and Action (per IU)	**Completion Time**
1.	If TSV headspace pressure is not within limits Place the associated IU in Mode 3.	 1 hour

LCO 3.1.2 specifies the operating range of the pressure in the TSV headspace to be -4.5 psig to 0.3 psig and provides the actions to be taken if it is not. The NRC staff finds that the lower TSV headspace pressure limit would prevent excessive water uptake into the TOGS from increased evaporation or boiling. The staff finds that the upper TSV headspace pressure limit would prevent excessive pressure within the PSB that could result in a PSB leak or rupture. The staff finds that if the TSV headspace pressure is not within limits, placing the IU into Mode 3 would remove the target solution from the TSV and limit hydrogen generation in the IU. The staff

also finds that the TOGS would provide hydrogen mitigation during the completion time. Therefore, the staff finds LCO 3.1.2 acceptable.

SR 3.1.2 requires verification of the TSV headspace pressure limits daily. The NRC staff finds that this frequency is consistent with guidance in ANSI/ANS-15.1-2007. Therefore, the staff finds SR 3.1.2 acceptable.

The proposed TS 3.1, LCO 3.1.3 states the following:

LCO 3.1.3	Target solution volume in the TSV shall be [[PROP/ECI]]. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 2
Action	According to Table 3.1.3
SR 3.1.3	1. Verify the minimum target solution volume in the TSV daily.

The proposed TS Table 3.1.3, "TSV Volume Actions," states the following:

	Condition and Action (per IU)	**Completion Time**
1.	If the volume of target solution in the TSV is less than the minimum volume, Place the associated IU in Mode 3.	 1 hour

LCO 3.1.3 specifies a minimum target solution volume in the TSV during irradiation and provides the actions to be taken if it is not met. The minimum volume accounts for the expected holdup of water in the TOGS. The NRC staff finds that the minimum volume would maintain the peak target solution temperature below the boiling temperature. The staff finds that if the target solution volume falls below the minimum volume, transferring the target solution into the TSV dump tank would prevent boiling of the target solution. The staff also finds that the completion time would allow time to determine the reason for the low volume. The staff finds that the TRPS would respond to events where the level is lost rapidly during the completion time. Therefore, the staff finds LCO 3.1.3 acceptable.

SR 3.1.3 requires verification of the minimum target solution volume daily. The NRC staff finds that this surveillance would ensure that irradiation is not performed without the minimum target solution volume. The staff finds that this frequency is consistent with guidance in ANSI/ANS-15.1-2007. Therefore, the staff finds SR 3.1.3 acceptable.

The proposed TS 3.1, LCO 3.1.4 states the following:

LCO 3.1.4	The average temperature of the target solution within the TSV shall be ≤ 176°F as determined from the average of at least one Operable thermocouple at each TSV temperature measurement elevation. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1 or 2
Action	According to Table 3.1.4
SR 3.1.4	1. Verify TSV target solution average temperature is below the limit daily. 2. A Channel Check shall be performed on the TSV temperature indication quarterly. 3. A Channel Calibration shall be performed on the TSV temperature indication annually.

The proposed TS Table 3.1.4, "Target Solution Temperature Actions," states the following:

	Condition and Action (per IU)	**Completion Time**
1.	If target solution average temperature is not below the limit, Open at least one high voltage power supply (HVPS) breaker AND Place the associated IU in Mode 3.	 Immediately 6 hours
2.	If fewer than one thermocouple per TSV temperature measurement elevation is Operable, Place the associated IU in Mode 3.	 6 hours

LCO 3.1.4 specifies the maximum average target solution temperature in the TSV to be 176°F during startup and irradiation (i.e., Modes 1 and 2) and provides the actions to be taken if it is not. The LCO also specifies that the average target solution temperature is measured using a minimum of one operable thermocouple at each temperature measurement elevation in the TSV and provides the actions to be taken if this is not the case. The LCO accounts for the expected distribution of the liquid temperature throughout the TSV. The NRC staff finds that this LCO would prevent the target solution from boiling in the TSV during operation and in the TSV dump tank after shutdown. The staff finds that if the target solution temperature is not below the limit or the required thermocouples are not operable, transferring the solution into the TSV dump tank would stop adding heat via irradiation and prevent boiling of the target solution. The staff also finds that the completion time would align with temperature trending capabilities. Therefore, the staff finds LCO 3.1.4 acceptable.

SR 3.1.4 requires verification of the TSV target solution average temperature daily and a channel check to be performed on the TSV temperature indication quarterly. The NRC staff finds that these frequencies are consistent with guidance in ANSI/ANS 15.1-2007. SR 3.1.4 also requires a channel calibration to be performed on the TSV temperature indication annually. The staff finds that this frequency is also in accordance with guidance in ANSI/ANS-15.1-2007. Therefore, the staff finds SR 3.1.4 acceptable.

The proposed TS 3.1, LCO 3.1.5 states the following:

LCO 3.1.5	Both TSV dump valves shall be Operable. TSV dump valves are considered Operable if: 1. Each TSV valve is capable of fully opening within two seconds of demand. AND 2. Each TSV dump line is capable of draining the TSV from [[PROP/ECI]] full within 183 seconds. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1 or 2
Action	According to Table 3.1.5
SR 3.1.5	1. Verify each TSV dump valve opens in ≤ 2 seconds of demand quarterly. 2. Verify the drain time of each TSV dump line is ≤ 183 seconds starting when the TSV is ≥ [[PROP/ECI]] full quarterly.

The proposed TS Table 3.1.5, "TSV Dump Valve Actions," states the following:

	Condition and Action (per IU)	**Completion Time**
1.	If one or more TSV dump valve(s) are not Operable, Place the associated IU in Mode 3.	 1 hour

LCO 3.1.5 requires both TSV dump valves to be operable, provides conditions for the TSV dump valves to be considered operable, and provides the actions to be taken if they are not. The NRC staff finds that this condition would ensure that the target solution is able to drain from the TSV to the TSV dump tank within the time assumed in the accident analysis and that the drain rate allows for the failure of one dump valve. The staff finds that if the dump valves are not operable, the valves fail to the open position and the target solution would be transferred to the TSV dump tank. The staff also finds that the completion time would allow time to repair minor problems. Therefore, the staff finds LCO 3.1.5 acceptable.

SR 3.1.5 requires verification of the opening time of each TSV dump valve and the drain time of each TSV dump line quarterly. The NRC staff notes that while the guidance in

ANSI/ANS-15.1-2007 does not discuss valve opening times and dump line drain times, surveillance requirement guidance for similar systems of a research reactor can be applied. The staff finds that these frequencies are consistent with guidance in ANSI/ANS 15.1-2007. Therefore, the staff finds SR 3.1.5 acceptable.

The proposed TS 3.1, LCO 3.1.6 states the following:

LCO 3.1.6	Temperature and average power density of the target solution in the TSV shall be within the "Acceptable" region of Figure 3.1.6, defined by the following equation: Power Density Limit (kW/L) = [[PROP/ECI]] Note – This LCO does not apply during driver restart transients;see LCO 3.1.7 for the transient average power density limit. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 2
Action	According to Table 3.1.6
SR 3.1.6	1. Verify temperature and average power density of the target solution in the TSV is within the "Acceptable" region of Figure 3.1.6 hourly during power ramp up [[PROP/ECI]].

The proposed TS Table 3.1.6, "Average Power Density Limit Actions," states the following:

	Condition and Action (per IU)	**Completion Time**
1.	If the average power density-temperature conditions are not within the acceptable region for ≥ 1 second, Place the associated IU in Mode 3.	 Immediately

LCO 3.1.6 specifies the average power density limit as a function of temperature and provides the actions to be taken if it is not in the acceptable region. The NRC staff finds that this condition would prevent the precipitation of uranyl peroxide in the target solution undergoing irradiation. The limit has an approximately 30 percent margin to the precipitation limit observed in historical operating data. The staff finds that if the conditions are not within the acceptable region, immediately transferring the target solution to the TSV dump tank would stop adding heat and power via irradiation. Therefore, the staff finds LCO 3.1.6 acceptable.

SR 3.1.6 requires verification, during power ramp up, of the temperature and average power density of the target solution hourly. The NRC staff finds that this surveillance would ensure that the temperature and average power density are maintained within the limits during ramp up to full power. Therefore, the staff finds SR 3.1.6 acceptable.

The proposed TS 3.1, LCO 3.1.7 states the following:

LCO 3.1.7	Transient average power density of target solution within the TSV shall be [[PROP/ECI]]. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 2
Action	According to Table 3.1.7
SR 3.1.7	1. Verify transient average power density of the target solution in the TSV did not exceed [[PROP/ECI]] during any driver restart transient after a loss of driver event.

The proposed TS Table 3.1.7, "Transient Average Power Density Actions," states the following:

	Condition and Action (per IU)	**Completion Time**
1.	If the transient average power density limit is exceeded, Place the associated IU in Mode 3.	Immediately

LCO 3.1.7 specifies the average power density limit of the target solution during transients and provides the actions to take if it is not in the acceptable range. The NRC staff finds that the condition for operation would limit temperature, pressure, and hydrogen generation during transient events. The staff also finds that the precipitation of uranyl peroxide is not a concern in these instances since there is not enough time for peroxide concentrations to reach steady state. The staff finds that if the limit is exceeded, immediately transferring the target solution to the TSV dump tank would limit hydrogen generation, temperature increases, and pressure increases. Therefore, the staff finds LCO 3.1.7 acceptable.

SR 3.1.7 requires verification of the transient average power density during any driver restart transient after a loss of driver event. The NRC staff finds that the surveillance would ensure that the transient average power density was maintained within analyzed limits during the restart. The staff also finds that power excursions would result in control room alarms to alert the operator. Therefore, the staff finds SR 3.1.7 acceptable.

The proposed TS 3.1, LCO 3.1.8 states the following:

LCO 3.1.8	Target solution shall be held in the TSV dump tank for ≥ the required minimum hold time specified in Table 3.1.8 if the target solution batch has been irradiated at > 1 effective full power minute during the immediately preceding irradiation cycle.
Applicability	Associated IU in Mode 4
SR 3.1.8	1. Verify the minimum hold time requirement of Table 3.1.8 has been achieved prior to transfer of target solution from the TSV dump tank.

The proposed TS Table 3.1.8, "Required Minimum Hold Time," states the following:

Maximum Historical Irradiation Power	Required Minimum Hold Time
> 0 kW but ≤ 10 kW	[[PROP/ECI]]
> 10 kW but ≤ 70 kW	[[PROP/ECI]]
> 70 kW	[[PROP/ECI]]

LCO 3.1.8 specifies the target solution minimum hold time in the TSV dump tank before being transferred to the RPF based on the maximum historical irradiation power level. The NRC staff finds that this condition for operation would limit the radionuclide inventory of isotopes with short half-lives and ensure that the source term does not exceed the conditions assumed in the accident analysis. Therefore, the staff finds LCO 3.1.8 acceptable.

SR 3.1.8 requires verification of the hold time before the target solution is transferred from the TSV dump tank to the RPF. The NRC staff finds that this surveillance would ensure that target solution is not transferred before the minimum hold time. Therefore, the staff finds SR 3.1.8 acceptable.

The proposed TS 3.3, "Coolant Systems," LCO 3.3.1 states the following:

LCO 3.3.1	The light water pool water level shall be ≥ 14 feet, relative to the bottom of the pool. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3, or 4, according to Table 3.3.1
Action	According to Table 3.3.1
SR 3.3.1	1. The light water pool water level shall be verified to be above the minimum specified level daily and prior to entering Mode 1.

The proposed TS Table 3.3.1, "Light Water Pool Level Actions," states the following:

	Applicability (per IU)	**Action (per IU)**	**Completion Time**
1.	Mode 1 or 2	If the light water pool is less than the minimum level, Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 6 hours [[PROP/ECI]]
2.	Mode 3 or 4	If the light water pool is less than the minimum level, Place the associated IU in Mode 0.	 [[PROP/ECI]]

LCO 3.3.1 specifies the minimum light water pool level relative to the bottom of the pool and the actions to be taken if the level is not met. The NRC staff finds that the minimum light water pool level would provide adequate biological shielding and cooling. The staff finds that if the light water pool level is less than the minimum limit, transferring the target solution from the TSV to the TSV dump tank would limit the radiation levels and temperature of the metal components and the biological shield. The staff also finds that a rapid loss of light water pool level is not expected. Therefore, the staff finds LCO 3.3.1 acceptable.

SR 3.3.1 requires verification of the light water pool level daily and before entering Mode 1. The NRC staff finds that this surveillance would ensure that the light water pool level is above the applicable limit daily and prior to entering Mode 1 operations. Therefore, the staff finds SR 3.3.1 acceptable.

The proposed TS 3.8, "Facility-Specific," LCO 3.8.2 states the following:

LCO 3.8.2	The concentration of uranium in the target solution in the TSV shall be [[PROP/ECI]].
Applicability	Target solution in the associated TSV
SR 3.8.2	1. After preparing a new batch of target solution, the target solution uranium concentration shall be verified to be below the uranium concentration limit prior to transferring the batch to a TSV in Mode 1 2. After adding uranyl sulfate makeup solution to an existing batch, the target solution uranium concentration shall be verified to be below the uranium concentration limit prior to transferring the batch to a TSV in Mode 1

LCO 3.8.2 specifies the target solution uranium concentration limit. The NRC staff finds that the condition for operation would ensure that the target solution remains subcritical in an inadvertent fill scenario. Since the concentration limit is less than the concentration of maximum reactivity, the staff finds that the limit would also prevent boiling of the target solution. Therefore, the staff finds LCO 3.8.2 acceptable.

SR 3.8.2 requires verification of the target solution uranium concentration before entering Mode 1 for both a new batch and after adding uranyl sulfate makeup solution to an existing batch. The NRC staff finds that the surveillance would prevent target solution with uranium concentration above the limit from being transferred to the TSV in Mode 1. The staff also finds that uranium concentration would not change during irradiation. Therefore, the staff finds SR 3.8.2 acceptable.

The proposed TS 3.8, LCO 3.8.3 states the following:

LCO 3.8.3	[[PROP/ECI]] and pH of the target solution shall be within the "Acceptable" region of Figure 3.8.3, defined by the following equation: [[PRO /ECI]]
Applicability	Target solution in the associated TSV
SR 3.8.3	1. After preparing a new batch of target solution, the [[PROP /ECI]] and pH shall be verified to be within the "Acceptable" region of Figure 3.8.3 prior to transferring the batch to a TSV in Mode 1 2. After adding uranyl sulfate makeup solution to an existing batch, the [[PROP/ ECI]] and pH shall be verified to be within the "Acceptable" region of Figure 3.8.3 prior to transferring the batch to a TSV in Mode 1

LCO 3.8.3 specifies the acceptable region of the target solution catalyst concentration and pH based on the defining equation. The NRC staff finds that the condition for operation would prevent uranyl peroxide precipitation in the target solution. Therefore, the staff finds LCO 3.8.3 acceptable.

SR 3.8.3 requires verification of the target solution catalyst concentration and pH after both preparing a new batch and adding uranyl sulfate makeup solution to an existing batch. The NRC staff finds that the surveillance would prevent target solution with target solution catalyst concentration and pH outside the acceptable region from being transferred to the TSV in Mode 1. The staff also finds that target solution catalyst concentration and pH would not change during irradiation. Therefore, the staff finds SR 3.8.3 acceptable.

The proposed TS 3.8, LCO 3.8.6 states the following:

LCO 3.8.6	The beam off pressure in the target chamber shall be [[PROP/ECI]]. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3 or 4
Action	According to Table 3.8.6
SR 3.8.6	1. Verify the tritium pressure in each NDAS target chamber is below the limit daily.

The proposed TS Table 3.8.6, "Target Chamber Pressure Actions," states the following:

	Condition and Action (per IU)	**Completion Time**
1.	If the target chamber pressure is above the allowable limit,	
	Open at least one HVPS breaker	1 hour
	AND	
	Evacuate tritium from the NDAS target chamber until pressure is below the limit.	12 hours

LCO 3.8.6 specifies the beam off pressure in the NDAS target chamber limit and the actions to be taken if it is not within the limit. The NRC staff finds that the condition for operation would ensure that the amount of tritium in an IU cell is below the limit described in the accident analysis and limits the tritium source term. The staff finds that if the NDAS target chamber pressure is above the limit, opening at least one HVPS breaker would shut down the neutron driver. The staff also finds that opening at least one HVPS breaker within one hour would minimize the probability of a release exceeding that assumed in the accident analysis. The staff finds that evacuating tritium from the NDAS target chamber until pressure is below the limit within 12 hours would also minimize the probability of a release. Therefore, the staff finds LCO 3.8.6 acceptable.

SR 3.8.6 requires verification of the tritium pressure in each NDAS target chamber daily. The NRC staff finds that the surveillance would ensure that the pressure limit is not exceeded during irradiation. The staff also finds that PICS monitors the pressure in the NDAS target chamber. Therefore, the staff finds SR 3.8.6 acceptable.

The proposed TS 4.1, “Site and Facility Description,” DF 4.1.3 states the following:

DF 4.1.3	1. The PVVS carbon delay bed minimum efficiency for iodine is 99%. 2. The PVVS carbon delay bed delay time is 40 days, based on the travel time of xenon and the depth of the bed. 3. The TOGS zeolite bed minimum efficiency for iodine is 95%. 4. The TOGS recombiner minimum efficiency for hydrogen recombination is 95% for hydrogen concentrations above 3% by volume when heated to ≥ 212°F. 5. The supercell RVZ1 outlet carbon filter minimum efficiency for iodine is 99%.

DF 4.1.3 states the PVVS carbon delay bed minimum efficiency and delay time. The NRC staff finds that the carbon delay bed minimum efficiency for iodine would capture the iodine and maintain iodine concentrations within acceptable levels. The staff also finds that the carbon delay bed delay time would delay airborne radioactive sources to acceptable levels prior to release to the environment. DF 4.1.3 also states the TOGS minimum efficiency for the zeolite bed and the recombiner. The staff finds that the hydrogen recombiners minimum efficiency would prevent the hydrogen concentration from reaching a level at which deflagration or detonation could occur. The staff also finds that the zeolite bed minimum efficiency would remove iodine from the sweep gas and maintain iodine concentrations within acceptable levels. This limits the amount of iodine that could be released in the event of a breach of the TOGS pressure boundary. DF 4.1.3 states the RVZ1 outlet carbon filter minimum efficiency. The staff finds that the RVZ1 outlet carbon filter minimum efficiency for iodine would capture iodine and maintain iodine concentrations within acceptable levels. Therefore, the staff finds DF 4.1.3 acceptable.

The proposed TS 4.3, “Subcritical Assembly System and Target Solution,” DF 4.3.1 states the following:

DF 4.3.1	Target solution is an aqueous uranyl sulfate solution containing uranium enriched to less than 20 wt. % in U-235.

DF 4.3.1 states that the target solution is an aqueous uranyl sulfate solution containing uranium enriched to less than 20 percent by weight in U-235. SHINE FSAR section 4a2.2.1.12 states that the target solution is a uranyl sulfate solution with an enrichment of 19.75 +/- 0.2 percent. The NRC staff finds that the target solution design information is sufficiently supported in the FSAR with adequate functional descriptions, tables, text, and referenced reports. The design limits of the target solution are clearly described such that the safety related implications of these limits, and their relationship to the rest of facility, is also described. Therefore, the staff finds DF 4.3.1 acceptable.

The proposed TS 4.3, DF 4.3.2 states the following:

DF 4.3.2	1. The subcritical assembly system principally consists of the TSV, subcritical assembly support structure (SASS), neutron multiplier and TSV dump tank, and is described in FSAR Section 4a2.2. 2. Redundant overflow tubes are provided for the TSV to protect the TSV headspace to allow for TOGS operation.

DF 4.3.2 states the components of the SCAS and that the TSV headspace is protected by redundant overflow tubes in the TSV. The NRC staff finds that the SCAS components are sufficiently described in SHINE FSAR section 4a2.2. The staff finds that the TSV can be emptied into criticality-safe geometry TSV dump tanks via the TSV dump valves, and that the valves can be opened by the TRPS and fail to the safe open position. The staff also finds that there are redundant flow paths to meet single failure criteria. Therefore, the staff finds DF 4.3.2 acceptable.

4a.5 Review Findings

The NRC staff reviewed the descriptions and discussions of SHINE's IF, as described in SHINE FSAR section 4a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the design of the IF and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4b Radioisotope Production Facility

Section 4b, “Radioisotope Production Facility,” of this SER provides an evaluation of the final design of SHINE’s RPF as presented in SHINE FSAR section 4b, “Radioisotope Production Facility Description.”

The facility description addresses the principal features, operating characteristics, and parameters of the RPF. The primary functions of the RPF are to recover, purify, and package Mo-99.

4b.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 4b against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE RPF. As part of this review, the staff evaluated descriptions and discussions of the SHINE RPF, with special attention to the principal safety considerations that were factored into the design and operation of the RPF. The final design bases of the SHINE RPF were evaluated to ensure that the design bases and functions of the SSCs are presented in sufficient detail to allow a clear understanding of the facility and to ensure that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the operating staff and the public. Drawings and diagrams were evaluated to determine if they present a clear and general understanding of the physical facility features and of the processes involved.

Areas of review for this section include the RPF facility and process description, the RPF biological shield, the radioisotope extraction system, and special nuclear material (SNM) processing and storage.

4b.2 Summary of Application

The SHINE FSAR includes information that describes the RPF, presents the design bases and the limits on its operation, and presents a safety analysis of the SSCs of the facility. The SHINE RPF includes the target solution preparation system (TSPS); the Mo-99 extraction and purification system (MEPS); iodine and xenon purification and packaging (IXP); target solution staging system (TSSS); uranium receipt and storage system; process vessel vent system (PVVS); radioactive liquid waste storage (RLWS); radioactive liquid waste immobilization (RLWI); VTS; and molybdenum isotope product packaging system.

4b.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 4 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the bases and the information provided by SHINE for the issuance of an operating license.

4b.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE RPF are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.57, "Issuance of operating license."
- 10 CFR Part 20, "Standards for Protection Against Radiation."

4b.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

As stated in the ISG augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC RGs, IEEE standards, ANSI/ANS standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B of this SER.

4b.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR section 4b, as supplemented, to assess the sufficiency of the final design and performance of SHINE's RPF for the issuance of an operating license. The sufficiency of the final design and performance of SHINE's RPF is determined by ensuring that it meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 4b.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in Section 4b.5, "Review Findings," of this SER.

4b.4.1 Facility and Process Description

The NRC staff evaluated the sufficiency of SHINE's facility and process description of the RPF, as presented in SHINE FSAR section 4b.1, "Facility and Process Description," using the guidance and acceptance criteria from section 4b.1, "Facility and Process Description," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 4b.1 of the ISG augmenting NUREG-1537, Part 2, the information submitted in SHINE FSAR section 4b.1 is descriptive in nature and requires no technical analysis. The information in this section serves as background for more detailed descriptions in later sections of the application. However, the NRC staff considered whether the information presented in this section is consistent with that in other sections of the FSAR.

SHINE FSAR section 4b.1 contains a summary description of the RPF. It includes the principal safety considerations that were factored into the RPF design, construction, and operation. The design bases and functions of the SSCs are presented in sufficient detail to allow a clear understanding and for the NRC staff to assess that the RPF can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the workers and the public. Drawings and diagrams are provided to allow a clear and general understanding of the physical RPF features and of the processes involved. The primary functions of the RPF are to extract, purify, package, and ship medical radioisotopes. The primary fission product barrier in the RPF consists of vessels and associated piping, which contain the irradiated SNM and fission products (in solid, liquid, or gaseous form) during the separation process.

SHINE FSAR section 4b.1 provides a summary of the maximum amount of SNM and the physical and chemical forms of SNM used in the RPF processes.

SHINE FSAR section 4b.1 contains a summary description of the raw materials, byproducts, wastes, and finished products of the RPF. This information includes data on expected levels of trace impurities or contaminants in the final product (particularly fission products or transuranic elements) characterized by identity and concentration.

SHINE FSAR section 4b.1 contains a general description of the design basis and implementation of any criticality safety features of the RPF for establishing and maintaining a nuclear criticality safety program. The NRC staff evaluation of the criticality safety program is discussed in section 6b.4.3, “Nuclear Criticality Safety,” of this SER.

SHINE FSAR section 4b.1 contains a description of the radiological protection features designed to prevent the release of radioactive material and used to maintain radiation levels below applicable radiation exposure limits. The NRC staff evaluation of the engineered safety features that will provide radiological protection to workers and the environment in accident scenarios is discussed in chapter 13.0, “Accident Analysis,” of this SER.

SHINE FSAR section 4b.1 contains a description of the design basis and method for implementation of any hazardous chemical safety features of the RPF and for establishing and maintaining a hazardous chemical safety program. The NRC staff evaluation of the chemical safety program is discussed in section 13b.4.3, “Analyses of Accidents with Hazardous Chemicals,” of this SER.

Based on the information presented in SHINE FSAR section 4b.1, the NRC staff finds that the summary description of the facility and processes of the SHINE RPF meets the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4b.4.2 Radioisotope Production Facility Biological Shield

The NRC staff evaluated the sufficiency of the SHINE RPF biological shield, as presented in SHINE FSAR section 4b.2, “Radioisotope Production Facility Biological Shield,” using the guidance and acceptance criteria from section 4.4, “Biological Shield,” of NUREG-1537, Parts 1 and 2, and section 4b.2, “Processing Facility Biological Shield,’’ of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 4.4 of NUREG-1537, Part 2, the NRC staff considered whether the objectives of the biological shield design bases are sufficient to protect the health and safety of the public and facility staff.

SHINE FSAR section 4b.2.1 states that the production facility biological shield (PFBS) provides a barrier to protect SHINE facility personnel, members of the public, and various components and equipment of the SHINE facility by reducing radiation exposure. The RPF receives irradiated target solution from an IU cell and distributes the target solution to various downstream processes. The target solution has a fission product activity (source locations and source term characterizations) that is defined in SHINE FSAR chapter 11. The major systems and areas outside of the IU cell that the target solution and by-product material occupy are as follows: supercell (consisting of the cells containing the extraction, purification, and packaging system; the cells containing the PVVS; and the cells containing the IXP); process tank vaults; process valve pits; pipe trenches; carbon delay bed vault; solid waste drum storage bore holes; and the RLWI shielded enclosure.

In relation to the function of the PFBS, the minimization of dose to workers and the public during normal operation and design basis accidents, the SHINE FSAR references and describes the ventilation function of the RVZ1e. The RVZ1e function in relation to worker and public dose during normal and emergency operations is presented in SHINE FSAR section 9a2.1.1.2. The FSAR description includes a summary of the design basis of all RVZ1e components and functions that are engineered to control the release of radioactive contaminants to the environment under normal and emergency operating conditions.

The safety function of RVZ1e is to control the spread of contamination, and it services several portions of the PFBS: the target solution preparation tank, dissolution tank, and preparation system glovebox; the supercell; the uranium receipt and storage system glovebox; and the RLWI shield. RVZ1e is engineered to exhaust air from high contamination areas (through an exhaust stack) and to maintain negative pressure inside the confinement. The SHINE FSAR describes the RVZ1e processes with a supporting figure that illustrates (through a flow diagram) the portions of the PFBS that RVZ1e services. The PFBS also has a confinement function to support the following engineered safety features: supercell confinement; below grade confinement; and PVVS isolation.

SHINE FSAR section 4b.2.2, “Biological Shield Design Basis,” describes the PFBS design, including a detailed description of the dimensions of the PFBS, the materials from which it is constructed, the applicable engineering standards to which it is designed, the shield materials, and the functional requirements of each shielding segment.

For the selected materials, SHINE listed the design bases and applicable engineering standards to which they were selected, which are RG 1.69 and ACI 349-13. SHINE stated that the purpose of the shielding materials is to reduce dose during normal operation, consistent with ALARA objectives and the dose limits in 10 CFR Part 20, and to mitigate exposure during accidents as described in SHINE FSAR chapter 13.

For the PFBS design and geometry, SHINE FSAR section 4b.2.2.2 presents the general shapes of the shielding segments for each functional portion of the RPF. The FSAR describes the range of thicknesses of the shielding segments, the lead and concrete from which the segments were constructed, and the dimensions and materials of the matching cover plugs for the accessible portions of the PFBS. The geometry and dimensions are adequately supported in the FSAR by the referenced figures. The figures also note which portions of the RPF are above ground and which are below ground.

SHINE indicated that the shield thicknesses were engineered to support ALARA principals and to keep calculated doses within the 10 CFR Part 20 limits. For portions of the PFBS with higher doses, such as the interfaces between shielding segments, SHINE FSAR section 11.1 discusses a radiation protection program that will be put in place to monitor doses in these known locations.

SHINE FSAR section 4b.2.2.2.1 “Functional Design of Biological Shield,” describes the functional basis of the PFBS. The functions and compensations of the shielding system are engineered to meet ALARA objectives with the thicknesses of the slabs, the use of below grade solution transfers (between the PFBS and the irradiation cell biological shield (ICBS)), supplemental shielding, access plugs for removable segments, engineered features to break up the streaming path at interfaces, shielded gates in combination with compensated shielding, and leaded observation windows for the hot cells within the supercell of the RPF.

SHINE FSAR section 4b.2.2.2.1 and section 4b.2.3.3, “Radiation Streaming,” describe the efforts put in place to meet ALARA during routine operations and inspections, and these descriptions are adequately supported by the supplied figures. The engineered shielding features for the waste drum, pipe trench, tank vault, carbon delay bed, RLWI, and the supercell are adequately presented, along with the matching configuration changes (access plug removals, compensating gates, door gates for drum removal and material transfers, and supplemental shielding at manipulator penetrations). The shield design also describes the entry and exit facilities for products, wastes, process equipment, and operating staff. Transitions between PBFS and ICBS are adequately described and supported in the FSAR.

SHINE FSAR section 4b.2.3 addresses the selected materials and their justification, the radiation damage calculations and criteria for acceptance, the dose and damage to the other materials, and radiation streaming. Materials that are customarily used for shielding were employed for all portions of the PBFS (steel, lead, lead glass, and standard-density concrete with reinforcing steel). For those portions of the PBFS with high activity and potential dose, lead was used.

SHINE performed radiation damage calculations with MCNP to approximate the flux and integrated fluence throughout the PFBS. The geometry of the PFBS was explicitly modeled with enough direct representations of neutrons and gammas to calculate statistically meaningful results, with variance reduction techniques in hard-to-converge areas. Neutron and gamma transport from the fresh and irradiated target solution and the interactions with the shielding materials were simulated. The MCNP models were developed with conservative assumptions.

This analysis was done for all portions of the post-irradiated target solution, fresh target solution within the staging system, the MEPS, and the IXP. To address radiation streaming, particularly at the interfaces of dissimilar materials, at gaps between segments, at segments of shielding that are engineered to be thinner than nominal, and at penetrations, SHINE employed non-linear paths and supplemental shielding to reduce dose. SHINE explicitly modeled tolerance gaps to accurately calculate dose and to correct with supplemental shielding.

For its overall shielding methodology, SHINE determined the thickness conservatively to control dose and structural integrity. Regulatory Guide 1.69 references ANSI/ANS 6.4-2006, “Nuclear Analysis and Design of Concrete Radiation Shielding for Nuclear Power Plants,” as an acceptable basis for shielding calculations. SHINE used this standard as guidance during the development of its MCNP models to determine the neutron and gamma-ray dose rates behind shielding thicknesses and to determine the amount of flux that a shielding material can receive and still maintain structural integrity. SHINE used this standard to define the acceptable criteria with respect to flux and temperature. With MCNP calculations throughout the PFBS, SHINE demonstrated that these criteria are met and that the nuclear heating can be neglected. SHINE also calculated the cumulative 30-year lifetime gamma dose (2E+9 rad) to the shielding concrete to demonstrate that the concrete will not suffer from degradation consistent with the results of the studies documented in NUREG/CR-7171. SHINE also used MCNP to determine that fluxes within the steel, lead, and lead glass do not lead to the degradation of these materials and to demonstrate that groundwater and soils are not activated.

For structural integrity of concrete shielding, SHINE references ACI 349-13 as the appropriate standard, whereas RG 1.69 references ACI 349-06. ACI 349-13 superseded ACI 349-06 and was published after the publication of RG 1.69. ACI 349-13 was also developed for nuclear safety related concrete. Both ACI 349-13 and ACI 349-06 were developed based upon the strength design method, with acceptable compressive, tensile, and shear loadings determined by a calculated temperature criterion of 150°F (66°C) within the concrete; SHINE’s calculated concrete temperature was below this limit. The SHINE FSAR also takes the same exceptions to ACI 349-13 as are taken by RG 1.69 with respect to ACI 349-06.

SHINE developed proposed TSs that are appropriate for defining operating limits that establish the integrity of the PFBS such that it can fulfill its safety function and control dose to workers and the public during normal operation and accidents. The proposed TSs define limiting conditions of operation and surveillances with respect to the operability of: the supercell confinement damper; RVZ1e outlet isolation valves for confinement; PVVS tank flowrates; and radiation monitors in the supercell for the RVZ1e exhaust lines (PVVS hot cell; extraction and IXP hot cells; and purification and packaging hot cells).

The NRC staff finds that all of the essential physical and operational features of the biological shield that are required to prevent the release of radioactive material and to maintain radiation levels below the 10 CFR Part 20 limits for the protection of workers and the public are identified in SHINE FSAR section 4b.2.

Based on the information presented in SHINE FSAR section 4b.2, the NRC staff finds that the technical analysis, applicable standards, and relevant criteria offer reasonable assurance that the PFBS will control exposure to radiation within the 10 CFR Part 20 limits and the guidelines of the facility ALARA program, and that the biological shield will control radiation-induced degradation to the components of the RPF. Therefore, the staff finds that the description of the biological shield meets the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4b.4.3 Radioisotope Extraction System

The NRC staff evaluated the sufficiency of the SHINE RPF radioisotope extraction system, as presented in SHINE FSAR section 4b.3, "Radioisotope Extraction System," using the guidance and acceptance criteria from Section 4b.3, "Radioisotope Extraction System," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 4b.3 of the ISG augmenting NUREG-1537, Part 2, the NRC staff considered whether the information provided a clear understanding of the processes and is consistent with the information in other sections of the FSAR.

SHINE FSAR section 4b.3 provides the design, detailed description, and the following processing details of the MEPS:

- Process description, including process functions; safety functions; primary system interfaces; the process sequence, including molybdenum extraction and concentration and purification process sequences; and process equipment.

- Physical, chemical, and radioisotope properties of the target solution, including volumes in process and radioactive inventory in process.

- Criticality control features of the systems that are provided through use of favorable geometry equipment.

- Shielding and radiological protection features of the MEPS.

The MEPS processes are performed in shielded hot cells, which keeps worker exposure to radiation within the regulatory limits of 10 CFR Part 20. The processes are remotely and manually controlled, and performed with tele-manipulators, with minimal automated sequences. Radiation monitors and alarms are used to monitor release of radiological materials, monitor high background gamma dose levels, and detect criticality events. Piping that contains potentially radiological material is routed through shielded pipe chases to limit worker exposure to radiation. Tanks within the MEPS are inside shielded hot cells, so additional tank shielding is not required.

On the basis of its review, the NRC staff determined that the MEPS process descriptions in SHINE FSAR section 4b.3 provide a detailed account of the SNM in process, along with any included fission-product radioactivity. The description of the post-irradiation processing after the target solution is removed from the IF gives a clear understanding that these operations can be conducted safely in the RPF. The MEPS processing facilities and apparatus are described in sufficient detail to provide confidence that the SNM and byproduct material can be controlled throughout the process so that the health and safety of the public will be protected.

Based on the information presented in SHINE FSAR section 4b.3, the NRC staff finds that the description of the SHINE RPF radioisotope extraction system meets the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4b.4.4 Special Nuclear Material Processing and Storage

SHINE FSAR section 4b.4, "Special Nuclear Material Processing and Storage," describes the processing components and procedures involved in handling, processing, and storing SNM in the SHINE RPF. The processing and storage of SNM is conducted in the SHINE facility building and the waste staging and shipping building. SNM is used throughout the radiologically controlled area in both unirradiated and irradiated forms for the production of medical radioisotopes. Mo-99 is extracted from the irradiated SNM in the MEPS as described in SHINE FSAR section 4b.3. Following Mo-99 extraction, the target solution is directed to one of the target solution hold tanks, the target solution storage tanks, or the RLWS system. In the target solution hold tanks, sampling and adjustments to chemistry are performed as required. Target solution is stored in favorable geometry tanks designed to keep the target solution subcritical.

4b.4.4.1 Processing of Irradiated Special Nuclear Material

The NRC staff evaluated the sufficiency of the SHINE RPF irradiated SNM processing and storage, as presented in SHINE FSAR section 4b.4.1, "Processing of Irradiated Special Nuclear Material," using the guidance and acceptance criteria from section 4b.4.1, "Processing of Irradiated Special Nuclear Material," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 4b.4.1 of the ISG augmenting NUREG-1537, Part 2, the NRC staff considered whether the information provided a clear understanding of the processes and is consistent with the information in other sections of the FSAR.

SHINE FSAR table 4b.4-1 specifies the chemical form, physical form, and approximate maximum inventory in pounds and kilograms of the SNM in the SHINE facility. SHINE FSAR section 4b.4.1, along with figure 4b.4-1, presents a clear description of the process systems and components to provide an understanding that the facility can be operated safely within regulatory limits. The processing components are compatible with the process material that they contain so as to withstand the effects of corrosion and radiation. The processing system is designed to manage fission-product and radiolysis gases that evolve in the process.

SHINE FSAR section 4b.4.1.2 describes the physical properties of the system. This includes process fluid properties, physical and chemical properties, radioisotope properties, and hazardous chemicals. Additionally, SHINE FSAR section 4b.4.1.2.4 states that for solution adjustments in the TSSS, adjustments may include uranyl sulfate and sulfuric acid additions, which are hazardous chemicals. Chemicals are prepared within well-ventilated areas and within enclosures as needed to prevent exposure. Off-gases evolved within the TSSS are isolated from workers and ventilated by the PVVS, as described in SHINE FSAR section 9b.6. Uranyl sulfate is prepared in the TSPS, as described in SHINE FSAR section 4b.4.2.2. SHINE has chemical inventory controls, including separation of chemicals, based on the potential for exothermic reactions. SHINE FSAR table 4b.4-4 provides the approximate TSPS hazardous chemical inventory.

SHINE FSAR section 4.b.4.1.2.5 states that the SNM within the irradiated target solution in the RPF are LEU and small amounts of plutonium. The LEU is in the form of uranyl sulfate, and the plutonium is in aqueous form in the target solution. The TSSS contains up to eight batches of target solution in the target solution hold tanks and up to two batches in the target solution storage tanks. SHINE FSAR table 4a2.2-1 provides the uranium inventory in a target solution batch. SHINE FSAR table 4a2.6-2 provides the plutonium inventory in a target solution batch. SHINE FSAR section 4b.1 provides the maximum SNM inventory within each RPF process system.

SHINE FSAR section 4b.4.1.3, "Criticality Control Features," states that the TSSS criticality safety controls are discussed in detail in SHINE FSAR section 6b.3.2.1.

SHINE FSAR section 4.b.4.1.4, "Shielding and Radiological Protection," states that storage and adjustment of the target solution is performed in the TSSS within the shielded tank vaults of the PFBS. Piping that contains potentially radioactive material is transferred through shielded pipe trenches to limit the exposure of individuals to radiation. Radiation monitors and alarms are used to detect the release of radiological materials, detect high background gamma dose levels, and detect criticality were it to occur, as described in SHINE FSAR section 7.7.

On the basis of its review, the NRC staff determined that the process descriptions in SHINE FSAR section 4b.4.1, including tables and figures, provide a detailed account of the irradiated SNM in process, along with any included fission-product radioactivity. The staff finds that the process descriptions for the TSSS processes are sufficient to provide a clear understanding that these operations can be conducted safely in the RPF. The staff determined that the TSSS processing facilities and apparatuses are described in sufficient detail to provide confidence that the irradiated SNM and byproduct material can be controlled throughout the process so that the health and safety of the public will be protected.

Based on the information presented in SHINE FSAR section 4b.4.1, the NRC staff finds that the description of the SHINE RPF irradiated SNM processing and storage meets the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4b.4.4.2 Processing of Unirradiated Special Nuclear Material

The NRC staff evaluated the sufficiency of the SHINE RPF unirradiated SNM processing and storage, as presented in SHINE FSAR section 4b.4.2, "Processing of Unirradiated Special Nuclear Material," using the guidance and acceptance criteria from section 4b.4.2, "Processing of Unirradiated Special Nuclear Material," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 4b.4.2 of the ISG augmenting NUREG-1537, Part 2, the NRC staff considered whether the information provided a clear understanding of the processes and is consistent with the information in other sections of the SHINE FSAR.

SHINE FSAR section 4b.4.2 states that shipments of uranium received by the SHINE facility consist of LEU and that the nominal enrichment of the received uranium is 19.75 +/- 0.2 percent. The SNM is transported in approved shipping containers and is stored in those containers in accordance with packaging limitations for use. The shipping containers are manually transferred to where the SNM may be removed from the shipping containers. Each package of SNM is inspected upon receipt. Dependent on the form received, the SNM is repackaged from the shipping containers to either uranium metal storage canisters or uranium oxide storage canisters and placed in a favorable configuration on the uranium metal storage rack or uranium oxide storage rack for criticality safety. The uranium metal is converted to uranium oxide by a furnace within the uranium receipt and storage system glovebox. The uranium oxide produced from the oxidation of unirradiated uranium metal is stored in uranium oxide storage canisters in favorable configuration for criticality safety on the uranium oxide storage rack. Uranium oxide is stored for future production of uranyl sulfate target solution.

SHINE FSAR sections 4b.4.2.2 through 4b.4.2.5 describe the operations involving SNM before it is used as target solution in the IF. The process descriptions include detailed procedures used in each operation, including a description of the quantity, physical and chemical form of the SNM involved in each operation, and enough detail to enable the development and analysis of potential accident sequences in SHINE FSAR chapter 13.

All the essential physical and operational features of the unirradiated SNM processing system that are required to prevent the release of radioactive material and to maintain radiation levels below applicable radiation exposure limits in 10 CFR Part 20, for the protection of workers and the public, are identified and included in the proposed TSs.

On the basis of its review, the NRC staff determined that the process descriptions in SHINE FSAR section 4b.4.2 provide a detailed account of the unirradiated SNM in process. Each operation with unirradiated SNM in receipt, transport, storage, and preparation for use is described in sufficient detail to show that there is reasonable assurance that these operations can be conducted safely. The storage, transport, and processing facilities and apparatuses are described in sufficient detail to provide confidence that the unirradiated SNM can be controlled throughout the process so that the health and safety of the public will be protected.

Based on the information presented in SHINE FSAR section 4b.4.2, the NRC staff finds that the description of the SHINE RPF unirradiated SNM processing and storage meets the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 for the issuance of an operating license.

4b.4.5 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant’s proposed TSs for the SHINE RPF as described in SHINE FSAR chapter 4.

The proposed TS 2.1, SL 2.1.3 states the following:

SL 2.1.3	The pressure within process tanks containing irradiated uranyl sulfate in the RPF and connected piping up to the first valve shall be ≤ 18 psi gauge (psig).
Applicability	This specification applies at all times to the gauge pressure within the irradiated uranyl sulfate process tanks in the RPF. This specification also applies to piping and piping components, up to the first valve, that share a pressure boundary with the irradiated uranyl sulfate process tanks.

SL 2.1.3 provides that the process tanks containing irradiated uranyl sulfate in the TSSS, RLWS system, RLWI system, and radioactive drain system have a design pressure of 15 psig and have overpressure protection that prevents the design pressure from rising more than 3 psig above the design pressure. During normal operation, the PVVS ventilates the process tanks with a sweep gas to prevent the buildup of radiolytic hydrogen gas, which could lead to a deflagration or detonation resulting in an event that exceeds the design pressure. In the event of a loss of power or loss of flow through the PVVS, the N2PS provides a source of sweep gas stored in pressurized tanks containing nitrogen. The N2PS is designed to function during design basis events and will provide sweep gas for three days. The NRC staff determined that the tanks are hydrostatically tested to a pressure not less than 130 percent of design pressure, which is 19.5 psig, to ensure that they meet ASME Boiler and Pressure Vessel Code, Section VIII, Division 1. The staff finds that SL 2.1.3 would prevent stresses on the tanks or piping that could exceed the allowable condition of the material. Therefore, the staff finds SL 2.1.3 acceptable.

4b.5 Review Findings

The NRC staff reviewed the descriptions and discussions of SHINE's RPF, as described in SHINE FSAR section 4b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the design of the RPF and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's RPF are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

5.0 COOLING SYSTEMS

The principal purpose of the cooling systems is to safely remove fission and decay heat from the target solution and dissipate it to the environment under normal and accident conditions. Cooling systems, including auxiliary and subsystems that use and contribute to the heat load of the primary or secondary cooling systems, should be shown to safely remove and transfer heat to the environment from all significant heat sources identified in the SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR). The final design of the cooling systems is based on interdependent parameters, including thermal power level, type and form of special nuclear material, neutronic physics, and radiation shielding.

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE irradiation facility (IF) and radioisotope production facility (RPF) cooling systems, as presented in Chapter 5, “Cooling Systems,” of the SHINE FSAR and supplemented by the applicant’s responses to staff requests for additional information (RAIs).

5a Irradiation Facility Cooling Systems

Section 5a, “Irradiation Facility Cooling Systems,” of this SER provides an evaluation of the final design of SHINE’s IF cooling systems as presented in SHINE FSAR sections 5a2, “Irradiation Facility Cooling Systems,” and 5b, “Radioisotope Production Facility Cooling Systems,” within which the applicant described the primary closed loop cooling system (PCLS), radioisotope process facility cooling system (RPCS), process chilled water system (PCHS), primary closed loop cooling system cleanup side stream, facility demineralized water system (FDWS), nitrogen-16 (N-16) control, and auxiliary systems using primary coolant.

5a.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 5a2 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design of the SHINE IF cooling systems.

SHINE FSAR section 5b describes the SHINE cooling systems as integrated throughout the facility as described in SHINE FSAR section 5a2. Specifically, SHINE FSAR section 5a2.3, “Radioisotope Process Facility Cooling System,” describes that the RPCS serves as a secondary cooling system for the irradiation units (IUs) in the IF and provides cooling to the RPF. Therefore, the areas of review related to the RPCS presented in this section are applicable to both the IF and the RPF.

5a.2 Summary of Application.

As stated above and described in SHINE FSAR sections 5a2.3 and 5b, the RPCS serves as a secondary cooling system for the IUs in the IF and provides cooling to the RPF. Therefore, the summary provided below applies to both the IF and the RPF.

The IF cooling systems consist of a primary cooling system and a secondary cooling system. The primary cooling system comprises the PCLS and the light-water pool system (LWPS). The PCLS and the LWPS provide the heat removal to the IU equipment that is submerged within the light-water pool. There are eight IUs and each of the IUs includes a PCLS and a LWPS. The secondary cooling system is referred to as the RPCS. The RPCS removes heat from the PCLS/LWPS and transfers it to the facility chilled water supply system (FCHS). The RPCS is a closed loop system that provides cooling water to all of the process areas within the radiologically controlled area (RCA). The thermal partitions between the PCLS/LWPS and the RPCS cooling systems are the heat exchangers at the system interfaces. The primary coolant cleanup loops provide treatment of the PCLS and the LWPS coolant to meet water quality limits. The FDWS provides makeup water to the PCLS, RPCS, FCHS, molybdenum extraction and purification system (MEPS), and LWPS. In addition to providing a secondary cooling function for the IF, the RPCS also provides cooling to the RPF. While the PCLS uses a delay tank to reduce N-16, there is no independent N-16 control system.

5a.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR Chapter 5 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the bases and the information provided by SHINE for the issuance of an operating license.

5a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE IF cooling systems are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.34, “Contents of applications; technical information,” paragraph (b), “Final safety analysis report.”
- 10 CFR 50.36, “Technical specifications.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR 50.57, “Issuance of operating license.
- 10 CFR Part 20, “Standards for Protection Against Radiation.”

5a.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

5a.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR sections 5a2 and 5b, as supplemented, to assess the sufficiency of the final design of SHINE’s IF cooling systems for the issuance of an operating license. The sufficiency of the final design is determined by ensuring that it meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 5a.3, “Regulatory Requirements and Guidance and Acceptance Criteria,” of this SER. The findings of the staff review are described in section 5a.5, “Review Findings,” of this SER.

As described in SHINE FSAR sections 5a2.3 and 5b, the RPCS serves as a secondary cooling system for the IUs in the IF and provides cooling to the RPF.

5a.4.1 Summary Description

The NRC staff evaluated the sufficiency of the summary description of the SHINE IF cooling systems, as presented in SHINE FSAR section 5a2.1, “Summary Description,” using the guidance and acceptance criteria from section 5.1, “Summary Description,” of NUREG-1537, Parts 1 and 2, and section 5a2.1, “Summary Description,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 5a2.1 states that the IF cooling systems safely remove the fission and decay heat from the target solution and dissipate it to the environment. SHINE FSAR section 5a2.1 further states that the cooling systems in the facility consists of a PCLS, RPCS, and PCHS. The SHINE FSAR describes the PCLS as a closed loop water system that rejects heat to the RPCS, which rejects heat to the PCHS, then to the environment using air-cooled chillers. The RPCS, an intermediate chilled water system, rejects heat to the PCHS. The PCHS, a closed chilled loop rejects heat to the atmosphere using air-chillers.

The NRC staff finds that the principal features of the primary and secondary cooling systems are summarized in SHINE FSAR section 5a2.1. The staff notes that the primary and secondary cooling systems are closed cooling systems using water as a coolant to transfer heat generated in the target solution vessel (TSV) to the environment by the use of air-chillers. Because the principal features of the primary and secondary cooling systems are adequately described in SHINE FSAR section 5a2.1, the staff finds that the summary description of the facility cooling systems meets the acceptance criteria in NUREG-1537, Part 2 for the issuance of an operating license.

5a.4.2 Primary Cooling System

The NRC staff evaluated the sufficiency of the final design of SHINE's primary cooling system, as presented in SHINE FSAR section 5a2.2, "Primary Closed Loop Cooling System," in part, by reviewing the design basis, PCLS process functions, system process and safety functions, proposed technical specifications, primary cooling system components and interfaces, PCLS cooling functions and operation, LWPS cooling functions and operation, instrumentation and sampling, secondary cooling system interaction, and radiation exposure protection using the guidance and acceptance criteria from section 5.2, "Primary Coolant System," of NUREG-1537, Parts 1 and 2, and section 5a2.2, "Primary Cooling System," of the ISG augmenting NUREG-1537, Parts 1 and 2.

5a.4.2.1 Thermal-Hydraulic Design

As described in SHINE FSAR Chapter 4a2, "Irradiation Facility Description," the TSV of an IU is an annular pressure vessel that contains the target solution during the irradiation process. During irradiation, heat is generated in the target solution. The heat generation is volumetric and nonuniform. The highest generation rates are predicted to be towards the center of the target solution. During irradiation, the heat transfer mechanism from the target solution to the walls of the TSV and to the PCLS is a combination of temperature-driven natural convection of the bulk solution and bubble-driven convection by the flow of gas bubbles in the target solution. Radiolysis of the water in the target solution causes volumetric generation of hydrogen and oxygen bubbles. These bubbles flow upwards through the target solution to the surface of the solution, circulating the solution and enhancing the heat transfer. The heat transferred to the PCLS is carried away by forced external convection of the primary cooling water supplied by the PCLS. The PCLS is discussed in section 5a.4.2.7 of this SER.

During Mode 2 (Irradiation Mode - Operating mode, neutron driver active), with the exception noted below, the PCLS flow rate must be above the minimum required flow rate to ensure sufficient forced convection. In Mode 2, the thermal-hydraulic design allows for short periods (up to 3 minutes) without forced cooling water flow from the PCLS when there is no accelerator output. This allows for time to recover from potential cooling system transients without the necessity of dumping target solution from the TSV to the dump tank. During this time, the system operates with natural convection cooling water flow. During Mode 1 (Startup Mode - Filling the TSV), no PCLS forced flow is required to maintain operating limits of the target solution. During Mode 3 (Post-Irradiation Mode - TSV dump valves open), no PCLS forced flow is required as the target solution is transferred to the TSV dump tank, and cooling of the solution is provided through natural convection to the LWPS. The TSV dump tank is discussed in section 5a.4.2.3 of this SER.

The applicant performed thermal-hydraulic and heat transfer calculations based on best estimate analytical methods employing thermal-hydraulic correlations, using conservative assumptions, as discussed in the following sections of this SER. Limiting core conditions were assumed in the thermal-hydraulic analysis of the TSV and the TSV dump tank. No credit was taken for heat removal by the TSV off-gas system (TOGS). This is a conservative assumption because the heat transfer to TOGS will reduce the average and peak temperatures of the target solution.

Heat Removal Systems

The SHINE facility thermal-hydraulic design includes systems that provide heat removal from the subcritical assembly during normal irradiation and shutdown operations. These systems include the PCLS and the LWPS for each IU. The TSV rejects heat through the inner shell, the outer shell, and the internal interfaces between the TSV and PCLS. The systems that are credited for the heat removal analysis are described below.

Primary Closed Loop Cooling System

The PCLS removes up to 137.5 kilowatts (kW) of heat by forced convection from a single TSV during full-power IU operation. The PCLS also removes up to 20 kW of heat by forced convection from a single neutron multiplier during full-power IU operation. There are eight PCLSs in the facility, and each PCLS is separate and independent for each IU. The PCLS circulates deionized water in the upward direction through the TSV along the outside of the TSV walls during normal operation. The heat absorbed by PCLS water is transferred to the RPCS through a heat exchanger. The RPCS is discussed in section 5a.4.3.1 of this SER. The PCLS removes approximately 98 percent of TSV fission power when assuming no heat removal by the TOGS. The PCLS is discussed in more detail in section 5a.4.2.6 of this SER.

Light Water Pool System

The LWPS contains no forced cooling components. In Mode 3, the LWPS performs direct cooling of the TSV dump tank by natural convection within the dump tank and natural convection of the pool water. The LWPS is expected to remove 100 percent of the decay thermal power (i.e., heat) from the TSV dump tank without boiling water in the LWPS or inside the dump tank. The applicant designed the system to prevent boiling of the target solution either within the TSV or the TSV dump tank.

The LWPS does not provide direct cooling of the TSV or neutron multiplier. Due to the radiation shielding provided by the LWPS, power is deposited into the pool by long range radiation from the TSV, neutron multiplier, and neutron driver. Up to 2.3 kW of heat is estimated to be deposited in the pool during full-power IU operation. There are no heat exchangers that cool the LWPS. The pool is heated to slightly above PCLS temperature from radiation heating, and heat is primarily transferred from the pool through piping and component walls to the PCLS cooling water. The pool is maintained within the temperature range of 50 degrees Fahrenheit (°F) (10 degrees Celsius (°C)) to 95°F (35°C) during normal operation, and the pool temperature is monitored. If PCLS cooling is lost, the irradiation process is shut down due to the TSV reactivity protection system (TRPS) initiating an IU Cell Safety Actuation on low PCLS flow or high PCLS temperature. Heat transfer also occurs through evaporation to the IU cell atmosphere and conduction through the surrounding concrete. However, these two mechanisms are not credited in the analysis, which is conservative because these mechanisms will lower actual pool temperatures, which the NRC staff finds to be acceptable. The fraction of heat removed by the LWPS is estimated to be about 2 percent of the thermal power of the TSV.

In the event of a failure of the PCLS forced cooling function, the target solution is drained from the TSV to the TSV dump tank and the large thermal mass of the LWPS water provides decay heat removal capacity and cools the target solution. As a result, the temperature in the LWPS is calculated not to exceed a specific temperature level after a certain decay heat period assuming that the pool is at its minimum allowable level for accident conditions. The LWPS is expected to remove decay heat from the target solution in the TSV dump tank after the target solution has been irradiated, prior to its transfer to the extraction cell. For calculating LWPS heatup in Mode 3, the PCLS is assumed to not be operating. This is a conservative assumption because the PCLS provides cooling to the pool and assuming it is not operating will result in higher pool and target solution temperatures. The NRC staff evaluation of the LWPS heatup analysis is provided in section 5a.4.2.4 of this SER.

The LWPS liner is designed as Seismic Category I and is expected to remain intact during normal operation, as well as during a design-basis earthquake and design-basis accident events. Penetrations through the LWPS liner are above the minimum required water level. Because the combination of the above design criteria will ensure that the minimum required water level can be readily maintained, the NRC staff finds this acceptable.

5a.4.2.2 Target Solution Vessel

The TSV is an annular vessel with cooling capability. The TSV transfers heat through the TSV inner shell, the TSV outer shell, and the TSV inner structures to the PCLS. Among these surfaces, approximately 50 percent of the heat is expected to be transferred through the inner and outer shells.

The PCLS removes heat directly from the surfaces mentioned above during normal operation and transients. Cooling water flows up from the lower plenum of the subcritical assembly support structure (SASS), past the TSV and neutron multiplier, and collects in the SASS upper plenum before returning to the PCLS heat exchanger. Three cooling channels are formed by the SASS, TSV, neutron multiplier, and tritium target chamber. Cooling channel 1 (CC1) is the annular gap between the tritium target chamber and the neutron multiplier inner shell exterior surface. Cooling channel 2 (CC2) is the annular gap between the TSV and neutron multiplier. Cooling channel 3 (CC3) is the annular gap between the TSV and the SASS inner baffle. Only CC2 and CC3 cool the TSV. There is no coupling between cooling flows except at the SASS upper and lower plenums. The PCLS is not designed to cool the tritium target chamber because the target chamber is internally cooled by forced cooling water supplied by the neutron driver assembly system through an outer cooling jacket.

The thermal-hydraulic analysis was based on assuming the lowest allowable PCLS flow rate and the maximum allowable PCLS cooling water temperature of 77°F (25°C). These limits are protected by the TRPS IU Cell Safety Actuation setpoints. The TSV headspace pressure is maintained slightly below atmospheric pressure. The pressure over the target solution in the TSV is normally between -2 pounds per square inch gage (psig) and 0 psig. Because the primary cooling water temperature is maintained well below the boiling point at atmospheric pressures, the pressure profiles of the cooling water in the flow channels are not important to safety. The total cooling water flow rate and the inlet temperature are the principal variables of importance for heat transfer. These variables are monitored by the TRPS.

The TSV is maintained at a nominal 120°F (50°C) during irradiation, which is well below the boiling point of water, even at a pressure slightly below atmospheric. No plating out of chemicals is expected from boiling because no boiling occurs in the TSV. Evaporation of the target solution and collection of solid salts on the TSV walls at the liquid surface is postulated; however, this does not affect the heat transfer as this will be above the liquid surface. Potential precipitates are not expected to have significant impact on heat transfer in the TSV. Small amounts of precipitates could form in the target solution; however, because the heat transfer surfaces are vertical, collection of settled precipitates is reduced.

The applicant analyzed two scenarios in the event of a loss of off-site power (LOOP). For short duration LOOP events (nominally less than 3 minutes), the target solution normally remains in the TSV. The PCLS pumps will not function on a LOOP and PCLS flow will be lost. For long duration LOOP events (nominally greater than 3 minutes), the target solution is dumped to the TSV dump tank. In the dump tank, the LWPS serves as the passive decay heat sink for the target solution. The applicant performed bounding analyses for the natural convection cooling in the TSV dump tank once the target solution is transferred to the TSV dump tank. The highest target solution temperature within the TSV dump tank is predicted to be less than 194°F (90°C), as shown in SHINE FSAR figure 4a2.7-4, "Target Solution Vessel Dump Tank Bounding Temperature Profile." A minimum water level in the LWPS is required such that it can safely remove decay heat from the TSV dump tank. The NRC staff evaluation of the target solution heat-up analysis inside the TSV dump tank is provided in section 5a.4.2.4 of this SER.

5a.4.2.3 Target Solution Vessel Dump Tank

Under normal circumstances, the target solution heat will decay within the TSV dump tank for a period of time after irradiation and prior to processing. Additionally, when the PCLS is not available, the target solution is dumped from the TSV into the TSV dump tank and decay heat is passively removed by the LWPS water surrounding the TSV dump tank. During certain abnormal circumstances, the target solution could be allowed to remain within the TSV dump tank for an extended period of time. Such circumstances could include an unplanned shutdown of the IU.

The TSV dump tank is a horizontal annular tank, submerged in the LWPS water. It is only partially filled with the target solution when the solution is transferred to the dump tank. The NRC staff's review of the TSV dump tank design finds that the dump tank geometry and dimensions enhance the heat transfer surface area in order to facilitate decay heat removal from the target solution by the natural convection heat transfer process to the LWPS water through the inner and outer shell surfaces of the dump tank. Because the described design supports decay heat removal as described in the following section of this SER, the staff finds it acceptable.

The NRC staff evaluation of the methodology and the assumptions used for passive decay heat removal from the TSV dump tank and safe shutdown of the SHINE facility is discussed in section 5a.4.2.4 of this SER.

5a.4.2.4 Thermal-Hydraulic Calculation and Testing

Heat flux along the cooling surfaces was calculated using the limiting core condition. A correlation-based methodology was used for safety-related calculations of the TSV thermal-hydraulics. The methodology included a heat transfer correlation developed based on test data applicable to the SHINE facility and accounted for relevant engineering tolerances and uncertainties. This heat transfer correlation was used for heat transfer between the target solution and the walls of the PCLS cooling channels.

For the PCLS cooling channel flow, a heat transfer correlation for turbulent internal forced convection was used. The NRC staff compared the results of this correlation to other heat transfer correlations for turbulent internal forced convection and found that SHINE's correlation conservatively underestimated heat transfer. Additionally, the staff performed confirmatory analysis to evaluate whether uncertainty in this correlation might impact the evaluation of PCLS performance and concluded that other conservatisms in SHINE's evaluation offset potential variation in heat transfer due to uncertainty in the heat transfer coefficient. Based on the above information, the staff finds the use of this correlation to be acceptable.

TSV Tests

For the heat transfer process inside the TSV, tests were performed at the University of Wisconsin – Madison to develop a heat transfer correlation for the unique condition that exists inside the TSV involving volumetric heat generation in the target solution with bubble formation, cooled walls, and the TSV cooling arrangement. The applicant reviewed the existing correlations in the published literature. Volumetric heat generation was approximated using cartridge heaters. Short and long cartridge heaters were used to study the sensitivity of the power density. Volumetric bubble generation was approximated by injecting a roughly uniform sheet of bubbles at the base of the vessel. The cooled vessel walls were made of stainless steel, and aluminum heat exchangers were applied to the outer surface of these walls to simulate the cooled wall condition. A water and magnesium sulfate solution was used as a uranyl sulfate target solution surrogate in the experiments. The magnesium sulfate heat transfer properties were found to be comparable to that of uranyl sulfate.

The experimental results demonstrated that thermal stratification of the surrogate target solution was negligible. Bulk fluid was assumed to rise from the bottom of the TSV to the target solution surface with downward recirculation along the cold walls, similar to the chimney effect. The velocity of the upward flow was estimated based on the conservation of mass principle and the calculation of the downward flow rate along the cold walls. The downward flow rate was calculated based on the boundary layer characteristic velocity and the fully developed thickness of the target solution boundary layer. A flat plate approximation was assumed. A transit time was calculated based on the distance from the bottom of the TSV to the target solution surface and the velocity of the upward flow. The total temperature rise was calculated based on the power density in the control volume, the transit time, the solution heat capacity, and the solution mass density. Finally, the peak temperature was determined by adding the total temperature rise to the average temperature. Adding the total temperature rise to the average temperature is conservative because some of the temperature rise will occur at temperatures below the average temperature. The NRC staff finds that this approach to developing this heat transfer correlation is technically sound and consistent with current engineering practice. Further, the staff concludes that the parameters of the SHINE facility are within the range of parameters for which this correlation is valid and that this correlation is applicable to the SHINE facility.

Calculational Results – Normal Operations

The calculational results based on the above methodology show that the peak target solution temperature in the TSV was less than 194°F (90°C), which provides reasonable assurance that no significant boiling is expected to occur in the TSV. Furthermore, the bulk target solution temperature in the TSV was less than 176°F (80°C), which is an assumption of the passive decay heat removal and safe shutdown calculation discussed in the "Calculational Results – Passive Decay Heat Removal and Safe Shutdown" section of this SER.

Section 4a2.6, "Thermal-Hydraulic Design," of the ISG augmenting NUREG-1537, Part 2 states that the criteria for the thermal-hydraulic design should include that there should be no coolant flow instability in any cooling coil that could lead to a significant decrease in cooling, and that the departure from nucleate boiling (DNB) ratio should be no less than 2.0 along any cooling coil. To address this guidance, the applicant described that the PCLS cools the external surfaces of the neutron multiplier which contains natural uranium. Calculations performed for the worst-case power transient scenario in the neutron multiplier determined that the DNB ratio for the cooling surface is 4.8. The NRC staff finds that this meets the ISG acceptance criterion that the DNB ratio should be no less than 2.0 along any cooling coil. The staff concludes that this is acceptable because there is adequate margin available to avoid DNB in the worse-case scenario of a power transient in the neutron multiplier.

With respect to the PCLS cooling surface of target solution, the NRC staff understands that the target solution is the heat source, which is essentially water in liquid phase at near atmospheric pressure, the PCLS coolant is water in liquid phase at a higher pressure than the target solution, and both target solution and coolant are at temperatures less than the boiling point. Under such a condition, the PCLS cooling surface is not expected to experience a heat flux higher than the critical heat flux of water at that condition or expected to cause coolant flow instability. Hence, the staff concludes that the occurrence of DNB along any PCLS cooling surface is not plausible.

Calculational Results – Passive Decay Heat Removal and Safe Shutdown

The target solution temperature and pressure limits ensure that the target solution does not undergo boiling. Pressure of the target solution is controlled by the TOGS. Gas pressure in the TSV headspace is regulated to -2 psig to 0 psig. Should a TOGS pressure control malfunction occur, a minimum pressure of 10.2 pounds per square inch absolute (psia) is maintained within the primary system boundary (PSB) by vacuum relief valves on the TSV. After shutdown or when the PCLS is inoperable, the target solution is transferred into the TSV dump tank and decay heat is passively removed by natural convection by the LWPS water surrounding the dump tank.

The TSV dump tank passive decay heat removal to the LWPS was calculated using the following conservative assumptions:

- The PCLS is not available.
- The TSV fission power prior to shutdown was 137.5 kW (licensed power limit is 125 kW).
- The bulk target solution temperature during irradiation (prior to shutdown) is less than 176°F (80°C).
- Natural convection from the outer surface of the dump tank to the LWPS water was assumed to be from a horizontal flat plate with heated surface facing downward.

- Horizontal heated tube internal natural convection from the inner surface of the dump tank to the LWPS water was assumed for the TSV dump tank inner shell and the LWPS.

- Permutations of tolerances were evaluated to ensure conservative results.

- The LWPS is maintained at a minimum water level below finished floor for the duration of the analysis.

- The target solution is assumed to remain in the TSV for up to 3 minutes prior to dump valve opening.

- The opening time of the dump valve is not more than 30 seconds.

- The drain time of the TSV is calculated assuming only one dump valve (out of two) opens.

Natural convection from the outer surface of the dump tank to the LWPS water was assumed to be from a horizontal flat plate with heated surface facing downward instead of a horizontal cylinder. This will result in a conservative estimate of the local convection coefficient at the bottom of the TSV dump tank where heat transfer is expected to be the worst. Using a horizontal cylinder would be less conservative because the sides of the cylindrical tank cool more readily than the underside of the tank. The sides of the tank resemble a vertical or inclined plate, which provides no restriction to convection currents, hence greater heat transfer would be expected.

The NRC staff verified that the modeling of heat transfer from the TSV dump tank inner shell to the LWPS water was appropriately conducted and relied on correlations that have been compared to test data to demonstrate their validity, and that the modeling of heat transfer within the target solution was based on conservative assumptions.

The NRC staff concluded that the adequate conservatism assumed in the calculational methodology for passive decay heat removal results in a bounding peak temperature of the target solution inside the TSV dump tank during shutdown. The large thermal mass provided by the LWPS provides adequate decay heat removal capability to provide cooling for the target solution. Figure 4a2.7-4 of the SHINE FSAR shows that the peak target solution temperature reaches approximately 194°F (90°C) after approximately 22 minutes (1318 seconds) and then decreases. The staff, therefore, concludes that the target solution remains below operating limits and that no boiling is expected to occur in the TSV dump tank during shutdown.

By assuming that active cooling was lost during shutdown and by conservatively neglecting all other heat transfer paths, the LWPS water temperature rise was also conservatively calculated. The heat rejected by the target solution from inside the TSV dump tank to the LWPS, the specific heat capacity of the LWPS water, and the mass of the LWPS water were used to calculate the water temperature rise. Safe shutdown with the target solution in the TSV dump tank can be achieved by less pool water than required for normal operation. The calculation assumed a pool depth as the minimum water level required to ensure safe shutdown. The temperature rise in the LWPS is predicted after a decay heat period as shown in SHINE FSAR figure 4a2.4-1, “Light Water Pool Loss of Cooling Heatup Curve,” assuming that the pool is at the minimum allowable level and that there is no cooling to the pool. The water temperature of the LWPS remains below 140°F (60°C). A nominal pool water level would result in a temperature rise in the LWPS of less than 13°F (7°C) after a decay heat period.

The NRC staff reviewed the SHINE calculational methodology for the thermal-hydraulic analysis. The following SHINE documents were reviewed by the staff:

- “Target Solution Vessel Cooling,” SHINE CALC-2017-0006
- “Light Water Pool Temperature,” SHINE CALC-2018-0036
- “Target Solution Vessel (TSV) Dump Tank Thermal Hydraulics,” SHINE CALC-2018-0037
- “Target Solution Vessel (TSV) Thermal Hydraulics,” SHINE CALC-2018-0046

In addition, the NRC staff reviewed the applicability of the heat transfer correlations used in the calculations. The staff’s review of the documents verified that a correlation-based analytical methodology was employed for the safety-related calculations using limiting core conditions and conservative assumptions to obtain bounding results. Thermal-hydraulic correlations used in the analyses were derived from published peer reviewed literature, with the exception of the correlation for the heat transfer mechanism inside the TSV as described in the “TSV Tests” section of this SER. The staff’s review of the documents verified that the correlations employed were applicable to the SHINE facility and that the parameters of the SHINE facility are within the range of the parameters for which the correlations are valid. The staff concludes that the calculated results are acceptable and include adequate safety margin and that, therefore, adequate cooling capacity exists by the PCLS and the LWPS to prevent target solution overheating and loss of PSB integrity for anticipated system operating conditions.

Cooling System Design Bases

The SHINE facility does not have an active emergency cooling system for the TSV because the LWPS provides adequate passive heat removal capabilities, as discussed above. There is no forced cooling system in the LWPS. Heat is primarily removed from the LWPS by the PCLS through components submerged in the pool that are cooled by the PCLS.

The loss of the PCLS results in an IU Cell Safety Actuation on low PCLS flow or high PCLS temperature, depending on the cause of the reduction in cooling. The decreased cooling results in increased bulk temperatures in the TSV prior to target solution transfer to the TSV dump tank. The temperature of the target solution is expected to remain below 194°F (90°C).

The operational limits to prevent bulk boiling in the TSV are:

- TSV fission power less than 137.5 kW during normal operation (licensed power limit is 125 kW).
- PCLS cooling water minimum flow rate.
- PCLS cooling water temperature entering the SASS lower plenum of less than 77°F (25°C).
- PSB minimum pressure of 10.2 psia.

- Target solution uranium concentration to ensure that the power density of the limiting core condition is bounding.

The TSV fission power, PCLS cooling water flow rate, and PCLS cooling water temperature are protected by the TRPS. The PSB minimum pressure is protected by vacuum relief valves in the TOGS. The target solution uranium concentration is prepared and measured to ensure it is within 1 percent of the desired concentration.

Temperature monitoring of the target solution is provided for by indications to the operators. Temperature elements are located within thermowells contained within the TSV. Measurements are provided at multiple heights to compare TSV temperature profiles to expected profiles.

5a.4.2.5 Thermal-Hydraulic Design Conclusion

The SHINE FSAR describes and discusses all systems that remove and dispose of the heat from the target solution. Based on the above, the NRC staff concludes that adequate cooling capacity exists by the PCLS and the LWPS to prevent DNB in the cooling surfaces, and that the design does not allow overheating of target solution causing loss of PSB integrity for anticipated system operating conditions and during shutdown. The staff further concludes that the thermal-hydraulic methodology and the assumptions used are sufficiently conservative such that the calculated results include adequate safety margin and, therefore, are acceptable.

In addition, the NRC staff concludes that shutdown decay heat is satisfactorily removed from the target solution by the LWPS in a passive manner, including during long-term cooling and, therefore, the design provides reasonable assurance that the subcritical assembly achieves a safe shutdown condition from any operating condition.

5a.4.2.6 Primary Closed Loop Cooling System

The PCLS provides forced convection water cooling to the TSV and neutron multiplier during irradiation of the target solution and immediately prior to transferring the target solution from the TSV to the TSV dump tank. The PCLS also provides cooling of the LWPS by natural convection heat transfer to the PCLS components submerged in the pool. Each PCLS includes two pumps, a heat exchanger, and a cooling water cleanup system located in the primary cooling rooms.

The PCLS is designed to remove 170 kW of heat from the TSV and neutron multiplier in a single IU during full-power operation and during shutdown conditions when target solution is in the TSV. The PCLS is designed to maintain the pressure of the cooling water in the SASS higher than the internal pressure of the TSV. The major components are constructed of austenitic stainless steel.

Two PCLS pumps operate in parallel to provide the design flowrate to the PCLS heat exchanger. Should one pump fail, the second pump, operating at a minimum system flowrate, is expected to provide adequate cooling to allow continuation of full-power irradiation while maintaining the bulk target solution temperature less than 176°F (80°C) within the TSV. The NRC staff’s evaluation of the thermal-hydraulic calculations for the PCLS is provided in section 5a.4.2.4 of this SER.

The LWPS and the TSV are located within the primary confinement, which also provides confinement of the components of the PCLS located within the IU cell. The PCLS piping penetrations through the primary confinement are located above the minimum required water level in the pool.

Low cooling water flow causes an IU Cell Safety Actuation, which opens the TSV dump valves and allows the target solution to drain to the TSV dump tank. The dump valves are located in redundant flow paths and fail to a safe (open) position. The TSV dump valves are automatically opened by TRPS disconnecting power to the valves, resulting in a dump of the target solution to the TSV dump tank. The thermal mass of the target solution prevents boiling of the solution during the draining process. Once the target solution has drained to the TSV dump tank, the LWPS prevents the solution from boiling by natural convection heat transfer from the target solution to the surrounding water in the LWPS.

To prevent the drainage of primary cooling water from the subcritical assembly system (SCAS), the SCAS is located below grade in the LWPS. Portions of the PCLS located outside of the LWPS are above grade to prevent gravity drainage of the SCAS cooling channels.

Pressure, flow, temperature, conductivity, and level instrumentation monitor the operating parameters of the PCLS. Flow instrumentation is provided to monitor the flowrate of the PCLS cooling water. The PCLS is normally operated as a constant flowrate system during irradiation. However, the PCLS may operate with either one or both pumps operating.

If the PCLS temperature or flowrate is outside allowable limits, the TRPS initiates an IU Cell Safety Actuation, resulting in a transfer of the target solution to the TSV dump tank where it is cooled by natural convection to the LWPS. The PCLS pressure, flow, temperature, and expansion tank level indications are available locally and in the control room. Sampling and analysis of cooling water from the PCLS is performed locally. Sampling and analysis of the water from the PCLS is performed to ensure that the water quality requirements are being maintained and that contaminants are not present in the cooling water. The system operational controls are in the control room.

5a.4.2.7 Primary Closed Loop Cooling System Conclusion

The purpose of the PCLS is to remove heat from the core, where the core consists of that region of the TSV occupied by the target solution containing the fission power producing fissile material. Based on the above, the NRC staff concludes that the PCLS satisfies the principal purpose of the cooling system, which is to safely remove the fission and decay heat from the target solution and dissipate it to the environment, and that the analyses show that the components and the functional design of the PCLS will ensure that no limiting safety system settings (LSSS) will be exceeded through the normal range of operation. The staff, therefore, finds that the SHINE facility PCLS is acceptable for the issuance of an operating license.

5a.4.3 Secondary Cooling System

The NRC staff evaluated the sufficiency of the final design of SHINE’s secondary cooling system, which consists of the RPCS and the PCHS, as presented in SHINE FSAR section 5a2.3 and 5a2.4, “Process Chilled Water System,” in part, by reviewing the design basis, process functions, components and interfaces, cooling functions and operation, cooling control, loss of cooling, component functions and locations, instrumentation and control, and other uses of the RPCS and the PCHS using the guidance and acceptance criteria from section 5.3, “Secondary Coolant System,” of NUREG-1537, Parts 1 and 2, and section 5a2.3, “Secondary Cooling System,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

5a.4.3.1 Radioisotope Process Facility Cooling System

The RPCS removes heat generated from within the RCA and rejects the heat to the PCHS. The RPCS is an intermediate closed loop forced liquid cooling system that recirculates cooling water. The RPCS removes heat from the PCLS. The RPCS is not a safety-related system and is not credited with preventing or mitigating any design basis events. The cooling function of the RPCS is not credited in the safety analysis for any system served by the RPCS. If active cooling to the TSV and neutron multiplier is not available due to a loss of the RPCS, irradiation of the target solution is suspended and any target solution in the TSV is transferred from the TSV to the TVS dump tank and is passively cooled by the LWPS water.

SHINE FSAR section 5a2.3.2, "RPCS Analyses," states that the RPCS is maintained at a higher pressure than the systems it serves. As such, a pressure cascade is maintained at each system heat exchanger that receives service such that the RPCS cooling water is maintained at a higher pressure than those systems with the potential to contaminate the RPCS. In addition, the PCHS is maintained at a higher pressure than the RPCS at the RPCS heat exchanger so that any leakage between the RPCS and the PCHS will tend to leak into the RPCS. The RPCS is a closed loop system located inside the RCA.

5a.4.3.2 Radioisotope Process Facility Cooling System Conclusion

The RPCS is an intermediate closed loop forced liquid cooling system that recirculates cooling water and removes heat from the PCLS. It is maintained at a higher pressure than the systems from which it removes heat to avoid potential leakage of radioactive contaminants into the RPCS. Based on the evaluation of the RPCS, the NRC staff concludes that, consistent with acceptance criteria in section 5a2.3 of the ISG augmenting NUREG-1537, Part 2, the SHINE facility is designed to ensure that the secondary cooling system (i.e., the RPCS) pressure is maintained at higher than the primary cooling system (i.e., the PCLS) pressure across the heat exchangers under all anticipated conditions, and that the secondary cooling system is closed. Therefore, the staff finds that the final design of the RPCS acceptable for the issuance of an operating license.

5a.4.3.3 Process Chilled Water System

SHINE FSAR section 5a2.4 describes the PCHS. The following design criterion from section 3.1 of the SHINE FSAR applies to this system:

> Criterion 26 - Cooling water: The radioisotope process facility cooling system and process chilled water system are provided to transfer heat from safety-related SSCs [structures, systems, and components] to the environment, which serves as the ultimate heat sink.

The PCHS is a closed loop chilled water system that rejects heat to the atmosphere by use of air-cooled chillers. The PCHS removes heat from the RPCS and rejects its heat to the environment. The RPCS is an intermediate closed loop cooling water system that removes heat from the PCLS under normal operating conditions. The overall cooling system is a cascading design where the PCLS rejects heat to the RPCS, which rejects heat to the PCHS, which rejects heat to the environment.

The PCHS is comprised of circulation pumps, flow control valves, an expansion tank, a buffer tank, a glycol makeup unit, instrumentation, and packaged air-cooled chillers. These PCHS components are located outside the RCA and the primary confinement boundary. The PCHS interfaces with the RPCS at the supply and return connections of the RPCS heat exchanger.

The PCHS system is classified as a non-safety system because it is not credited with preventing or mitigating any design-basis events. During normal operating conditions, the non-safety PCHS and the non-safety RPCS transfer heat from safety-related SSCs to the environment, which serves as the ultimate heat sink. There is no direct PCHS interface with PCLS primary cooling, and PCHS component malfunctions will not lead to damage or to an uncontrolled release of radioactivity to the environment.

Although not credited for preventing or mitigating any-basis events, the PCHS is discussed in SHINE FSAR Chapter 13, “Accident Analysis,” because failure of the non-safety PCHS could adversely impact the RPCS cooling function supporting the safety-related PCLS. As described in SHINE FSAR section 13a2.1.3, “Reduction in Cooling,” PCLS, RPCS, and PCHS cooling pumps are driven by offsite power. Loss of coolant flow occurs due to power failure which could occur due to failure of a pump, inadvertent valve closure, or a pipe break. Loss of normal power results in loss of PCHS, loss of coolant flow in the PCLS cooling loop, and loss of neutron driver function and, therefore, the irradiation process is stopped. Loss of PCLS function is detected by low flow or high temperature signals that terminate the irradiation process upon loss of PCLS cooling. If active cooling to the TSV and neutron multiplier is unavailable due to a loss of the PCLS, irradiation of the target solution is suspended and any target solution in the TSV is transferred from the TSV to the TSV dump tank, which is passively cooled by the LWPS. Since required cooling during an accident is not dependent on PCHS function, the PCHS is not credited with preventing or mitigating any design basis events.

To protect against leakage and the remote possibility of radioactive material moving beyond the RPCS, the PCHS is maintained at a higher pressure than the RPCS so that any system leakage will tend to leak into the RPCS.

To address flooding concerns within the facility, berms and ramps are used to prevent a release of water from the RCA due to the postulated failure of the RPCS room, PCHS, or the facility demineralized water system. SHINE FSAR section 3.3.1.1.2, “Flood Protection from Internal Sources,” specifies that the resulting flooded water depth in the RCA from fire protection discharge does not result in adverse safety consequences and bounds the total water available in the PCHS and the RPCS cooling systems. Therefore, the design of the PCHS is acceptable with respect to protection against adverse effects from internal flooding.

5a.4.3.4 Process Chilled Water System Conclusion

The purpose of the PCHS is to removes heat from the RPCS and reject this heat to the environment. The PCHS is classified as a not safety-related and closed-loop system, not credited with preventing or mitigating any design basis events, and independent of any radiological process. In compliance with SHINE Design Criterion 26, the non-safety PCHS and the non-safety RPCS transfer heat from safety-related SSCs to the environment under normal operating conditions. Therefore, the NRC staff finds that the final design of the PCHS of the SHINE secondary cooling system, as described in SHINE FSAR section 5a2.4, is acceptable for the issuance of an operating license.

5a.4.4 Primary Coolant Cleanup

The NRC staff evaluated the sufficiency of the final design of SHINE's primary coolant cleanup system, as presented in SHINE FSAR section 5a2.5, "Primary Closed Loop Cooling System Cleanup Side Stream," in part, by reviewing the design basis, process functions, process flow, system specifications, cleanup loop control and instrumentation, cleanup loop components, and maintenance and coolant testing of the primary coolant cleanup system using the guidance and acceptance criteria from section 5.4, "Primary Coolant Cleanup System," of NUREG-1537, Parts 1 and 2, and section 5a2.4, "Primary Coolant Cleanup System," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Primary cooling for the TSV and related components is provided by the PCLS. A total of eight independent instances of PCLS are installed at the SHINE facility, one for each IU. Each PCLS contains a cleanup side stream. The primary closed loop cooling system cleanup side stream is connected to PCLS piping through which the PCLS diverts a portion of the cooling water flow. The components that perform the PCLS cooling water treatment are located within the PCLS cleanup side stream flow path.

The PCLS cleanup side stream maintains the required water quality limits of the PCLS. These quality limits are defined in SHINE FSAR table 5a2.2-1, "PCLS Operating Parameters."

The process functions of the PCLS cleanup side stream are to:

- Maintain water quality to reduce corrosion and scaling and
- Limit concentrations of particulate and dissolved contaminants that could be made radioactive by neutron irradiation to achieve as low as is reasonably achievable (ALARA) goals.

The PCLS cleanup side stream is an integral part (or side stream) of the PCLS and is not an independent system. The safety functions of the PCLS are addressed in section 5a.4.2.6 of this SER. The cleanup components are located on a side stream through which the PCLS diverts a portion of the cooling water flow. The system cleanup side stream connects with PCLS piping at the outlet of the PCLS heat exchanger and returns inventory back into the PCLS piping downstream of the PCLS flow control valves prior to entering the primary confinement. The system removes contaminates that could become activated and radioactive materials from the PCLS cooling water. The side stream includes conductivity instrumentation to monitor water quality, a deionizer bed to remove ionic species, and filters on the inlet and outlet of the deionizer bed to remove particulates from the cooling water.

As set forth in 10 CFR Part 20, facilities require a means for controlling and limiting radioactive effluents and radiation exposures within the regulatory limits. As an integral part of the PCLS, the location, shielding, and radiation monitoring of the water cleanup system are consistent with that of the PCLS. The PCLS cleanup side stream components are located outside the primary confinement and entirely within the primary cooling room associated with their respective IU cell. Each primary cooling room is located within the irradiation cell biological shield (ICBS). The ICBS area provides barrier and radiation monitoring to protect SHINE facility personnel, members of the public, and various components and equipment of the SHINE facility by reducing radiation exposure.

SHINE FSAR section 11.2.2.2.9, “Primary Closed Loop Cooling System,” provides discussion of radioactive concerns with the PCLS. The PCLS has the potential for radioactive contamination due to minor leakage from the primary systems and activation products. Contamination would collect on the PCLS cleanup side-stream filters and deionizer resins. PCLS filters could become contaminated with radionuclides due to activation of corrosion particles as the water passes through the TSV, however, corrosion of the stainless-steel components within the PCLS is expected to be minimal. PCLS deionizer resins are contained in disposable deionizer units. The tanks are designed for complete replacement without removal of the ion exchange resins in the tanks. The disposable tanks are Class A waste. Spent filters and deionizer units are disposed of as radioactive waste via the solid radioactive waste processing system.

The PCLS does not discharge radioactive liquid effluent from the facility; therefore, there are no liquid effluent monitors. Monitoring of closed loop process cooling water systems to detect cooling water leakage between primary and secondary circuits due to failures in heat exchangers and other system boundaries is provided.

5a.4.4.1 Primary Coolant Cleanup Conclusion

Based on its review, the NRC staff finds that the level of detail provided on the PCLS cleanup side stream system demonstrates an adequate description for the final design because (1) the application sufficiently defines system operation in accordance with 10 CFR 50.34(b)(2) and (2) the system has been designed in accordance with the requirements of 10 CFR Part 20 and with regard to the ALARA program guidelines. Therefore, the final design of the system is acceptable for the issuance of an operating license.

5a.4.5 Primary Coolant Makeup Water System

The NRC staff evaluated the sufficiency of the final design of SHINE’s primary coolant makeup water system, as presented in SHINE FSAR section 5a2.6, “Facility Demineralized Water System,” in part, by reviewing the design basis, process functions, process flow, design specifications, control and instrumentation, and components of the primary coolant makeup water system using the guidance and acceptance criteria from section 5.5, “Primary Coolant Makeup Water System,” of NUREG-1537, Parts 1 and 2, and section 5a2.5, “Primary Coolant Makeup Water System,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The FDWS provides makeup water to the PCLS, RPCS, FCHS, MEPS hot water loop subsystem, light water pool, and PCHS. The FDWS provides a water supply to the radiological ventilation zone 2 (RVZ2) system and the facility ventilation zone 4 (FVZ4) system for humidity control. The quality control and analytical testing laboratories and the facility chemical reagent system (FCRS) are supplied demineralized water from the FDWS.

The FDWS is not safety related and not credited with preventing or mitigating any design-basis events. The FDWS consists of a reverse osmosis (RO) skid located outside of the RCA. On loss of normal power, the FDWS pumps will not be operational, which is acceptable because the FDWS is not relied on to provide water inventory in the loss of normal power condition.

The main function of the non-safety FDWS is to provide makeup of cooling water loss in the PCLS and light water pool that occurs gradually from radiolysis and evaporation. Water loss in the PCLS, RPCS, FCHS, MEPS hot water subsystem, and PCHS may also occur from off-normal events such as leaks or for maintenance. The FDWS supplies RO and deionized water for plant systems requiring RO-processed water, and through deionizers to other systems requiring deionized water. The FDWS deionizer units house deionization resins for the removal of contaminants and the reduction of water conductivity.

The FDWS consists of two recirculation loops (i.e., one inside the RCA and one outside the RCA) with an RO storage tank and two 100-percent capacity pumps for each recirculation loop. A portion of the RO water is supplied to systems outside the RCA with the balance supplied to the RO storage tank located inside the RCA. Redundant pumps circulate water from the respective RO storage tank to various systems within each loop. Each loop requires one of the two pumps to support normal operation. Recirculated water is supplied directly to systems requiring RO-processed water or processed through deionizers to meet the system criteria.

The FDWS RO loop outside the RCA is supplied water from the facility potable water system (FPWS) and stored in a tank located outside the RCA to maintain adequate system supply volume. The RO loop and tank outside the RCA are located downstream of a backflow prevention device that acts as the system boundary between the FPWS and the FDWS. The RO loop outside the RCA provides inventory to a second tank located inside the RCA. A second backflow prevention device is provided at the boundary where the FDWS enters the RCA. For additional protection, backflow prevention devices are also installed at the system boundaries of the systems served by the FDWS. The PCLS, RPCS, LWPS, and MEPS piping includes backflow prevention components at the interface with the FDWS, which prevents potentially contaminated cooling water from coming into contact with the makeup water.

Flow from the RO loop is controlled by level instrumentation in the RO storage tank. Tank level is provided with high- and low-level alarms. As indicated in SHINE FSAR table 5a2.6-2, “FDWS Components,” instrumentation is provided for FDWS operating parameters (pressure, temperature, conductivity, flow, and level). Sampling and trending of the system is performed to detect malfunctions in the deionizer units and the RO skid.

To address flooding concerns within the facility, berms and ramps are used to prevent a release of water from the RCA due to the postulated failure of the RPCS room, the PCHS, or the FDWS.

5a.4.5.1 Primary Coolant Makeup Water System Conclusion

The FDWS includes all components and piping associated with the system from the potable water source to the points of discharge to other systems. The system is classified as not safety-related, is not credited with preventing or mitigating any design-basis events, and is isolated from any radiological process. Therefore, the NRC staff finds that the final design of the FDWS, as described in SHINE FSAR section 5a2.5, is acceptable for the issuance of an operating license.

5a.4.6 Nitrogen-16 Control

The NRC staff evaluated the sufficiency of the final design of SHINE’s N-16 control, as presented in SHINE FSAR section 5a2.7, “Nitrogen-16 Control,” using the guidance and acceptance criteria from section 5a2.6, “Nitrogen-16 Control System,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 5a2.7 describes the methods to control N-16, which is generated in the PCLS and the light water pool by neutron activation of oxygen. The SHINE FSAR describes the function of a delay tank to allow for radioactive decay of N-16 prior to exiting the shielded area. It also describes the use of an air separator to remove entrained gases, which includes N-16, from the PCLS water and to direct the N-16 into the headspace of the PCLS expansion tank as shown in SHINE FSAR figure 5a2.2-1, “Primary Closed Loop Cooling System Flow Diagram.” The PCLS headspace is vented to the radiological ventilation zone 1 exhaust.

5a.4.6.1 Nitrogen-16 Control Conclusion

The NRC staff reviewed the description of the N-16 control method in the SHINE FSAR and finds that the final design of the delay tank and the venting of the PCLS expansion tank provides additional time for the decay of the relatively short-lived N-16 (7.1 seconds), which, along with the applicant’s radiation protection program and ALARA program discussed in Chapter 11 of this SER, are effective to help limit personnel exposures from N-16 to below the radiation exposure limits in 10 CFR Part 20. Therefore, the staff concludes that there is reasonable assurance that the facility will function in such a way as to maintain radiation exposure from N-16 below the limits in 10 CFR Part 20 to facility staff and the public and as such the final design of the system is acceptable for the issuance of an operating license.

5a.4.7 Auxiliary Systems Using Primary Coolant

The NRC staff evaluated the sufficiency of the final design of SHINE’s auxiliary systems using primary coolant, as presented in SHINE FSAR section 5a2.8, “Auxiliary Systems Using Primary Coolant,” using the guidance and acceptance criteria from section 5a2.7, “Auxiliary Systems Using Primary Coolant,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 5a2.8 states that the SHINE facility auxiliary systems do not utilize the PCLS for cooling. The NRC staff reviewed SHINE FSAR figure 5a2.2-1 and the PCLS design bases and functional requirements, as described in SHINE FSAR section 5a2.2.1, “Design Bases and Functional Requirements,” and finds that the PCLS directly cools the TSV and neutron multiplier. Additionally, the staff finds that the PCLS does not provide any additional direct cooling functions for any auxiliary systems in the SHINE facility.

5a.4.7.1 Auxiliary Systems Using Primary Coolant Conclusion

Since the PCLS does not cool any auxiliary systems in the SHINE facility, the NRC staff concludes that the PCLS functional cooling requirements to remove the heat from the TSV and neutron multiplier are not impacted and, therefore, are acceptable for the issuance of an operating license.

5a.4.8 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant’s proposed technical specifications (TSs) for the SHINE cooling systems as described in SHINE FSAR Chapter 5.

The proposed TS 2.2, “Limiting Safety System Settings (LSSS),” Table 2.2, “Limiting Safety System Settings,” states, in part, the following:

LSSS	Variable	Setpoint	Applicability
LSSS 2.2.7	Low PCLS flow	[[PROP /ECI]]; IU Cell Safety Actuation delayed by ≤ 180 seconds	Modes 1 and 2
LSSS 2.2.8	High PCLS temperature	≤ 72.9°F; IU Cell Safety Actuation delayed by ≤ 180 seconds	Modes 1 and 2

The LSSS 2.2.7 and LSSS 2.2.8 setpoints prevent overheating of the target solution, which could lead to boiling and pressurization of the TSV and could subsequently challenge the PSB pressure safety limit. Thermal-hydraulic analysis used to obtain the values of the setpoints was based on assuming the lowest allowable PCLS flow rate and the maximum PCLS cooling water temperature of 77°F (25°C), as described in section 4a2.7, “Thermal Hydraulic Design,” of the SHINE FSAR. The NRC staff evaluation is provided in section 5a.4.2.1 of this SER. The staff finds that the LSSS 2.2.7 and LSSS 2.2.8 setpoint values are bounded by the calculated low PCLS flow and high PCLS temperature values. The LSSSs are protected by the TRPS IU Cell Safety Actuation setpoints. The time delay prior to an IU Cell Safety Actuation is based on the acceptability of a complete loss of cooling without neutron driver operation for up to 3 minutes (180 seconds) prior to transferring target solution to the TSV dump tank. Because the proposed low PCLS flow and high PCLS temperature setpoints and the safety actuation time delay are based on the analytical limits calculated using thermal-hydraulic analysis assuming the lowest allowable PCLS flow rate and the highest PCLS temperature, the staff finds LSSS 2.2.7 and LSSS 2.2.8 acceptable.

The proposed TS 4.2, “Coolant Systems,” Design Feature (DF) 4.2.1 states the following:

DF 4.2.1	1. Each subcritical assembly system is submerged in an individual light waterpool. 2. Each light water pool is provided a seismically qualified stainless steel liner. 3. Piping penetrations into the stainless steel liner are located above the minimum acceptable light water pool water level for decay heat removal, ora specific evaluation is performed to determine the potential for loss of poolwater through the penetration. Piping penetrations into the light water pool with the potential for siphoning below the minimum acceptable water level contain anti-siphon devices or other means to prevent inadvertent loss of pool water. 4. Each light water pool is designed to maintain temperatures ≥ 50°F and ≤ 95°F.

The design features of the light water pool include that a subcritical assembly is submerged in the pool, which provides cooling to the TSV and TSV dump tank as described in section 4a2.4.2, “Light Water Pool,” of the SHINE FSAR. The design features of the pool were the basis for the thermal-hydraulic calculations demonstrating that adequate cooling is provided to the TSV and TSV dump tank during all anticipated operating and shutdown conditions, as discussed in section 5a.4.2.1 of this SER and, therefore, are acceptable. Furthermore, each light water pool is designed with a seismically qualified stainless-steel liner, which provides reasonable assurance that adequate cooling water is provided during normal operation, as well as during a design basis earthquake and design-basis accident events. Therefore, the NRC staff finds DF 4.2.1 acceptable.

5a.5 Review Findings

As described in SHINE FSAR sections 5a2.3 and 5b, the RPCS serves as a secondary cooling system for the IUs and provides cooling to the RPF. The review findings provided below apply to both the IF and RPF.

The NRC staff reviewed the descriptions and discussions of SHINE’s cooling systems, as described in SHINE FSAR sections 5a2 and 5b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the facility cooling systems and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE’s cooling systems are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

5b Radioisotope Production Facility Cooling Systems

Section 5b, “Radioisotope Production Facility Cooling Systems,” of this SER provides an evaluation of the final design of SHINE’s RPF cooling systems, as presented in SHINE FSAR section 5b, “Radioisotope Production Facility Cooling Systems.”

5b.1 Areas of Review

SHINE FSAR section 5a2.3 describes the RPCS, which serves as a secondary cooling system for the IUs in the IF and provides cooling to the RPF. Therefore, the areas of review related to the RPCS presented in section 5a.1, “Areas of Review,” of this SER are applicable to both the SHINE IF and RPF.

5b.2 Summary of Application

As stated above and described in SHINE FSAR sections 5a2.3 and 5b, the RPCS serves as a secondary cooling system for the IUs in the IF and provides cooling to the RPF. Therefore, the summary provided in section 5a.2, “Summary of Application,” of this SER applies to both the SHINE IF and RPF.

5b.3 Regulatory Requirements and Guidance and Acceptance Criteria

As described in SHINE FSAR section 5a2.3, the RPCS serves as a secondary cooling system for the IUs in the IF and provides cooling to the RPF. Therefore, the regulatory requirements and guidance and acceptance criteria provided in section 5a.3, “Regulatory Requirements and Guidance and Acceptance Criteria,” of this SER apply to both the SHINE IF and RPF.

5b.4 Review Procedures, Technical Evaluation, and Evaluation Findings

As described in SHINE FSAR section 5a2.3, the RPCS serves as a secondary cooling system for the IUs in the IF and provides cooling to the RPF; therefore, the review procedures, technical evaluation, and evaluation findings provided in section 5a.4, “Review Procedures, Technical Evaluation, and Evaluation Findings,” of this SER apply to both the SHINE IF and RPF.

5b.5 Review Findings

As described in SHINE FSAR section 5a2.3, the RPCS serves as a secondary cooling system for the IUs in the IF and provides cooling to the RPF; therefore, the review findings provided in section 5a.5, “Review Findings,” of this SER apply to both the SHINE IF and RPF.

6.0 ENGINEERED SAFETY FEATURES

Engineered safety features (ESFs) are active or passive features designed to mitigate the consequences of accidents and to keep radiological exposures to the public, the facility staff, and the environment within acceptable values at the SHINE Medical Technologies, LLC (SHINE, the applicant) irradiation facility (IF) and radioisotope production facility (RPF) (together, the SHINE facility). The concept of ESFs evolved from the defense-in-depth philosophy of multiple layers of design features to prevent or mitigate the release of radioactive materials to the environment during accident conditions. The need for ESFs is determined by SHINE's accident analysis.

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE IF and RPF ESFs as presented in chapter 6, "Engineered Safety Features," of the SHINE Final Safety Analysis Report (FSAR) and supplemented by the applicant's responses to staff requests for additional information (RAIs).

6a Irradiation Facility Engineered Safety Features

Section 6a, "Irradiation Facility Engineered Safety Features," in this SER provides an evaluation of the final design of SHINE's IF ESFs as presented in SHINE FSAR section 6a2, "Irradiation Facility Engineered Safety Features," within which the applicant described the features designed to mitigate the consequences of accidents and events in order to keep radiological exposures within acceptable values.

6a.1 <u>Areas of Review</u>

The NRC staff reviewed SHINE FSAR section 6a2 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE IF ESFs. The final design bases of the SHINE IF ESFs were evaluated to ensure that the design bases and functions of the structures, systems, and components (SSCs) are presented in sufficient detail to allow a clear understanding of the facility and to ensure that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the facility staff and the public. Drawings and diagrams were evaluated to determine if they present a clear and general understanding of the physical facility features and of the processes involved. In addition, the staff evaluated the sufficiency of SHINE's proposed technical specifications for the facility.

Areas of review for this section include a summary description of the SHINE IF ESFs, as well as a detailed description of IF confinement. Within these review areas, the NRC staff assessed, in part, the final design bases and functional descriptions of the required mitigative features of the confinement ESFs; drawings, schematic drawings and tables of important design and operating parameters, and specifications for confinement ESFs; necessary ESF equipment included as part of the confinement fabrication specifications; description of control and safety instrumentation, including locations and functions of sensors, readout devices, monitors, and isolation components, as applicable; and the required limitations on the release of confined effluents to the environment.

The ESFs described in SHINE FSAR section 6a2 are achieved through a combination of passive and active features of many SSCs. Detailed descriptions of many of the SSCs are in their applicable portions of the FSAR and referenced in this SER.

6a.2 Summary of Application

SHINE FSAR section 6a2 includes a summary of the ESFs installed in the SHINE IF, including references to SHINE FSAR tables and sections that address accidents considered in the facility's design. Additionally, SHINE FSAR table 6a2.1-1, "Summary of Engineered Safety Features and Design Basis Accidents Mitigated," contains a summary of the ESFs and the IF design basis accidents (DBAs) that they are designed to mitigate.

6a.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR section 6a2 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE IF ESFs for the issuance of an operating license.

6a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE IF ESFs are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CR 50.57, "Issuance of operating license."
- 10 CFR Part 20, "Standards for Protection Against Radiation."

6a.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

In addition, the following SHINE design criteria in SHINE FSAR chapter 3, “Design of Structures, Systems, and Components,” are applicable to the confinement part of the ESFs:

Criterion 29 - Confinement design

> Confinement boundaries are provided to establish a low-leakage barrier against the uncontrolled release of radioactivity to the environment and to assure that confinement design leakage rates are not exceeded for as long as postulated accident conditions require. Four classes of confinement boundaries are established:
>
> 1) the primary confinement boundary,
> 2) the process confinement boundary,
> 3) hot cells and gloveboxes, and
> 4) radiologically-controlled area ventilation isolations.

Criterion 32 - Provisions for confinement testing and inspection

> Each confinement boundary is designed to permit:
>
> 1) appropriate periodic inspection of important areas, such as penetrations;

2) an appropriate surveillance program; and

3) periodic testing of confinement leakage rates.

Criterion 33 - Piping systems penetrating confinement

Piping systems penetrating confinement boundaries that have the potential for excessive leakage are provided with isolation capabilities appropriate to the potential for excessive leakage.

Piping systems that pass between confinement boundaries are equipped with either:

1) a locked closed manual isolation valve, or

2) an automatic isolation valve that takes the position that provides greater safety upon loss of actuating power.

Manual isolation valves are maintained locked-shut for any conditions requiring confinement boundary integrity.

Criterion 34 - Confinement isolation

Lines from outside confinement that penetrate the primary confinement boundary and are connected directly to the primary system boundary are provided with redundant isolation capabilities.

Ventilation, monitoring, and other systems that penetrate the primary, process, glovebox or hot cell confinement boundaries, are connected directly to the confinement atmosphere and are not normally locked closed, have redundant isolation capabilities or are otherwise directed to structures, systems, and components capable of handling any leakage.

Isolation valves outside confinement boundaries are located as close to the confinement as practical and upon loss of actuating power, automatic isolation valves are designed to take the position that provides greater safety. Manual isolation valves are maintained locked-shut for any conditions requiring confinement boundary integrity.

All electrical connections from equipment external to the confinement boundaries are sealed to minimize air leakage.

Criterion 35 - Control of releases of radioactive materials to the environment

The facility is designed to include means to suitably control the release of radioactive materials in gaseous and liquid effluents and to handle radioactive solid wastes produced during normal operation, including anticipated transients. Sufficient holdup capacity is provided for retention of radioactive gases.

Criterion 39 - Hydrogen mitigation

> Systems to control the buildup of hydrogen that is released into the primary system boundary and tanks or other volumes that contain fission products and produce significant quantities of hydrogen are provided to ensure that the integrity of the system and confinement boundaries are maintained.

6a.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR section 6a2, as supplemented, to assess the sufficiency of the final design and performance of the SHINE IF ESFs for the issuance of an operating license. The sufficiency of the final design and performance is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 6a.3, “Regulatory Requirements and Guidance and Acceptance Criteria,” of this SER. The findings of the staff review are described in section 6a.5, “Review Findings,” of this SER.

6a.4.1 Summary Description

The NRC staff evaluated the sufficiency of the summary description of the SHINE IF ESFs, as presented in SHINE FSAR section 6a2.1, “Summary Description,” using the guidance and acceptance criteria from section 6.1, “Summary Description,” of NUREG-1537, Part 2, and section 6a2.1, “Summary Description,” of the ISG augmenting NUREG-1537, Part 2.

SHINE FSAR table 6a2.1-1 contains a summary of ESFs and the IF DBAs that they are designed to mitigate. The credited ESFs are primary confinement boundary, tritium confinement boundary, and combustible gas management.

SHINE FSAR figure 6a.2.1-1, “Irradiation Facility Engineered Safety Features Block Diagram,” provides a block diagram for the SHINE IF ESFs that shows the location and basic function of the SSCs providing ESFs in the IF portion of the SHINE facility. The diagram indicates the passive components for which credit is taken for the three ESFs (i.e., primary confinement boundary, tritium confinement boundary, and combustible gas management). The diagram also indicates the active components in the three ESFs that respond to confinement isolation signals from the engineered safety features actuation system (ESFAS) and the target solution vessel (TSV) reactivity protection system (TRPS). The active components that respond to TRPS and ESFAS are listed in SHINE FSAR chapter 7, “Instrumentation and Control Systems,” section 7.4, “Target Solution Vessel Reactivity Protection System,” and section 7.5, “Engineered Safety Features Actuation System,” respectively.

Based on its review, the NRC staff finds that the SHINE IF ESFs are adequately described in SHINE FSAR section 6a2.1; therefore, the staff finds that the summary description of the SHINE IF ESFs meets the acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, for the issuance of an operating license.

6a.4.2 Confinement

The NRC staff evaluated the sufficiency of the final design of the SHINE confinement and related systems, as presented in SHINE FSAR section 6a.2.2.1, “Confinement,” using the guidance and acceptance criteria from section 6.2.1, "Confinement," of NUREG-1537, Parts 1 and 2, and section 6a2.2.1, "Confinement," of the ISG augmenting NUREG-1537, Part 2. The staff reviewed confinement mitigation requirements, the defined confinement envelope, and detailed descriptions of the ESFs associated with confinement. Additionally, the staff evaluated the passive and active ESF components, under normal and upset operational conditions. The functional requirements, design bases, proposed technical specifications, and testing requirements were also evaluated for sufficiency.

Primary Confinement Boundary

The primary confinement boundary contains the primary system boundary that contains the fission products. The primary confinement boundary is primarily passive and consists predominantly of the irradiation unit (IU) cell, the TSV off-gas system (TOGS) shielded cell, and a cell enclosing the two heating, ventilation, and air conditioning (HVAC) units serving the IU and TOGS cells. The boundary of each IU is independent from the other IUs. The IU cell portion of the primary confinement boundary contains the TSV, TSV dump tank, portions of the TOGS, portions of the primary closed loop cooling system (PCLS), associated primary system boundary (PSB) piping, the light water pool, and the neutron driver. The primary confinement boundary is operated within a normally-closed atmosphere except through the PCLS expansion tank. The PCLS expansion tank connection to the radiological ventilation zone 1 (RVZ1) exhaust subsystem (RVZ1e) provides a vent path for radiolysis gases produced in the PCLS and light water pool, to avoid the buildup of hydrogen gas. The connection to RVZ1e is equipped with redundant dampers or valves that close on a confinement actuation signal, isolating the cells from RVZ1. SHINE FSAR section 9a2, "Irradiation Facility Auxiliary Systems," subsection 9a2.1.1.2, "System Description," provides a detailed description of RVZ1 including the associated exhaust system RVZ1e.

Each piping system capable of excessive leakage that penetrates the primary confinement boundary, as indicated in SHINE FSAR figure 6a2.2-1, "Primary Confinement Boundary," is equipped with one or more isolation valves that serve as active confinement components, except for the nitrogen purge system (N2PS) supply and process vessel vent system (PVVS) connections, which may remain open to provide combustible gas mitigation. Actuation of the isolation valves is controlled by the TRPS.

SHINE FSAR section 7.4.3.1, "Safety Functions," provides a listing of TRPS monitored variables that can cause the initiation of an IU Cell Safety Actuation. Following an actuation, PSB and primary confinement boundary isolation valves transition to their deenergized states, closing valves to safely isolate the corresponding system.

Tritium Confinement Boundary

Portions of the tritium purification system (TPS) serve as the tritium confinement boundary as indicated in the functional block diagram in SHINE FSAR figure 6a2.2-2, "Tritium Confinement Boundary."

Tritium in the SHINE IF is confined using active and passive features of the TPS. The TPS gloveboxes and secondary enclosure cleanup subsystems are credited as passive confinement barriers. The TPS gloveboxes enclose TPS process equipment, thus allowing credit as a passive confinement barrier. TPS gloveboxes are maintained at negative pressure relative to the TPS room and have a helium atmosphere. The TPS gloveboxes provide confinement in the event of a breach in the TPS process equipment that results in a release of tritium from the isotope separation process equipment.

The TPS gloveboxes include isolation valves on the helium supply, the glovebox pressure control exhaust, and the vacuum/impurity treatment subsystem process vents.

The TPS has isolation valves on the process connections to the neutron driver assembly system (NDAS) target chamber supply and exhaust lines. The TPS-NDAS interface lines themselves are part of the credited tritium confinement boundary up to the interface with the primary confinement boundary.

When the isolation valves for a process line or glovebox close, the spread of radioactive material is limited to the glovebox plus the small amount in the lines between the glovebox and its isolation valves. The liquid nitrogen supply and exhaust lines and the gaseous nitrogen pneumatic lines for the TPS equipment are credited to remain intact during a DBA and the internal interface between the gloveboxes and nitrogen lines serves as a passive section of the tritium confinement boundary.

Upon detection of TPS exhaust to facility stack high tritium concentration or TPS glovebox high tritium concentration, the ESFAS automatically initiates a TPS isolation. Upon TPS isolation initiation, required active components maintaining confinement are transitioned to their deenergized (safe) state. A description of the ESFAS and a complete listing of the active components that transition to a safe state upon a TPS isolation are provided in SHINE FSAR section 7.5. The evaluated DBAs for which the tritium confinement boundary is necessary are listed in SHINE FSAR table 6a2.1-1 and further discussed in SHINE FSAR chapter 13a2, “Irradiation Facility Accident Analysis.” SHINE FSAR section 9a2.7.1, “Tritium Purification System,” contains a detailed description of tritium purification and the interfaces that function for tritium confinement.

Combustible Gas Management

Hydrogen gas is produced by radiolysis in the target solution during and after irradiation. During normal operation, the concentration of hydrogen gas is monitored and maintained below the lower flammability limit (LFL) using the TOGS. If the TOGS becomes unavailable, the buildup of hydrogen gas is limited using the combustible gas management system, which uses the N2PS, PSB piping, and portions of the PVVS to establish an inert gas flow through the IUs. The objective of the combustible gas management system is to prevent conditions that could lead to a hydrogen deflagration within the PSB.

The N2PS provides back-up nitrogen sweep gas to each IU upon a loss of power or loss of normal sweep gas flow to maintain hydrogen concentrations in these systems below acceptable values. The combustible gas management system is depicted in SHINE FSAR figure 6a2.2-3, “Irradiation Facility Combustible Gas Management Functional Block Diagram.” Detailed descriptions of the PVVS and the N2PS are provided in SHINE FSAR section 9b.6.1, “Process Vessel Vent System,” and section 9b.6.2, “Nitrogen Purge System,” respectively.

On a loss of power or receipt of an appropriate TRPS or ESFAS actuation signal, solenoid-operated isolation valves on the nitrogen discharge manifold open and supply nitrogen to the IU cell supply header. The nitrogen is supplied to each TSV dump tank and flows through the TSV dump tank, the TSV, and the TOGS equipment and piping, and is then directed to the PVVS guard beds, delay beds, and high-efficiency particulate air (HEPA) filter before being discharged to the environment via a safety-related vent path.

The complete listing of variables within the TRPS that can cause the initiation of an IU Cell Nitrogen Purge is provided in SHINE FSAR section 7.4.3.1." These variables indicate a loss of flow or ability to recombine hydrogen by the TOGS. Upon initiation of an IU Cell Nitrogen Purge, active components required to function to establish and maintain the N2PS flow path are transitioned to their deenergized state by the TRPS and the ESFAS. Descriptions of the TRPS and the ESFAS are provided in SHINE FSAR sections 7.4 and 7.5, respectively.

Failure of the TOGS to manage the combustible gases generated by the subcritical assembly can potentially result in a deflagration within the PSB. Hydrogen deflagration within the PSB is an initiating event and DBA analyzed in SHINE FSAR chapter 13a2. The evaluated DBAs for which the combustible gas management system is necessary are listed in SHINE FSAR table 6a2.1-1 and further discussed in SHINE FSAR chapter 13a2.

<u>Dose Consequences</u>

SHINE FSAR table 6a2.1-2, "Comparison of Unmitigated and Mitigated Radiological Doses for Select Irradiation Facility DBAs," provides unmitigated and mitigated doses for select DBAs in the SHINE IF. The maximum mitigated doses in SHINE FSAR table 6a2.1-2 are 0.8 rem total effective dose equivalent (TEDE) to the public and 1.9 rem TEDE to the worker. In SHINE FSAR section 13a2.2, "Accident Analysis and Determination of Consequences," the applicant proposed the following accident dose criteria:

- Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 1 rem TEDE for the duration of the accident; and

- Radiological consequences to workers do not exceed 5 rem TEDE during the accident.

The NRC staff finds these dose criteria to be acceptable in section 13a.4.1, "Radiological and Design Criterion," of this SER. The dose consequences, in some cases, would be unacceptable with respect to these criteria without mitigation by ESFs. As described in SHINE FSAR chapter 13a2, specific postulated accident scenarios indicate the need for the confinement ESFs.

Based on its review, the NRC staff finds that there is reasonable assurance that the confinement ESFs are designed to ensure that the radiological consequences to a member of the public and a worker would remain below 1 rem and 5 rem, respectively, and, therefore, that the confinement ESFs are acceptable with respect to dose consequences.

<u>Design Criteria</u>

Section 6b.4.2, "Confinement," of this SER describes the NRC staff's evaluation of the design criteria as it applies to both the SHINE IF and RPF.

Conclusion

Based on the evaluation of the SHINE IF ESFs, the NRC staff concludes that the final design of the SHINE IF ESFs, including the principal design criteria, design bases, and information relative to confinement, satisfies the relevant acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds the final design of the SHINE IF ESFs acceptable.

6a.4.3 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed technical specifications (TSs) for the SHINE IF ESFs as described in SHINE FSAR section 6a2.

The proposed TS 3.4, "Confinement," Limiting Condition For Operation (LCO) 3.4.1 and surveillance requirement (SR) 3.4.1 state the following:

LCO 3.4.1	Each primary Confinement boundary or PSB isolation valve listed in Table 3.4.1-a shall be Operable. A valve is considered Operable if: 1. The valve is capable of opening or closing on demand from TRPS Note – A single isolation valve in a flow path may be inoperable for up to 2 hours during the performance of required surveillances. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3, or 4
Action	According to Table 3.4.1
SR 3.4.1	1. Valves and dampers listed in Table 3.4.1-a shall be verified to stroke upon demand from TRPS annually.

The proposed TS Table 3.4.1, "Confinement Boundary and Isolation Actions," states the following:

	Condition and Action (per IU)	Completion Time
1.	If one or more isolation valve(s) in one or more flow path(s) is inoperable, Close at least one valve in the affected flow path OR Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 6 hours 6 hours [[PROP/ECI]]

2.	If one or more isolation valve(s) in one or more flow path(s) is inoperable, Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 6 hours [[PROP/ECI]]

LCO 3.4.1 specifies that each confinement boundary and PSB isolation valve in TS table 3.4.1-a, “Isolation Valves,” shall be operable from TRPS in IU Modes 1, 2, 3, and 4 and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure that the TRPS automatically isolates the confinement system and PSB to prevent the inadvertent release of radioactive material. The staff also finds that if the valves listed in table 3.4.1-a are inoperable, then their flow path is isolated by closing at least one valve or the target solution would be transferred to the TSV dump tank and then to the RPF. The staff finds that for systems that do not have an option to close one valve in the flow path, the target solution would be transferred to the TSV dump tank and then to the RPF. The staff finds that the completion time allows for investigation and the performance of minor repairs and is based on the continued availability of the redundant isolation valve or redundant check valve in the flow path. Therefore, the staff finds LCO 3.4.1 acceptable.

SR 3.4.1 requires that the valves in TS table 3.4.1-a be verified to stroke upon demand from TRPS annually. Section 4.4.2, “Confinement,” of ANSI/ANS-15.1-2007, “The Development of Technical Specifications for Research Reactors,” states, in part, that a functional test should be performed. NUREG-1431, Revision 5.0, “Standard Technical Specifications: Westinghouse Plants,” Volume 1, “Specifications” (Agencywide Documents Access and Management System Accession No. ML21259A155), SR 3.6.3.8 states, in part, that a test to verify that automatic containment isolation valves actuate to the isolation position on an actual or simulated signal be performed every 18 months. As described in chapter 14, “Technical Specifications,” of this SER, the NRC staff used guidance in NUREG-1431 to review SHINE’s proposed TSs. Based on the foregoing, the staff finds that the stroke test of SR 3.4.1 is an appropriate functional test and that its frequency is adequate to confirm the operability of the confinement boundary or PSB. Therefore, the staff finds SR 3.4.1 acceptable.

The proposed TS 3.4, LCO 3.4.2 and SR 3.4.2 state the following:

LCO 3.4.2	The Confinement check valves listed in Table 3.4.2-a shall be Operable. Note – This LCO is applied to each IU or TPS train independently; actions are only applicable to the IU(s) or TPS train(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3, or 4, according to Table 3.4.2-a
Action	According to Table 3.4.2
SR 3.4.2	1. The check valves listed in Table 3.4.2-a shall be inspected annually.

The proposed TS Table 3.4.2, “Confinement Check Valve Actions,” states the following:

	Condition and Action (per IU or per TPS train)	Completion Time
1.	If the check valve is inoperable, Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 6 hours [[PROP/ECI]]
2.	If the check valve is inoperable, Place the associated IU in Mode 3 AND Close the PCLS supply isolation valve.	 6 hours 6 hours
3.	If the check valve is inoperable, Close the TPS isolation valve in the affected flow path.	 6 hours

LCO 3.4.2 specifies that each confinement check valve in TS table 3.4.2-a, “Confinement Check Valves,” shall be operable in IU Modes 1, 2, 3, and 4, with tritium not in storage for the TPS, and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure redundant isolation of the confinement system to prevent the inadvertent release of radioactive material. The staff also finds that if the TOGS radioisotope process facility cooling system (RPCS), subcritical assembly system (SCAS) nitrogen purge, and PCLS supply check valves are inoperable, the target solution would be transferred to the TSV dump tank and to the RPF, if required. For the PCLS and TPS check valves, the staff finds that the flow path for the system is also isolated. For the PCLS and TPS check valves, the staff finds that the completion time allows for investigation and the performance of minor repairs and is based on the continued availability of the redundant isolation valve in the flow path. For the TOGS RPCS and SCAS nitrogen purge check valves, the staff finds that the completion time is based on the orderly shutdown of the IU and continued availability of redundant components. Therefore, the staff finds LCO 3.4.2 acceptable.

SR 3.4.2 requires that the valves in TS table 3.4.2-a be inspected annually. The NRC staff finds that this surveillance and frequency would ensure that the check valves maintain operability to isolate the system to prevent the inadvertent release of radioactive material from the system. Therefore, the staff finds SR 3.4.2 acceptable.

The proposed TS 3.4, LCO 3.4.5 and SR 3.4.5 state the following:

LCO 3.4.5	Primary Confinement boundary shield plugs shall be Operable. Primary Confinement boundary shield plugs are Operable if: The shield plug sealing surfaces have a proven satisfactory leak rate. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3, or 4
Action	According to Table 3.4.5
SR 3.4.5	1. IU cell primary Confinement boundary shall be verified to be Operable by measuring leak rate past shield plug sealing surfaces upon each reinstallation of the IU cell confinement boundary shield plug or inspection port. The IU cell shield plug leak rate must be less than 2.10E+06 standard cubic centimeters per minute (sccm) at ≥ 3.9 psi. 2. TOGS cell primary Confinement boundary shall be verified to be Operable by measuring leak rate past shield plug sealing surfaces upon each reinstallation of the TOGS cell confinement boundary shield plug or inspection port. TOGS cell shield plug leak rate must be less than 1.16E+05 sccm at ≥ 3.9 psi.

The proposed TS Table 3.4.5, “Primary Confinement Boundary Shield Plug Actions,” states the following:

	Action (per IU)	Completion Time
1.	If a primary Confinement boundary shield plug is not Operable Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 Immediately [[PROP/ECI]]

LCO 3.4.5 specifies that each primary confinement boundary shield plug shall be operable by the sealing surfaces having a proven satisfactory leak rate for IU Modes 1, 2, 3, and 4 and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure that the primary confinement boundary is maintained after maintenance activities that result in the reinstallation of the shield plugs in the IU and TOGS primary confinement boundary. The staff also finds that if the shield plugs are inoperable, the target solution would be transferred to the TSV dump tank immediately and then to the RPF. The staff finds that the completion time to drain the TSV to the TSV dump tanks immediately secures operations to limit the generation of radioactive material available for potential release during a DBA. Therefore, the staff finds LCO 3.4.5 acceptable.

SR 3.4.5 requires that each IU and TOGS shield plug sealing surface leak rate be measured after reinstallation of the shield plug or inspection port. Section 4.4.1, “Containment,” of

ANSI/ANS-15.1-2007 states that a leak-tightness test should be performed following modifications or repair. The NRC staff finds that this frequency to perform a leak-tightness test of the shield plug or inspection port after reinstallation is in accordance with ANSI/ANS-15.1-2007. In response to NRC staff RAI 13-16 (ML21214A266 Enclousre 2 ML21243A269), SHINE stated that the analytical leak rate out of the IU cell is 6E+04 standard cubic centimeters per minute (sccm) at 0.5 kilopascal (kPa) (0.072 pounds per square inch (psi)) and out of the TOGS cell is 4E+04 sccm at 6 kPa (0.87 psi). Because the leak rates in SR 3.4.5 provide margin to the analytical leak rates, the staff finds these leak rates acceptable. Therefore, the staff finds SR 3.4.5 acceptable.

The proposed TS 5.5.5, “Maintenance of Safety-Related SSCs,” states, in part, the following:

> The SHINE maintenance program, which includes inspection, testing, and maintenance, ensures that the safety-related SSCs are available and reliable when needed. The maintenance program includes corrective maintenance, preventative maintenance, surveillance and monitoring, and testing. The maintenance program includes the following activities to ensure that safety-related SSCs can perform their functions as required by the accident analysis:
>
> 1. Inspection and maintenance of Confinement boundaries; ….

TS 5.5.5 specifies that SHINE’s maintenance program ensures that safety-related SSCs, such as the confinement boundaries, are available and reliable to perform their safety function during a postulated accident. The NRC staff finds that this TS is an administrative control to implement a maintenance program that would help ensure that the confinement boundaries are reliable and available to perform their safety function. Therefore, the staff finds TS 5.5.5 acceptable.

6a.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE IF ESFs, as described in SHINE FSAR section 6a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the IF ESFs and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE IF ESFs are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

6b Radioisotope Production Facility Engineered Safety Features

Section 6b, "Radioisotope Production Facility Engineered Safety Features," of this SER provides an evaluation of the final design of SHINE's RPF ESFs as presented in SHINE FSAR section 6b, "Radioisotope Production Facility Engineered Safety Features," within which the applicant described the RPF ESFs and nuclear criticality control.

6b.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 6b against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE RPF ESFs. The final design bases of the SHINE RPF ESFs were evaluated to ensure that the design bases and functions of the SSCs are presented in sufficient detail to allow a clear understanding of the facility and to ensure that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the facility staff and the public. In addition, the staff evaluated the sufficiency of SHINE's proposed TSs for the facility.

Areas of review for this section include a summary description of the SHINE RPF ESFs, as well as a detailed description of RPF confinement and nuclear criticality safety analysis. Within these review areas, the NRC staff assessed, in part, the confinement system and components, functional requirements of confinement, management of the nuclear criticality safety program, planned responses to criticality accidents, criticality safety controls, nuclear criticality safety evaluations, and the criticality accident alarm system (CAAS).

The ESFs described in SHINE FSAR section 6b are achieved through a combination of passive and active features of many SSCs. Detailed descriptions of many of the SSCs are in their applicable portions of the FSAR and referenced in this SER.

6b.2 Summary of Application

SHINE FSAR section 6b.1, "Summary Description," describes the SSCs that constitute the confinement ESFs in the RPF final design and summarizes the postulated accidents whose consequences could be unacceptable without mitigation. As described in greater detail in SHINE FSAR chapter 13b, "Radioisotope Production Facility Accident Analyses," specific postulated accident scenarios indicate the need for the RPF confinement ESFs.

6b.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR section 6b against the applicable regulatory requirements, using regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE RPF ESFs for the issuance of an operating license.

6b.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE RPF ESFs are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.57, "Issuance of operating license."
- 10 CFR Part 20, "Standards for Protection Against Radiation."

In addition to any radiological hazards associated with operations in a production facility, 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," specifies limits regarding exposure to hazardous chemicals. Although not a requirement for 10 CFR Part 50 licenses, these limits were considered when reviewing this section of the SHINE FSAR consistent with the ISG augmenting NUREG-1537, Part 2, which states that "the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, Revision 2, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotope production facilities."

6b.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power

Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

- NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," issued June 2015.

- NUREG/CR-6698, "Guide for Validation of Nuclear Criticality Safety Calculational Methodology," issued January 2001.

As stated in the ISG augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, IEEE standards, ANSI/ANS standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, "References," of this SER.

6b.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR section 6b, as supplemented, to assess the sufficiency of the final design and performance of the SHINE RPF ESFs for the issuance of an operating license. The sufficiency of the final design and performance is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 6b.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. While the technical evaluation of these systems provided in this section is specific to the SHINE RPF, the staff's review considers the interface of these systems between the IF and RPF as part of a comprehensive technical evaluation. The findings of the staff review are described in section 6b.5, "Review Findings," of this SER.

6b.4.1 Summary Description

The NRC staff evaluated the sufficiency of the summary description of the SHINE RPF ESFs, as presented in SHINE FSAR section 6b.1, using the guidance and acceptance criteria from section 6.1, "Summary Description," of NUREG-1537, Parts 1 and 2, and section 6b.1, "Summary Description," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR table 6b.1-1, "Summary of Engineered Safety Features and Design Basis Accidents Mitigated," contains a summary of ESFs and the RPF DBAs that they are designed to mitigate. The credited ESFs are supercell confinement, below grade confinement, process vessel ventilation isolation, and combustible gas management.

SHINE FSAR figure 6b.1-1, "Radioisotope Production Facility Engineered Safety Features Block Diagram," provides a block diagram for the SHINE RPF ESFs that shows the location and basic function of the SSCs providing ESFs in the RPF portion of the SHINE facility. The diagram indicates the passive components for which credit is taken for the ESFs. The diagram also indicates the active components in the ESFs that respond to confinement isolation signals from the ESFAS. The active components that respond to ESFAS are listed in SHINE FSAR section 7.5.

Based on its review, the NRC staff finds that the SHINE RPF ESFs are adequately described in SHINE FSAR section 6b.1; therefore, the staff finds that the summary description of the SHINE RPF ESFs meets the acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, for the issuance of an operating license.

6b.4.2 Confinement

The NRC staff evaluated the sufficiency of the final design of the SHINE confinement and related systems, as presented in SHINE FSAR section 6b.2.1, "Confinement," using the guidance and acceptance criteria from section 6.2.1, "Confinement," of NUREG-1537, Parts 1 and 2, and section 6b.2.1, "Confinement," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff reviewed confinement mitigation requirements, the defined confinement envelope, and detailed descriptions of the ESFs associated with confinement. Additionally, the staff evaluated the passive and active ESF components, under normal and upset operational conditions. The functional requirements, design bases, proposed technical specifications, and testing requirements were also evaluated for sufficiency.

Supercell Confinement

The supercell is a set of hot cells in which isotope extraction, purification, and packaging is performed, and gaseous waste is handled. The supercell provides shielding and confinement to protect the workers, members of the public, and the environment by confining the airborne radioactive materials during normal operation and in the event of a release. SHINE FSAR figure 6b.2-1, "Supercell Confinement Boundary," provides a block diagram of the supercell confinement boundary. The RVZ1e draws air through each individual confinement box to maintain negative pressure inside the confinement, minimizing the release of radiological material to the facility. Filters and carbon adsorbers are provided on the ventilation inlets and outlets. Radiation monitoring on the outlet side to detect off-normal releases will isolate the hot cells by closing both inlet and outlet dampers or valves. Additionally, the actuation signal closes isolation valves on the molybdenum extraction and purification system (MEPS) heating loops and conducts a vacuum transfer system (VTS) safety actuation. As part of VTS safety actuation, connections to the supercell from the facility chemical reagent system (FCRS) skid isolate, closing the MEPS and iodine and xenon purification and packaging (IXP) supply valves as described in SHINE FSAR subsection 7.5.3.1.17, "VTS Safety Actuation." The active components required to function to maintain the confinement barrier are actuated by the ESFAS, as described in SHINE FSAR section 7.5. If sufficient radioactive material reaches the radiation monitors in the RVZ1e exhaust duct, ESFAS will isolate the RVZ building supply and exhaust. The evaluated DBA for which the supercell confinement is necessary is listed in SHINE FSAR table 6b.1-1 and further discussed in SHINE FSAR section 13b.2, "Analyses of Accidents with Radiological Consequences."

Below Grade Confinement

RPF tank vaults, valve pits, pipe trench, and carbon delay bed vaults are part of the below grade confinement. SHINE FSAR figure 6b.2-2, “Below Grade Confinement Boundary,” provides a block diagram of the below grade confinement. Radioactive material is confined primarily by the structural components, including gaskets, and other non-structural features are used, as necessary, to provide sealing. Each vault is equipped with a concrete cover plug fabricated in multiple sections with inspection ports to facilitate remote inspection of the confined areas. The pipe trench, vaults, and valve pits with equipment containing fissile material are equipped with drip pans and drains to the radioactive drain system (RDS). The below grade confinement is primarily passive. Process piping for auxiliary systems entering the boundary from outside confinement is provided with appropriate manual or automatic isolation capabilities. Contaminated air is confined to the vaults, valve pits, and pipe trench. The facility accident analysis considers the effect of air exchange from the confinement to the general areas in its evaluation of radiological consequences. Three mechanisms by which the confinement boundary exchanges air with the RPF are considered: pressure-driven flow, counter-current flow, and barometric breathing. The combined effect of these mechanisms is a minor outflow of radioactive material from the confined area to the RPF and the environment under accident conditions. If sufficient radioactive material reaches the radiation monitors in the RVZ1e duct, ESFAS will isolate the RVZ building supply and exhaust. The evaluated DBA for which the below grade confinement is necessary is listed in SHINE FSAR table 6b.1-1 and further discussed in SHINE FSAR section 13b.2.

Process Vessel Ventilation Isolation

The PVVS captures or provides holdup for radioactive particulates, iodine, and noble gases generated within the RPF and primary system boundary. The PVVS draws air from the process vessels through a series of processing components that remove the radioactive components by condensation, acid adsorption, mechanical filtration with HEPA filters, and adsorption in carbon beds. The PVVS guard and delay beds are equipped with isolation valves to isolate affected guard bed or group of delay beds from the system. The isolation valves serve a dual purpose: they prevent release of radioactive material to the environment and isolate fire-impacted beds from unimpacted beds. The delay beds are equipped with sensors to detect fires, which provide indication to ESFAS. The redundancy in the beds and the ability to isolate individual beds allow the PVVS to continue to operate following an isolation. The evaluated DBA for which PVVS isolation is necessary is listed in SHINE FSAR table 6b.1-1 and further discussed in SHINE FSAR section 13b.2.

Combustible Gas Management

Hydrogen gas is produced by radiolysis in the target solution during and after irradiation. During normal operation, the PVVS removes radiolytic hydrogen and radioactive gases generated within the RPF and primary system boundary. If the PVVS becomes unavailable, the buildup of hydrogen gas is limited using the combustible gas management system, which uses the N2PS, process system piping, and portions of the PVVS to establish an inert gas flow through the process vessels. The objective of the combustible gas management system is to prevent the conditions that could lead to a hydrogen deflagration in the gas spaces in the RPF process tanks.

The N2PS provides a back-up supply of sweep gas following a loss of electrical power or loss of sweep gas flow to the RPF tanks normally ventilated by the PVVS. SHINE FSAR figure 6b.2-3, “RPF Combustible Gas Management Functional Block Diagram,” provides a functional block diagram of the RPF combustible gas management system. The source of nitrogen is high pressure nitrogen gas stored in pressurized vessels. On a loss of power or receipt of an ESFAS actuation signal, isolation valves on the radiological ventilation zone 2 (RVZ2) air supply to the PVVS shut and isolation valves on the N2PS discharge manifold open, releasing nitrogen into the RPF N2PS distribution piping. The nitrogen gas flows through the RPF equipment and into the PVVS process piping and the PVVS passive filtration equipment before being discharged out through an alternate vent path in the PVVS. The variable within the ESFAS that can cause the initiation of an RPF Nitrogen Purge (low PVVS flow) is provided in SHINE FSAR subsection 7.5.3.1.23, “RPF Nitrogen Purge.” The active components required to function to initiate the RPF Nitrogen Purge are actuated by the ESFAS. A detailed description of the ESFAS is provided in SHINE FSAR section 7.5. Combustible gas management prevents deflagrations and detonations in RPF process tanks that could lead to a tank or pipe failure and cause a target solution spill inside the process confinement boundary. The evaluated DBAs for which combustible gas management is necessary are listed In SHINE FSAR table 6b.1-1 and further discussed in SHINE FSAR section 13b.2.

Dose Consequences

SHINE FSAR table 6b.1-2, “Comparison of Unmitigated and Mitigated Radiological Doses for Select Radioisotope Production Facility DBAs,” provides unmitigated and mitigated doses for select DBAs in the SHINE RPF. The maximum mitigated doses in SHINE FSAR table 6b.1-2 are 0.042 rem TEDE to the public and 0.076 rem TEDE to the worker. In SHINE FSAR section 13a2.2 and Determination of Consequences,” the applicant proposed the following accident dose criteria:

- Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 1 rem TEDE for the duration of the accident; and
- Radiological consequences to workers do not exceed 5 rem TEDE during the accident.

The NRC staff finds these dose criteria to be acceptable in section 13a.4.1 of this SER.

The dose consequences, in some cases, would be unacceptable with respect to these criteria without mitigation by ESFs. As described in SHINE FSAR chapter 13b, specific postulated accident scenarios indicate the need for the confinement ESFs.

Based on its review, the NRC staff finds that there is reasonable assurance that the confinement ESFs are designed to ensure that the radiological consequences to a member of the public and a worker would remain below 1 rem and 5 rem, respectively, and, therefore, that the confinement ESFs are acceptable with respect to dose consequences.

Design Criteria

As stated in SHINE FSAR section 3.1, “Design Criteria,” the nuclear safety classification of safety-related SSCs at SHINE entails those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public and to control or mitigate the consequences of such accidents. SHINE FSAR table 3.1-1, “Safety-Related Structures, Systems, and Components,” identifies the SSCs at SHINE that are classified as safety-related. The list includes the confinement features and all its supporting structures and systems. SHINE FSAR table 3.1-3, “SHINE Design Criteria,” provides the generally applicable design criteria to the SHINE facility. The NRC staff review focused on the design criteria applicable to confinement, namely criteria 29, 32, 33, 34, 35, and 39. These criteria are described in section 6a.3.2, “Applicable Regulatory Guidance and Acceptance Criteria,” of this SER.

For design criterion 29, the NRC staff finds that SHINE appropriately identified passive confinement boundaries and active components for the establishment of the four classes of confinement boundaries. Specifically, the primary confinement boundary, the process confinement boundary, the hot cells and gloveboxes, and the radiologically controlled area (RCA) ventilation isolations are addressed in sufficient detail in SHINE FSAR sections 6a2.2.1, and 6b.2.1, and SHINE FSAR figures 6a2.2-1, 6a2.2-2, 6b.2-1, and 6b.2-2.

For design criterion 32, the NRC staff finds that periodic inspection, surveillance, and periodic testing are satisfied by the proposed technical specifications.

For design criterion 33, the NRC staff finds that the piping systems penetrating confinement boundaries have been provided with automatic isolation capabilities, manual valve positions, and isolation valves in close proximity of the outside of confinement based on descriptions in SHINE FSAR sections 6a2 and 6b and SHINE FSAR figures 6a2.2-1, 6a2.2-2, 6b.2-1, and 6b.2-2.

For design criterion 34, the NRC staff finds that based on the descriptions in SHINE FSAR sections 6a2 and 6b, along with SHINE FSAR figures 4a2.8-1, “Subcritical Assembly System and TSV Off-Gas System Flow Diagram,” 6a2.2-1, 6a2.2-2, 6b.2-1, 6b.2-2, 9a2.1-3, “Radiological Ventilation Zone 1 Exhaust Subsystem (RVZ1e) Flow Diagram,” and 9a2.7-1, “TPS Process Flow Diagram,” the confinement isolation of process piping and ventilation is sufficiently described and depicted in the FSAR.

For design criterion 35, the NRC staff finds that the SHINE facility is equipped with isolation provisions in the ventilation system at the RCA boundary and that the PVVS exhaust beds are designed for holdup capacity for retention of radioactive gases.

For design criterion 39, the NRC staff finds that the applicant has described systems to control the buildup of hydrogen to ensure that the integrity of the system and confinement boundaries are maintained.

Based on the foregoing, the NRC staff concludes that the applicant provided final analysis and evaluation of the design and performance of SSCs and satisfies 10 CFR 50.34(b)(4) as it relates to confinement.

Conclusion

Based on the evaluation of the SHINE RPF ESFs, the NRC staff concludes that the final design of the SHINE RPF ESFs, including the principal design criteria, design bases, and information relative to confinement, satisfies the relevant acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds the final design of the SHINE RPF ESFs acceptable.

6b.4.3 Nuclear Criticality Safety

The NRC staff evaluated the sufficiency of SHINE's nuclear criticality safety design criteria and methods, as presented in SHINE FSAR section 6b.3, "Nuclear Criticality Safety," using the guidance and acceptance criteria from section 6b.3, "Nuclear Criticality Safety for the Processing Facility," of the ISG augmenting NUREG-1537, Part 2. Where appropriate, the staff referenced the guidance in NUREG-1520, Revision 2 and NUREG/CR-6698 to support its evaluation of the acceptance criteria from the ISG augmenting NUREG-1537, Part 2.

6b.4.3.1 Nuclear Criticality Safety Program

General requirements to protect the public health and safety in 10 CFR 50.34(b) are implemented for the SHINE facility, in part, by establishing and maintaining a nuclear criticality safety program (CSP) that assures subcriticality under normal and all credible abnormal conditions, with a margin of subcriticality for safety. Assurance of subcriticality is typically implemented in conjunction with the double contingency principle as stated in ANSI/ANS-8.1-2014, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."

SHINE FSAR section 6b.3.1, "Nuclear Criticality Safety Program," describes the SHINE CSP and states that it applies to all nuclear processes within the RPF and the IF, excluding the TSVs. The NRC staff evaluates the insertion of reactivity within the TSVs in section 13a.4.3.4.2, "Insertion of Excess Reactivity," of this SER.

Organization and Administration

SHINE FSAR section 6b.3.1 discusses the objectives of the SHINE CSP and states that its goal is to ensure that workers, the public, and the environment are protected from the consequences of a nuclear criticality event. The CSP is executed by qualified facility staff using written procedures, which are maintained by SHINE's document control program.

SHINE FSAR section 6b.3.1.1, "Nuclear Criticality Safety Program Organization," discusses the organization of the SHINE CSP. SHINE committed to, and described a program whose structure is consistent with, the requirements of ANSI/ANS-8.1-2014 and ANSI/ANS-8.19-2014, "Administrative Practices for Nuclear Criticality Safety," both of which are endorsed by NRC Regulatory Guide (RG) 3.71, Revision 3, "Nuclear Criticality Safety Standards for Nuclear Materials Outside Reactor Cores" (ML18169A258). SHINE FSAR section 6b.3.1.1 also discusses the responsibilities and roles of key program personnel, including the Chief Executive Officer, Safety Analysis Manager, SHINE facility management, fissionable material operation (FMO) supervisors, and nuclear criticality safety (NCS) staff. The overall responsibility for the CSP lies with the SHINE Chief Executive Officer, and the Safety Analysis Manager is the facility manager responsible for the program's implementation. NCS staff are kept administratively independent from operations to the extent practicable. The NRC staff finds that the information provided with respect to the SHINE CSP organization is consistent with ANSI/ANS-8.1-2014 and ANSI/ANS-8.19-2014 and the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

SHINE FSAR sections 6b.3.1.2, "Nuclear Criticality Safety Staff Qualifications," and 6b.3.1.6, "Nuclear Criticality Safety Training," discuss NCS staff training and qualifications. The NCS staff consists of three qualification levels: (1) NCS analyst; (2) NCS engineer; and (3) senior NCS engineer. The NCS training program consists of two tiers, with Tier 1 being directed toward personnel who manage, work in, or work near areas where a potential for a criticality accident exists and Tier 2 being specific to NCS staff. Tier 1 content is derived from ANSI/ANS-8.20-1991, “Nuclear Criticality Safety Training,” and Tier 2 content is derived from ANSI/ANS-8.26-2007, “Criticality Safety Engineer Training and Qualification Program.” Both tiers include content on procedural compliance, stop-work authority, response to CAAS alarms, including evacuation to designated areas using designated routes, and reporting of defective or anomalous conditions. SHINE committed to the requirements of ANSI/ANS-8.26-2007 for the training of NCS staff, and SHINE’s specific training requirements for NCS staff are taken from this standard. The NRC staff finds that the information provided with respect to NCS staff training and qualifications is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2, as well as ANSI/ANS-8.20-1991and ANSI/ANS-8.26-2007 (both endorsed by RG 3.71) and is, therefore, acceptable.

Management Measures

The management measures applied to the SHINE CSP consist of training, procedures (including NCS postings), and audits and assessments. These aspects of the CSP are discussed in SHINE FSAR section 6b.3.1.

SHINE FSAR section 6b.3.1.6 discusses NCS training, which the NRC staff finds acceptable, as discussed above.

SHINE FSAR section 6b.3.1.8, “Criticality Safety Nonconformances,” discusses NCS-related non-conformances. Personnel are trained to promptly report any deviations from procedures and/or unintended changes in process conditions to management. Non-conformances are entered into SHINE’s corrective action program, investigated promptly, corrected as appropriate, and documented. Corrective actions are performed in accordance with procedures and with guidance from the NCS staff.

SHINE FSAR section 6b.3.1.7, “Criticality Safety Program Oversight,” discusses NCS procedures (including NCS postings). As previously discussed, SHINE committed to the requirements of ANSI/ANS-8.19-2014 and ANSI/ANS-8.20-1991, which both discuss the use of procedures. SHINE FSAR section 6b.3.1.7 also states that “[a]ctivities involving fissile material are conducted using written and approved procedures.” Section 6b.3.1.7 further states that for situations in which approved procedures are inadequate or do not exist, personnel are required to take no action until the NCS staff has evaluated the situation and provided instructions. To supplement procedures, SHINE also uses postings and labeling.

SHINE FSAR section 6b.3.1.7 discusses audits and assessments related to the SHINE CSP. SHINE performs several different types of audits and assessments, which are consistent with the requirements of ANSI/ANS-8.19-2014 and have been incorporated into the SHINE facility technical specifications (TSs). The audits and assessments consist of: (1) annual audits of operations to evaluate procedural compliance and process conditions, including walkthroughs of facility processes and procedures by NCS staff; (2) periodic reviews of active procedures by supervisors; (3) periodic reviews of procedural non-compliance and other NCS-related deficiencies; (4) annual reviews of nuclear criticality safety evaluations (NCSEs) to ensure their continued validity, with each NCSE and its associated calculations being reviewed at least once every 3 years; and (5) a triennial audit of the overall effectiveness of the CSP, with active participation from SHINE management. The adequacy of NCS controls is routinely assessed by SHINE’s audits and assessments. Deficiencies that are identified during an audit or assessment are promptly reported to management via the SHINE corrective action program, investigated promptly, corrected as appropriate, and documented. Action to correct deviations or alterations is taken in accordance with procedural requirements and with guidance obtained from the NCS staff. Action is taken to prevent recurrence for significant conditions adverse to quality. Records of NCS deficiencies and associated corrective actions are maintained in the corrective action program. The ISG augmenting NUREG-1537, Part 2 contains an acceptance criterion that all aspects of the CSP will be audited at least every 2 years; however, SHINE stated that it will conduct such audits triennially. In its RAI response dated January 29, 2021 (ML21029A102), SHINE stated that this longer audit frequency is justified based on SHINE's commitment to the requirements of ANSI/ANS-8.19-2014, which states in paragraph 4.7 that "Management shall participate in auditing the overall effectiveness of the nuclear criticality safety program at least once every 3 years." The NRC staff notes that RG 3.71 endorses the use of ANSI/ANS-8.19-2014 without exception. Therefore, based on SHINE's commitment to the requirements of ANSI/ANS-8.19-2014, the staff determined that a triennial program audit is acceptable.

In addition to the management measures applied to the SHINE CSP, SHINE FSAR section 6b.3.1.5, "Computational System Validation," states that any process or design change that could impact NCS limits or controls is evaluated against the requirements of 10 CFR 50.59, "Changes, tests, and experiments." Prior to implementing the change, the applicable NCSE is reviewed and revised, if necessary, to maintain the assurance of subcriticality under normal and all credible abnormal conditions with a margin of subcriticality for safety. The NRC staff's evaluation of SHINE's change control process is discussed in chapter 12, "Conduct of Operations," of this SER.

Based on the above, the NRC staff finds that the information provided with respect to management measures applied to the SHINE CSP is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and applicable NRC-endorsed guidance and is, therefore, acceptable.

Use of Industry Standards

In SHINE FSAR section 6b.3.1.3, "Use of National Consensus Standards," SHINE committed to the requirements of the following ANSI/ANS standards related to NCS, subject to any clarifications and exceptions provided in RG 3.71, with certain SHINE-specific limitations. The NRC staff notes that although in some instances the acceptance criteria in section 6b.3 of the ISG augmenting NUREG-1537, Part 2 reference different versions of the standards than those committed to by SHINE, SHINE's commitments are to the latest version of each standard, which is consistent with section 3.1, "Design Criteria," of NUREG-1537, Part 2, which states that design criteria should include references to applicable up-to-date standards, guides, and codes, and are, therefore, acceptable.

- ANSI/ANS-8.1-2014, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."

  SHINE committed to the requirements of ANSI/ANS-8.1-2014, noting that the clarification applied to this standard by RG 3.71 is related to subcritical limits for plutonium isotopes and is, therefore, not applicable to the SHINE facility.

- ANSI/ANS-8.3-1997, “Criticality Accident Alarm System.”

SHINE committed to the requirements of ANSI/ANS-8.3-1997, acknowledging that the clarifications and exceptions applied to this standard by RG 3.71 are applicable to the SHINE facility.

- ANSI/ANS-8.5-1996, “Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material.”

Borosilicate-glass Raschig rings are not used in the SHINE facility; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.6-1983, “Safety in Conducting Subcritical Neutron-Multiplication Measurements In Situ.”

SHINE committed to the requirements of ANSI/ANS-8.6-1983.

- ANSI/ANS-8.7-1998, “Nuclear Criticality Safety in the Storage of Fissile Materials.”

SHINE committed to the requirements of ANSI/ANS-8.7-1998.

- ANSI/ANS-8.9-1987, “Nuclear Criticality Safety for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Material.”

ANSI/ANS-8.9-1987 was withdrawn in May 1997 and is no longer maintained as an ANSI/ANS standard; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.10-2015, “Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement.”

SHINE does not rely on the criteria provided in ANSI/ANS-8.10-2015 for determining the adequacy of shielding and confinement; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.12-1987, “Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors.”

Plutonium is not used as a target component at the SHINE facility; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.14-2004, “Use of Soluble Neutron Absorbers in Nuclear Facilities Outside Reactors.”

The SHINE facility does not use soluble neutron absorbers for criticality control; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.15-2014, "Nuclear Criticality Safety Control of Selected Actinide Nuclides."

SHINE does not conduct operations with non-negligible quantities of selected actinides; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.17-2004, "Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR [Light-Water Reactor] Fuel Outside Reactors."

SHINE does not handle, store, or transport LWR fuel rods or units; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.19-2014, "Administrative Practices for Nuclear Criticality Safety."

SHINE committed to the requirements of ANSI/ANS-8.19-2014.

- ANSI/ANS-8.20-1991, "Nuclear Criticality Safety Training."

SHINE committed to the requirements of ANSI/ANS-8.20-1991.

- ANSI/ANS-8.21-1995, "Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors."

SHINE does not rely on the use of fixed absorbers as a means of criticality control; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.22-1997, "Nuclear Criticality Safety Based on Limiting and Controlling Moderators."

SHINE committed to the requirements of ANSI/ANS-8.22-1997.

- ANSI/ANS-8.23-2007, "Nuclear Criticality Accident Emergency Planning and Response."

SHINE committed to the requirements of ANSI/ANS-8.23-2007, acknowledging that the clarification applied to this standard by RG 3.71 is applicable to the SHINE facility.

- ANSI/ANS-8.24-2017, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations."

SHINE committed to the requirements of ANSI/ANS-8.24-2017, acknowledging that the clarifications applied to this standard by RG 3.71 are applicable to the SHINE facility.

- ANSI/ANS-8.26-2007, "Criticality Safety Engineer Training and Qualification Program."

SHINE committed to the requirements of ANSI/ANS-8.26-2007.

- ANSI/ANS-8.27-2015, “Burnup Credit for LWR Fuel.”

  SHINE does not possess irradiated LWR fuel assemblies; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

The NRC staff determined that SHINE committed to the requirements of the applicable ANSI/ANS standards, and NRC clarifications and exceptions thereto, related to NCS. Therefore, the staff determined that the above commitments are consistent with the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and are, therefore, acceptable.

Subcriticality and Double Contingency Principle

In SHINE FSAR section 6b.3.1.3, SHINE committed to the requirements of ANSI/ANS-8.1-2014, as endorsed by RG 3.71, which includes adherence to the double contingency principle (DCP) where practicable as a method of ensuring subcriticality. Further, SHINE FSAR section 6b.3.1.5 provides that processes within the RPF generally comply with the DCP. This is expanded upon by SHINE FSAR section 6b.3.2, “Criticality Safety Controls,” which states that control on two independent criticality parameters is generally preferred over multiple controls on a single parameter, and if multiple controls on a single parameter are used, then a preference is given to diverse means of control on that parameter. SHINE FSAR section 6b.3.1.5 also states that the failure of a single NCS control that maintains two or more controlled parameters is considered a single process upset with respect to the DCP. By letter dated December 10, 2020, in response to NRC staff RAI 6b.3-3 (ML20357A084), Enclosure 3 (ML20357A087), SHINE stated that “[p]rocess upsets are considered credible unless they are not physically possible or are caused by a sequence of events involving many unlikely human actions or errors for which there is no reason or motive.” SHINE further stated in its response that the credibility of process upsets is based on the judgement of key professionals involved in the evaluation process from operations, design engineering, and safety analysis disciplines, considering factors such as the conditions of the system, its construction, and the applicable accident sequences. The NRC staff notes that the guidance provided in appendix A to chapter 5.0 of NUREG-1520, Revision 2, acknowledges that a qualitative approach to the DCP is acceptable. Therefore, the staff finds that SHINE’s qualitative approach to evaluating the credibility and likelihood of process upsets is consistent with the DCP and guidance provided by appendix A to chapter 5.0 of NUREG-1520, Revision 2, and is, therefore, acceptable.

Based on the above, the NRC staff finds that the information provided with respect to the DCP is consistent with ANSI/ANS-8.1-2014 (as endorsed by RG 3.71) and the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Technical Practices

SHINE FSAR sections 6b.3.1.4, “Nuclear Criticality Safety Evaluations,” 6b.3.1.5, “Computational System Validation,” and 6b.3.2, “Criticality Safety Controls,” describe the NCS technical practices at the SHINE facility. These include the performance and documentation of NCSEs, the treatment of NCS parameters and their methods of control, the derivation of NCS limits, computational system validation, and the establishment and use of a margin of subcriticality for safety.

SHINE FSAR section 6b.3.1.4 discusses SHINE's performance and documentation of NCSEs. NCSEs are conducted for each FMO to ensure subcriticality under normal and all credible abnormal conditions with a margin of subcriticality for safety, with the exception of the IU cells and the material staging building (see section 6b.4.3.2 of this SER for further discussion of criticality hazards in the IU cells and the material staging building and SHINE's request for exemption from the requirements of 10 CFR 70.24, "Criticality accident requirements," for these areas). For analytical purposes, all fissionable isotopes are conservatively assumed to be fissile. NCSEs are conducted using hazard evaluation techniques, including "What-if," "What-if Checklist," and Event Tree Analysis, to identify potential accident sequences leading to inadvertent criticality. When the DCP is used, the NCSEs also describe how the DCP is implemented. SHINE performs NCSEs using the industry-accepted and peer-reviewed methods discussed in the requirements of ANSI/ANS-8.1-2014 and ANSI/ANS-8.19-2014, both endorsed by RG 3.71.

NCS limits identified in NCSEs are derived using one of three methods: (1) industry-accepted and peer-reviewed references including ANSI/ANS standards; (2) hand calculations using industry-accepted and peer-reviewed techniques consistent with their limitations; or (3) computational methods. Limits are derived by assuming optimum or most-reactive credible values unless otherwise controlled. For cases in which less than optimum values are used, the basis is documented in the appropriate NCSE. Operating limits are derived conservatively in consideration of any potential process variability and uncertainty to ensure that NCS limits are unlikely to be exceeded. When computational methods (i.e., "code") are used to derive NCS limits and/or to perform NCS analyses, they are used consistent with the limitations and penalties identified in the code's validation report. SHINE TS table 5.5.4, "Controls," states, in part, that engineered criticality "controls are identified in the criticality safety evaluations to prevent criticality in the SHINE Facility, excluding the TSVs."

SHINE FSAR section 6b.3.2 discusses the various NCS control methods, including preference for engineered controls over administrative controls, and passive engineered controls over active controls. Controls are established to restrict certain NCS parameters within subcritical limits. The NCS parameters that SHINE controls are mass, moderation, enrichment, geometry, volume, concentration, interaction, physiochemical form, reflection, heterogeneity, density, and process variables. SHINE does not use fixed or soluble neutron absorbers as a method of control and, therefore, did not provide any information on the treatment of absorption as an NCS parameter. The discussion associated with the treatment of each of these parameters is below.

The NRC staff notes that under one or more of the individual parameters, several of the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 are covered by the more general discussions in SHINE FSAR section 6b.3.2. For example, the expectation that instrumentation relied on to verify compliance with limits on mass, density, enrichment, etc., will be subjected to facility management measures is bound by a general statement in SHINE FSAR section 6b.3.2. The expectations that firefighting procedures will be evaluated for moderator intrusion, or that all precipitating agents will be identified and controlled against, are corollary to the general requirement that the licensee ensures that processes are subcritical under normal and all credible abnormal conditions, as well as SHINE's commitment to the requirements of ANSI/ANS-8.22-1997. Regarding the acceptance criteria stating that process variables that can affect the value of a particular parameter should be controlled by safety-related controls identified in NCSEs, the staff finds it sufficient for the applicant to follow its SHINE Safety Analysis (SSA) methodology as described in SHINE FSAR section 13a2, "Irradiation Facility Accident Analysis," in determining what controls should be designated as safety-related controls. The staff's evaluation of the SSA methodology is discussed in chapter 13, "Accident Analysis," of this SER.

The NRC staff noted that several subsections of SHINE FSAR section 6b.3.2, pertaining to NCS parameters, contain provisions that are simply definitions of the parameter or state that the parameter may be used on its own in combination with other parameters. In accordance with the guidance in appendix A to chapter 5.0 of NUREG-1520, Revision 2, this is acceptable in the context of the DCP and is, therefore, acceptable. The above discussion is applicable to each of the parameters discussed in the subsections of SHINE FSAR section 6b.3.2. Significant points regarding the specific parameters are discussed in the paragraphs below.

Mass: SHINE stated that whenever mass limits are based on assuming a certain weight percent of uranium, either the entire mass present will be ascribed to uranium or the actual weight percent determined by physical measurement. Thus, any material associated with a special nuclear material (SNM) process will be treated as having a high uranium content until demonstrated otherwise. SHINE also assumed a conservative process density to calculate mass when the dimensions of equipment or containers with fixed geometry are used to limit mass, and to demonstrate that the largest mass resulting from a single failure remains subcritical wherever over-batching is credible. The use of instrumentation to measure mass is addressed by a general statement that when measurement of a parameter is needed, instrumentation subject to facility management measures is used. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Geometry and Volume: SHINE restricts SNM volume with geometry and to verify all dimensions relied on in demonstrating subcriticality before beginning operations, in response to changes in operations, and at periodic intervals. Relevant dimensions and material properties are maintained by the facility's configuration management program. Abnormal conditions involving the loss of geometry are evaluated in NCSEs, if credible. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Density: SHINE's discussions regarding the treatment of density as a controlled parameter are provided by general statements that apply to all other controlled parameters. Limits on density are established with consideration given to any tolerances and uncertainty. If control is based on measuring density, independent means of measurement are used subject to facility management measures. If process variables can affect the normal or most reactive credible value of density, controls to maintain density within a certain range are used. For cases where a single parameter limit on density is used, all other parameters are evaluated at their optimum or most reactive credible value. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Enrichment: SHINE assumed a bounding enrichment for all fissile material based on a facility-wide maximum authorized enrichment controlled by receipt inspections of feed material. Measurements of the enrichment of feed material are performed using instrumentation subject to facility management measures. The SHINE facility does not have any processes capable of enriching SNM further. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Reflection: SHINE considers wall thickness and all adjacent reflecting material when determining subcritical limits for individually evaluated units of fissile material. Although SHINE did not explicitly state that individually evaluated units will be farther than 12 inches away from reflecting adjacent materials, SHINE will establish and document criteria for determining whether materials are sufficiently spaced to be considered neutronically isolated. When reflection is not controlled, full reflection is assumed and is represented by 12 inches of tight-fitting water or 24 inches of tight-fitting concrete, as appropriate. Unit arrays are evaluated using the most reactive combination of interstitial moderation and exterior array reflection. Minimum reflection conditions, equivalent to a 1-inch tight-fitting water reflector, are assumed to account for personnel and other transient reflectors not explicitly included in criticality calculations. When less than full reflection is assumed, controls to limit reflection around individual units are established, with rigid barriers preferred. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG--1537, Part 2 and is, therefore, acceptable.

Moderation: SHINE committed to the requirements of ANSI/ANS-8.22-1997. Physical structures are designed to prevent the ingress of moderators, and conspicuously marked moderation-controlled areas are used to exclude moderators from process areas. Firefighting procedures for use in moderation-controlled areas, as well as the effects of fire and the activation of fire suppression systems, are evaluated in NCSEs, and restrictions are applied to the use of moderating firefighting agents. The use of instrumentation to measure moderation is addressed by a general statement that when measurement of a parameter is needed, instrumentation subject to facility management measures is used. Process variables that can affect moderation are also addressed by a general statement to identify in accident analyses the process variables relied on to control or monitor controlled parameters, with sufficient management measures applied. The associated parameter (in this case moderation) is explicitly identified and the correlation of process variables to the associated parameter is established by experiment or plant-specific measurements. When moderation needs to be sampled, dual independent sampling methods are used. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG--1537, Part 2 and is, therefore, acceptable.

Concentration: SHINE implements controls to limit concentration unless the process has been demonstrated to be subcritical under the most reactive credible uranium concentrations. For solution tanks under concentration control, precautions are taken to preclude the introduction of precipitating agents, including keeping the tank closed and locked. When concentration needs to be sampled, such as prior to a transfer of solution to an unfavorable geometry tank, dual independent sampling methods and/or in-line monitoring are used such that no single error may result in the transfer of concentrated solution. Process variables that can affect the solubility of fissile solutions are controlled and monitored, and the need to ensure homogeneity of solution is assessed in NCSEs. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Interaction: SHINE maintains physical separation between fissile-bearing units with engineered controls. If engineered controls are not feasible, visual aids are used to support administrative controls. The structural integrity of spacers, storage racks, etc. is sufficient to ensure subcriticality under normal and all credible abnormal conditions, including seismic events. Movable engineered devices are periodically inspected to verify that no deformation has occurred. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Physiochemical Form and Process Variables: Physiochemical form and process variables are not explicitly discussed in the acceptance criteria of the ISG augmenting NUREG-1537, Part 2, but rather are used to indirectly control one or more NCS parameter. For example, specifying the material form as uranyl nitrate solution may be necessary to use certain dimensional or mass limits, and implicitly takes credit for the neutron absorbing properties of nitrogen. As another example, specifying the form as uranium dioxide powder implicitly assumes a maximum enrichment and density. Reliance on this parameter is based on known scientific principles or known physical or chemical properties, in conjunction with experimental data supported by operating history. By letter dated December 10, 2020, in response to NRC staff RAI 6b.3-9 (ML20357A0840, Enclosure 3 (ML20357A087), SHINE stated that correlation of process variables to controlled parameters is accomplished by direct or indirect measurements. Direct correlations apply when monitored process variables are directly measured. Indirect correlations may be established when direct measurements of controls are not possible and may be developed using known empirical or theoretical relationships or developed through plant-specific data collection. Correlation inputs will be defined and documented for a specific controlled parameter, including process assumptions and characteristics. The NRC staff finds that this is sufficient to ensure that reliance is not placed on as-found conditions or on process assumptions and characteristics that are not appropriately controlled. SHINE will establish controls to limit material composition to a particular form. Process variables that can change fissile material composition to a more reactive physiochemical form are identified as controls, and both in situ changes in physiochemical form and the migration of material between process areas are considered in evaluating credible abnormal conditions. While the ISG augmenting NUREG-1537, Part 2 does not contain acceptance criteria specifically associated with these parameters, the staff finds that this information is consistent with the general principles that apply to all parameters as discussed above and is, therefore, acceptable.

Heterogeneity: The ISG augmenting NUREG-1537, Part 2 does not provide specific acceptance criteria regarding the treatment of heterogeneity. Rather, it simply states that heterogeneous effects should be considered as appropriate. Given the enrichment and material forms of SHINE's processes, it is necessary to consider heterogeneity effects. Therefore, the acceptance criteria from NUREG-1520, Revision 2, were used as guidance in determining whether the information provided regarding heterogeneity is acceptable. SHINE evaluates potential methods of causing fissile solution to become inhomogeneous and establishes controls as necessary. If heterogeneity is considered credible, its effect is evaluated in NCSEs. Assumptions that can affect the physical scale of homogeneity are based on observed physical characteristics, and process variables that can affect the scale of heterogeneity are controlled.

Given that SHINE's methods for determining the subcritical limits for uranyl sulfate systems are based on comparison with uranyl fluoride and uranyl nitrate systems, and that SHINE's computational method for performing NCS analyses was validated, in part, against uranyl fluoride and uranyl nitrate benchmark experiments, the NRC staff performed a literature search and an independent analysis to assess the potential impacts of heterogeneity as both uranyl fluoride and uranyl nitrate present special concerns due to the formation of water hydrates at low hydrogen-to-uranium (H/U) ratios. Oak Ridge National Laboratory (ORNL) report ORNL/TM-12292, "Estimated Critical Conditions for [Uranyl Fluoride – Water] Systems in Fully Water-Reflected Spherical Geometry," suggests that special considerations should be given to uranyl fluoride systems with an H/U ratio of less than 4.0 and to uranyl nitrate systems with an H/U ratio of less than 12. A review of Atlantic Richfield Hanford Company report ARH-600, "Criticality Handbook, Volume I," suggests that uranyl sulfate may be subject to the same phenomena and require special considerations for an H/U ratio of less than 7. Below these values, the formation of water hydrates complicates efforts to determine the bulk fissile material density as concentration values can be somewhat erroneous. Above these values, these effects are not of concern, and a general molar volume additive approach can be used. As stated in SHINE's validation report, CALC-2018-0012, "MCNP5 Validation for Reactivity in Solution Systems for the SHINE Facility," the H/U ratios for uranium solutions in SHINE processes that are evaluated using SHINE's computational method are all well above these limits. Although SHINE does have processes in which low H/U ratios may occur (e.g., the dissolution of uranium oxides in sulfuric acid to form uranyl sulfate solution), SHINE assumes the most reactive material composition in analyses. In this particular example, the process of dissolving uranium oxide into uranyl sulfate solution would be evaluated assuming the most reactive composition (moderated uranium oxide) for the entire process. This generally negates the need to consider the potential effects of low H/U ratios involving uranyl sulfate because uranyl sulfate would not be the material composition evaluated. Additionally, the application of subcritical limits (SPLs) derived from ANSI/ANS standards for uranium metal and oxides generally negates the need to conduct an analysis to identify the optimum solution concentration as the SPLs already inherently assume optimum conditions. In cases where optimum solution concentration does need to be determined, such as in the design of a favorable geometry vessel or in accident sequences involving precipitation, the optimum concentration for a 20 weight percent U-235 uranyl sulfate system corresponds to an H/U ratio significantly greater than the H/U ratios listed above for the formation of water hydrates. This alleviates any concern of skewed results due to the formation of water hydrates. Based on its literature search and independent analysis, the NRC staff determined that SHINE's practices for controlling heterogeneity appropriately bound any potential concerns regarding the formation of water hydrates at low H/U ratios. While the ISG augmenting NUREG-1537, Part 2 does not contain acceptance criteria specifically associated with this parameter, the staff finds that this information is consistent with the general principles that apply to all parameters as discussed above and is, therefore, acceptable.

SHINE FSAR section 6b.3.1.5 discusses the validation and verification of computational methods. SHINE committed to the requirements of ANSI/ANS-8.24-2017 and stated that computational systems are verified and validated using the guidance contained in NUREG/CR-6698. SHINE validated its computational methods by comparing the results calculated with computer models to the results of 128 benchmark experiments from the Handbook of the International Criticality Safety Benchmark Evaluation Project (ICBEP). Benchmarks were selected for evaluation based on their similarity to SHINE solution systems, and a modified form of the Shapiro-Wilk test for normality from NUREG/CR-6698 was used to determine whether the resulting benchmark data was normally distributed. The single-sided tolerance limit approach from section 2.4.4, "Select Statistical Method of Treatment of Data," of NUREG/CR-6698 was used to calculate the upper subcritical limit (USL), which is defined in SHINE FSAR section 6b.3.1.5 as the difference between unity and the sum of the bias, the bias uncertainty, and the minimum margin of subcriticality (MMS). For cases involving positive bias, SHINE conservatively assumed the bias to be zero. SHINE FSAR section 6b.3.1.5 states that verification of the Monte Carlo N-Particle (MCNP) software installation was performed using developer-supplied verification tools, and that re-verification of the computational system is conducted following any changes to the hardware or operating system. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

SHINE's discussion regarding the use of an MMS is in SHINE FSAR section 6b.3.1.5. SHINE's computational method identified in SHINE document CALC-2018-0012, "MCNP5 Validation for Reactivity in Solution Systems for the SHINE Facility," is MCNP5 using the ENDF/B-VII.1

standard cross-section library and the ENDF/B.VII.0 thermal scattering cross-section library, which is validated to establish the areas of applicability in which the code can be used.

SHINE relied on the use of SPLs and other data from NRC-endorsed ANSI/ANS standards to establish safe limits for non-solution processes. For solution processes (i.e., the TSV dump tank and the TOGS), a margin of 0.05 is applied with an additional penalty of 0.01 to account for any differences between benchmark material composition and the material composition of the SHINE processes. This results in an MMS of 0.06, which corresponds to a USL of 0.94. Appendix B to chapter 5.0 of NUREG-1520, Revision 2, states that an MMS of 0.05 is generally acceptable for low-enriched uranium facilities provided that: (1) a criticality code validation study has been performed consistent with ANSI/ANS-8.24-2017 and/or NUREG/CR-6698; (2) there is an acceptable number of critical experiments with similar geometric forms, material compositions, and neutron energy spectra to the applicable processes; and (3) the processes evaluated include materials and process conditions similar to those that occur in low-enriched fuel cycle applications. As previously discussed, SHINE performed a validation study consistent with NUREG/CR-6698 and ANSI/ANS-8.24-2017 involving 128 benchmark experiments from the ICBEP selected for evaluation based on their similarity to SHINE solution systems. Although SHINE's processes involve some operations that are not typical of a fuel cycle facility (e.g., irradiation of fissile solution), such processes are limited to the TSVs and the TSVs are not subject to the SHINE CSP. The majority of SHINE's processes are largely similar to that of a fuel cycle facility. Furthermore, SHINE applied a penalty to the USL to account for any differences between benchmark material composition and the material composition of SHINE's processes. Appendix B to chapter 5.0 of NUREG-1520, Revision 2, states that the justification of an MMS should be based on: (1) conservative practices in calculational models; (2) validation methodology and results; and (3) additional risk informed considerations. Given that SHINE uses conservative NCS practices (see section 6b.4.3.1 of this SER) and has performed a validation study consistent with NUREG/CR-6698 and ANSI/ANS-8.24-2017 using a sufficient quantity of data from a quality source (i.e., the ICBEP) with an acceptable statistical methodology and benchmarks similar to SHINE processes, the NRC staff determined that an MMS of 0.06 (corresponding to a USL of 0.94) is acceptable.

6b.4.3.2 Criticality Accident Alarm System

SHINE FSAR section 6b.3.3, "Criticality Accident Alarm System," discusses the use of a CAAS at the SHINE facility. SHINE FSAR section 6b.3.3 states that the SHINE facility maintains CAAS coverage in areas where quantities of fissile material greater than the limits identified in 10 CFR 70.24(a) are used, handled, or stored, except for those areas for which SHINE has requested an exemption from the requirements of 10 CFR 70.24, which the NRC staff discusses below (i.e., the IU cells and the material storage building). SHINE FSAR section 6b.3.3 further states that the CAAS is designed to meet the requirements of 10 CFR 70.24 and conforms to the requirements of ANSI/ANS-8.3-1997, as endorsed by RG 3.71.

SHINE FSAR section 6a2.3.2, "Criticality Accident Alarm System," states that coverage of SNM in the IU cells is provided by the neutron flux detection system (NFDS) and level instrumentation in the TSV dump tank, which provide indication of abnormal conditions in the IU cells.

<u>Criticality Accident Alarm System</u>

Consistent with the ISG augmenting NUREG-1537, SHINE FSAR section 6b.3.3 states that the SHINE facility is designed to meet the requirements of 10 CFR 70.24 and conforms to the requirements of ANSI/ANS-8.3-1997, as endorsed by RG 3.71, Revision 3. Despite this being a different version of RG 3.71 than the version referenced in the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 (i.e., RG 3.71, Revision 1 (ML051940351)), the NRC staff finds this acceptable because both versions endorse ANSI/ANS-8.3-1997 with the following exceptions:

- At or above the mass thresholds established in ANSI/ANS-8.3-1997, section 4.2.1, the applicant should commit to CAAS coverage in each area where SNM is handled, stored, or used, as opposed to merely an evaluation for such areas.

- Two detectors are required for each area requiring CAAS coverage, as opposed to coverage by a single reliable detector.

- The CAAS is required to be capable of detecting a criticality condition that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within 1 minute, as opposed to requiring CAAS coverage in areas where personnel would be subject to "excessive radiation dose," defined as any dose corresponding to a neutron and gamma combined absorbed dose equal to or greater than 12 rads in free air.

The NRC staff finds that the applicant's commitments to the requirements of ANSI/ANS-8.3-1997, as endorsed by RG 3.71, Revision 3, and to maintain a CAAS that provides two detector coverage and is capable of detecting a criticality that produces a combined neutron and gamma radiation absorbed dose in soft tissue of 20 rads at an unshielded distance of 2 meters within 1 minute are sufficient to satisfy the requirements of 10 CFR 70.24(a)(1) and are, therefore, sufficient to satisfy the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and are acceptable.

To accommodate maintenance and testing activities, SHINE FSAR section 6b.3.3.2, "Criticality Accident Alarm System Design," states that the CAAS detectors are arranged such that all areas within the SHINE main production facility requiring coverage generally receive coverage from at least three detectors, allowing a single detector for any given area to be taken out of service for a specified period of time. For maintenance or testing evolutions requiring multiple detectors or the logic unit to be taken out of service, SHINE implements administrative controls to secure the movement of fissile material and limit personnel access (i.e., quarantine) to affected areas until CAAS coverage is restored. Portable instruments may be used in rare circumstances. SHINE FSAR section 6b.3.3.2 states that the CAAS is designed to be resistant to credible events, such as fire, explosion, a corrosive atmosphere, seismic shock, and other adverse conditions that do not result in evacuation of the entire facility. SHINE FSAR section 6b.3.3.2 further states that the CAAS will energize clearly audible alarm signals if accidental criticality were to occur. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

SHINE FSAR section 6b.3.3.1 states that the minimum accident of concern (MAC) for the SHINE facility was developed based on a critical sphere of 20 weight percent U-235 uranyl sulfate solution. Transport analysis was used to convert the neutron and gamma spectrum of the MAC to a point source, which was then used to determine the appropriate detector placement based on the facility structure, shielding, and potential intervening equipment. The thresholds defined in 10 CFR 70.24 were used to establish detection thresholds. Neutron detectors were selected for use to reduce potential inappropriate interference from multiple gamma sources throughout the facility.

The NRC staff determined that although processes at the SHINE facility involve uranium compositions other than uranyl sulfate solution (such as uranium metal and oxides), uranyl sulfate is the uranium composition for the majority of the SHINE facility's processes. Additionally, the information contained in Los Alamos National Laboratory Report LA-13638, "A Review of Criticality Accidents" (ML003731912), demonstrates that 21 of the 22 historical process-related criticalities involved solutions and suggests that solutions (such as uranyl sulfate) represent the uranium compositions most likely to be involved in a process-related criticality accident. The NRC staff also determined that the use of neutron detectors is appropriate given the potential for interference from gamma sources throughout the SHINE facility. The NRC staff determined that SHINE's CAAS is appropriate for the facility and type of radiation detected, the intervening shielding, and the magnitude of the accident of concern; therefore, the staff finds this information acceptable.

<u>Request for Exemption from 10 CFR 70.24(a)</u>

SHINE FSAR section 6b.3.3 states that SHINE's CAAS is designed to meet the requirements of 10 CFR 70.24(a)(1), except for the IU cells and the material staging building (MATB). Accordingly, by letter dated January 29, 2021 (ML21029A038), SHINE requested an exemption from the requirements of 10 CFR 70.24(a) for the IU cells and the MATB. In accordance with 10 CFR 70.17(a), the Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of 10 CFR Part 70 as it determines: (1) are authorized by law; (2) will not endanger life or property or the common defense and security; and (3) are otherwise in the public interest. The NRC staff evaluation of SHINE's request for exemption from the requirements of 10 CFR 70.24(a) for the IU cells and the MATB follows.

Irradiation Unit Cells

For the IU cells during normal operation, SHINE stated that the cells are each a robust shielded enclosure that is designed to protect workers and the public from the irradiation operation. SHINE further stated that SNM handling within an IU cell occurs in a light-water pool, which provides radiation shielding during irradiation operations and would also provide protection from radiation due to an accidental criticality. The components within an IU cell are designed to be subcritical based on control of geometry with no credible means of deformation or loss of credited geometric properties. Furthermore, SHINE stated that the NFDS would detect the MAC if a criticality were to occur in the TSV dump tank in an IU cell, presenting as an increased count rate visible to operators through the process integrated control system. Inadvertent criticality in the TOGS associated with an IU cell would require a precursor condition to occur (i.e., target solution overflowing into the TOGS), which would be detected by safety-related high-level indicators in the TSV dump tank alerting operations personnel of the need to take appropriate response actions.

Based on the above, the NRC staff determined that although a credible criticality hazard exists in the TOGS associated with IU cells, appropriate measures are in place to limit the risk of criticality and to protect workers, the public, and the environment should criticality occur. The staff's evaluation of shielding is discussed in chapter 4, "Irradiation Units and Radioisotope Production Facility Description," of this SER. Therefore, the staff determined that an exemption from the requirements of 10 CFR 70.24(a) for the IU cells will not endanger life or property or the common defense and security.

The NRC staff also determined that the exemption will be otherwise in the public interest because, as discussed above, a CAAS is not necessary to protect life or property or the common defense and security and maintaining a CAAS anyway would require personnel to occasionally perform maintenance and testing on the system. Such maintenance and testing would require personnel to enter the IU cells and thus increase the frequency with which those personnel are exposed to sources of ionizing radiation, increasing their radiation doses. Therefore, granting this exemption will allow SHINE to safely produce medical isotopes while preventing maintenance workers from receiving unnecessary dose. Thus, because this exemption prevents unnecessary worker dose while not affecting safety, it is otherwise in the public interest.

Additionally, the NRC staff has the ability to grant exemptions under 10 CFR 70.17. The staff determined that the requested exemption is permissible under the Atomic Energy Act of 1954, as amended, and that no other prohibition of law exists to preclude the activities that would be authorized by the exemption. Accordingly, the staff finds that granting this exemption is in accordance with law.

Based on the above, the NRC staff grants the exemption with respect to the IU cells.

Material Staging Building

The MATB provides a location for packaged radioactive material, both as-generated solid waste and solidified liquid waste, to decay until it can be transported to an offsite final disposal location. In its exemption request, SHINE stated that the material in the MATB is as-generated solid waste packaged and staged for transport that meets the requirements of 10 CFR 71.15(a) and solidified liquid waste stored in packages that meet the requirements of 10 CFR 71.15(c). The NRC staff notes that these transportation exemptions do not apply to SNM being stored under 10 CFR Part 50 or 10 CFR Part 70, including 10 CFR 70.24(a). Nevertheless, the staff reviewed NUREG/CR-7239, "Review of Exemptions and General Licenses for Fissile Material in 10 CFR 71" (ML18052A520), and SHINE's submittal to determine if a technical basis exists to use these criteria as justification for an exemption from the requirements of 10 CFR 70.24(a) for the MATB. More specifically, the staff reviewed NUREG/CR-7239, sections 4.1.1, "10 CFR 71.15(a): Individual Package Containing 2 g or Less Fissile Material"; and 4.1.3, "10 CFR 71.15(c) Low Concentrations of Solid Fissile Material Comingled with Solid Nonfissile Material," which describe the basis for the criteria in 10 CFR 71.15(a) and (c), respectively, to consider transportation packages exempt from the criticality safety requirements of 10 CFR Part 71.

10 CFR 71.15(a)

The transportation exemption criterion in 10 CFR 71.15(a) is for individual packages containing 2 grams or less of fissile material. Section 4.1.1 of NUREG/CR-7239 states that criticality would not be credible based on practical and economic considerations for such packages. Specifically, section 4.1.1 of NUREG/CR-7239 states that a cubic array of 84,853 one-liter packages, each containing 2 grams of U-235 with no absorbers or packaging material at near-optimal moderation, is required for criticality to be possible. The NRC staff determined that this basis does not necessarily apply to the MATB because the purpose of the MATB is to store many such packages, and the MATB is not physically restricted to less than 84,853 liters. However, the staff determined that similar logic can be applied to the MATB.

Packages that meet 10 CFR 71.15(a) requirements stored in the MATB would contain as-generated solid waste absent of interstitial moderation. Packages containing, or potentially containing, interstitial moderation would not satisfy the conditions for treatment as solid waste and, therefore, would likely be treated as solidified liquid waste and packaged to meet 10 CFR 71.15(c) or further processed to remove the presence of interstitial moderation. The logic discussed in NUREG/CR-7239, which establishes that a minimum of 84,853 one-liter packages would be required for criticality, assumes near-optimal moderation with no absorbers or packaging material. Absent a significant amount of moderating material, criticality would not be possible. In order to introduce a significant amount of moderating material into the MATB, a number of significant, difficult, and unauthorized changes in process conditions would need to occur. The NRC staff considers such a condition to be not credible short of a willful, concerted effort. In addition to the required presence of significant amounts of moderating material, the packages would also need to be arranged in a specific geometrical configuration for criticality to occur. Each package is limited to 2 grams of fissile material and spacing between the fissile material in each package is provided by packaging material. The staff considers a geometrical arrangement that could support criticality to be contrived and not credible short of several unauthorized, willful changes in process conditions. Given the required presence of significant amounts of moderating material and the specific geometrical configuration required, the staff determined that the conditions required for inadvertent criticality to occur in the MATB involving packages that meet 10 CFR 71.15(a) are highly contrived and are extremely unlikely short of an unauthorized, concerted effort. The staff's review of SHINE's physical security plan is in section 12.4.8, "Security Planning," of this SER. Accordingly, the staff determined that packages meeting 10 CFR 71.15(a) do not present a credible criticality hazard, and an exemption from the requirements of 10 CFR 70.24(a) for such packages stored in the MATB will not endanger life or property or the common defense and security.

10 CFR 71.15(c)

The transportation exemption criterion in 10 CFR 71.15(c) is for packages of large volumes of low-concentration, solid fissile material commingled with solid non-fissile material. The quantity of fissile material is not limited, but it must be an essentially homogeneous mixture of fissile and non-fissile material such that no more than 180 grams of fissile material is distributed within 360,000 grams of solid non-fissile material. This 2000:1 ratio represents approximately 60 percent of the minimum critical fissile material concentration of 1.33 grams of U-235 per liter in a 1600-gram silicon dioxide per liter (SiO_2/L) matrix (NUREG/CR-7239 section 4.1.3). The NRC staff determined that the technical basis for this exemption criterion applies to material being stored at the MATB as it also involves large volumes of diluted dry materials packaged in accordance with 10 CFR 71.15(c). Accordingly, the staff determined that packages meeting 10 CFR 71.15(c) do not present a credible criticality hazard, and an exemption from the requirements of 10 CFR 70.24(a) for such packages stored in the MATB will not endanger life or property or the common defense and security.

The NRC staff also determined that the exemption will be otherwise in the public interest because, as discussed above, a CAAS is not necessary to protect life or property or the common defense and security and maintaining a CAAS anyway would require personnel to occasionally perform maintenance and testing on the system. Such maintenance and testing would require personnel to enter the MATB and thus increase the frequency with which those personnel are exposed to sources of ionizing radiation, increasing their radiation doses.

Therefore, granting this exemption will allow SHINE to safely produce medical isotopes while preventing maintenance workers from receiving unnecessary dose. Thus, because this exemption prevents unnecessary worker dose while not affecting safety, it is otherwise in the public interest.

Additionally, the NRC staff has the ability to grant exemptions under 10 CFR 70.17. The staff determined that the requested exemption is permissible under the Atomic Energy Act of 1954, as amended, and that no other prohibition of law exists to preclude the activities that would be authorized by the exemption. Accordingly, the staff finds that granting this exemption is in accordance with law.

Based on the above, the NRC staff grants the exemption with respect to the MATB.

Environmental Considerations

NRC approval of the requested exemption from the requirements of 10 CFR 70.24(a) for the IU cells and the MATB is categorically excluded under 10 CFR 51.22(c)(25), and there are no extraordinary circumstances present that would preclude reliance on this exclusion. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the approval of the requested exemption.

For the IU cells, the NRC staff determined that although a credible criticality hazard exists in the TOGS associated with IU cells, appropriate measures, such as shielding, subcriticality design, and indications to operations personnel, are in place to limit the risk of criticality and to protect workers, the public, and the environment should criticality occur. For the MATB, the staff determined that the storage of packages containing radioactive materials that meet the requirements of 10 CFR 70.15(a) and (c) does not represent a credible criticality hazard. Accordingly, related to the requested exemption, there is no significant hazards consideration; there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; there is no significant increase in individual or cumulative public or occupational radiation exposure; and there is no significant increase in the potential for or consequences from radiological accidents. Additionally, because there are no construction activities associated with the requested exemption, there is no significant construction impact. Finally, the requirement from which the exemption is sought involve the types of activities enumerated in 10 CFR 51.22(c)(25)(vi). Specifically, in accordance with 10 CFR 51.22(c)(25)(vi)(A), (B), and (C); 10 CFR 70.24, which requires the installation of a CAAS that would provide continuous monitoring, surveillance; and recordkeeping for criticality events, pertains to inspection or surveillance requirements as well as related recordkeeping and reporting requirements. Accordingly, the requested exemption is an action within the category of actions categorically excluded from further environmental review by 10 CFR 51.22(c)(25).

Emergency Planning and Response

SHINE FSAR section 6b.3.1.3 states that SHINE commits to the requirements of ANSI/ANS-8.23-2007, as endorsed by RG 3.71. SHINE FSAR section 6b.3.1.8.1, "Planned Response to Criticality Accidents," states that "SHINE maintains an emergency plan which includes the planned response to criticality accidents." SHINE FSAR section 6b.3.1.8.1 further states that the emergency plan contains information on the provision of personnel accident dosimeters in areas that require CAAS coverage, arrangements for onsite decontamination of personnel, and the transport and medical treatment of exposed individuals. The SHINE Emergency Plan, section 8.6.2, "Assembly," states, in part, that "SHINE has the capability of quickly identifying individuals who have received doses of 10 rads or more due to a criticality accident via reading of electronic dosimeters worn by personnel in the RCA." The SHINE Emergency Plan, section 9.6, "Personnel Monitoring Equipment," states that SHINE maintains emergency dosimetry that is readily available to emergency support personnel, and that equipment for prompt onsite readouts is maintained onsite. Fixed criticality accident dosimeters or instruments are located within the SHINE facility to provide spectrum information and assist in the reconstruction of a criticality accident. The SHINE Emergency Plan, section 11.7, "Emergency Plan and Procedure Use and Maintenance," states that SHINE maintains implementing procedures for the emergency plan for each area in which SNM is handled, used, or stored to ensure that all personnel evacuate to designated areas in the event of a CAAS alarm. The SHINE Emergency Plan, sections 3.3.6, "Criticality Safety Engineer," 3.5.2, "Criticality Safety Lead Engineer," and 11.1.6, "Criticality Safety Engineer," state that qualified NCS engineers are responsible for advising and assisting the emergency organization in response to a criticality event, and that they are trained on their responsibilities. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

SHINE FSAR section 6b.3.3.2, "Criticality Accident Alarm System Design," states that the CAAS is equipped with a back-up connection to the uninterruptible electrical power supply system (UPSS) and batteries to keep the system in operation for at least two hours following a facility loss of offsite power, providing operators with sufficient time to secure the movement of fissile material before a loss of alarm system coverage occurs.

SHINE FSAR section 6b.3.3.2 states that for maintenance or other conditions that would disable multiple detectors or the logic unit, administrative controls are used to secure the movement of fissile material and limit personnel access to the affected areas until alarm system coverage is restored. The SHINE FSAR further provides that these administrative controls are specific to the various processes within the RPF and include short time allowances to restore the system to full operation in lieu of immediate process shutdown in areas where process shutdown creates additional risk to personnel.

Based on the above, the NRC staff determined that information provided for the CAAS and emergency planning and response provide reasonable assurance of adequate protection against the consequences of a criticality accident in accordance with the requirements of 10 CFR 70.24(b).

Reporting Requirements

SHINE FSAR section 6b.3.1.8 states that NCS events are reported to the NRC in accordance with the reporting requirements of 10 CFR 70.50, "Reporting requirements"; 10 CFR 70.52, "Reports of accidental criticality"; and Appendix A to 10 CFR Part 70, "Reportable Safety Events." However, SHINE does not have an integrated safety analysis and associated controls designated as items relied on for safety (IROFS) pursuant to 10 CFR 70.61, "Performance requirements," because SHINE does not meet the Subpart H applicability criteria specified in 10 CFR 70.60, "Applicability." Consequently, SHINE will never experience events meeting some of the reporting requirements in Appendix A to 10 CFR Part 70. In these instances, the SHINE TSs commit to reporting events roughly equivalent to those specified in Appendix A to 10 CFR Part 70. TS 5.8.3, "Additional Event Reporting Requirements," states, in part, that the following events shall be reported to "the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:”

- An inadvertent nuclear criticality.

- An acute intake by an individual of 30 mg [milligrams] or greater of uranium in a soluble form.

- An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could endanger the life of a worker or could lead to irreversible or other serious, long-lasting health effects to any individual located outside the owner controlled area.

- An event or condition such that no credited controls, as documented in the SHINE Safety Analysis, remain available and reliable, in an accident sequence evaluated in the SHINE Safety Analysis.

TS 5.8.3 further states, in part, that the following events shall be reported to “the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:”

- Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that described in the SHINE Safety Analysis, and which results in inadequate controls in place to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

- Loss or degradation of credited controls, as documented in the SHINE Safety Analysis, other than those items controlled by a limiting condition of operation established in section 3 of the technical specifications, that results in a failure to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

- An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that could lead to irreversible or other serious, long-lasting health effects to a worker, or could cause mild transient health effects to any individual located outside the owner controlled area.

- Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more safety-related structures, systems, or components.

TS 5.8.2, “Special Reports,” describes the special reports that will be submitted to the NRC. Special reports will be reported no later than the following working day by telephone and confirmed in writing by facsimile or similar conveyance to the NRC Operations Center, to be followed by a written report to the NRC Document Control Desk describing the circumstances of the event within 14 days. This includes reports for observed inadequacies in the implementation of administrative or procedural controls such that the inadequacy causes or could have caused the existence or development of an unsafe condition with regard to operations, as well as reports for safety system component malfunctions that render or could render the safety system incapable of performing its intended safety function.

The NRC staff determined that the above information is consistent with, and meets the intent of, the reporting requirements of 10 CFR 70.50, 10 CFR 70.52, and Appendix A to 10 CFR Part 70. The staff determined that the above information is sufficient to provide reasonable assurance that events constituting a required report to the NRC will be reported appropriately.

6b.4.3.3 Conclusion

The NRC staff reviewed the SHINE CSP and various aspects of the SSA and Emergency Plan against the ISG augmenting NUREG-1537, Part 2 referencing NUREG-1520, Revision 2, and NUREG/CR-6698, as appropriate. Based on its review, the staff has reasonable assurance of the following:

(1) SHINE will have in place a CSP that will be developed, implemented, and maintained to ensure that all nuclear processes are subcritical under normal and all credible abnormal conditions, with an approved margin of subcriticality for safety. Double contingency protection will be provided, where practicable.

(2) SHINE will establish and maintain NCS controls that are subject to facility management measures to support limiting the risk of inadvertent criticality to acceptable limits, as defined in the SSA. Controls will be included in the TSs as required by 10 CFR 50.36.

(3) SHINE will have in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the CSP in accordance with the facility organization and administration and management measures.

(4) SHINE's conduct of operations will be based on NCS technical practices that ensure that fissile material will be possessed, stored, and used safely.

(5) SHINE will develop, implement, and maintain a CAAS in accordance with 10 CFR 70.24 and the facility emergency management program. An exemption from the requirements of 10 CFR 70.24 for the IU cells and for the MATB is warranted.

Based on the above determinations, the NRC staff finds SHINE's nuclear criticality safety design criteria and methods, as presented in SHINE FSAR section 6b.3, consistent with the guidance and acceptance criteria from section 6b.3 of the ISG augmenting NUREG-1537, Parts 1 and 2 for the issuance of an operating license.

6b.4.4 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed TSs for the SHINE RPF ESFs as described in SHINE FSAR section 6b.

The proposed TS 3.4, LCO 3.4.3 and SR 3.4.3 state the following:

LCO 3.4.3	Each tritium Confinement boundary valve for each TPS glovebox listed in Table 3.4.3-a shall be Operable. A valve is considered Operable if: 1. The valve is capable of closing on demand from ESFAS Note – A single valve in a flow path may be inoperable for up to 2 hours during the performance of required surveillances. Note – This LCO is applied to each TPS train independently; actions are only applicable to the TPS train(s) that fail to meet the LCO.
Applicability	Tritium present in associated TPS process equipment and not in storage
Action	According to Table 3.4.3
SR 3.4.3	1. Valves listed in Table 3.4.3-a shall be verified to close on demand from ESFAS annually.

The proposed TS Table 3.4.3, "TPS Glovebox Confinement Boundary Valve Actions," states the following:

	Condition and Action (per TPS Train)	**Completion Time**
1.	If one or more isolation valve(s) in one or more flow path(s) is inoperable, Place tritium in the associated train of TPS process equipment in its storage location OR Close at least one valve in the affected flow path.	 12 hours 12 hours

LCO 3.4.3 specifies that each confinement boundary valve in TS Table 3.4.3-a, "TPS Glovebox Confinement Valves," shall be operable by closing on demand from ESFAS and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure that ESFAS automatically isolates the TPS glovebox system to prevent the inadvertent release of tritium, a radioactive gas. The staff also finds that if the valves listed in TS table 3.4.1-a are inoperable, the tritium is placed in storage or at least one valve is closed to isolate the flow path. The staff finds that the completion time allows for investigation and the performance of minor repairs and adequate time to place the tritium in its storage location, and is based on the continued availability of the redundant actuation valve or redundant check valve in the flow path. Therefore, the staff finds LCO 3.4.3 acceptable.

SR 3.4.3 requires that the valves in TS table 3.4.3-a be verified to close on demand from ESFAS annually. section 4.4.2 of ANSI/ANS-15.1-2007 states that a functional test should be performed. NUREG-1431, Volume 1, SR 3.6.3.8 states, in part, that a test to verify that automatic containment isolation valves actuate to the isolation position on an actual or simulated signal be performed every 18 months. As described in chapter 14 of this SER, the NRC staff used guidance in NUREG-1431 to review SHINE's proposed TSs. Based on the foregoing, the staff finds that the stroke test of SR 3.4.3 is an appropriate functional test and that its frequency is adequate to confirm the operability of the TPS confinement boundary. Therefore, the staff finds SR 3.4.3 acceptable.

The proposed TS 3.4, LCO 3.4.4 and SR 3.4.4 state the following:

LCO 3.4.4	Each supercell Confinement damper listed in Table 3.4.4-a shall be Operable. A damper is considered Operable if: 1. The damper is capable of closing on demand from ESFAS
Applicability	Supercell process operations in-progress in the associated hot cell
Action	According to Table 3.4.4
SR 3.4.4	1. Dampers listed in Table 3.4.4-a shall be verified to close on demand from ESFAS annually.

The proposed TS Table 3.4.4, "Supercell Confinement Damper Actions," states the following:

	Condition and Action	**Completion Time**
1.	If one isolation damper in one or more flow path(s) is inoperable,	
	Close at least one damper in the affected flow path	72 hours
	OR	
	Suspend hot cell operations involving the introduction of liquids into the associated hot cell	72 hours
	AND	
	Drain target solution and radioactive liquids in process lines from the associated hot cell.	72 hours

2.	If two redundant isolation dampers in one or more flow path(s) are inoperable, Close at least one damper in the affected flow path OR Suspend hot cell operations involving the introduction of liquids into the associated hot cell AND Drain target solution and radioactive liquids in process lines from the associated hot cell.	 6 hours 6 hours 6 hours

LCO 3.4.4 specifies that each supercell confinement damper in TS table 3.4.4-a, "Supercell Confinement Dampers," shall be operable by being capable of closing on demand from ESFAS when supercell process operations are in-progress in the associated hot cell and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure that ESFAS automatically isolates the supercell areas to prevent the inadvertent release of radioactive material. The staff also finds that if the dampers listed in TS table 3.4.4-a are inoperable, either the flow path is isolated by closing a damper or hot cell operations are suspended, which involves no further introduction of liquids into the hot cell and the draining of all solutions that are in the process lines. The staff finds that the completion time allows for investigation and the performance of minor repairs and is based on the continued availability of the redundant isolation damper with the low likelihood of a release occurring during a 6-hour duration. Therefore, the staff finds LCO 3.4.4 acceptable.

SR 3.4.4 requires that each supercell confinement damper in TS table 3.4.4-a be verified to close on demand from ESFAS annually. Section 4.4.1, "Containment," of ANSI/ANS-15.1-2007 states that a functional test should be performed. NUREG-1431, Volume 1, SR 3.6.3.8 states, in part, that a test to verify that automatic containment isolation valves actuate to the isolation position on an actual or simulated signal be performed every 18 months. As described in chapter 14, "Technical Specifications," of this SER, the NRC staff used guidance in NUREG-1431 to review SHINE's proposed TSs. Based on the foregoing, the staff finds that the verification to close on demand from ESFAS of SR 3.4.4 is an appropriate functional test and that its frequency is adequate to confirm the operability of the supercell confinement boundary. Therefore, the staff finds SR 3.4.4 acceptable.

6b.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE RPF ESFs, as described in SHINE FSAR section 6b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the RPF ESFs and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 70, 10 CFR Part 50, and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE RPF ESFs are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

7.0 INSTRUMENTATION AND CONTROL SYSTEMS

Instrumentation and control (I&C) systems comprise the sensors, electronic circuitry, displays, and actuating devices that provide the information and means to safely control the SHINE Medical Technologies, LLC (SHINE, the applicant) irradiation facility (IF) and radioisotope production facility (RPF) and to avoid or mitigate accidents. Together, the IF and RPF constitute the SHINE facility. The final design description of the I&C systems in the SHINE final safety analysis report (FSAR) focuses on those structures, systems, and components (SSCs) and associated equipment that constitute the I&C systems and includes the overall design bases, system classifications, functional requirements, and system architecture.

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE I&C systems, as presented in chapter 7, "Instrumentation and Control Systems," of the SHINE FSAR and supplemented by the applicant's responses to staff requests for additional information (RAIs).

7.1 Areas of Review

The NRC staff reviewed SHINE FSAR chapter 7 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of SHINE's I&C systems. The final design of SHINE's I&C systems was evaluated to ensure that the design bases and functions of the systems and components are presented in sufficient detail to allow a clear understanding of the facility and that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the operating staff and the public. Drawings and diagrams were evaluated to ensure that they present a clear and general understanding of the physical facility features and of the processes involved. In addition, the staff evaluated the sufficiency of SHINE's proposed technical specifications (TSs) for the facility.

7.2 Summary of Application

SHINE FSAR chapter 7 describes the I&C systems, which provide the capability to monitor, control, and protect the facility systems manually and automatically during normal and accident conditions.

Systems and topics addressed in SHINE FSAR chapter 7 include:

- The process integrated control system (PICS) and vendor-provided control systems;
- The target solution vessel (TSV) reactivity protection system (TRPS);
- The engineered safety features actuation system (ESFAS);
- The highly integrated protection system (HIPS) platform implementing the TRPS and ESFAS;

- The SHINE facility control room control consoles and displays;

- The radiation monitoring systems (RMS), including

  - Process radiation monitors considered part of the ESFAS, TRPS, and tritium purification system (TPS)
  - Process radiation monitors included as part of other facility processes
  - The radiation area monitoring system (RAMS)
  - The continuous air monitoring system (CAMS)
  - The stack release monitoring system (SRMS); and

- The neutron flux detection system (NFDS).

7.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 7 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the bases and the information provided by SHINE for the issuance of an operating license.

7.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's I&C systems are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.2, "Definitions."

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."

- 10 CFR 50.36, "Technical specifications."

- 10 CFR 50.40, "Common standards."

- 10 CFR 50.57, "Issuance of operating license."

- 10 CFR Part 55, "Operators' Licenses."

- 10 CFR Part 20, "Standards for Protection Against Radiation."

7.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.
- NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," issued June 2015.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides (RG), Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, "References," of this SER.

7.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR chapter 7, as supplemented, to assess the sufficiency of the final design and performance of SHINE's I&C systems for the issuance of an operating license. The sufficiency of the final design and performance of SHINE's I&C systems is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 7.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in section 7.5, "Review Findings," of this SER.

7.4.1 Summary Description

The NRC staff evaluated the sufficiency of the summary description of the SHINE facility I&C systems, as presented in SHINE FSAR section 7.1, "Summary Description," using the applicable guidance and acceptance criteria from section 7.1, "Summary Description," of NUREG-1537, Parts 1 and 2, and section 7b.1, "Summary Description," of the ISG augmenting NUREG-1537, Parts 1 and 2.

7.4.1.1 Design of Instrumentation and Control Systems

The SHINE facility is monitored and controlled through the PICS. The PICS performs the monitoring and control functions of the IF's eight irradiation units (IUs) and at the facility level. This includes transferring target solution from one location to another, adjusting cooling systems, and the monitoring of temperature, pressure, level, and flow in various locations throughout the facility.

Each of the eight IUs has an independent TRPS and NFDS. PICS also controls certain systems in the RPF as described in SHINE FSAR section 4b, "Radioisotope Production Facility Description." The ESFAS is provided for protective functions that are common to the entire facility. The RMS monitors radiation levels within the facility and emissions from the facility.

The purpose of the TRPS is to monitor process variables and provide automatic initiating signals in response to off-normal conditions, providing protection against unsafe IU operation during the IU filling, irradiation, and post-irradiation modes of operation.

The SHINE facility includes engineered safety features (ESF) to mitigate the consequences of postulated accidents.

The SHINE facility control consoles and displays (i.e., operator workstations and main control board) are provided as the human system interface. A single PICS provides the monitoring and control functions of the IUs and facility-level monitoring and control functions.

The SHINE facility also includes the RMS, which consists of the inputs to the TRPS, and ESFAS, the RAMS, the SRMS, and the CAMS. The systems monitor radiation at a facility level separate from the IUs. The criticality accident alarm system (CAAS) is discussed in SHINE FSAR section 6b.3.3, "Criticality Accident Alarm System," and the criticality safety program relies on two of the ESFAS safety functions for satisfying the double contingency principal.

The NFDS is used for monitoring the reactivity and power of the subcritical assembly system in each IU. The NFDS is a system with redundant channels of neutron flux detectors. The NFDS detects and provides remote indication of the neutron flux levels during TSV filling and irradiation to determine the multiplication factor and power levels, respectively. The NFDS provides outputs to the TRPS used for trip determination. The TRPS also provides these same outputs to the PICS, which are used for the monitoring of conditions within the IU.

7.4.1.2 System Description

7.4.1.2.1 Design Criteria

NUREG-1537, Part 1, section 3.1, "Design Criteria," states, in part:

> In this section the applicant should specify the design criteria for the facility structures, systems, and components .... The design criteria should be both specific and general ….

SHINE FSAR section 3.1, "Design Criteria," includes tables 3.1-1 and 3.1-2, which list the design criteria applicable to each I&C system. In addition, the SHINE FSAR identifies additional design criteria for each I&C system; these criteria are provided in SHINE FSAR sections 7.3 through 7.8 and evaluated for each I&C system below. In effect, the SHINE FSAR identifies two types of design criteria: (1) SHINE Design Criteria (i.e., those listed in SHINE FSAR table 3.1-3) and (2) system-specific design criteria (e.g., "PICS Criterion 1"). SHINE FSAR table 3.1-1, note 2 states that the generally applicable SHINE Design Criteria 1-8 from SHINE FSAR table 3.1-3 are not specifically listed even though they are generally applicable to most SSCs.

NUREG-1537, Part 1, section 7.2.1, "Design Criteria," states, in part:

> In this section of the [F]SAR, the applicant should discuss the criteria for developing the design bases for the I&C systems. The basis for evaluating the reliability and performance of the I&C systems should be included.

There are a few design criteria that are applicable to multiple I&C systems, in part, because the required functionality is only achieved through the interaction of these I&C systems. For example, the NFDS includes the neutron flux sensors and dedicated electronics, while the TRPS includes the logic for initiating the associated protective actions, while the PICS displays the flux values to the operator. The PICS displays are part of the SHINE facility control console and display instruments.

The NRC staff's evaluation of the I&C systems against the applicable SHINE Design Criteria considers only the role that an I&C system plays in meeting the design criteria and should not be understood to mean that the I&C system, by itself, satisfies all of the aspects of the SHINE Design Criteria.

The SHINE FSAR identifies the following design principles:

- Independence
  - Physical
  - Electrical
  - Communication
  - Functional
- Redundancy
- Predictability and repeatability
- Diversity

- Simplicity

These design principles are incorporated into the additional design criteria for I&C systems, as applicable.

7.4.1.2.2 Design Bases

NUREG-1537, Part 1, section 7.2.2, "Design-Basis Requirements," states, in part:

> I&C system design requirements … are generally derived from the results of analyses of normal operating conditions and of accidents and transients that could occur.

The I&C design bases describe I&C system-specific functions to be performed, operational characteristics, specific values or ranges of values chosen for monitoring and controlling parameters, and design principles. The design basis for the I&C systems is described in SHINE FSAR sections 7.3 through 7.8 and evaluated below.

SHINE FSAR tables 7.2.1 through 7.2.6 identify the design radiation and environmental parameters for the different areas in the SHINE facility where the I&C systems are installed.

7.4.2 HIPS Design

The NRC staff evaluated the sufficiency of the design of the SHINE facility I&C systems, as presented in SHINE FSAR section 7.2, "Design of Instrumentation and Control Systems," using the applicable guidance and acceptance criteria from section 7.2, "Design of Instrumentation and Control Systems," of NUREG-1537, Parts 1 and 2, and section 7b.2, "Design of Instrumentation and Control Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 7.4.5 states that the HIPS platform is used for the TRPS and ESFAS design and incorporates by reference the HIPS platform topical report (TR), TR-1015-18653, Revision 2, "Design of the Highly Integrated Protection System Platform" (Agencywide Documents Access and Management System Accession No. ML17256A892). In its safety evaluation of the HIPS TR, the NRC staff concluded that the HIPS platform meets the standards of IEEE Standard 603-1991, "Standard Criteria for Safety Systems for Nuclear Power Generating Stations," including the correction sheet dated January 30, 1995, IEEE Standard 7-4.3.2-2003, "Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations," NRC Digital I&C Interim Staff Guidance (DI&C ISG)-04, "Highly-Integrated Control Rooms-Communications Issues," and the NRC Staff Requirements Memorandum (SRM), dated July 21,1993, to SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs." The staff safety evaluation of the HIPS TR requires the user to address 65 application-specific action items (ASAIs) to ensure that the generic approval granted by the safety evaluation remains valid for a specific system or plant application using the HIPS platform.

In its response to NRC staff RAI 7-10 (ML22144A231), SHINE provided technical report TECRPT-2018-0028, Revision 2, "HIPS Platform Application Specific Action Item Report for the TRPS and ESFAS." This technical report addresses the 65 ASAIs in relation to the design of the TRPS and ESFAS for the SHINE facility and evaluates each ASAI for applicability to SHINE's operating license application. If the ASAI is determined to be not applicable, justification for why it is not considered applicable is provided. If the ASAI is determined to be applicable, a reference is given for the appropriate sections of the SHINE FSAR or for the appropriate design basis document that provides the material that addresses the ASAI. The results of the applicant's disposition of the ASAIs are provided in table 3-1 of TECRPT-2018-0028. The ASAIs specified in the HIPS TR safety evaluation are intended for power reactor applications and therefore some of the ASAIs are not applicable to the SHINE application of the HIPS platform. Based on its evaluation of SHINE technical report TECRPT-2018-0028, the NRC staff finds the applicant's dispositions of the ASAIs acceptable.

For the TRPS and ESFAS applications, the applicant has made a few modifications and additions to the fundamental HIPS platform equipment design and functionality as described in the HIPS TR. The following modifications and additions to the HIPS platform are described in section 5 of TECRPT-2018-0028. These changes to the fundamental HIPS platform equipment design and functionality, listed below, are evaluated in applicable sections of section 7.4.2 of this SER.

- Hardwired Module (HWM) Input Routing
- Use of Fiber Optic Communications
- Communications Module (CM) Bi-Directional Communications
- Implementation of Equipment Interface Modules (EIM) Switching Outputs
- Specific Implementation of Communications Modules
  - Scheduling, Bypass, and Voting Modules (SBVM)
  - Gateway Communications Modules (GWCM)
- SBVM Safety Data Bus Frame
- Self-Testing
  - Analog to Digital Converter
  - EIM Input and Output Testing
  - HWM Input Channel Test
  - End-to-End Testing
- HIPS Module LEDs
- Remote Input Submodule (RISM)
- SBVM Manual Testing Capability

7.4.2.1 System Description

The HIPS is a digital system that uses field programmable gate array (FPGA) and discrete components. The HIPS uses different modules installed in a chassis. These modules and inputs and outputs are connected to each other through the back panel and backplane of the chassis. The back panel provides structural support to mount the backplane to the chassis. The backplane consists of a printed circuit board, connectors (to connect modules), and copper traces (for communication). The HIPS TR includes a representative architecture to illustrate how the HIPS platform meets the fundamental digital I&C principles of independence, redundancy, predictability and repeatability, and diversity and defense-in-depth. The architectures of the TRPS and ESFAS are described in SHINE FSAR sections 7.4.1 and 7.5.1, respectively, and include modifications and additions made to the generic architecture described in the TR.

The HIPS platform supports an installation that provides redundant electrical power sources to the HIPS chassis backplane. The TRPS divisions A and B are powered from a separate division of the uninterruptible electrical power supply system (UPSS); TRPS division C receives auctioneered power from both UPSS divisions A and B. While the UPSS is not classified as a Class 1E system, portions of Class 1E standards are applied to the UPSS. The acceptability of the UPSS is evaluated in chapter 8, "Electrical Power Systems," of this SER.

HIPS Modules

The HIPS platform consists of a system of modules that are interchangeable between chassis. The platform is designed to work with different module types configured to the individual application where multiple chassis can be connected to create a larger system as needed. The different HIPS modules and platform inputs and outputs are connected to each other through backplane and back panel of the chassis. As a part of the NRC staff's review of the HIPS TR, fundamental building blocks of the HIPS platform consisting of safety function modules (SFMs), CM, EIM, and HWM were found to be acceptable for use in a safety-related I&C architecture based on the HIPS platform. The same fundamental building blocks of the HIPS platform have been customized in building the TRPS and ESFAS. HIPS modules used in the TRPS and ESFAS are:

- Safety Function Modules
  - Remote Input Submodule (RISM)
  - Self-Testing of Analog to Digital Converter
- Communications Modules configured as:
  - Scheduling and Bypass Modules (SBM)
  - Scheduling Bypass and Voting Modules (SBVM)
  - SBVM Safety Data Bus Frame
  - Gateway Communications Modules (GWCM)
  - Monitoring and Indication CM (MI-CM)
  - CM Bi-Directional Communications
- Hardwired Modules
  - Hardwired Submodules (HW-SM)
  - HWM Input Routing
  - Self-Testing of HWM Input Channel Test
  - FPGA on HWM for Operational Status
- Equipment Interface Modules
  - Implementation of EIM Switching Outputs
  - Self-Testing of EIM Input and Output

- Maintenance Work Station (MWS)
- HIPS Module LEDs

In its response to RAI 7-10, the applicant provided technical report TECRPT-2018-0028, which describes the design differences between the generic HIPS platform modules presented in the HIPS TR and the specific HIPS modules implemented in the TRPS and ESFAS. The following is the NRC staff's technical evaluation of the modifications and additions to the generic HIPS platform module design and functionality for SHINE applications.

<u>Safety Function Module</u>

Fundamental design and functionality of the SFMs used in the TRPS and ESFAS are the same as those evaluated in the HIPS TR. SFMs used in the SHINE applications are composed of three functional areas: (1) ISM; (2) SFM digital logic circuits; and (3) communications engines, which are the same as described in section 2.5.1 of the HIPS TR. For the SHINE applications, the SFMs have been modified to accept remote input signals via a new input submodule (ISM) designated as RISM. The RISM is directly associated with a single SFM that allows for remotely locating one ISM from its associated SFM. The ISM used on a RISM is the same as described in the HIPS TR. Once an input signal is in digital format on the ISM, the input information is provided by the RISM via an isolated, one-way RS-485 connection to its associated SFM within the division for triplication and trip determination. There is an additional RS-485 connection between the RISM and its associated SFM which independently supports modification of tunable parameters necessary on the RISM. The technical evaluation of ISM in section 3.1.4.1.1 of the NRC staff's safety evaluation of the HIPS TR is not affected by this additional application of ISM. Therefore, the staff finds this modification of SFM acceptable.

Section 8.2.1 of the HIPS TR describes an auto calibration feature for the analog to digital converter (ADC) for an ISM. The auto-calibration function includes the use of external passive components, whereas the analog ISM used in the TRPS and ESFAS incorporates critical passive components onto the ADC chip. This results in very precise values that are factory calibrated and are significantly less prone to drift over time and temperature; therefore, the auto-calibration function is not implemented for the TRPS and ESFAS designs. Since all analog input signals to the TRPS and ESFAS will be periodically surveilled for accuracy, the NRC staff finds the modification to ISM acceptable.

<u>Communications Module</u>

Fundamental design and functionality of the CMs used in the TRPS and ESFAS architecture is the same as that evaluated in the HIPS TR. Specific configurations of HIPS CMs used in the TRPS and ESFAS design are SBM, SBVM, MI-CM, and GWCM.

Throughout the HIPS TR, the use of SBM and SVM [scheduling and voting module] is discussed as part of a "representative architecture," which is provided in the TR to help describe the design principles implemented within the HIPS platform. Both modules are example configurations of the HIPS CM. The TRPS and ESFAS designs use a configuration of CM that is referred to as a SBVM in Divisions A and B. The SBVM combines all functions, capabilities, and design principles described in the HIPS TR for a SBM and a SVM into a single module. This was implemented to minimize the total number of HIPS hardware modules necessary for the required TRPS and ESFAS functionality. As such, the use of a SBVM in the TRPS and ESFAS designs does not represent a modification or addition to the HIPS Platform as described in the

HIPS TR. Since the SVM functionality on each SBVM will load each of the specific TRPS or ESFAS application's voting registers with the partial trip determination actuation (PTDA) information received by its SBM functionality, figure 7-8 of the HIPS TR is modified in TECRPT-2018-0028, figure 5-1 to add a note that the "Wait for Sync" is not necessary for the SBVMs. Because the TRPS and ESFAS implement 1-out-of-2, 2-out-of-2, or 2-out-of-3 voting, which is different than the 2-out-of-4 voting discussed in the HIPS TR, this figure has also been modified to show the three TRPS/ESFAS divisions as opposed to the four divisions of the representative architecture in the HIPS TR.

Sections 7.6.3 through 7.7.1 of the HIPS TR describe the operations and safety data bus frames for the SBM and SVM. The TRPS and ESFAS will incorporate a change to how the SBVM votes on the PTDA and communicates actuation data to the EIMs. Instead of sending separate trip determination actuation (TDA) information for each safety function group (SFG) to the EIMs, all SFGs are voted on at the same time and the TDA for all SFGs are then transferred to the EIMs at once. To reflect this change, figure 7-12 of the HIPS TR is modified in TECRPT-2018-0028, figure 5-3 to show a single transaction for the TRPS and ESFAS implementation. Figure 7-14 of the HIPS TR is also modified in TECRPT-2018-0028, figure 5-3 to show the SBM and SVM functionality being performed by the SBVM module.

The GWCM is a HIPS platform communications module not described in the HIPS TR, which performs only monitoring and indication functions. The TRPS and ESFAS monitoring and indication information is transmitted redundantly from each system's divisional monitoring and indication communications module (MI-CM) via one-way isolated RS-485 connections to respective redundant GWCMs, which are in two redundant gateway chassis. Figure 7-15-1, "TRPS and ESFAS Gateway Communications Architecture," of SHINE's response to NRC staff RAI 7-15 (ML22144A231) depicts the TRPS and ESFAS communications architecture. The GWCMs for the TRPS are functionally and logically independent from the GWCMs for the ESFAS and vice versa. They are physically located within two chassis and located in the ESFAS Division C cabinet. This figure shows the specific inputs and outputs from the independent TRPS GWCMs and the independent ESFAS GWCMs. As described in section 2.5.3 of the HIPS TR, the GWCMs, which are HIPS platform communications modules, have four communications ports, each of which can be configured as receive-only or transmit only. Three of the four communications ports of each GWCM are configured as receive-only ports for their respective status and diagnostics information input. The fourth communications port of each GWCM is configured for two-way communications with the respective PICS channel using the MODBUS communications protocol. Two-way communication is a departure from the HIPS TR description of a communications module. The staff finds this is acceptable because the communication from each MI-CM to a GWCM is isolated and one-way only.

Hardwired Module

Fundamental design and functionality of the HWMs used in the TRPS and ESFAS architecture is the same as those evaluated in the HIPS TR. The HWM converts hard-wired contact inputs into logic levels for direct connection on dedicated backplane traces to particular modules as per the detail application design. The following are the TRPS and ESFAS design specific HWM configurations.

In its response to NRC staff Request for Confirmatory Information (RCI) 7-1 (ML22318A178), SHINE confirmed that section 3.1.1, "Independence," of TECRPT-2019-0048, Revision 5, "TRPS System Design Description," states that hard-wired submodules (HW-SB) on the SBVMs are used for signals between TRPS Division A to ESFAS Division A or between TRPS Division B to ESFAS Division B (for actuations impacting both systems), which are processed using unidirectional communications type cables via divisional raceways / wireways.

Section 2.5.2 of the HIPS TR states that Trip/Bypass inputs to the HWM are "routed only to the scheduling and bypass modules (SBMs) where it is used." There are two differences for this statement in the TRPS and ESFAS designs. The first is that the inputs to the HWMs are used at the SBMs (Division C), the SBVMs (Divisions A and B), the MI-CMs (for monitoring and indication information), and at the EIMs for manual actuation of protective functions and manual functions. The second difference is that the inputs to the HWMs are made available to all modules in the same chassis. The modules listed above use the signals that are made available on the backplane from the HWMs. Additionally, discussion of the use of the trip/bypass switches with the SBMs in the TR applies the same to the use of the trip/bypass switches with the SBVMs in Divisions A and B of the TRPS and ESFAS designs. Input channel self-test identified in section 8.2.7, "Module Testing," of the HIPS TR for HWM input signals is not being implemented for the TRPS and ESFAS designs.

In its response to NRC staff RAI 7-14 (ML21239A049), SHINE states that the HWM includes an FPGA, which is a departure from the HIPS TR description of an HWM. Function of the FPGA on the HWM is only to drive the module front panel LED indications and to provide module operational status to the MI-CM. The staff concludes that the FPGA on the HWM cannot affect the function of receiving hardwired inputs and making them available on the backplane of the chassis; therefore, this change is acceptable.

Equipment Interface Module

The fundamental design and functionality of the EIMs used in the TRPS and ESFAS architecture are the same as the ones evaluated in the HIPS TR. The configuration of EIMs for the TRPS and ESFAS designs is discussed below.

Section 2.5.4.4 of the HIPS TR states that each EIM "can control two groups of field components and each group can have up to two field devices." The HIPS platform has been modified for the TRPS and ESFAS designs such that each EIM can control up to eight field devices. Redundancy of dual high side and dual low side contacts for each output switch is not implemented in the TRPS and ESFAS EIM designs. Loads actuated by the TRPS and ESFAS are small solenoids; therefore, a single high side and a single low side EIM contact was used. In its response to NRC staff RCI 7-2 (ML22318A178), SHINE confirmed that section 3.1, "System Architecture," of TECRPT-2019-0048 and TECRPT-2020-0002, Revision 5, "Engineered Safety Features Actuation System Design Description," state that an EIM is included in each actuation division (Divisions A and B) for each component actuated by the TRPS and ESFAS. Each EIM has eight separate logic paths to allow for connection to separate actuated components. Each component is connected to two separate EIMs, resulting in two EIMs providing redundant control to each component as shown in figure 3-6, "Equipment Interface Module Configuration," of TECRPT-2019-0048. This allows an EIM to be taken out of service and replaced online without actuating the connected equipment.

The self-testing described in sections 8.2.3.2 and 8.2.3.4 of the HIPS TR for discrete input circuitry (open/closed contact tests) and high drive output testing is not being implemented for the TRPS and ESFAS designs. In accordance with SHINE TSs surveillance requirement (SR) 3.2.1 and SR 3.2.2, operability of EIMs will be periodically tested; therefore, the NRC staff finds the lack of an EIM self-test feature acceptable.

Maintenance Workstation

Each division of the TRPS and ESFAS has an MWS for the purpose of online monitoring and offline maintenance and calibration. The HIPS platform MWS supports online monitoring through one-way isolated communication ports. The MWS is used to update setpoints and tunable parameters in the HIPS chassis when the safety function is out of service. Physical and logical controls are put in place to prevent modifications to a safety channel when it is being relied upon to perform a safety function. A temporary cable and out-of-service (OOS) switch are required to be activated before any changes can be made to an SFM. Application of the MWS in the TRPS and ESFAS designs is the same as described in the HIPS TR. In its response to NRC staff RAI 7-18 (ML21239A049), the applicant described the use of the MWS in the TRPS and ESFAS designs for modification of setpoints and tunable parameters and SHINE FSAR section 7.4.5.3.3 provides additional detail on how the MWS is used to change setpoints and tunable parameters.

HIPS Module ACTIVE and FAULT LEDs

Section 8.2.7 of the HIPS TR identifies that LED tests will be performed to identify if an incorrect LED status is being displayed. This test will not be performed on a continuous basis for the TRPS and ESFAS designs for the following reasons:

- Module front panel indication is not a safety function
- Correct LED operation will be tested as part of factory and installation testing

Section 8.4 of the HIPS TR describes the two LEDs on the front of each HIPS module which are used to indicate the state of the module latches, the operational state of the module, and the presence of any faults for the module. The TRPS and ESFAS designs will include the following changes to the function of the LEDs from that presented in the TR:

- The ACTIVE and FAULT LEDs are Green during normal operation with no fault present
- The ACTIVE LED will turn Red on a vital fault or when the module has one latch open
- The FAULT LED will never flash and not turn Red
- The FAULT LED will turn Yellow for any fault (non-vital or vital)

The NRC staff finds this change does not affect the acceptability of the HIPS Module ACTIVE and FAULT LEDs.

7.4.2.1.1 HIPS Communication

Data communication in the TRPS and ESFAS design is same as described in the HIPS TR. For the TRPS and ESFAS design, copper RS-485 physical layer is being implemented. Whereas the representative protection system architecture in the HIPS TR is based on fiber optic physical layer. Sections 2.5.3, 4.3, and 4.6.2 of the HIPS TR describe the use of fiber optic ports for inter-divisional transmit-only or receive-only fiber optic ports. The TRPS and ESFAS designs do not use fiber optic ports for inter-divisional communications. The inter-divisional communications in the TRPS and ESFAS are implemented with transmit-only or receive-only copper RS-485 connections.

7.4.2.1.2 HIPS Operation

The HIPS TR describes operation of the HIPS platform with an example of a representative four channel protection system architecture. SHINE FSAR sections 7.1.2, 7.1.3, 7.4.1, and 7.5.1 and figures 7.1-1, 7.1-2, and 7.1-3 and TS Basis for Limiting Condition for Operation (LCO) 3.2.1 and LCO 3.2.2 describe how operation of the HIPS is implemented for the TRPS and ESFAS. Differences between the representative HIPS platform presented in the HIPS TR and the specific SHINE implementation for the TRPS and ESFAS are documented in section 5 of TECRPT-2018-0028, which the applicant submitted in response to RAI 7-10. Detailed documentation of TRPS and ESFAS architecture is contained in TRPS and ESFAS system design descriptions. Consistent with the HIPS TR, the TRPS and ESFAS designs incorporate the fundamental I&C design principles as well as functionality including the capability for test and calibration.

TRPS and ESFAS are comprised of three independent divisions of equipment identified as Division A, Division B, and Division C. The TRPS and ESFAS use redundant and independent sensor inputs to each of these three divisions to complete the logical decisions necessary to initiate the required protective trip and actuations in Division A and Division B.

The HIPS architecture for TRPS and ESFAS consists primarily of SFMs, which receive the sensor signals and initiate trip signals that is communicated to the SBVMs via three safety data buses (SDBs). The output of the three redundant SBVMs in Divisions A and B is communicated via three independent SDBs to the associated EIMs. Division C uses a SBM instead of an SBVM to pass signals through to Division A and B where the voting and actuations occur. When an input channel exceeds a predetermined limit, the SFMs in each division initiate redundant trip signals that are sent to the Division A and Division B SBVMs. The SBVMs perform coincident logic voting to initiate trip or actuation signals to the TRPS and ESFAS components through EIMs. Either 1-out-of-2 or 2-out-of-3 voting is used so that a single failure of a trip signal will not prevent an equipment actuation from occurring when required. Each voting layer receives trip or actuation information from the SFMs via the SDB. When the TRPS or ESFAS logic and voting determine a trip is required, the SBVM sends the trip demand signal to the appropriate EIMs, via the SDB, which then trip or actuate the appropriate equipment via dedicated copper wire. An EIM is included in each actuation division (Divisions A and B) for each component actuated by the TRPS and ESFAS. Each EIM has two separate logic paths to allow for connection to separate actuated components. Each component is connected to two separate EIMs, resulting in two EIMs providing redundant control to each component.
Both EIMs associated with a component are required to be deenergized for actuation of component(s) (fail-safe) to their actuated (deenergized) states. Use of redundant EIMs allows for one of the EIMs to be taken out of service and replaced online without actuating the connected equipment.

When a trip signal is generated in the SBVM, the appropriate switching outputs from the EIM open, power is interrupted to the actuation components, and the components change state to their deenergized position. Normal operation of the facility is performed from the facility control room (FCR) using the PICS. There are no required operator actions under postulated accident conditions. However, both automatic and manual initiation capability for all safety functions are provided in the TRPS and ESFAS design.

7.4.2.1.3 Equipment Qualification

The HIPS TR does not include environmental qualification of the HIPS platform. SHINE Design Criterion 16 states, in part, that the protection systems are designed to ensure that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions on redundant channels do not result in loss of the protection function or are demonstrated to be acceptable on some other defined basis. To comply with SHINE Design Criterion 16, the HIPS equipment for the TRPS and ESFAS is required to be qualified for the postulated environmental conditions. In its response to NRC staff RAI 7-16 (ML21239A049), the applicant provided additional information on HIPS equipment qualification and proposed changes to SHINE FSAR sections 7.4.2.2.11, 7.4.3.5, 7.4.3.6, 7.5.2.2.11, 7.5.3.4, and 7.5.3.5. These SHINE FSAR changes provide additional description of the environmental, seismic, and electromagnetic interference/radio-frequency interference (EMI/RFI) qualification testing of the HIPS equipment.

The applicant's response to RAI 7-16 states that the HIPS equipment for the TRPS and ESFAS has been qualified by the vendor. A discussion of the environmental, seismic, and EMI/RFI qualifications of the HIPS equipment for the TRPS and ESFAS follows.

Environmental Qualification

Mild environmental qualification was performed for the HIPS equipment for the TRPS and ESFAS using guidance provided in sections 4.1, 5.1, 6.1, and 7 of IEEE Standard 323-2003, "Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations." Environmental qualification was performed considering temperature, relative humidity, radiation, and pressure. Because the HIPS equipment for the TRPS and ESFAS is in a mild environment and will not be subject to harsh environmental conditions during normal operation or transient conditions, a qualified life determination is not required. The HIPS equipment has been designed for continuous operation up to 140 degrees Fahrenheit (°F) and limited operation up to 158°F. A proof test was performed in an environmental chamber, which verified the normal and abnormal temperature exposure levels for the HIPS equipment. The temperature conditions under which the proof test was performed and satisfactorily completed envelop the normal and transient temperature conditions that the HIPS equipment is expected to operate in, as provided in SHINE FSAR tables 7.2-2 and 7.2-3.

The HIPS equipment for the TRPS and ESFAS is acceptable for mild environment relative humidity conditions. Non-condensing humidity does not represent a credible failure mode applicable to the HIPS equipment. During the proof test discussed above, humidity was not controlled and varied based upon the temperature at the time of testing. Acceptance criteria of the proof test were met, demonstrating that the equipment is expected to operate under required conditions for humidity.

As provided in SHINE FSAR table 7.2-1, the total integrated dose for areas of the facility in which the HIPS equipment will be installed is calculated as 1.0E+03 rad total integrated dose. When performing the HIPS equipment qualification, the vendor reviewed industry studies that compiled radiation effects data on a wide range of materials showing that the least radiation resistance threshold for organic compounds (i.e., nonmetallic materials) is greater than 1.0E+04 rad gamma. For electronic components, studies have shown that metal oxide semiconductor devices may be susceptible at a lower level of 3.0E+03 rad gamma. Since the service conditions for the HIPS equipment for the TRPS and ESFAS are less than these bounding values, no further evaluation for radiation in the environmental qualification was required.

The HIPS equipment for the TRPS and ESFAS is acceptable for normal atmospheric pressure, which is the normal and transient pressures provided in SHINE FSAR tables 7.2-2 and 7.2-3. Normal atmospheric pressure is not considered adverse to the HIPS equipment operation; the HIPS components are not pressure sealed and, therefore, do not create any differential pressure or failure mechanism.

Seismic Qualification

The HIPS equipment for the TRPS and ESFAS was subjected to a proof test in accordance with section 8 of IEEE Standard 344-2013, "Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations." The HIPS equipment for the TRPS and ESFAS underwent biaxial and triaxial excitation testing. Five operating basis earthquake (OBE) tests were performed in each direction for a total of 20 OBE runs. One safe shutdown earthquake (SSE) test was performed in each direction for a total of four SSE runs. For the triaxial excitation testing, the HIPS equipment was tested in each of three orientations with respect to the excitation. The triaxial excitation test was performed in all three directions for each test. A total of five OBE tests were performed. The results of the proof test demonstrated that for all test runs, structural integrity of the HIPS equipment was maintained, and no mechanical damage was observed. In its response to RAI 7-16, SHINE stated that the acceptance criteria of the seismic testing were met to demonstrate qualification of the equipment for the TRPS and ESFAS.

Electromagnetic Interference/Radio-Frequency Interference Qualification

Although the regulatory positions of Regulatory Guide 1.180, Revision 2, "Guidelines for Evaluating Electromagnetic and Radio-Frequency Interference in Safety-Related Instrumentation and Control Systems" (ML19175A044), are specific to nuclear power plants and are not applicable to non-power production and utilization facilities, this regulatory guide, which provides an acceptable method for qualifying computer-based digital systems, informed the EMI/RFI qualification of the HIPS equipment. The installation of HIPS equipment in the SHINE facility will be grounded per section 5.2.1 of IEEE Standard 1050-2004, "Guide for Instrumentation and Control Equipment Grounding in Generating Stations."

Emissions testing for HIPS equipment was performed using the testing methods listed in Regulatory Position 3, table 2, of RG 1.180. Susceptibility Testing for HIPS equipment was performed using the testing methods listed in Regulatory Position 4, table 6, of RG 1.180. Surge withstand testing for HIPS equipment was performed using the International Electrotechnical Committee (IEC) methods listed in Regulatory Position 5, table 21, of RG 1.180. The results of this testing were satisfactory and demonstrate the EMI/RFI qualification of HIPS equipment for the TRPS and ESFAS and confirm that the effects of EMI/RFI and power surges are addressed.

Based on the successful environmental, seismic, and EMI/RFI qualifications of the HIPS equipment for the TRPS and ESFAS, the NRC staff finds that the SHINE I&C systems meet the applicable parts of SHINE Design Criterion 16, which ensures that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions on redundant channels do not result in loss of the protection function.

7.4.2.1.4 HIPS Diagnostic and Self-testing

In its response to RAI 7-15, the applicant provided the following details related to the HIPS diagnostics and self-testing features and SHINE FSAR section 7.4.5.5 provides additional description of the diagnostic and maintenance features associated with the HIPS platform for the TRPS and ESFAS.

The TRPS and ESFAS are designed with the capability for calibration and surveillance testing, including channel checks, calibration verification, and time response measurements to verify that I&C safety systems perform required safety functions. The TRPS and ESFAS allow SSCs to be tested while retaining the capability to accomplish required safety functions. The TRPS and ESFAS use modules from the HIPS platform which are designed to eliminate non-detectable failures through a combination of self-testing and periodic surveillance testing.

Testing from the sensor inputs of the TRPS and ESFAS through to the actuated equipment is accomplished through a series of overlapping sequential tests, most of which may be performed during normal plant operations. Performance of periodic surveillance testing does not involve disconnecting wires or installation of jumpers for at-power testing. The self-test features maintain division independence by being performed within the division.

The part of TRPS and ESFAS that cannot be tested during normal operations is the actuation priority logic circuit on the EIM. This includes the manual control room switches and the nonsafety-related interface that provide inputs to the actuation priority logic. The actuation priority logic consists of discrete components and directly causes actuation of field components. The actuation priority logic is a simple circuit that has acceptable reliability to be tested when the IU is in Mode 0.

While the TRPS and ESFAS are in normal operation, self-tests run without affecting the performance of the safety function, including its response time. TRPS and ESFAS data communications are designed with error detection to enhance data integrity. The protocol features ensure that communications are robust and reliable with the ability to detect transmission faults. Similar data integrity features are used to transfer diagnostics data.
The TRPS and ESFAS provide a means for checking the operational availability of the sense and command feature input sensors relied upon for a safety function during normal plant operation. This capability is provided by one of the following methods:

- Perturbing the monitored variable
- Cross-checking between channels that have a known relationship (channel check)
- Introducing and varying a substitute input to the sensor

The TRPS and ESFAS have redundant gateways that gather the output of the MI-CMs for each of the three divisions. The data for each of the three divisions are compared to perform a channel check, and the results are provided to the PICS.

The TRPS and ESFAS incorporate failure detection and isolation techniques. Fault detection and indication occurs at the module level, which enables plant personnel to identify the module that needs to be replaced. Self-testing will generate an alarm and report a failure to the operator and place the component (e.g., SFM, SBVM, or EIM components) in a fail-safe state.

The self-testing features of the HIPS platform are designed, developed, and validated at the same level as the functional logic. The overlapped self-test features of the HIPS platform are integral to the operation of the system and are therefore designed, developed, and validated to the same rigor as the rest of the platform.

Diagnostic data for the division of the TRPS and ESFAS are provided to the MWS. Diagnostics data is communicated via the monitoring and indication bus (MIB), which is a physically separate communications path from the safety data path, ensuring that the diagnostics functionality is independent of the safety functionality.

Self-testing features and use of the MWS employed in the TRPS and ESFAS designs is the same as described in Appendix B of the HIPS TR and complies with sections 5.5.2 and 5.5.3 of IEEE Standard 7-4.3.2-2003. By incorporating diagnostic and maintenance test features that test from the sensor inputs of the TRPS and ESFAS through to the actuated equipment, the necessary test coverage is provided in the SHINE-specific application of the HIPS platform.

The NRC staff assessed these self-testing features of the SFM and EIM modules and finds that they do not affect the ability of any module to perform its safety function.

7.4.2.1.5 Operational and Maintenance Bypass

In its response to RAI 7-14, the applicant provided additional details on the operational and maintenance bypass features employed in the TRPS and ESFAS designs. SHINE FSAR sections 7.4.4.2, 7.4.4.3, and 7.5.4.4 describe the design, configuration, and implementation of the bypass function considered for the HIPS equipment for the TRPS and ESFAS. SHINE FSAR sections 7.4.2.1.3 and 7.5.2.1.3 provide additional description of how SHINE Design Criterion 15 is met for the TRPS and ESFAS. The RAI response provides the following additional details on operational and maintenance bypass.

<u>Operational Bypass</u>

SHINE FSAR section 7.4.4.2 describes the use of operational bypasses for the TRPS during the operation of the IU cells. Operational bypasses for the TRPS are based upon the mode of operation and are automatically implemented within the SBVMs to bypass safety actuations that are not required for each mode. Operator action is required to request the TRPS to transition to the next mode of operation. A mode transition request occurs via separate discrete inputs from PICS to each of the Division A and B HWMs, which then converts the mode transition input to a logic level signal and makes the signal available to the associated SBVMs within the division. When associated permissives are satisfied and the manual operator action for mode transition occurs, the TRPS progresses to the next mode and the TRPS SBVMs will (1) automatically bypass the final trip determinations for safety actuations that are not required for that particular mode of operation and (2) automatically remove any bypasses of the final trip determinations for safety actuations that are required for that particular mode of operation. If the permissive conditions are not met for transitioning to the next mode and the operator action occurs, the TRPS will not advance to the next mode of operation.

The status of TRPS operational bypasses is first provided by the SBVMs to the associated divisional MI-CM on the MIB. This status information is then provided to PICS for indication to the operators.

Maintenance Bypass

For the SHINE-specific application of the HIPS platform, maintenance bypasses are associated with the sense and command features only for the TRPS and ESFAS. There are no maintenance bypass capabilities associated with execute features in the SHINE-specific application of the HIPS platform.

Channels associated with an SFM of the TRPS and ESFAS can be taken out of service by direct component replacement or the manipulation of manual switches. Components that are designed to be replaced directly are the SBMs, SBVMs, EIMs, and HWMs.

When an SBM is removed from its chassis, the Division A and B SBVMs, which correspond with the SDB of the removed SBM, will assert all partial trip signals associated with that SBM to the trip state for input to the coincident voting performed in the SBVMs. The impacted SDB will be in a 1-out-of-3 trip state for all safety functions that require Division C input within the SBVM and the other two SDBs will be in a 0-out-of-3 trip state within the SBVMs. When this occurs, the Division C SFMs and Division A and B SBVMs will provide fault indication information to the PICS for alerting the operators that there is an issue with the SBM.

When a SBVM is removed from its chassis, the other corresponding divisional SBVM will assert all partial trip signals associated with the missing SBVM to the trip state for input to the coincident voting performed in the SBVM. The impacted SDB will be in a 1-out-of-3 trip state within the SBVM and the other two SDBs will be in a 0-out-of-3 trip state within the SBVMs. When this occurs, the following modules will provide fault indication information to the PICS for alerting the operators that there is an issue with the SBVM:

- All SFMs in the same division as the removed SBVM
- All EIMs in the same division as the removed SBVM
- All SBMs
- The other corresponding divisional SBVM

When an EIM is removed from its chassis, nothing will occur because the redundant EIM to the one removed will continue to provide actuation capability for all actuation components associated with the EIM. When this occurs, all the SBVMs in the same division as the removed EIM will provide fault indication information to the PICS for alerting the operators that there is an issue with the EIM.

When a HWM is removed from its chassis, all hardwired inputs to the associated division via the HWM will become inactive. For the TRPS, removal of an HWM will effectively bypass the associated TSV Fill Isolation Valve Full Closed and HVPS Breaker Full Open input signals, which are safety inputs to the TRPS. For the ESFAS, a removed HWM will not affect any safety functions because there are no safety inputs to the HWMs.

The HWM includes an FPGA, which is a departure from the HIPS TR description of an HWM. Function of the FPGA on the HWM is only to drive the module front panel LED indications and to provide module operational status to the MI-CM. The FPGA on the HWM cannot affect the function of receiving hardwired inputs and making them available on the backplane of the chassis. When an HWM is removed from its chassis, the MI-CM for the division will provide fault indication information to the PICS, alerting the operators that there is an issue with the HWM.

SFM input channels of the TRPS and ESFAS can be taken OOS using the OOS switches located on the front of each SFM, and an associated separate trip/bypass switch located below each SFM. The OOS switch has two positions: Operate and OOS. When the switch is placed in the OOS position, the respective divisional SBMs or SBVMs will force the partial trip information associated with the SFM to the trip or bypass state, depending on the position of the trip/bypass switch, and take the channel OOS. Any time an SFM module is placed in an OOS condition, the SBMs or SBVMs associated with the SFM read the state of the trip or bypass switch to determine if the SFM input channels should be bypassed or treated as a trip when continuing the flow of data through the system. With the OOS switch in the OOS position, the trip/bypass switch is used to activate maintenance trips and maintenance bypasses. The trip/bypass switch signal is input first to an HWM, which then converts the trip/bypass discrete input to a logic level signal and makes the signal available to the associated SBMs or SBVMs within the same division as the trip/bypass switch. When the OOS switch is in the Operate position and the SFM is functioning normally, the SBMs or SBVMs associated with the SFM will ignore the associated trip/bypass switch input.

The SFMs continually provide the status of their OOS switch to the associated divisional SBMs or SBVMs along with their partial trip information. With an SFM’s OOS switch in the OOS position and the associated trip/bypass switch in the trip position, the associated divisional SBMs or SBVMs will then assert all partial trip information associated with the SFM to the trip state for input to coincident logic voting in the SBVMs. All the partial trip information associated with all inputs for this SFM would be in a maintenance trip condition for this case. For those safety functions that use 2-out-of-3 coincident voting, a single failure of the same SFM in another division would not defeat the safety function because the third remaining divisional SFM is available to complete a 2-out-of-3 vote if required. For those safety functions that only use 1-out-of-2 coincident voting, the safety functions would be actuated when the OOS switch is placed into the OOS position with the associated trip/bypass switch in the trip position.

For safety functions that use either 1-out-of-2 or 2-out-of-3 coincident voting, a single failure of the same SFM in another division would defeat the safety function. Placing a single SFM in maintenance bypass is allowed by the SHINE TSs for up to two hours for the purpose of performing required surveillance testing. A time limit of two hours is acceptable based on the small amount of time that the channel could be in bypass, the continual attendance by operations or maintenance personnel during the test, the continued operability of the redundant channel(s), and the low likelihood that an accident would occur during the two-hour period. TS LCO 3.2.3 and 3.2.4 contain a note that specifies that any single SFM may be bypassed for up to two hours while the variable(s) associated with the SFM is in the condition of applicability for the purpose of performing a Channel Test or Channel Calibration. By only allowing a single SFM to be bypassed at one time, SHINE ensures that the same SFM across multiple divisions (which would be more than one SFM) will not be placed into maintenance bypass. By specifying this in the TSs, SHINE ensures that administrative controls are in place and consistent with the HIPS TR to prevent an operator from placing the same SFM across more than one division into maintenance bypass.

With an SFM’s OOS switch in the OOS position and the associated trip/bypass switch in either the trip or bypass position, the input channels associated with the SFM are inoperable. The input to the voting logic for the maintenance trip and bypass states are discussed above. The maintenance bypass function supports the in-service testability requirement of SHINE Design

Criterion 15 for the TRPS and ESFAS. By allowing a single SFM module to be placed in maintenance bypass in accordance with the TS requirements, TS surveillances can be performed to verify the operability of TRPS and ESFAS components during system operation. As described above, the time that the maintenance bypass feature is allowed to be used is limited to two hours. This satisfies the SHINE Design Criterion 15 requirement that the removal from service of any component or channel does not result in loss of the required minimum redundancy unless the acceptable reliability of operation of the protection system can be otherwise demonstrated.

Self-testing capabilities in the TRPS and ESFAS designs provide indication of component degradation and failure, which allows action to be taken to ensure that no single failure results in the loss of the protection function. The results of these self-tests, along with the ability to perform in-chassis calibration and modification to configurable variable and set-points with using MWS, ensure that protection systems are designed to permit periodic testing, including a capability to test channels independently to determine failures and losses of redundancy that may have occurred. The self-tests provide indications of component degradation or failure, and the MWS provides the ability to obtain diagnostic information and perform maintenance on individual channels to identify and address component failures.

7.4.2.1.6 Manual Actuation

Manual controls in the FCR consist of a single system level manual actuation switch for each automatic TRPS and ESFAS safety function. These manual actuation switches are connected to the HWM in the TRPS and ESFAS chassis. The HWM converts the manual actuation signals to logic level voltages that are placed on the backplane for use by the modules that require them. The manual actuation components are input into the actuation and priority logic (APL) associated with each EIM via the HWM. The APL accepts inputs from the following sources:

- 1a Digital trip signal from the SBVM
- 1b Non-digital manual system level trip signal from the FCR
- 2a Non-digital manual enable nonsafety signal from the FCR
- 2b Non-digital position indication signal from an HWM
- 2c Non-digital control signals from the PICS

The non-digital signals are diverse from the digital portion of the TRPS and ESFAS. Discrete logic is used by the APL for actuating a single device based on the highest priority. Regardless of the state of the digital trip signal from the SBVM, manual initiation can always be performed at the system level. If the enable nonsafety control permissive is active and there are no automatic or manual actuation signals present, the PICS is capable of operating trip and actuation components. The result from the APL is used to actuate equipment connected to the EIM. Actuation component status is transmitted to the EIM and is sent to the MIB, along with the status of the SDB signals.

7.4.2.2 HIPS Design Attributes

SHINE FSAR section 7.4.5.2 states that the HIPS design for TRPS and ESFAS incorporates the following fundamental design principals outlined in the HIPS TR that are summarized in the following sections.

- Independence
- Redundancy
- Predictably and Repeatability
- Diversity

In addition, the TRPS and ESFAS designs include the following design attributes, which are also summarized below.

- Completion of Functions
- Prioritization of Functions
- Access Control

7.4.2.2.1 Independence

SHINE FSAR section 7.4.5.2.1 states that the HIPS-platform-based TRPS and ESFAS incorporates the independence principles outlined in the HIPS TR. As discussed above, in its response to RAI 7-10, the applicant provided acceptable dispositions to ASAIs related to independence design attributes of the TRPS and ESFAS. Through a review of design attributes of the HIPS platform and other design details in the HIPS TR, the NRC staff finds that the proposed design exhibits independence among (1) redundant portions of a safety system, (2) safety systems and the effects of design-basis events (DBEs), and (3) safety systems and other systems. For each of these areas, the staff evaluated the following:

- Physical independence
- Electrical independence
- Communications independence
- Functional independence

NUREG-1537 includes an acceptance criterion for addressing separation and independence of the control system and the protection system to ensure that failures of other systems won't interfere with the protection system. This attribute includes the physical, electrical, and communications independence of the protection system both within its divisions or channels, as well as independence between the protection system and systems that are not safety-related.

SHINE FSAR section 7.4.5.2.1 summarizes the independence design attributes of the HIPS-platform-based TRPS and ESFAS.

For physical independence SHINE FSAR section 7.4.5.2.1 states that the TRPS and ESFAS SSCs that comprise a division are physically separated and independent to retain the capability of performing the required safety functions. Physical separation is used to achieve separation of redundant sensors. TRPS and ESFAS Divisions A and C are located on the opposite side of the FCR from where Division B is located.

For electrical independence, SHINE FSAR section 7.4.5.2.1 states that wiring for redundant divisions uses physical separation and isolation to provide independence for circuits. Separation of wiring is achieved using separate wireways and cable trays for each of Division A, Division B, and Division C. The HIPS modules provide isolation for the nonsafety-related signal path. In its response to NRC staff RAI 7-10 and RCI 7-3 (ML22318A178), the applicant stated that the results of isolation testing of HIPS platform equipment, consistent with the guidelines of Regulatory Guide 1.75, Revision 3, “Criteria for Independence of Electrical Safety Systems” (ML043630448), is provided in the HIPS platform EMI/RFI and isolation test report Rock Creek Innovations, RCI942-1000-61001, “EMC and Isolation Qualification Report for HIPS Platform EQTS,” Revision 0. Section 4 of this report concludes that isolation testing of the HIPS modules meets the requirements as specified in section 4.6.4 of EPRI TR-107330, “Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants,” dated December 1996, which, in turn, references IEEE Standard 384-1981, “Standard Criteria for Independence of Class 1E Equipment and Circuits.” Each division of TRPS and ESFAS is independently powered, and the power supply for the TRPS and ESFAS is independent and separated from the PICS. In its response to RAI 7-10, the applicant also stated that the design bases description for the TRPS and ESFAS power source is provided in SHINE FSAR section 8a2.2. Division A of both the TRPS and ESFAS is powered from Division A of the uninterruptible power supply system (UPSS). Division B of both the TRPS and ESFAS is powered from Division B of the UPSS. Division C of both the TRPS and ESFAS receives auctioneered power from Division A and Division B of the UPSS. Both the TRPS and ESFAS require 125 VDC power, which the UPSS provides as described above.
Each TRPS and ESFAS cabinet is provided a single 125 VDC power supply, which is used to power three (3) redundant 125 VDC to 24 VDC converters located at the top of the cabinet. The 24 VDC supply is then distributed to each of three (3) chassis mounting bays as needed, where it is then used to power two (2) redundant 24 VDC to 5 VDC converters located beneath each chassis bay. These provide independent +5V A and +5V B power channels to each chassis.

For communications independence, SHINE FSAR section 7.4.5.2.1 states that the design of the TRPS and ESFAS is such that each safety division functions independently of other safety divisions. Apart from interdivisional voting, communication within a division does not rely on communication outside the respective division to perform the safety function. Safety-related inputs to the TRPS or ESFAS which originate within a specific division of the TRPS or ESFAS are input to, and processed in, only the same division prior to being provided to any other division of the system for voting purposes. The inter-divisional communications in the TRPS and ESFAS are implemented with transmit-only or receive-only copper RS-485 connections. The voting function of the SBVM is not dependent on voting data from other divisions because the SBVM voters will still be able to complete their safety function in the presence of erroneous or missing voting. The SBVM voting function applies a safe default value for the missing inputs. TRPS and ESFAS monitoring and indication information is transmitted redundantly from each system’s divisional MI-CM via one-way isolated copper RS-485 connections to respective redundant nonsafety GWCMs, which are in two redundant gateway chassis. The GWCMs for the TRPS are functionally and logically independent from the GWCMs for the ESFAS and vice versa. They are physically located within two chassis and located in the ESFAS Division C cabinet. As described in section 2.5.3 of the HIPS TR, the GWCMs, which are HIPS platform communications modules, have four communications ports, each of which can be configured as receive-only or transmit-only. Three of the four communications ports of each GWCM are configured as receive-only ports for their respective status and diagnostics information input. The fourth communications port of each GWCM is configured for two-way communications with the respective PICS channel using the MODBUS communications protocol. Data communication between the GWCM and PICS is a nonsafety function, and the upstream communication from each MI-CM to a GWCM is isolated and one-way only.

For functional independence, SHINE FSAR section 7.4.5.2.5 states that dedicating an SFM to a function or group of functions based on its inputs provides inherent function segmentation creating simpler and separate SFMs that can be more easily tested. This segmentation also helps limit module failures to a subset of safety functions. The discrete and programmable logic circuits on an EIM provide a clear distinction between those portions that are and are not vulnerable to software common-cause failures (CCFs). Implementation of triple redundant communication within a division of TRPS and ESFAS increases the number of components (e.g., additional CMs) but provides for simpler maintenance and self-testing. A failure of a data path or CM with triple redundant communication does not cause all safety functions of that division to be inoperable. Based on the NRC staff's evaluation in section 7.4.2.2.4, "Diversity" of this SER, the staff finds that adequate functional independence design attributes have been implemented in the TRPS and ESFAS.

Based on the above discussion, the NRC staff finds that the HIPS-platform-based TRPS and ESFAS incorporate the independence principles outlined in the HIPS TR and the staff confirmed that the proposed design exhibits independence among (1) redundant portions of a safety system, (2) safety systems and the effects of DBEs, and (3) safety systems and other systems. Therefore, the staff finds that the TRPS and ESFAS designs meet the protection system independence requirements of SHINE Design Criterion 15.

7.4.2.2.2 Redundancy

SHINE FSAR section 7.4.5.2.2 states that the HIPS-platform-based TRPS and ESFAS designs incorporate redundancy principles outlined in the HIPS TR. Use of these redundancy design principles meets portions of the criteria for redundancy in SHINE Design Criterion 15, which requires that no single failure results in loss of the protection function. This SHINE FSAR section also states that a failure modes and effects analysis (FMEA) was conducted to analyze failure modes of system components associated with the TRPS and ESFAS for evaluating the consequences of a single system component failure. The results of the FMEA determined that there are no single failures or non-detectable failures that can prevent the TRPS or ESFAS from performing their required safety functions. In conjunction with the FMEA, a single failure analysis of the TRPS and ESFAS was conducted. The assessment was applied to the sense and command and execute features of the TRPS and ESFAS used for safety-related functions. The scope of the assessment included sensors, trip determination, signal conditioning, DC-DC converters and power supplies, and actuation logic. The single failure analysis determined that for functions requiring either one-out-of-two voting or two-out-of-three voting, a single failure of a channel will not prevent a protective action when required.

To confirm the application of the single failure criterion to the TRPS and ESFAS designs, the NRC staff audited Rock Creek Innovations report SMT-016-1000-64012, Revision 3, "Failure Modes and Effects Analysis," and SHINE technical report TECRPT-2019-0031, Revision 3, "TRPS and ESFAS Single Failure Analysis." In its response to the NRC staff RCIs 7-4 and 7-5

(ML22318A178), SHINE confirmed that the scope of this single failure assessment applies to the sense and command and execute features of the TRPS and ESFAS used for safety-related functions. The actuation devices (e.g., solenoids and valve actuators) are not included in the scope of this analysis except to establish that the actuated systems include independent, redundant means of completing safety functions. Equipment feedback such as valve position is considered if used as an input to a safety function. This analysis applied the following definition of single-failure to the TRPS and ESFAS:

> The TRPS and ESFAS shall perform their required functions, for a design basis event, in the presence of the following:
>
> - Any single detectable failures within the TRPS or ESFAS concurrent with all identifiable, but nondetectable failures
> - All failures cause by the single failure
> - All failures and spurious system actions that cause, or are caused by, the design basis event requiring the safety functions.

Based on the information in SHINE TECRPT-2019-0031, the NRC staff finds the following conclusions of this report to be consistent with the TRPS and ESFAS designs and, therefore, acceptable:

- For functions that require 1-out-of-2 voting, a single failure of a single measurement channel or process interface division will not prevent a protective actuation when required. For functions that require 2-out-of-3 voting, a single failure of a single measurement channel or process interface division with another channel or process interface division OSS will not prevent a protective actuation when required and will not cause a spurious TRPS or ESFAS actuation when it is not required. The single failure criterion is satisfied for all potential failures of an instrument channel.

- For TRPS and ESFAS functions with 1-out-of-2 voting, the protective action will be initiated if one of the two channels vote to trip. If one of the two channels fail such that it will not produce a trip, the remaining channel can initiate the required protective action. The only TRPS protective actions with 1-out-of-2 voting are for the IU Cell Safety Actuation and Fill Stop based on the TSV Fill Valve Fully Closed inputs. The TSV Fill Valve position signals input is received into HWMs, which cannot be placed OOS by design. Administrative controls are required on ESFAS input channels for 1-out-of-2 voting functions which do not allow them to be placed OOS in order to satisfy the single failure criterion. SHINE TS actions for LCO 3.2.4 provide adequate administrative controls on ESFAS input channels for 1-out-of-2 voting functions.

- For TRPS and ESFAS functions with 2-out-of-3 voting, the protective action will be initiated if two of the three channels vote to trip. In the 2-out-of-3 configuration, the single failure criterion is satisfied for all potential failures of an instrument channel with a redundant channel OOS with its respective trip/bypass switch in the trip position. There is a need for administrative controls on components which are placed OOS. The TRPS and ESFAS satisfy the single failure criterion with administrative controls on OOS conditions.

SHINE TS actions for LCO 3.2.3 and 3.2.4 provide adequate administrative controls on TRPS and ESFAS input channels for 2-out-of-3 voting functions.

- For the TRPS permissives derived from two process interface inputs, administrative controls not allowing bypass of any input channels associated with the permissive are required to satisfy the single failure criterion. SHINE TS remedial actions for LCO 3.2.3 provides adequate administrative controls on TRPS input channels for 1-out-of-2 voting functions.

Based on its review of the FMEA and the single failure analysis, the NRC staff finds that the TRPS and ESFAS are capable of initiating protective actions in the presence of a single failure. Therefore, the staff finds that the TRPS and ESFAS designs meet the single failure criteria related requirements of SHINE Design Criterion 15.

7.4.2.2.3 Predictability and Repeatability

SHINE FSAR section 7.4.5.2.3 states that the HIPS-platform-based TRPS and ESFAS designs incorporate the predictability and repeatability principles outlined in the HIPS TR and meets portions of the criteria for ensuring an extremely high probability of accomplishing safety functions as required by SHINE Design Criterion 19. As discussed above, the NRC staff finds applicant's dispositions of ASAIs 19, 56, and 59 that relate to the predictability and repeatability design attributes of the TRPS and ESFAS to be acceptable.

The predictability and repeatability design features of the TRPS and ESFAS are summarized in SHINE FSAR section 7.4.5.2.3.

To meet a response time performance requirement of 500 milliseconds for the HIPS parts of the TRPS and ESFS, the HIPS-platform-based system must acquire the input signal that represents the start of a response time performance requirement, perform logic processing, and generate an output signal that represents the end of a response time performance requirement. These HIPS platform response time components exclude plant process delays through the sensor input to the platform, and the output delays through a final actuating device. The required response times credited in the safety analysis for TRPS and ESFAS include the process delays through the sensor input to the SFM and the delays through the final actuating device. TECRPT-2018-0028 figure 5-3 represents the overall timing diagram for TRPS and ESFAS. In its response to NRC staff RCI 7-7 (ML22318A178), SHINE confirmed that Section 4.1 of TECRPT-2019-0048 states that total response time includes the Analog Input Delay, SFM Logic Delay, t1, t2, EIM Logic Delay, and the Analog Output Delay times. The response times of instrumentation is manufacturer and instrumentation loop dependent. The final design testing of the HIPS platform (during factory acceptance testing and site acceptance testing) will better define the actual response time.

TRPS and ESFAS process safety functions through three redundant CMs to provide error detection and fault tolerance of the safety function. The HIPS uses an independent safety logic and trip determination, using internal dedicated communication buses. The trip determinations are transmitted to the voter, which uses discrete logic to generate the system outputs. In this manner, each channel deterministically performs its function without interferences from other channels or other divisions. Section 3.5 of the HIPS TR safety evaluation concludes that functions within the FPGA of each module are implemented with finite-state machines to achieve deterministic behavior. Deterministic behavior allows implementation of a simple communication protocol using a predefined message structure with fixed time intervals. This simple periodic communication scheme is used throughout the architecture. Communication between SFMs and CMs is implemented through a simple and well-established copper RS-485 physical layer. The configurable transmit-only or receive-only ports on a CM use a physical point-to-point physical layer. Communication between modules is done asynchronously, which simplifies implementation by avoiding complex syncing techniques.

Based on the above, the NRC staff finds that the TRPS and ESFAS are designed to perform their intended safety functions deterministically. Therefore, the staff finds that the TRPS and ESFAS are designed to ensure an extremely high probability of accomplishing their safety functions as required by SHINE Design Criterion 19.

7.4.2.2.4 Diversity

SHINE FSAR section 7.4.5.2.4 states that the HIPS-platform-based design of the TRPS and ESFAS incorporates the diversity design principals in the HIPS TR. The use of these diversity design principles meets portions of the criteria for diversity in SHINE Design Criterion 16. To ensure performance in the presence of a digital CCF, SHINE performed a diversity and defense-in-depth (D3) assessment of the TRPS and ESFAS to identify potential vulnerabilities to digital CCFs in TECRPT-2019-0041, Revision 3, "Diversity and Defense-in-Depth Assessment of TRPS and ESFAS."

In its response to NRC staff RAI 7-11 (ML21239A049), the applicant stated that the D3 assessment was performed on TRPS and ESFAS and to identify potential vulnerabilities to digital-based CCFs. Additionally, the applicant stated that guidance provided in NUREG/CR-6303, "Method for Performing Diversity and Defense-in-Depth Analyses of Reactor Protection Systems" (ML071790509), is used in performing the D3 assessment of the TRPS and ESFAS. This D3 assessment is based on the following factors:

- SECY-93-087, which provides that two principal factors for defense against CCFs are the use of quality and diversity;

- Safety-related TRPS and ESFAS are designed and manufactured under a prescribed quality assurance program that provides protection from items such as manufacturing errors and design deficiencies;

- Digital-based CCFs in TRPS and ESFAS are considered credible but beyond design basis; and

- Branch Technical Position 7-19, Revision 8, "Guidance for Evaluation of Defense in Depth and Diversity to Address Common-Cause Failure due to Latent Design Defects in Digital Safety Systems" (ML20339A647), according to which a diversity strategy is used by combining diversity attributes to make an overall case for eliminating digital-based CCFs in the TRPS and ESFAS from further consideration.

SHINE FSAR section 7.4.5.2.4 states that the D3 assessment concludes the following:

- Potential digital-based CCFs associated with the TRPS and ESFAS would not lead to a failure to initiate protective actions when required.
- Potential digital-based CCFs associated with the TRPS, ESFAS, and certain detectors could lead to spurious actuations without adverse impacts on safety.
- Potential digital-based CCFs associated with most detectors would not lead to a failure to initiate protective actions when required; however, in each instance where a potential digital-based CCF could cause a failure to initiate protective actions, there exists either an alternate, automatic means of mitigating events or an alternate means for the operator to identify, initiate, and assess protective actions.

The D3 assessment states that for the SHINE design, four echelons of defense identified in NUREG/CR-6303 are modified and summarized as follows:

- Control System – The control system echelon usually consists of equipment that is used in the normal operation and routinely prevents operations in unsafe operational regimes.
- Reactor Trip – The reactor trip echelon consists of equipment designed to prevent escalation of an event. The reactor trip echelon spans across both the TRPS and ESFAS.
- Engineered Safety Features Actuation System – The ESF echelon (which should not be confused with the SHINE ESFAS) consists of equipment that mitigates design basis events. The ESF echelon spans across both the TRPS and ESFAS.
- Monitoring and Indicator System – The monitoring and indicator system echelon consists of sensors, safety parameter displays, data communication systems, and independent manual controls relied upon by operators to respond to operating events.

Based on the guidance in NUREG/CR-6303 for D3 assessments, SHINE I&C architecture is sectioned of into the following blocks as described in the applicant's response to RAI 7-11:

- Monitoring and Indication Block (Function of PICS)
- Manual Controls Block
- Sensor Blocks
- Safety Blocks
- PICS Block

In its response to RAI 7-11, the applicant also stated that the blocks are selected to represent a physical subset of equipment and software whose internal failures can be assumed not to propagate to other blocks based on respective attributes. For each of the blocks, the report identifies applicable diversity attributes both within and in between blocks.

Diversity attributes within Monitoring and Indication Block - Within this block, there are two types of displays: displays that provide operators capability for both indication and control (operator workstation) and displays that provide indication only (main control board display). Displays providing both indication and control receive and transmit information to components within the PICS block. The displays' different purposes and different input sources result in functional, software, and design diversity within the same block.

The NRC staff notes that there are no credited diversity attributes within the Manual Control Block. There are no credited diversity attributes within the Sensor Block I of II. Digital-based sensors in these blocks are evaluated separately. Safety Blocks include software diversity, design diversity, and functional diversity. The PICS Block provides a degree of diversity by segmenting I/O networks by system and facility location.

The diversity attributes between the blocks include, as provided in the applicant's response to RAI 7-11:

> Equipment diversity - Equipment diversity is the use of different equipment to perform similar safety functions. Initiation of protective actions can be done manually by operators using physical switches or done automatically by safety blocks associated with the TRPS and ESFAS. Between blocks, fundamentally different FPGA technology is used to achieve equipment diversity. At the chip level, the three FPGA types operate in fundamentally different ways during operation and programming. The FPGAs require different internal subcomponents and different manufacturing methods. FPGA equipment diversity in the form of three fundamentally different FPGA technologies when coupled with the different development tools is an effective solution for the digital-based CCF vulnerabilities present in the HIPS platform.
>
> Design diversity - Design diversity is the use of different approaches including both software and hardware to solve the same or similar problem. To limit the potential and the consequences of a digital-based CCF, different FPGA chip architecture or different equipment manufacturers are used. The diverse FPGA technologies or manufacturers inherently have additional design diversity attributes based on the different development tools used for each FPGA technology. This equipment and tool diversity results from the different FPGA chip architectures and programming methods. The diversity in FPGA equipment, chip designs, and development tools are the fundamental methods for mitigating the potential for digital-based CCFs since these diversity attributes directly mitigate CCFs associated with a specific FPGA technology.
>
> Human diversity - The use of different instrumentation and controls (I&C) platforms creates inherent human diversity between certain blocks. Each I&C system implements different functions with different hardware architectures. Safety blocks are primarily designed for safety-related actuation based on trip or no-rip indication. PICS is primarily designed for monitoring and control of process parameters. Monitoring and indication blocks have a primary purpose of providing information to the operator and accepting operator input. Human diversity is an implicit attribute of the FPGA

equipment, chip design, and software tool diversity of the Safety Block; however, it is neither explicitly defined nor verified for this block.

Software diversity - Software diversity is a subset of design diversity and is the use of different programs designed and implemented by different development groups with different key personnel to accomplish the same safety goals.

Functional diversity - Functional diversity is introduced by having different purposes and functions between blocks. Safety blocks are associated with the TRPS and ESFAS. These blocks will initiate protective actions if operating limits are exceeded to prevent or mitigate design basis events (DBEs). Monitoring and indication blocks allow for an operator to monitor and control both safety and non-safety systems. The operator can maintain a plant within operating limits or initiate necessary protective actions. PICS provides automatic control of systems to maintain the plant within operating limits including constraining certain operational transients. Sensor blocks function to provide parameter information to the safety blocks.

Digital-technology-based sensors in the D3 assessment are radiological ventilation zone, IU Cell exhaust radiation, RCA exhaust radiation, and supercell area exhaust radiation, which are evaluated for digital CCFs based anomalous readings. Each TRPS has three radiation detectors while the ESFAS has twenty-seven radiation detector inputs. In total, the SHINE facility has fifty-one safety-related digital-based radiation detectors.

In its response to NRC staff RCI 7-10 (ML22318A178), SHINE confirmed that TECRPT-2019-0041 presents the following conclusions, in part:

- Potential digital-based CCF within Safety Block I or Safety Block II may lead to spurious initiation of protective actions within TRPS and ESFAS without adverse impacts to safety. There are no potential Type 2 digital-based CCF, failures that do not directly cause transients but are undetected until environmental effects or physical equipment failures cause a transient or design basis accident to which protective equipment may not respond, within Safety Block I, II, or II that may lead to failure of initiating protective actions for any AOO or PA [Anticipated Operational Occurrence or Postulated Accidents]. At least two other Safety Blocks remain functional which can result in automatic alarms within the Monitoring and Indication block due to parameters deviating by a predefined amount. The PICS block will continue to monitor, alarm, and attempt to automatically correct parameter deviations. In addition, the operator always retains the capability to manually initiate all protective actions as needed.

- A digital-based CCF of radiation detector sets may lead to spurious actuations with production impacts without adverse safety impacts.

- A digital-based CCF of any radiation detector may cause failure to initiate protective actions; however, for each set, there exists alternate means for either the operator to identify, initiate, and assess protective actions, or alternate automatic means of mitigating events.

Based on its evaluation of the diversity attributes implemented in the TRPS and ESFAS designs and the assessment in TECRPT-2019-0041 to confirm SHINE FSAR information, the NRC staff finds that the TRPS and ESFAS designs have adequate diversity that is commensurate with the potential consequences and large safety margins described in chapter 13, "Accident Analyses," of this SER. The diversity attributes comply in part with SHINE Design Criterion 16, which requires that design techniques, such as functional diversity or diversity in component design and principles of operation, are used to the extent practical to prevent loss of the protection function. The staff recognizes that the D3 assessment applies the functional allocation of different process parameters on different SFMs as "functional diversity" in the context of SHINE Design Criterion 16. However, the staff notes that functional diversity is more commonly defined as the ability to protect against the same event by monitoring two different parameters to initiate protective actions, and the staff did not confirm the existence of functional diversity for all events and credited safety functions.

7.4.2.2.5 Completion of Functions

SHINE FSAR sections 7.4.3.3 and 7.5.3.2 state that the TRPS and ESFAS are designed such that once initiated, protective actions will continue to completion. Only deliberate operator action can be taken to reset the TRPS or ESFAS following a protective action.

Based on its review of the logic diagrams of SHINE FSAR figure 7.4-1, Sheets 11 through 13, and figure 7.5-1, Sheets 21 through 26, the NRC staff finds that a protective action, once initiated automatically or manually by either the TRPS or ESFAS, latches-in the actuation signal to maintain the state of a protective action until a deliberate operator action to reset the output to normal operating conditions. An enable nonsafety switch allows an operator, after the switch has been brought to enable, to control the state of the TRPS and ESFAS components with a hardwired binary control signal from the nonsafety-related controls. The enable nonsafety switch is used to prevent spurious nonsafety related control signals from adversely affecting safety-related components. If the enable nonsafety switch is active, and no automatic safety actuation or manual actuation signals are present, the operator is capable of energizing or deenergizing any EIM outputs using the nonsafety-related hardwired control signals. If the enable nonsafety switch is not active, the nonsafety-related hardwired control signals are ignored. Therefore, the staff finds that all of the protective actions initiated by the TRPS and ESFAS are designed to continue to completion and that a deliberate operator action is required to reset these protective actions.

7.4.2.2.6 Prioritization of Functions

SHINE FSAR sections 7.4.3.12 and 7.5.3.11 state that the APL in the EIM is designed to provide priority to safety-related signals over nonsafety-related signals. Division A and Division B priority logic of the TRPS and ESFAS prioritizes the automatic safety actuation and manual safety actuation over the manual control of safety components from PICS nonsafety control signals. The manual actuation signals input from the operators in the FCR is brought directly into the discrete APL. The manual safety actuation input into the priority logic does not have the ability to be bypassed and will always have equal priority to the automated actuation signal over any other signals that are present. Failures of the EIM do not defeat APL prioritization of the automatic or manual safety actuations over the PICS control signals.

Based on its review of TRPS and ESFAS logic diagrams, SHINE FSAR figure 7.4-1, Sheets 12 and 13, and figure 7.5-1, Sheets 22 through 26, the NRC staff finds that the PICS can only control a safety-related component when the 'Enable Nonsafety Switch' is in the 'Enable (E)' position and no automatic safety actuation or manual safety actuation signals are present. A non-safety control signal from the PICS is provided to the APL via the HWM, which provides electrical isolation between safety and nonsafety circuits. Therefore, the staff finds that the automatic safety actuations and manual safety actuations have priority over the manual control of safety components from PICS nonsafety control signals.

7.4.2.2.7 Access Control

SHINE FSAR section 7.4.5.3.3 states that the HIPS-platform-based TRPS and ESFAS include the following access control features, which are consistent with the access control features evaluated in the safety evaluation for the HIPS TR:

- Required use of a physical key at the main control board to prevent unauthorized use.
- Rack mounted equipment is installed within cabinets that can be locked so access can be administratively controlled.
- FPGAs on any of the HIPS modules cannot be modified or replaced while installed in the HIPS chassis.
- Capability to modify modules installed in the HIPS chassis is limited to setpoints and tunable parameters that may require periodic modification.

Each division of the TRPS and ESFAS has a nonsafety-related MWS for the purpose of online monitoring and offline maintenance and calibration. The MWS supports online monitoring through one-way isolated communication ports. The MWS is used to update TRPS and ESFAS setpoints and tunable parameters only when the safety function is out of service. Access to the MWS is password protected. Physical and logical controls are put in place to prevent modifications to a safety channel when it is being relied upon to perform a safety function. Controls are also put in place to prevent inadvertent changes to a setpoint or tunable parameter. A temporary cable and OOS switch are required to be activated before any changes can be made to an SFM. When the safety function is removed from service, either in bypass or trip, an indication is provided in the facility control room to inform the operator. Adjustments to parameters are performed in accordance with TSs, including any that establish the minimum number of redundant safety channels that must remain operable for the applicable operating modes and conditions. The SFM includes a load switch to update the nonvolatile memory parameters when setpoints are changed during maintenance.

Based on the above, the NRC staff finds that the HIPS-platform-based TRPS and ESFAS designs incorporate adequate access control features to prevent any inadvertent changes to the TRPS and ESFAS.

7.4.2.3 HIPS Design Process

SHINE FSAR section 7.4.5.4 and figure 7.4-3 describe the TRPS and ESFAS programmable logic lifecycle process. The TRPS and ESFAS are implemented on a logic-based HIPS platform that does not use traditional software or microprocessors for operation. It is composed of logic implemented using discrete components and FPGA technology. The same programmable logic development process is used for both systems. SHINE FSAR section 7.4.5.4 states that SHINE’s vendor is responsible for developing and delivering the HIPS platform for the TRPS and ESFAS in accordance with the vendor’s programmable logic development plan (PLDP), which describes a planned and systematic approach to design, implement, test, and deliver the programmable logic for the TRPS and ESFAS. SHINE is responsible for providing oversight of the vendor, verifying that deliverables are developed in accordance with approved quality and procurement documents, and maintaining the vendor as an approved supplier on the SHINE approved supplier list.

NUREG-1537, Part 1, section 7.2.1, recommends that all systems and components of the I&C systems should be designed, constructed, and tested to quality standards commensurate with the safety importance of the functions to be performed. Further, ANSI/ANS-10.4-2008, "Verification and Validation of Non-Safety-Related Scientific and Engineering Computer Programs for the Nuclear Industry," provides guidance for the verification and validation of scientific and engineering computer programs for the nuclear industry.

The guidance on quality assurance for design development in ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," recommends that the applicable design inputs, such as design bases, performance requirements, regulatory requirements, and codes and standards be identified and documented. ANSI/ANS-15.8 further states that, for purchased items and services, the supplier is responsible for the quality of the product and must provide evidence of that quality. Further, the supplier-generated documents must be controlled, handled, and approved in accordance with established methods.

The following sections describe the system lifecycle activities and the plans used during the development of the HIPS-platform-based TRPS and ESFAS.

7.4.2.3.1 Programmable Logic Lifecycle Process

SHINE FSAR figure 7.4-3 illustrates the lifecycle process for the TRPS and ESFAS from planning through installation phases. Design interfaces are established during the design development process, and during the design review and approval process. Design interfaces are controlled in accordance with the project management plan. The design interfaces include addressing any impacts on the safety system, control console, or display instruments during the lifecycle process. The programmable logic development lifecycle consists of the following phases:

- Planning
- Requirements
- Design
- Implementation
- Test
- Shipment and installation

SHINE FSAR sections 7.4.5.4.2.1 through 7.4.5.4.2.6 describe these phases which are being implemented by the vendor. The vendor is performing a programmable logic lifecycle process for HIPS core logic for developing HIPS components for the TRPS and ESFAS designs. The HIPS core logic project is being conducted independent of the TRPS and ESFAS programmable logic development project. The purpose of the HIPS core logic project is to formally develop HIPS modules/components for safety-related applications. The core logic for the HIPS modules will be used as safety-related pre-developed HIPS components in the TRPS and ESFAS designs. The TRPS and ESFAS applications will use the latest approved version of the HIPS modules for their development and any changes will be tracked under their development project. The SHINE TRPS and ESFAS are the first safety-related applications of the HIPS platform. Successful completion of the HIPS core logic project will result in pre-developed HIPS components, as part of the TRPS and ESFAS planning phase activity, as depicted on figure 7.4-3 of the SHINE FSAR. SHINE has delegated verification and validation (V&V) activities related to the safety-related control system development to the vendor. The vendor Project V&V Plan is designed to detect and report errors that may have been introduced during the system development process.

IEEE Standard 1012-2004, "Standard for Software Verification and Validation," section 4, provides guidance on the selection of criticality levels for software based on its intended use and application. The software and hardware developed for the safety-related systems are classified as Software Integrity Level 2 (SIL2). The vendor Project V&V Plan for the system development was tailored and adapted for FPGA technology from the guidance in IEEE Standard 1012-2004. The V&V activities are commensurate with the expectations for SIL2 software classification. Successful completion of V&V activities is documented in a V&V summary report for each of the lifecycle phases.

<u>Planning Phase</u>

SHINE procurement and technical documents are inputs to the planning phase. This includes the results of the HIPS core logic development project performed by Rock Creek Innovations (RCI). Model-based development and verification tools are being used by RCI for developing the FPGA programable logic for HIPS core modules, and the TRPS and ESFAS applications. Model-based software development is used to develop time-based block diagrams and event-based state machines. The use of these tools was audited and the NRC staff confirmed that they were appropriate for modeling and verification of the FPGA programmable logic for HIPS core modules.

As described in section 7.4.5.4.5 of the SHINE FSAR, RCI's project V&V plan for the system development is adapted for the FPGA technology from the guidance in IEEE Standard 1012-2004. The V&V activities are commensurate with the expectations for a SIL2 classification.

The specific validation process is described in the HIPS platform V&V plan. The NRC staff audited V&V of the core programmable logic developed for the HIPS modules, including the summary reports for the conceptual and requirements phases. The staff confirmed that the vendor is applying a reasonable V&V process for the core logic, consistent with IEEE Standard 1012-2004, including the incorporation of specific software logic into the core logic, consistent with the requirement specifications provided for the TRPS and ESFAS. The staff also confirmed that the vendor has completed the conceptual and requirements phases for the development of the core logic for HIPS modules.

The NRC staff audited the planning phase of the TRPS and ESFAS programmable logic development lifecycle activities as depicted in SHINE FSAR section 7.4.5.4.2 and figure 7.4-3. In the RCI system design control procedure, planning phase activities as described in the SHINE FSAR are performed in the RCI's planning and system concept phases. During the planning phase, RCI reviewed the SHINE procurement requirement specifications, design input documents, and identified design output documents and data required by the SHINE contract.

During the system concept phase, RCI generated a system requirements specification (SyRS) defining the system design requirements details, and a system design specification (SyDS) defining the system design details. SHINE FSAR section 7.4.5.4.1 presents the planning documents for the implementation of the programmable logic lifecycle process as follows:

- Project PLDP
- Project Configuration Management Plan
- Project V&V Plan
- Project Equipment Qualification Plan
- Project Test Plan
- Project Security Plan

The following system concept phase documents were created by RCI:

- Project configuration management plan
- Project V&V plan
- Project EQ plan
- Project master test plan
- Security assessment
- Programmable logic development plan

During its audit, the NRC staff confirmed that the vendor implemented similar planning documents for this phase consistent with SHINE FSAR section 7.4.5.4.1.

SHINE FSAR sections 7.4.5.4.5.2 and 7.4.5.4.5.3 present the objectives of the planning and requirements phase as follows:

- Determine that the V&V methods enable the objectives of the development standards and regulatory guidelines
- Verify that the development processes can be applied consistently
- Verify that each development process produces evidence that its outputs can be traced to their activity and inputs, showing the degree of independence of the activity, the environment, and the methods used
- Compliance with system requirements
- Accuracy and consistency
- Compatibility with the target hardware

- Testability
- Conformance to applicable standards and procedures
- Traceability

RCI performed the following V&V tasks during the concept phase:

- System requirements review
- Concept documentation evaluation
- Criticality analysis
- Traceability analysis
- Management review of the V&V effort

During its audit, the NRC staff confirmed that the vendor performed similar V&V tasks to support the objectives in SHINE FSAR sections 7.4.5.4.5.2 and 7.4.5.3.5.3.

RCI's planning/concept phase for the TRPS and ESFAS development activities is similar to SHINE FSAR section 7.4.5.4.2.1 and the NRC staff finds that the TRPS and ESFAS planning phase development activities meet the objectives of ANSI/ANS 10.4-2008 and IEEE Standard 7-4.3.2-2003. The results of the staff's audit are documented in the audit report (ML22347A177), which confirms that RCI's TRPS and ESFAS planning, and concept phase development activities are consistent with the development process defined in SHINE FSAR sections 7.4.5.4.2.1 and 7.4.5.4.2.2.

<u>Requirements Phase</u>

During the requirements phase, a programmable logic requirements specification (PLRS) is generated to translate the conformed design specification into project-specific programmable logic requirements.

SHINE FSAR section 7.4.5.4.5 describes the V&V process, which is performed at the end of each lifecycle phase. RCI's project V&V plan for the system development is adapted for the FPGA technology from the guidance in IEEE Standard 1012-2004. The V&V activities are commensurate with the expectations for a SIL2 classification. The NRC staff audited the RCI project master test plan which describes the TRPS and ESFAS hardware and programmable logic testing. The staff confirmed that the test activities in the master test plan are consistent with IEEE Standard 1012-2004 and IEEE Standard 829-2008, "Standard for Software and System Test Documentation." Additionally, as described in section 7.4.5.4.5 of the SHINE FSAR, V&V personnel review each design output at the end of its lifecycle phase prior to approving the deliverables and test procedures are prepared by the V&V personnel based on the project traceability matrix to ensure that each requirement is adequately tested.

The NRC staff audited the programmable logic requirements phase of the TRPS and ESFAS development lifecycle activities consistent with SHINE FSAR section 7.4.5.4.2 and figure 7.4-3. According to RCI's system design control procedure, the TRPS and ESFAS system programmable logic requirements specification (PLRS) is developed that translates the programmable logic requirements from the conforming specifications into project-specific design requirements. The PLRS is organized consistent with the guidance in IEEE Standard 830-1998, "Recommended Practice for Software Requirements Specifications." Consistent with objectives of SHINE FSAR section 7.4.5.4.5.3, the staff confirmed during the audit that the vendor performed similar V&V tasks during the programmable logic requirements phase.

RCI performed the following V&V tasks during the programmable logic requirements phase:

- Evaluation of programmable logic requirements (software requirements) for each HIPS module used in the TRPS and ESFAS architecture
- Traceability analysis
- Interface analysis
- Management review of the V&V effort

During its audit, the NRC staff noted that RCI identified several anomalies during the V&V of the system requirements phase. The V&V summary report recommends proceeding to the next development phase and requires dispositioning of the anomalies before completion of the programmable logic design phase. The staff sampled a number of key anomalies and did not identify any significant issues that would prevent proceeding to the next development phase. The staff also noted a discrepancy between SHINE FSAR figure 7.4-3 and RCI's system design control procedure. The SHINE FSAR figure shows development of the test plans during the requirements phase whereas RCI's procedure calls for developing the test plans during the design phase. In its response to NRC staff RCI 7-11 (ML22318A178), SHINE acknowledged this inconsistency and confirmed that test plans will be developed during the design phase. Based on the information and results reviewed in the system requirements phase audit, the staff has reasonable assurance that the TRPS and ESFAS programmable logic requirements phase development activities meet the objectives of ANSI/ANS 10.4-2008 and IEEE Standard 7-4.3.2-2003. The results of the staff's audit are documented in the audit report (ML22347A177), which concludes that RCI's TRPS and ESFAS programmable logic requirements phase development activities are consistent with the development process defined in SHINE FSAR section 7.4.5.4.2.2.

<u>Design Phase</u>

The SHINE FSAR states that a hardware design specification will be generated to define the system hardware requirements and design details. The hardware design specification is generated in accordance with the vendor hardware design specification development procedure. A programmable logic design specification (PLDS) is generated to translate the PLRS into a description of the functional requirements, a description of the system or component architecture, and a description of the control logic, data structures, input/output formats, interface descriptions, and algorithms. Design tests are performed to validate that the design meets the system requirements in accordance with the vendor test control procedure. The NRC staff confirmed during its audit that the design phase process described in SHINE FSAR section 7.4.5.4.2.3 is consistent with the vendor's system design phase procedure.

Implementation Phase

The SHINE FSAR states that the HIPS platform hardware and programmable logic components will be integrated into the project during the implementation phase to provide the target hardware and to incorporate the HIPS platform programmable logic that has been previously designed, developed, tested, qualified, and implemented. The implementation phase V&V summary report documents the implementation phase exit. If control point exit criteria are not met, a conditional release can be issued in accordance with the vendor conditional release procedure prior to beginning test phase activities. The NRC staff confirmed during its audit that the implementation phase process described in SHINE FSAR section 7.4.5.4.2.4 is consistent with the vendor’s system implementation phase procedure

Test Phase

The SHINE FSAR states that the test phase is the validation phase. Outputs from the test phase, which are requirements of the project, will be completed prior to test phase exit. Verification that test phase tasks are complete and output documents are approved serves as the control point to transition the project from the test phase to the shipment phase. The purpose of the test phase V&V is to uncover errors that may have been introduced during the development processes. Testing objectives include the development and execution of test cases and procedures to verify the following:

- Code complies with the PLRS
- Code complies with the PLDS
- Code is robust
- Code complies with the target hardware

The test phase V&V summary report documents the test phase exit. Approved documents are placed into configuration management prior to test phase exit. The NRC staff confirmed during its audit that the test phase process described in SHINE FSAR section 7.4.5.4.2.5 is consistent with the vendor’s test phase procedure.

Shipment Phase and Installation

The SHINE FSAR states that the shipment phase prepares and ships the system to SHINE. Output documents from this phase are completed prior to shipment phase exit. The shipment phase V&V summary report is completed. The final V&V report documents the completed project V&V activities. Shipment phase documents will be verified to be complete and approved documents are placed into configuration management prior to shipment phase exit.

Systems are installed and site acceptance tests will be performed in accordance with written plans and instructions prepared and controlled under the installer’s quality assurance program. SHINE is responsible for providing oversight of the installer and maintaining the installer as an approved supplier on the SHINE approved supplier list.

Programmable Logic Regression Analysis

SHINE FSAR section 7.4.5.4.3 states that whenever a modification is made to the PLRS and PLDS a regression analysis is necessary to determine what V&V activities to perform. Also, a regression analysis is performed if changes are made to previously tested programmable logic to determine the impact to all parts of the system.

Project Requirements Traceability Matrix

A system requirements traceability matrix is developed during each of the project phases by the vendor. The system requirements traceability matrix is used to generate comprehensive validation test procedures that ensure that each requirement is adequately tested and meets the system requirements. SHINE FSAR section 7.4.5.4.7 describes independent testing that includes factory acceptance testing (FAT) and the development of the test phase V&V summary report.

Configuration Management

Section 7.4.5.4.6 of the SHINE FSAR describes configuration management of HIPS platform development activities. Configuration management for developing the TRPS and ESFAS applications on the HIPS platform has been delegated to RCI, which applies to data and documentation used to produce, verify, test and show compliance with programable logic used in the system. As presented in SHINE FSAR section 7.4.5.4.6, any changes to baselined configuration items are planned, documented, approved, and tracked in accordance with a change control process. The NRC staff finds that the configuration management will ensure that any changes to the system and/or configuration of the logic are maintained and documented.

The NRC staff audited RCI's HIPS platform configuration management plan that applies to the programmable logic and hardware-related documentation developed for HIPS platform applications to confirm the information in SHINE FSAR section 7.4.5.4.6. The staff notes that this project configuration management plan (PCMP) was developed using guidance from Regulatory Guide 1.169, Revision 1, "Configuration Management Plans for Digital Computer Software Used in Safety Systems of Nuclear Power Plants" (ML12355A642), and IEEE Standard 828-2005, "Standard for Software Configuration Management Plans." The staff confirmed that item storage and management, including version control, revision control, traceability, and baselining, was appropriately considered in the PCMP. Specifically, RCI uses commercial configuration management software tools for configuration item storage and management which is software that ensures that all files in the project are revision controlled and traceable.

Section 7.4.5.4.6.1 of the SHINE FSAR describes that the programmable logic design models are one item under the configuration management. Each item under configuration management needs to be identified, which includes, in part, facilitation of tracking and assigning of version numbers. During its audit of the PCMP, the NRC staff confirmed that, when using the model-based software development tool set in the programmable logic development process, the design models are developed with the appropriate mechanisms to ensure the assignment of version numbers and tracking to maintain appropriate configuration control of the design models. Additionally, the PCMP describes the configuration management resources, which provides additional assurance of reasonable configuration management. The results of the staff's audit are documented in the audit report (ML22347A177), which confirms that RCI's

PCMP activities are consistent the configuration management objectives and process described in SHINE FSAR section 7.4.5.4.6.

Based on the description in SHINE FSAR section 7.4.5.4.6 and its audit of the RCI PCMP, the NRC staff finds that RCI's configuration management of the HIPS application of the TRPS and ESFAS is consistent with the configuration management objectives and process described in SHINE FSAR section 7.4.5.4.6 and meets ANSI/ANS-15.8-1995.

7.4.2.3.2 Conclusion for HIPS Design Process

Based on its review of the information provided in the SHINE FSAR and its audit of the TRPS and ESFAS programmable logic development activities, the NRC staff determined that the vendor established and followed a clear and robust software development process for the planning and requirements phase of the TRPS and ESFAS development. In addition, the vendor performed the V&V activities described in the V&V plan. The results of these activities are recorded in the V&V summary reports.

The HIPS vendor created a project V&V plan. This plan describes V&V activities performed during each phase of the lifecycle process. In SHINE FSAR section 7.4.5.4.5, the applicant noted that because the HIPS platform is based on FPGA technology, the vendor tailored and adapted the guidance in IEEE Standard 1012-2004 to the V&V activities necessary for the TRPS and ESFAS. The NRC staff agrees that the SIL2 software integrity level for the TRPS and ESFAS is acceptable and generally commensurate with the specific design features and safety importance of the TRPS and ESFAS, including consideration of the potential criticality and radiological consequences, and the safety margins associated with the accident analyses that credit TRPS and ESFAS functions, as described in chapter 13 of this SER. Therefore, V&V activities are commensurate with the expectations for a SIL2 classification, as described in IEEE Standard 1012-2014.

The vendor performed and completed the system conceptual and requirements phases V&V activities described in the V&V plan and that were accepted by the applicant. Based on the V&V results of the conceptual and requirements phases, and the V&V plans and activities described for the remaining system development phases described in RCI's project V&V plan, the NRC staff has reasonable assurance that design, implementation, and testing can be successfully completed by the vendor to provide high-quality components using accepted engineering and industrial practices. The results of these phases will be subject to NRC inspection oversight.

Based on the above, the NRC staff finds that the system development process and documents for the TRPS and ESFAS for the SHINE facility meet the design acceptance criteria for a structured development process for safety systems in NUREG-1537, including acceptance criteria that apply to non-power reactor digital I&C systems from the guidance and industry standards for digital upgrades referenced in chapter 7 of NUREG-1537.

7.4.2.4 Conclusion

The NRC staff has reasonable assurance that the HIPS digital I&C platform used to implement the TRPS and ESFAS is designed to be consistent with the approved HIPS TR and incorporates the fundamental design principals of independence, redundancy, predictably and repeatability, and diversity. The staff has reasonable assurance that the system will be developed and tested to demonstrate quality and reliability commensurate with the safety importance of the functions, in consideration of the safety margins associated with the accident analyses that credit TRPS and ESFAS functions as described in chapter 13 of this SER. The staff also finds that the HIPS design meets the applicable portions of SHINE Design Criteria 15, 16, and 19. Therefore, the staff concludes that the HIPS platform used to implement the TRPS and ESFAS is capable of performing the allocated design basis safety function under postulated conditions.

7.4.3 Process Integrated Control System

The NRC staff evaluated the sufficiency of the SHINE facility PICS, as described in SHINE FSAR section 7.3, "Process Integrated Control System," using the applicable guidance and acceptance criteria from section 7.3, "Reactor Control System," of NUREG-1537, Parts 1 and 2, and section 7b.3, "Process Control Systems," of the ISG augmenting NUREG-1537, Part 2.

NUREG-1537, Part 1 includes an assumed I&C system architecture:

> The [protection system] should monitor selected … operating parameters [and] is designed to ensure [facility] and personnel safety by limiting parameters to operate within analyzed operating ranges. The [protection system] can also give the [engineered safety features] actuation system information for the operation of [engineered safety features] when the instruments indicate that abnormal or accident conditions could occur. The [operational control system(s)] may monitor many of the same parameters as the [protection system] and give information for automatic or manual control of the … operating conditions .... The … facility instruments present operating parameter and system status information to the operator for monitoring … operation and for deciding on manual control actions to be taken. Instrument systems are the means through which automatic or operator control actions are transmitted for execution by the [operational control system(s)]. Radiation instruments show radiation levels in selected areas in the … facility and could give data to the [protection system], give information to help in the control of personnel radiation exposure, or monitor the release of radioactive material from the [facility].

For the SHINE facility, the PICS includes the operational control system, instrument systems, and control console described in the NUREG-1537, Part 1. The protection system and the radiation monitors are considered separate systems in this evaluation.

7.4.3.1 System Description

The PICS is a distributed control system to monitor and control the various processes in the IF and RPF. PICS includes the main control board, operator and supervisor workstations, and associated control cabinets.

The PICS interfaces with other controllers or systems, supplied for several equipment and components to maintain the operating characteristics and parameters of the facility IUs and RPF as further described in chapter 4 of this SER. SHINE FSAR figure 7.3-1, "Process Integrated Control System Architecture," depicts the PICS system architectures, including the vendor-provided control systems, and the control console and displays. SHINE FSAR section 7.3.1 describes these systems, and this description was considered during an NRC staff audit when SMT20A-FS-001, Revision 1, "System Architecture Functional Specification SHINE Process Integrated Control System," was confirmed to be consistent with this SHINE FSAR description. The PICS system network routes signals to the main distribution switch located in the server room. Information from the facility control room, remote input/output cabinets, remote human machine interface panels, programmable logic controllers, vendor-provided control systems, and virtual machines communicate through the main distribution switch with a combination of copper cabling and fiber optic cabling. Some key aspects associated with PICS which are described in other SHINE FSAR sections are summarized below.

Main Control Board

The main control board consists of a console, static display screens, and manual actuation interfaces. The configuration of the main control board is shown in SHINE FSAR figure 7.6-2.

The main control board contains eight sections, each containing one column of displays dedicated to a single IU. This board also includes a ninth section containing two columns of displays dedicated to the SHINE facility status. Each column includes three static display screens to display safety functions of the IU cells and other facility processes so that the operator can easily verify the status of the SHINE facility. In addition, these columns include manual actuation devices and the enable nonsafety switch (labeled E/D). The facility status section includes the facility master operating permissive (labeled O/S).

Operator Workstation

The operator workstations consist of display screens and human interface equipment to operate the PICS and the neutron driver assembly system (NDAS) with two desks for the PICS and two desks for the NDAS controls. SHINE FSAR figure 7.6-1 also shows the layout of the operator workstation.

Both PICS workstations can display any screens about the operation in the SHINE facility. However, only one workstation is assigned to manipulate the controls necessary for operation, while the other can only monitor. The PICS allows for the transfer of controls between the PICS workstations and to the supervisor workstation, if necessary. In addition, a limited set of control functions can be transferred to the PICS local control stations. Only one workstation (operator, supervisor, or local) is allowed to input control commands to a particular component at any time.

The PICS workstations include the screens to operate and monitor the facility. The operator uses the IU screen to advance the modes of operation for the IUs. Also, one of the screens is configured to always display alarms present in the facility.

The NDAS workstations are used to monitor and operate the neutron drivers for each IU cell. These workstations can only send commands to the NDAS control system, as long as the PICS permissive is satisfied.

Supervisor Workstation

The supervisor workstation is similar to the PICS operator workstations and may be used to control a process or IU but is normally used for monitoring facility status only. The supervisor workstation does not have any NDAS control capabilities.

Maintenance Workstation

Although not part of the PICS, there are two maintenance workstations for the TRPS and ESFAS. These workstations are used to perform maintenance and to modify tunable parameters including setpoints of the TRPS or ESFAS. This is done through a temporary connection to the monitoring and indication communication module of the associated division. Each workstation is assigned to Division A or Division B and for Division C, the SHINE staff would use the workstation assigned to Division A. The workstations are in the facility control room, one inside the Division A TRPS cabinet and the other inside the Division B TRPS cabinet. SHINE FSAR figure 7.6-3 shows the location of the workstations within the cabinets.

The PICS also includes an engineering workstation located in the PICS server room, which is used to perform system administrator functions.

7.4.3.2 Evaluation of PICS Design Criteria

SHINE FSAR section 3.1, "Design Criteria," states, in part:

> Safety-related SSCs at SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents.

SHINE FSAR table 3.1-2 and section 7.3.2 identify the design criteria for the PICS, which is classified as nonsafety-related.

Based on these two facts, the NRC staff concludes that: (1) the PICS does not include functions intended to prevent accidents, (2) the PICS cannot cause undue risk to the health and safety of workers and the public, and (3) the PICS does not control or mitigate the consequences of accidents. The evaluation of the PICS documented below is based on this conclusion.

7.4.3.2.1 SHINE Facility Design Criteria

The SHINE design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety that provide reasonable assurance that the SHINE facility can be operated without undue risk to the health and safety of the public. Section 50.34(a)(3)(ii) of 10 CFR requires the applicant to describe the design bases and the relation of the design bases to the principal design criteria and 10 CFR 50.34(b) requires updating the information to take into account any pertinent information developed since the issuance of the construction permit.

By letter dated April 22, 2022, in its response to NRC staff RAI 7-49 (ML22112A195), the applicant stated:

> SHINE Design Criteria 3 and 6 are applicable to the process integrated control system (PICS). SHINE does not rely on the PICS to satisfy SHINE Design Criteria 1, 2, 4, 5, 7, and 8. SHINE has revised Subsections 7.3.2.1 and 7.6.2 of the FSAR to describe the relationship between the PICS design basis to SHINE Design Criteria 3 and 6.

SHINE Design Criteria 3 and 6 are described in SHINE FSAR section 3.1, as follows.

> <u>Criterion 3 – Fire protection</u>
>
> Safety-related SSCs are designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.

Noncombustible and heat resistant materials are used wherever practical throughout the facility, particularly in locations such as confinement boundaries and the control room.

Fire detection and suppression systems of appropriate capacity and capability are provided and designed to minimize the adverse effects of fires on safety-related SSCs. Firefighting systems are designed to ensure that their rupture or inadvertent operation does not significantly impair the safety capability of these SSCs.

The NRC staff evaluation of the SHINE facility fire protection program (and any specific crediting of SSCs) that is found in SHINE FSAR section 9a2.3, "Fire Protection Systems and Programs," is provided in section 9a.4.3, "Fire Protection Systems and Programs," of this SER.

Criterion 6 - Control room

A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

The NRC staff evaluation of the suitability of the SHINE facility control room for operations (and any specific crediting of SSCs) is provided in section 7.4.9, "Human Factors Engineering" of this SER.

SHINE FSAR table 3.1-2 and section 7.3.2.1 state that SHINE Design Criterion 13 applies to the PICS. SHINE Design Criterion 13 is described in SHINE FSAR section 3.1, as follows:

Criterion 13 – Instrumentation and controls

Instrumentation is provided to monitor variables and systems over their anticipated ranges for normal operation, for anticipated transients, and for postulated accidents as appropriate to ensure adequate safety, including those variables and systems that can affect the fission process, the integrity of the primary system boundary, the primary confinement and its associated systems, and the process confinement boundary and its associated systems. Appropriate controls are provided to maintain these variables and systems within prescribed operating ranges.

SHINE FSAR section 7.3.1 describes the PICS functions, as well as the systems that interface with it; specifically, section 7.3.1 describes the "Monitoring and Alarms," "Control Functions," and "Interlocks and Permissives," of the PICS with respect to the specific systems identified. Furthermore, PICS interfaces with the safety-related TRPS, ESFAS, NFDS, and radiation monitors. SHINE FSAR tables 7.4-1 and 7.5-1 identify the monitored variables for the TRPS and ESFAS. SHINE FSAR tables 7.7-1 through 7.7-3 identify the radiation monitors installed in the SHINE facility. The monitored variables and instrument ranges for the safety-related radiation monitors are identified in SHINE FSAR tables 7.4-1 and 7.5-1. SHINE FSAR section 7.8.3.1 describes the monitored variables for the NFDS, including instrument operational ranges and analytical limits. SHINE FSAR table 7.4-1 also identifies monitored variables and instrument ranges for the NFDS.

SHINE FSAR section 4a2.8.6, "Radiation and Hydrogen Concentration Control/Monitoring," states that the TSV off-gas system (TOGS) is designed to maintain hydrogen concentrations at or less than 2 percent during normal operation and if the hydrogen concentration exceeds 2.5

percent by volume, an alarm alerts the operator to take action. SHINE FSAR section 7.3.1.1.2, “Target Solution Vessel Off-Gas System,” states that “PICS directly monitors and provides alarms for TOGS hydrogen concentration.” High measured hydrogen concentration is addressed only by the control system, and not directly by protection system functions. However, the TRPS initiates an IU Cell Nitrogen Purge when monitored variables indicate a loss of hydrogen recombination capability in the IU (see SHINE FSAR sections 7.4.4.1.10, 7.4.4.1.11, and 7.4.4.1.12). An IU Cell Nitrogen Purge results in purging the primary system boundary for the affected IU with nitrogen.

The NRC staff did not review or evaluate the PICS equipment design to determine the adequacy of the control systems to maintain the required variables within operational limits during facility operation; however, the staff verified that the impact of control system failures is appropriately considered in the accident analyses and is addressed by the protection systems. Based on the system description, confirmed in part by the staff observations of the equipment during an audit where TECRPT-2022-0033, Revision 0, “Evaluation of Indirect Safety Impacts of Multiple PICS Failures,” was confirmed to support the statements made in SHINE FSAR section 7.3.2.2.4, “Effects of Control System Operation/Failures,” the staff finds that the PICS is designed to meet the acceptance criteria in section 7.3 of NUREG-1537, Part 2, that the instrumentation is designed to provide continuous indication of the neutron flux over the licensed power range in the IUs and the entire expected range of the monitored process variables for both the IUs and the production facility as defined in SHINE TS, and that alarms and/or indications will be provided.

7.4.3.2.2 PICS System Design Criteria

SHINE FSAR section 7.3.2.2 provides PICS design criteria that are incorporated into the PICS design and implementation. The NRC staff reviewed these design criteria and attributes of the PICS, as described below, as part of the basis for verifying that appropriate controls can be designed and implemented for the PICS and consistent with the acceptance criteria in section 7.3 of NUREG-1537, Part 2, to the extent practical. The staff did not independently review or confirm specific PICS design features, programming logic, or other configurations (e.g., typically developed in the requirements or implementation phases) that demonstrate how the attributes are achieved.

7.4.3.2.2.1 Access Control

SHINE FSAR section 3.1 states that design criteria derived from external codes, guides, and standards specific to the design, construction, or inspection of SSCs are included in the applicable SHINE FSAR chapter describing those SSCs. SHINE FSAR section 7.3.2.2.1 includes PICS Criterion 1. SHINE FSAR section 7.6.2.2.1 includes PICS Criterion 10 for control consoles and displays. These criteria are as follows:

> PICS Criterion 1 – The PICS design shall incorporate design or administrative controls to prevent/limit unauthorized physical and electronic access to critical digital assets (CDAs) during the operational phase, including the transition from development to operations. CDAs are defined as digital systems and devices that are used to perform or support, among other things, physical security and access control, safety-related functions, and reactivity control.
>
> PICS Criterion 10 – The operator workstation and main control board design shall incorporate design or administrative controls to prevent or limit unauthorized physical

and electronic access to critical digital assets (CDAs) during the operational phase, including the transition from development to operations. CDAs are defined as digital systems and devices that are used to perform or support, among other things, physical security and access control, safety-related functions, and reactivity control.

SHINE FSAR section 7.3.5 describes how SHINE performs access control and cyber security and states that the "PICS and other vendor-provided nonsafety-related control systems do not allow remote access," and that the "PICS and other vendor-provided nonsafety-related control systems do not use any wireless interface capabilities for control functions." SHINE FSAR section 7.6.3.4 describes access control for the facility control room and the facility control systems and states that to use the PICS, operators need to request authorization and set up a personal username and password.

Since the PICS does not allow remote or wireless access, the NRC staff concludes that the PICS design includes design features to allow administrative control of access during operation. The specific administrative controls employed are addressed as part of the cyber security assessment.

7.4.3.2.2.2 Software Requirements Development

SHINE FSAR section 3.1 states that design criteria derived from external codes, guides, and standards specific to the design, construction, or inspection of SSCs are included in the applicable SHINE FSAR chapter describing those SSCs. SHINE FSAR section 7.3.2.2.2 includes PICS Criteria 2, 3, and 4, which are as follows:

> PICS Criterion 2 – A structured process, which is commensurate with the risk associated with its failure or malfunction and the potential for the failures challenging safety systems, shall be used in developing software for the PICS.
>
> PICS Criterion 3 – The PICS software development lifecycle process requirements shall be described and documented in appropriate plans which shall address verification and validation (V&V) and configuration control activities.
>
> PICS Criterion 4 – The configuration control process shall assure that the required PICS hardware and software are installed in the appropriate system configuration and ensure that the correct version of the software/firmware is installed in the correct hardware components.

SHINE FSAR section 7.3.2.2.2 describes how SHINE meets these criteria. Also, SHINE FSAR section 7.3.3.4 describes the development process followed for the PICS, NDAS, and third-party developed systems (e.g., radioactive liquid waste immobilization (RLWI) system).

ANSI/ANS 10.4-2008 provides guidance for the V&V of scientific and engineering computer programs for the nuclear industry. Section 9 of the standard recommends that the test results for the V&V activities during the installation phase be documented and reported as specified in the V&V Plan and, if the findings necessitate any retesting or revision of the test report, the updated test results should be verified again before final program acceptance.

SHINE FSAR section 7.3.3.4 states that the PICS validation master plan describes the V&V activities.

The NRC staff evaluated the PICS and other nonsafety-related I&C systems designs using the acceptance criteria identified in SHINE FSAR section 3.1 and section 7.3 of NUREG-1537, Part 2. While NUREG-1537, Part 2 provides criteria for verifying that the hardware and software for control systems should meet the guidelines of IEEE 7-4.3.2-1993, "Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generation Stations," the staff agrees with SHINE's use of ANSI/ANS-10.4-2008 for the testing V&V activities given the function of the PICS, the associated failure analysis provided for the system (see SHINE FSAR section 7.4.3.2.2.4), and the safety margins described in section 13 of this SER. Based on its review, the staff finds that the PICS and other nonsafety-related I&C systems designs result in a reliable, redundant, and fail-safe system that helps ensure the continued operation of the facility within the safety limits and limiting safety system settings (LSSS) established in the SHINE TSs, assuming that the final design implementation and testing of the PICS conforms to the PICS criteria and design attributes described in SHINE FSAR section 7.3.

7.4.3.2.2.3 Fail Safe

SHINE FSAR section 3.1 states that design criteria derived from external codes, guides, and standards specific to the design, construction, or inspection of SSCs are included in the applicable SHINE FSAR chapter describing those SSCs. SHINE FSAR section 7.3.2.2.3 includes PICS Criterion 5, which is as follows:

> <u>PICS Criterion 5</u> – The PICS shall assume a defined safe state with loss of electrical power to the PICS.

The fail-safe acceptance criterion of NUREG-1537, Part 2 ensures that, on a loss of power, the control system and associated equipment are designed to assume a safe state and will enable safe shutdown.

SHINE FSAR sections 7.3.3.6 and 7.6.3.5 note that there are local batteries for the PICS servers, the operator workstations, and the main control to allow continued operation for at least 10 minutes after power is lost. If power is not restored to the PICS within this time, the PICS control outputs open and all controlled components will transition to their safe states, as confirmed during the NRC staff audit. In addition, in case normal power is interrupted, the standby generator system (SGS) will provide backup power to PICS. SHINE FSAR section 7.3.3.6 states that the SGS requires five minutes to start. Finally, SHINE FSAR sections 7.3.2.2.3 and 7.3.3.6 state that components controlled by the PICS assume a defined safe state on loss of electrical power. Fail-safe states are also discussed in the component classification and HAZOP [hazard and operability] processes when they are relevant to consequences of concerns. The PICS will not attempt to reposition those components upon detecting that they have gone to their safe states, as confirmed during the staff audit.

Based on the above, the NRC staff finds that the applicant's implementation of fail-safe acceptance criteria for the PICS is acceptable. The PICS design includes methods for its components to assume a safe state on loss of electrical power.

7.4.3.2.2.4 Effects of Control System Operation/Failures

Effects of Control Failures on TRPS and ESFAS Safety Functions

SHINE FSAR section 3.1 states that design criteria derived from external codes, guides, and standards specific to the design, construction, or inspection of SSCs are included in the applicable SHINE FSAR chapter describing those SSCs. SHINE FSAR section 7.3.2.2.4 includes PICS Criterion 6, which is as follows:

> PICS Criterion 6 – The PICS shall be designed so that it cannot fail or operate in a mode that could prevent the TRPS or ESFAS from performing its designated functions.

SHINE FSAR section 7.3.2.2.4 describes that any nonsafety-related signal transmitted from the PICS to the TRPS and/or ESFAS won't interfere with their operation. SHINE FSAR sections 7.4.3.4 and 7.5.3.4 describe the communication mechanisms between the PICS and the TRPS and ESFAS. In addition, SHINE FSAR section 7.6.4.5 provides additional descriptions for these communications. Finally, in its response to NRC staff RAI-7-9(c) (ML21272A340), Enclosure 3 (ML21272A344), the applicant stated:

> There are no sensor outputs that have both a target solution vessel (TSV) reactivity protection system (TRPS) safety-related protection function and a nonsafety-related control function. As described in Subsection 7.5.2.1.6 of the FSAR, there are no sensor outputs that have both an engineered safety features actuation system (ESFAS) safety-related protection function and a nonsafety-related control function. SHINE has revised Subsections 7.3.1.1.2 and 7.4.2.1.6 of the FSAR to clarify that there are no sensor outputs that have both a TRPS protection function and a nonsafety-related control function.

SHINE FSAR section 7.3.1.3.11, "Target Solution Vessel Reactivity Protection System and Engineered Safety Features Actuation System," provided in Supplement 23 by letter dated June 10, 2022 (ML22161A974), Enclosure 2 (ML22161A977), states:

> Safety-related components that are capable of being actuated by the TRPS or ESFAS, but also have a nonsafety-related function related to production, achieve their safe state by having power removed. PICS controls these components directly by cycling power through the use of relays and contacts and does not send a signal to the TRPS or ESFAS during these normal operations. Should a safety actuation be required, the TRPS or ESFAS opens a contact in series with the power supply to the component, causing it to achieve its safe state regardless of the control signal from the PICS. Following the safety actuation, the PICS provides a nonsafety-related control signal to the TRPS or ESFAS to allow for component repositioning. The actuation and priority logic (APL) in the TRPS or ESFAS processes these signals based upon the position of the enable nonsafety switch ….
>
> Safety-related components that are capable of being actuated by the TRPS or ESFAS and do not have a nonsafety-related production function are not controlled directly by PICS. Following the safety actuation, the PICS sends a nonsafety-related control signal to the TRPS or ESFAS and the APL in the TRPS or ESFAS processes this signal based upon the position of the enable nonsafety switch. If not prevented by higher priority inputs to the APL, the TRPS or ESFAS will position the component as requested by the PICS.

SHINE also stated that the FMEA for ESFAS and TRPS evaluates the infaces with PICS for any direct impacts and ensures that no failures within the PICS system could directly impact the ability of TRPS or ESFAS to perform their functions.

The NRC staff evaluated the PICS failures using the acceptance criteria identified in SHINE FSAR section 3.1 and section 7.3 of NUREG-1537, Part 2. For this review, acceptance criteria of NUREG-1537, Part 2 indicate that the systems should assume a safe state, enable safe shutdown, and not prevent the TRPS or ESFAS from performing their designed safety functions in the case of control system action or inaction. Conceptually, the SHINE facility design is the same as that for many reactor-rod-control systems for safe shutdown.

Based on the above, the NRC staff has reasonable assurance that the SHINE facility design is adequate for ensuring that the PICS cannot fail in a mode that would prevent the TRPS or ESFAS from performing their safety functions, assuming that the final design implementation and testing of the PICS conforms to the PICS criteria and design attributes described in SHINE FSAR section 7.3.

Effects of Control Failures in SHINE Safety Analysis Methodology

As stated in the SHINE FSAR and confirmed in the NRC staff audit of the PICS failure analysis described below, the SHINE safety analysis methodology uses process hazards analysis (PHA) methods appropriate to the system or process being analyzed, including HAZOPs, FMEAs, and What-If/Checklist, to identify the necessary inputs to the safety systems (i.e., TRPS and ESFAS) to identify potentially unsafe conditions. These PHA methods are generally focused on the consequences of process deviations and how those deviations can be detected independent of cause. Those variables that need to be monitored to detect process deviations that could lead to undue risk are the monitored variables in the TRPS and ESFAS. Therefore, any unsafe conditions caused by the PICS would be identified by the TRPS and ESFAS monitored variables and the appropriate safety actuation would be initiated. The FMEA for the TRPS and ESFAS evaluates the infaces with the PICS for any direct impacts and ensures that no failure within the PICS system could directly impact the ability of the TRPS or ESFAS to perform their functions.

SHINE also performed a PICS failure analysis to evaluate the potential impacts of PICS failures (including a failure of cards and racks) on the ability of the safety-related control systems to detect unsafe conditions and perform the appropriate safety functions in TECRPT-2022-0033. The potential impacts on controls listed in the SHINE Safety Analysis (SSA) Summary Report that are not implemented through the safety-related control systems were also evaluated by SHINE. The purpose was to demonstrate that PICS failures will not adversely impact the safety analysis of the SHINE facility as documented in SHINE FSAR chapters 4 and 13. Where multiple PICS failures could potentially lead to a failure to detect unsafe conditions or perform the appropriate safety function, requirements for separation within the PICS system design have been developed.

The NRC staff evaluated the PICS failure assessment and associated requirements for separation within the PICS system. During its audit, the staff confirmed instances in which PICS design requirements were purposely defined, in part as a result of the failure assessment, to maintain the effects of potential PICS failures within the operating conditions and accident basis analyzed in the SHINE FSAR. The staff has reasonable assurance that potential PICS failure events will remain within the bounds of the safety assessment, assuming that the final design implementation and testing of the PICS conforms to the PICS criteria and design attributes described in SHINE FSAR section 7.3 and TECRPT-2022-0033.

7.4.3.2.2.5 Operational Bypass

SHINE FSAR section 3.1 states that design criteria derived from external codes, guides, and standards specific to the design, construction, or inspection of SSCs are included in the applicable FSAR chapter describing those SSCs. SHINE FSAR chapter 7.3.2.2.5 includes PICS Criterion 7, which is as follows:

> PICS Criterion 7 – Bypasses of PICS interlocks, including provisions for testing, shall be under the direct control of a control room operator and shall be indicated on control room displays.

Sections 7.3 and 7.4 of NUREG-1537, Part 2 provide guidance related to operational bypass. SHINE FSAR section 7.3.2.5 states that a control room operator can bypass nonsafety-related interlocks using the PICS workstation. In addition, the PICS workstation display will annunciate when an interlock is bypassed, as confirmed during the NRC staff audit that PICS interlocks or permissives are not credited with performing any safety-related function in order to reduce the likelihood or consequences of an accident sequence.

The acceptance criteria in section 7.3 of NUREG-1537, Part 2 indicate that the control system should include interlocks to limit personnel hazards or prevent damage to systems during the full range of normal operations. SHINE FSAR section 7.3.1 identifies the PICS interlocks for each associated I&C system in the SHINE facility.

Based on a review of the interlock description against the criteria identified, the NRC staff agrees that the description of bypasses of PICS interlocks and associated provisions for control room indication is acceptable.

7.4.3.2.2.6 Surveillance

SHINE FSAR section 3.1 states that design criteria derived from external codes, guides, and standards specific to the design, construction, or inspection of SSCs are included in the applicable SHINE FSAR chapter describing those SSCs. SHINE FSAR section 7.3.2.2.6 includes PICS Criteria 8 and 9, which are as follows:

> PICS Criterion 8 – Subsystems of and equipment in the PICS shall be designed to allow testing, calibration, and inspection to ensure functionality.

> PICS Criterion 9 – Testing, calibration, and inspections of the PICS shall be sufficient to confirm that surveillance test and self-test features address failure detection, self-test capabilities, and actions taken upon failure detection.

Section 7.3 of NUREG-1537, Part 2 recommends application of the functional design and analyses to the development of bases of TSs, including surveillance tests and intervals. Additionally, ANSI/ANS-15.15-1978, “Criteria for the Reactor Safety Systems of Research Reactors,” recommends that the system design include the capability for periodic checks, tests, and calibrations. It also recommends that, if on-line periodic testing is necessary, such testing should not reduce the capability of the system to perform its safety function.

SHINE FSAR section 7.3.2.2.6 describes how the PICS meets these criteria. SHINE FSAR section 7.3.4.2 describes the testing and maintenance capabilities of the PICS. SHINE will test PICS during factory acceptance test (FAT) and post installation testing to demonstrate its functionality and to demonstrate conformance of the system equipment to the design performance requirements, including requirements for testing.

Therefore, the NRC staff concludes that the PICS allows testing, calibration, and inspection to ensure functionality, and includes features for failure detection and self-test capabilities.

SHINE FSAR section 7.3.4.3 states that the PICS is not in the SHINE TSs because it does not perform safety-related controls and functions. Therefore, the NRC staff did not evaluate testing or surveillance procedures as referenced in PICS Criterion 9. The staff confirmed that an SR is not warranted for the PICS because any failures of the PICS would not prevent the safety systems (i.e., the TRPS and ESFAS) from performing their safety functions.

Based on its review, the NRC staff concludes that the design of the PICS meets the acceptance criteria in section 7.3 of NUREG-1537, Part 2 to include the capability for periodic checks, tests, and calibrations to facilitate the performance of the required testing to ensure PICS operability without affecting its ability to perform its intended function. Also, the staff concludes that the PICS testing provisions provide reasonable assurance of its continued reliable operation.

7.4.3.2.2.7 Conclusion of Evaluation of PICS Design Criteria

Based on the above, the NRC staff concludes that SHINE established the necessary design, fabrication, construction, testing, and performance requirements for the PICS to provide reasonable assurance that the facility will be operated without undue risk to the health and safety of the public.

7.4.3.3 PICS Design Basis

This section of the SER documents the NRC staff's review and evaluation of the design basis of the PICS against the design bases acceptance criteria identified in sections 3.1 and 7.3 of NUREG-1537, Part 2. Additionally, 10 CFR 50.34(a)(3)(ii) requires the applicant to describe the design bases and the relation of the design bases to the principal design criteria and 10 CFR 50.34(b) requires updating the information to take into account any pertinent information developed since the issuance of the construction permit.

SHINE FSAR sections 7.3.1 and 7.3.3 identify the design bases used for the PICS. The NRC staff reviewed and evaluated the PICS to verify that the impact of control system failures is appropriately included in the FSAR accident analyses.

SHINE FSAR tables 7.4-1 and 7.5-1 show that the sensors used for protective actions (for example, for the neutron flux detectors) can detect process parameter values at the same or over a larger range than required to safely operate the SHINE facility. These channels provide information to both the PICS and the TRPS and ESFAS to monitor the facility during normal, transient, and accident conditions.

7.4.3.3.1 Design Basis Functions

The PICS does not perform safety functions. The PICS is only used to assist operators performing normal operations of the SHINE facility. Also, the PICS receives information from safety systems for operators to monitor process variables and system operation status. The PICS can be used for diverse actuations to the safety systems but is not credited in SHINE FSAR chapters 7 or 13. In addition, SHINE FSAR section 7.4.2.2.6, "Prioritization of Functions," contains a design criterion for prioritization and states: “Priority is provided to automatic and manual safety-related actuation signals over nonsafety-related signals as described in Subsection 7.4.3.12.”

7.4.3.3.2 Modes of Operation

SHINE FSAR section 7.3.1.1 describes the modes of operation and specific monitoring, control, and interlock functions of the PICS in each mode of the IU systems, which include SCAS, NDAS, TOGS, the primary closed loop cooling system (PCLS), and the neutron flux detection system. SHINE FSAR figure 7.4-1, Sheet 8, shows the transition modes for the IU cell.

The PICS provides a signal to the TRPS, when manually initiated by the operator, to sequentially transition the TRPS from one mode to the next. To advance each mode of operation of the IU cell, the operator manually selects the next mode using the PICS. The TRPS controls the transition for these modes by implementing the required mode-specific system interlocks and bypasses to ensure safe operation of the SHINE facility. Before an operator can manually transition to a different mode, all transition criteria conditions must be met. Note that when an IU cell safety signal is activated, the operation of the IU cell will automatically transition to Mode 3, independently of the operating mode. The PICS is installed in the facility control room, where conditions are designed to be as described in SHINE FSAR table 7.2-2.

7.4.3.3.3 System Operation

Through the main control board and operator workstations, the PICS is used to operate the SHINE facility. PICS functions include signal conditioning, system controls, interlocks, and monitoring of the process variables and system status. SHINE FSAR figure 7.3-1 depicts the PICS architecture.

The building automation system receives commands from the PICS to start and stop select control sequences and provides information to the PICS for monitoring.

The PICS also receives information for monitoring only from the following vendor-provided systems:

- Supercell control system
- Radioactive liquid waste immobilization

In addition, the PICS monitors valve or damper position feedback as needed to perform control functions or implement interlocks and permissives. SHINE FSAR section 7.3.1 describes those components.

7.4.3.4 Conclusion

The NRC staff concludes that the design of the PICS is such that any single malfunction in its components would not prevent the TRPS and ESFAS from performing necessary functions or prevent achieving a safe shutdown condition of the facility and (based on the review documented above) that there is reasonable assurance the PICS conforms to its design criteria.

7.4.4 Target Solution Vessel Reactivity Protection System

The NRC staff evaluated the sufficiency of the SHINE facility TRPS, as described in SHINE FSAR section 7.4, “Target Solution Vessel Reactivity Protection System,” using the applicable guidance and acceptance criteria from section 7.4 of NUREG-1537, Parts 1 and 2, and chapter 7, “Instrumentation and Control Systems,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 7.4 describes the TRPS. The NRC staff audited TECRPT-2019-0048, Revision 5, “TRPS System Design Description,” to confirm the information in SHINE FSAR section 7.4. The TRPS is an I&C system consisting of eight independent instances, each dedicated to one of the eight IUs in the IF. Section 7.4.2 of this SER evaluates the HIPS design for implementation of each TRPS.

The IU’s operating cycle includes the following steps:

- Prepared target solution is transferred to the target solution hold tank and then into the TSV.
- The neutron driver is energized.
- The subcritical assembly is operated at power for approximately 5.5 days.
- The IU is shut down and the target solution heat is allowed to decay.
- The target solution is transferred to the RPF for processing.

SHINE FSAR section 7.8, “Neutron Flux Detection System,” describes three independent sets of two neutron detectors and associated electronics as a “system” for each TRPS. Each NFDS division includes an ionization chamber detector and a Boron Trifluoride (BF3) detector pair. These detector types are primarily sensitive to thermal neutrons. The NRC staff evaluated the NFDS as part of the TRPS similar to the other sensor and instrumentation inputs to the TRPS. Therefore, all findings for the TRPS are applicable to the NFDS as appropriate.

Each TRPS does not have its own dedicated display, rather, all TRPS information (including sensor input values) are sent to the PICS for display purposes. All information provided by the TRPS to the PICS is provided through a transmit-only communication mechanism.

7.4.4.1 System Description

SHINE FSAR section 7.4.1, “System Description,” identifies the safety functions of the TRPS, as follows:

> The TRPS monitors variables important to the safety functions of the irradiation process during each operating mode of the IU to perform one or more of the following safety functions:
>
> - IU Cell Safety Actuation
> - IU Cell Nitrogen Purge

- IU Cell Tritium Purification System (TPS) Actuation
- Driver Dropout

The TRPS also performs the nonsafety defense-in-depth Fill Stop function.

SHINE FSAR section 7.8.1, “System Description,” describes the NFDS:

> The NFDS is a three-division system with six detectors configured in three sets of two detectors (source range power/wide range), with each set positioned around the subcritical assembly support structure (SASS) at approximately 120-degree intervals to the TSV. Each division of the NFDS consists of watertight detectors located in the light water pool and an NFDS amplifier mounted in the radioisotope production facility (RPF) or irradiation facility (IF). The six watertight detectors are located in the light water pool and are supported using brackets attached to the outer shell of the SASS. These brackets serve to locate the flux detectors in a fixed location relative to the TSV, ensuring flux profiles are measured consistently such that the sensitivity in the source range reliably indicates the neutron flux levels through the entire range of filling with the target solution.

The signal from the NFDS detectors is transmitted to the NFDS amplifiers where signal conditioning is performed. Each NFDS amplifier provides an analog signal representative of neutron flux. The NFDS interfaces with the TRPS for monitoring and indication, which then transmits the flux values to the PICS. The NFDS provides continuous indication of the neutron flux during operation, from filling through maximum power during irradiation. To cover the entire range of neutron flux levels, there are three different ranges provided from the NFDS: source range, wide range, and power range. One set of three independent NFDS detectors is used for the source range input into the TRPS (i.e., measures low flux levels common to what would be expected during filling in the IU cell prior to irradiation of the target solution). The other set of three independent detectors provides the input for the power range and wide range measurements. Each independent detector provides analog input signals to an independent division of the TRPS.

7.4.4.2 Design Criteria

Section 50.34 of 10 CFR, paragraph (a)(3)(i) requires that a preliminary safety analysis report include: “The principal design criteria for the facility.” The principal design criteria for a facility establish the engineering design criteria that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. Once the principal design criteria for a facility are established, the remainder of the safety analysis report includes an explanation of how the principal design criteria for a facility are achieved (in addition to how other regulatory requirements are achieved). Section 50.34(a)(3)(ii) of 10 CFR requires the applicant to describe the design bases and the relation of the design bases to the principal design criteria and 10 CFR 50.34(b) requires updating the information to take into account any pertinent information developed since the issuance of the construction permit.

SHINE FSAR section 1.3.3.1, “Principal Design Criteria,” states: “Principal design criteria for the facility are described in Section 3.1.”

SHINE FSAR section 3.1 states:

> Structures, systems, and components (SSCs) present in the SHINE facility are identified in Tables 3.1-1 and 3.1-2, including the applicable FSAR section(s) which describe each SSC and the applicable SHINE design criteria. Design criteria derived from external codes, guides, and standards specific to the design, construction, or inspection of SSCs are included in the applicable FSAR section describing those SSCs. For each SSC, the FSAR section identifies location, function, modes of operation, and type of actuation for specific SSCs, as applicable.

SHINE FSAR section 3.1 also states:

> The SHINE facility uses design criteria to ensure that the SSCs within the facility demonstrate adequate protection against the hazards present. The design criteria are selected to cover:
>
> - The complete range of [IF] and [RPF] operating conditions.
> - The response of SSCs to anticipated transients and potential accidents.
> - Design features for safety-related SSCs including redundancy, environmental qualification, and seismic qualification.
> - Inspection, testing, and maintenance of safety-related SSCs.
> - Design features to prevent or mitigate the consequences of fires, explosions, and other manmade or natural conditions.
> - Quality standards.
> - Analyses and design for meteorological, hydrological, and seismic effects.
> - The bases for technical specifications necessary to ensure the availability and operability of required SSCs.
>
> The SHINE design criteria are described in Table 3.1-3.

The facility, as a whole, should meet the principal design criteria of the facility, and individual SSCs only support the facility’s ability to achieve the principal design criteria of the facility. This section of the SER documents the NRC staff’s review and evaluation of the TRPS design to perform its safety functions based on the appropriate design criteria to satisfy the 10 CFR 50.34(b) requirements. The staff’s evaluation of the design of the TRPS is based on acceptance criteria in section 7.4 of NUREG-1537, Part 2, including acceptance criteria from the guidance and industry standards referenced by NUREG-1537.

7.4.4.2.1 SHINE Facility Design Criteria

Generally, the SHINE Design Criteria are applicable to more than one system, and the determination of whether the SHINE facility as a whole meets the SHINE Design Criteria consists of two parts: (1) whether each individual system meets the applicable parts of the

SHINE Design Criteria and (2) whether the individual systems together ensure that the facility as a whole meets the SHINE Design Criteria.

SHINE FSAR table 3.1-1 and section 7.4.2.1 provide that SHINE Design Criteria 13 through 19, 38, and 39 apply to the TRPS. Each of these SHINE Design Criteria are addressed in separate subsections below that include an evaluation of the TRPS against each of the applicable SHINE Design Criteria to the extent that the TRPS supports the ability of the overall facility to demonstrate adequate protection against the hazards present.

SHINE FSAR table 3.1-1, Note 2, states that the SHINE Design Criteria 1-8 from FSAR table 3.1-3 are not specifically listed even though they are generally applicable to most SSCs. SHINE FSAR section 7.4.2.1, states, in part:

> The generally-applicable SHINE facility design criteria 1 through 6 apply to the TRPS. The TRPS is designed, fabricated, and erected to quality standards commensurate to the safety functions to be performed; will perform these safety functions during external events; will perform these safety functions within the environmental conditions associated with normal operation, maintenance, and testing; does not share components between irradiation units; and is able to be manually initiated from the facility control room. These elements of the TRPS design contribute to satisfying SHINE facility design criteria 1 through 6.

Quality Standards and Records

NUREG-1537, Part 1, section 7.2.1, states, in part:

> All systems and components of the I&C systems should be designed, constructed, and tested to quality standards commensurate with the safety importance of the functions to be performed. Where generally recognized codes and standards are used, they should be named and evaluated for applicability, adequacy, and sufficiency. They should be supplemented or modified as needed in keeping with the safety importance of the function to be performed. Evaluations and modifications of the standards should be described in the [FSAR].

Consistent with this guidance, the SHINE FSAR includes SHINE Design Criterion 1, which is as follows, and states that it is applicable to the TRPS.

> Criterion 1 – Quality standards and records
>
> Safety-related structures, systems, and components (SSCs) are designed, fabricated, erected, and tested to quality standards commensurate with the safety functions to be performed. Where generally recognized codes and standards are used, they are identified and evaluated to determine their applicability, adequacy, and sufficiency and are supplemented or modified as necessary to ensure a quality product in keeping with the required safety function.
>
> A quality assurance program is established and implemented in order to provide adequate assurance that these SSCs satisfactorily perform their safety functions.

Appropriate records of the design, fabrication, erection and testing of safety-related SSCs are maintained by or under the control of SHINE throughout the life of the facility.

SHINE FSAR section 7.4.2.2.2 states, in part:

The developmental process for creating the safety-related TRPS has been delegated to SHINE's safety-related control system vendor (Subsection 7.4.5.3.1), including any modifications to the system logic after initial development (Subsection 7.4.5.4). SHINE is responsible for providing oversight of the vendor, verifying deliverables are developed in accordance with approved quality and procurement documents, and maintaining the vendor as an approved supplier on the SHINE approved supplier list (Subsection 7.4.5.4.1).

The adequacy of the SHINE quality assurance program is reviewed and found acceptable by the NRC staff in chapter 12, "Conduct of Operations," of this SER. Inspections of records of the TRPS will evaluate whether this program was adequately applied to the fabrication, erection, and testing of the TRPS equipment.

Natural Phenomena Hazards

NUREG-1537, Part 1, section 7.2.1, states, in part:

Systems and components (including I&C systems) determined by the analyses in the [FSAR] to be important to the safe operation … should be able to withstand the effects of natural phenomena without loss of capability to perform their safety function ….

Consistent with this guidance, the SHINE FSAR includes SHINE Design Criterion 2, which is as follows, and states that it is applicable to the TRPS.

Criterion 2 – Natural phenomena hazards

The facility structure supports and protects safety-related SSCs and is designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches as necessary to prevent the loss of capability of safety-related SSCs to perform their safety functions.

Safety-related SSCs are designed to withstand the effects of earthquakes without loss of capability to perform their safety functions.

The evaluation of the TRPS against the effects of some natural phenomena is documented in section 7.4.4.3.6, "Seismic, Tornado, Flood," of this SER, below. SHINE FSAR section 8a2.1.4, "Grounding and Lightning Protections," addresses protections from lighting. Additionally, SHINE FSAR section 7.4.2.1.4, "Protection System Independence," and section 7.4.2.2.11, "Equipment Qualification," address protection from earthquakes, tornados, lightning, and floods. Chapter 3 of this SER evaluates the effects of natural phenomena. Based on the above, the NRC staff finds that the safety-related TRPS meets SHINE Design Criterion 2.

Fire Protection

NUREG-1537, Part 1, section 7.2.1, states, in part:

> I&C systems and components determined in the [FSAR] analyses to be important to the safe operation … should be designed, located, and protected so that the effects of fires or explosions would not prevent them from performing their safety functions.

Consistent with this guidance, the SHINE FSAR includes SHINE Design Criterion 3, which is as follows, and states that it is applicable to the TRPS.

> Criterion 3 – Fire protection
>
> Safety-related SSCs are designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.
>
> Noncombustible and heat resistant materials are used wherever practical throughout the facility, particularly in locations such as confinement boundaries and the control room.
>
> Fire detection and suppression systems of appropriate capacity and capability are provided and designed to minimize the adverse effects of fires on safety-related SSCs. Firefighting systems are designed to ensure that their rupture or inadvertent operation does not significantly impair the safety capability of these SSCs.

The evaluation of the TRPS against this criterion is based on the information provided in SHINE FSAR section 7.4.3.9, "Fire Protection." Additional information can be found in SHINE FSAR section 9a2.3, "Fire Protections Systems and Programs."

SHINE FSAR section 7.4.3.9 describes that the TRPS design uses physical separation to minimize the effects from fire and that equipment for different divisions is located in separate fire areas when practical. Some exceptions include components for all three divisions located in the facility control room, in an individual IU or in TOGS cells, and in other locations where end devices are installed.

The NRC staff examined these descriptions and finds that the combination of physical separation and the fire protection program provides reasonable assurance that this design criteria is met for the TRPS.

Environmental and Dynamic Effects

NUREG-1537, Part 1, section 7.2.1, states, in part:

> I&C systems and components determined in the [FSAR] to be important to the safe operation … should be designed to function reliably under anticipated environmental conditions (e.g., temperature, pressure, humidity, and corrosive atmospheres) for the full range of reactor operation, during maintenance, while testing, and under postulated accident conditions, if the systems and components are assumed to function in the accident analysis.

Consistent with this guidance, the SHINE FSAR includes SHINE Design Criterion 4, which is as follows, and states that it is applicable to the TRPS.

> <u>Criterion 4 – Environmental and dynamic effects</u>
>
> Safety-related SSCs are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility.

SHINE FSAR sections 7.4.2.1.4 and 7.4.2.2.11, "Equipment Qualification," are further evaluated in section 7.4.4.2.1, "SHINE Facility Design Criteria," Protection System Independence of this SER. Therefore, the NRC staff finds that the TRPS design meets SHINE Design Criterion 4.

<u>Sharing of Structures, Systems, and Components</u>

The SHINE FSAR states that SHINE Design Criterion 5, which is as follows, is applicable to the TRPS.

> <u>Criterion 5 – Sharing of structures, systems, and components</u>
>
> Safety-related SSCs are not shared between irradiation units unless it can be shown that such sharing will not significantly impair their ability to perform their safety functions.

Each IU contains an independent TRPS that is not shared. All IUs share the ESFAS for mitigation of potential accident consequences and have a common control room. There are three separate TPS trains that are shared with certain sets of irradiation units. The SHINE FSAR does not provide a specific evaluation that sharing does not significantly impair the ability of the TPS to perform its safety functions; however, the NRC staff used engineering judgment and finds that the sharing of I&C-related systems would not significantly impair their ability to perform the associated safety functions.

<u>Control Room</u>

The SHINE FSAR states that SHINE Design Criterion 6, which is as follows, is applicable to the TRPS.

> <u>Criterion 6 - Control room</u>
>
> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

SHINE FSAR section 7.6, "Control Console and Display instruments," describes the SHINE facility control room. HIPS equipment of the TRPS is in the control room. The adequacy of specific controls and displays is evaluated in section 7.4.6 of this SER. The adequacy of the control room is evaluated in chapter 13 of this SER.

Instrumentation and Controls

NUREG-1537, Part 1, section 7.2.2, "Design-Basis Requirements," states, in part:

> Design bases for the I&C system, subsystems, and components should include …. The range of values that monitored variables may exhibit for normal operation, shutdown conditions, and for postulated accidents.

NUREG-1537, Part 2, section 7.4 states, "[t]he range of operation of sensor (detector) channels should be sufficient to cover the expected range of variation of the monitored variable during normal and transient … operation."

SHINE FSAR section 7.4.2.1.1, "Instrumentation and Controls," states, in part:

> SHINE Design Criterion 13 – Instrumentation is provided to monitor variables and systems over their anticipated ranges for normal operation, for anticipated transients, and for postulated accidents as appropriate to ensure adequate safety, including those variables and systems that can affect the fission process, the integrity of the primary system boundary, the primary confinement and its associated systems, and the process confinement boundary and its associated systems. Appropriate controls are provided to maintain these variables and systems within prescribed operating range.

SHINE Design Criterion 13 is applicable to operator displays and controls including the PICS, as the first means of defense in maintaining process variables and systems within prescribed operating ranges. The second barrier against postulated accidents is the automatic protective systems that actuate controls during an accident condition or inadvertent operation. SHINE Design Criterion 14 also provides additional design criteria for protective functions. Finally, as part of post-protective-action accident-mitigation, the operator must be able to determine facility and process parameter states or statuses (e.g., post-accident monitoring). In addition, some of the indications (of facility parameter values) to the operator are based solely on TRPS related monitored variables. Therefore, SHINE Design Criterion 13 applies to the TRPS monitored variable sensor ranges.

SHINE FSAR section 7.4.2.1.1 also states, in part:

> The TRPS monitored variables for performance of design basis functions are presented in Table 7.4-1 and include the instrument range for covering normal and accident conditions ….

SHINE FSAR table 7.4-1, "TRPS Monitored Variables," identifies the instrument range for each monitored variable; SHINE FSAR section 7.4.4.1, "Monitored Variables and Response," states, in part:

> Table 7.4-1 identifies specific variables that provide input into the TRPS and includes the instrument range for covering normal and accident conditions ….

In its response to NRC staff RAI 7-13 (ML21239A049), the applicant stated that each division of the TRPS transmits monitoring and indication information to the PICS. The following information from the TRPS is displayed in the FCR:

- Mode and Fault status for each HIPS module
- Status and value of the monitored variables identified in SHINE FSAR table 7.4-1
- Trip/Bypass switch status
- Divisional partial trip determination status
- Divisional full trip determination status
- TRPS IU cell operational mode status
- Actuation output and fault status
- Actuated component position feedback status

The TRPS monitoring and indication information is available to the operators in the FCR at the PICS operator workstations. A subset of the TRPS monitoring and indication information is displayed at the main control board in the FCR near the manual control switches for actuating TRPS safety functions. The TRPS provides redundant outputs to the PICS. The PICS receives the outputs from the TRPS onto a fault-tolerant server comprised of internal redundant physical servers. The use of redundant outputs from the TRPS to redundant internal physical servers on the PICS ensures that a failure would not prevent the operator from obtaining or resolving conflicting information. By displaying the TRPS monitoring and indication information at multiple locations in the FCR, including near manual controls for actuating TRPS equipment, the design ensures that the operator has sufficient information to operate the facility and take manual operator action, as necessary. SHINE FSAR section 7.4.5.2.4 provides a description of the information available to the operators in the FCR. SHINE FSAR section 7.4.4.1 provides a discussion of the TRPS response to each monitored variable (signal input) and SHINE FSAR table 7.4-1 provides the instrument range, accuracy, response time, and a specified analytical limit. The NRC staff did not review specific design information or performance data for the sensors/instruments listed in table 7.4-1 and, therefore, did not specifically confirm the validity of performance parameters assigned to each instrument. SHINE will test and qualify the instrumentation in accordance with TSs and SHINE FSAR section 12.11.2.

Based on the above, the NRC staff has reasonable assurance that the variables listed in the SHINE FSAR are used to measure, display, and initiate defined protective actuations of the applicable TRPS functions. The adequacy of the PICS, consoles, and displays in meeting SHINE Design Criterion 13 are addressed in section 7.4.3 and 7.4.6 of this SER.

<u>Protection System Functions</u>

The design bases (defined in 10 CFR 50.2) predominately include the specific functions to be performed (by SSCs) and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. Section 50.34(a)(3)(ii) of 10 CFR requires the applicant to describe the design bases and the relation of the design bases to the principal design criteria and 10 CFR 50.34(b) requires updating the information to take into account any pertinent information developed since the issuance of the construction permit.

NUREG-1537, Part 1, section 3.1, states, in part: "general design criteria should include … Design to cope with anticipated transients and potential accidents, including those discussed in Chapter 13, 'Accident Analyses,' of the [FSAR]."

NUREG-1537, Part 1, section 7.2.1, states, in part:

> The [protection system] should be designed to automatically initiate the operation of systems or give clear warning to the operator to ensure that specified reactor design limits are not exceeded as a result of measured parameters indicating the onset of potential abnormal conditions.

NUREG-1537, Part 2, section 7.4 states, in part, that the applicant should "list[] the protective functions performed by the [protection system], and the parameters monitored to detect the need for protective action."

SHINE FSAR section 7.4.2.1.2, "Protection System Functions," describes how the TRPS meets SHINE Design Criteria 14, which is as follows:

> SHINE Design Criterion 14 – The protection systems are designed to: (1) initiate, automatically, the operation of appropriate systems to ensure that specified acceptable target solution design limits are not exceeded as a result of anticipated transients; and (2) sense accident conditions and to initiate the operation of safety-related systems and components.

SHINE FSAR section 7.4.2.1.2 contains the criteria for the protection system functions to address two types of events: (1) anticipated transients and (2) accidents. SHINE FSAR section 7.4.2.1.2 further states, in part, that "There are no anticipated transients that would result in target solution design limits being exceeded."

SHINE applies a tailored, risk-based methodology similar to the guidance described in NUREG-1520, Revision 2, in the development of the detailed accident analysis. Design basis accidents (DBAs) were identified as credible accident scenarios that range from anticipated events, such as a loss of electrical power, to events that are still credible, but considered unlikely to occur during the lifetime of the plant. The maximum hypothetical accident is defined as a fission product-based release that bounds the radiological consequences for all credible fission product-based accident scenarios at the SHINE facility. Section 7.4.4.1 of the SHINE FSAR describes the TRPS monitored variables and protective actions against events and references the protective actions to specific scenarios in SHINE FSAR chapter 13. For selected scenarios, SHINE FSAR chapter 13 further provides references to SHINE FSAR chapter 4 power and pressure "transient" analyses that support the accident scenarios. Portions of the SHINE FSAR do not always clearly distinguish between design basis accidents and anticipated transients. For example, SHINE FSAR section 1.2.4, "Potential Accidents at the Facility," states, in part:

> Potential design basis accidents (DBAs) at the SHINE facility were identified by the application of hazard analysis methodologies to evaluate the design of the facility and processes for potential hazards, initiating events (IEs), scenarios, and associated controls. As described in [FSAR] Chapter 13, these methodologies were

applied to both the IF and the RPF. The list of accident categories and IEs that were the basis for the identification of potential DBAs are described in Chapter 13.

Given the approach taken in the SHINE FSAR, the NRC staff could not independently identify and distinguish a set of "anticipated transients" apart from "design basis accidents" as described in SHINE FSAR section 7.4.2.1.2 with respect to the specific accident-initiating events and scenarios described in SHINE FSAR chapter 13. However, the SHINE FSAR explicitly identifies the safety functions of the TRPS (see section 7.4.1, above) and the safety analyses credit these functions in demonstrating reasonable assurance of adequate safety for normal operations and accident-initiating events. The adequacy of the safety analyses is addressed in chapters 5, 6, and 13 of this SER. The staff therefore reviewed SHINE FSAR chapters 4, 5, and 13 to identify the TRPS functions credited by these chapters regardless of its treatment as either a potential transient or accident in the context of SHINE Design Criterion 14. The staff concluded that SHINE FSAR section 7.4.3.1, "Safety Functions," includes the TRPS functions credited in these SHINE FSAR chapters, and that SHINE FSAR section 7.4 references the SHINE FSAR chapter 13 analyses where these functions are credited. Based on this evaluation the staff concludes that SHINE FSAR section 7.4 describes the TRPS safety functions explicitly credited in SHINE FSAR chapters 4, 5, and 13; therefore, the staff finds that SHINE FSAR section 7.4 includes the appropriate safety functions to meet the applicable principal design criteria of the facility to cope with the scenarios and pressure and power transients described in SHINE FSAR chapter 13.

SHINE FSAR section 7.4.2.1.2 identifies the target solution design limits as being in SHINE FSAR table 4a2.2-2, "Target Solution Operating Limits." Furthermore, this SHINE FSAR section references SHINE FSAR section 7.4.4.1, which has a subsection for each monitored variable and each of these subsections identifies the specific SHINE FSAR chapter 13 scenarios addressed by each monitored variable. SHINE FSAR chapter 4 also describes the analysis of events for which the TRPS initiates protective actions, but only SHINE FSAR chapter 13 events/scenarios are identified in SHINE FSAR section 7.4.4.1. The NRC staff traced the references in SHINE FSAR chapter 7 to chapter 13 scenarios, and subsequently to chapter 4 to the extent practical for selected events.

SHINE FSAR chapter 4, table 4a2.2-2 identifies certain acceptable target solution design limits, and includes temperature and power density, which can be protected by the TRPS. In addition, the proposed TSs contain LCOs for certain acceptable target solution design limits, as follows:

- LCO 3.1.3 Limits the minimum volume in the TSV (relates to power density)
- LCO 3.1.4 Limits the maximum temperature in the TSV
- LCO 3.1.6 Limits the average power density in the TSV
- LCO 3.1.7 Limits the transient average power density in the TSV
- LCO 3.8.3 Limits the [[PROP/ECI]] and pH of the target solution
- LCO 3.8.4 Limits the concentration of uranium present in the second uranium liquid waste tank and the liquid waste blending tank

SHINE LCO 3.1.6 establishes the power density limit of the irradiated target solution, which is effectively achieved by controlling power (i.e., controlling tritium). SHINE FSAR section 13a2.1.2.2, Scenario 4, “High Power Due to High Neutron Production and High Reactivity at Cold Conditions,” states that a high reactivity and power event can occur due to excess tritium injection into the NDAS during cold conditions and that this can occur as a result of a TPS control system or component failure during startup that injects excess tritium before the TSV is at operating temperature, and that the TRPS initiates an IU shutdown on high wide range neutron flux. The IU Cell Safety Actuation initiated by the High Wide Range Neutron Flux described in SHINE FSAR section 7.4.4.1.4, “High Wide Range Neutron Flux,” is well below the transient average power density described in LCO 3.1.7 but is above the average power density limit of LCO 3.1.6 for much of the operating range.

The maximum temperature limit is protected, in part, by actuations initiated by High Time-Averaged Neutron Flux, High PCLS Temperature, and Low PCLS Flow.

NUREG-1537, Part 1, section 7.2.2 states, in part:

> Design bases for the I&C system, subsystems, and components should include … The function or purpose of systems or instruments considering which … parameters are monitored or controlled.

SHINE FSAR section 7.4.3.1 describes the TRPS safety functions relied upon for specific accident scenarios. The NRC staff confirmed that credited protection system functions in chapters 4 and 13 were described in chapter 7. The adequacy of these safety functions in mitigating or preventing the accident-initiating events and scenarios are evaluated in chapters 4 and 13 of this SER (e.g., component actuations for confinement and criticality safety and physical effects). Based on its review of these SHINE FSAR chapters and the TRPS logic diagrams depicted in SHINE FSAR figure 7.4-1, the staff finds that the TRPS is reasonably designed to perform the safety functions credited by the SHINE safety analyses in chapter 13. Therefore, the staff finds that the TRPS design satisfies SHINE Design Criterion 14 for anticipated transients and accident conditions.

Protection System Reliability and Testability

NUREG-1537, Part 2, section 7.4, states, in part, that the protection system should be “designed to perform its safety function after a single failure and to meet requirements for … redundancy … and independence.”

SHINE FSAR section 7.4.2.1.3, “Protection System Reliability and Testability,” states that the TRPS meets SHINE Design Criterion 15, which is as follows:

> SHINE Design Criterion 15 – The protection systems are designed for high functional reliability and inservice testability commensurate with the safety functions to be performed. Redundancy and independence designed into the protection systems are sufficient to ensure that: (1) no single failure results in loss of the protection function, and (2) removal from service of any component or channel does not result in loss of the required minimum redundancy unless the acceptable reliability of operation of the protection system can be otherwise demonstrated. The protection systems are designed to permit periodic testing, including a capability to test channels independently to determine failures and losses of redundancy that may have occurred.

The inputs to the TRPS listed in SHINE FSAR table 7.4-1, “TRPS Monitored Variables,” have associated actuation logic of 2-out-of-3, 1-out-of-2, and 1-out-of-1. The HIPS equipment provides two modes in which an instrument channel can be removed from service: (1) it can be placed in trip or (2) it can be placed in bypass (i.e., not tripped). If 2-out-of-3 logic is placed in trip, then it becomes 1-out-of-2 logic and does not result in a loss of the required minimum redundancy; however, it if is placed in bypass it does result in a loss of the required minimum redundancy.

SHINE FSAR section 7.4.2.1.3, “Protection System Reliability and Testability,” states that the maintenance bypass function allows an individual safety function module to be removed from service for required testing without a loss of redundancy and references SHINE FSAR section 7.4.4.3 which states only that the redundant channels are not affected. Effectively, SHINE FSAR section 7.4.4.3 states that the independence aspect of SHINE Design Criterion 15 is satisfied. The NRC staff finds that with one channel in maintenance bypass, the TRPS cannot continue to perform its safety functions in the presence of certain single failures in the remaining two channels for certain events. SHINE Design Criterion 15 states that the loss of the required minimum redundancy is not acceptable unless the acceptable reliability of operation of the protection system can be otherwise demonstrated. The staff has reasonable assurance that the reliability of the HIPS equipment is acceptable, as described in SHINE FSAR section 7.2, with respect to protecting against a temporary (the two hours allowed by TS) reduction of minimum redundancy and given the low likelihood of a single failure of a channel concurrent with an accident event and another channel in bypass and the large safety margins described in chapter 13 of this SER.

<u>Protection System Independence</u>

NUREG-1537, Part 1, section 7.2.1, states, in part: “I&C systems should be designed so that a single failure will not prevent the safe shutdown of the reactor.”

Generally, this single failure criterion is met by having redundant and independent equipment. SHINE Design Criteria 16 addresses the independence of the redundant portion of the TRPS.

> <u>Criterion 16 – Protection system independence</u>
>
> The protection systems are designed to ensure that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions on redundant channels, do not result in loss of the protection function or are demonstrated to be acceptable on some other defined basis. Design techniques, such as functional diversity or diversity in component design and principles of operation, are used to the extent practical to prevent loss of the protection function.

SHINE Design Criterion 16 address two different aspect of “protections system independence” (i.e., effects and diversity – see associated subsections below). The criterion is meant to address a particular source of CCF. SHINE FSAR section 7.4.2.1.4, “Protection System Independence,” provides information related to this criterion. Section 7.2.1.4, “Equipment Qualification,” of this SER includes additional evaluation applicable to this criterion.

The evaluation of the TRPS against the effects of natural phenomena is documented in section 7.4.4.3.6 of this SER. The TRPS equipment is located in the control room which is a mild environment (i.e., not subject to extreme conditions due to accident conditions). SHINE FSAR section 8a2.1.4, “Grounding and Lightning Protections,” addresses protections from lighting.

SHINE FSAR sections 7.4.2.1.5, “Protection System Failure Modes,” and 7.4.3.5, “Operating Conditions,” state that the TRPS equipment is qualified in the environments in which it is required to operate.

SHINE FSAR section 7.4.2.2.11, “Equipment Qualification,” addresses the effects of EMI/RFI and power surges, which is evaluated in section 7.4.2.1.3, “Equipment Qualification,” of this SER.

SHINE FSAR section 7.4.2.1.4, states, in part:

> The TRPS control and logic functions operate inside of the facility control room, where the environment is mild, not exposed to the irradiation process, and is protected from earthquakes, tornadoes, and floods (Subsections 7.4.3.5 and 7.4.3.6). The TRPS structures, systems, and components that comprise a division are physically separated to retain the capability of performing the required safety functions during a design basis accident. This division independence is maintained throughout the design, extending from the sensor to the devices actuating the protective function (Subsection 7.4.5.2.1).

Based on its review of the SHINE FSAR chapters described above, the NRC staff concludes that the TRPS design meets the first design attribute of SHINE Design Criterion 16 that protection systems are designed to ensure that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions on redundant channels, do not result in loss of the protection function or are demonstrated to be acceptable on some other defined basis.

SHINE FSAR section 7.4.2.1.4 also states, in part:

> Functional diversity and diversity in component design are used to prevent loss of the protection function. Functional diversity is discussed in Subsection 7.4.5.2.5. Field programmable gate arrays (FPGAs) in each division are of a different physical architecture to prevent common cause failure (CCF) (Subsection 7.4.5.2.4).

SHINE FSAR section 7.4.5.2.5 further describes that the functional allocation of different process parameters on different SFMs and the diversity in component design are used to prevent a loss of the protection function. The NRC staff notes that “functional diversity” is commonly defined as the ability to protect against the same event by monitoring two different parameters to initiate protective actions. This is different than the allocation of functions to different SFMs. While some TRPS-monitored variables can protect against the same event or scenario, the SHINE FSAR and associated RAI responses did not credit or evaluate how this type of functional diversity is achieved in the SHINE design. Therefore, the staff determined that the SHINE FSAR does not demonstrate the existence of functional diversity for all events.

SHINE FSAR section 7.4.5.2.1, “Independence,” states that the HIPS design incorporates the independence principles outlined in section 4.0 of the HIPS TR. Section 4.2, “Safety Function Module,” of the HIPS TR states that each SFM, which is a TRPS channel, is dedicated to implementing a safety function or function group which results in the gate level implementation of each safety function being different than the other safety functions. However, the implementation of the TRPS with HIPS deviates from the HIPS TR because there are many functions on each SFM. Therefore, while the allocation provides some diversity, it does not provide complete functional diversity as previously credited in the HIPS TR.

SHINE FSAR sections 7.4.2.1.4 and 7.4.5.2.4 state that FPGAs in each division are of a different FPGA architecture (static random access memory, flash, or one-time programmable), which is consistent with diversity in component design and the principles of operation of SHINE Design Criterion 16. The only difference in component design identified is the use of different FPGAs, and possibly different tools associated with each FPGA; therefore, this design protects against CCFs that are a result of systematic errors in a particular FPGA type (or tool, if different tools are used).

The NRC staff audited the D3 assessment in TECRPT-2019-0041 of the TRPS and ESFAS that systematically identifies potential vulnerabilities to digital-based CCFs and concludes that:

(1) Potential digital-based CCFs in TRPS or ESFAS may lead to spurious initiation of protective actions without adverse impacts to safety. Diverse PICS will continue to monitor, alarm, and attempt to automatically correct parameter deviations, and the operator always retains the capability to manually initiate any one or all protective actions.

(2) A digital-based CCF of any radiation detector set may lead to spurious actuations with production impacts but no adverse safety impacts.

(3) A digital-based CCF of any radiation detector set may cause failure to initiate protective actions; however, for each set, there exists alternate means for either the operator to identify, initiate, and assess protective actions, or alternate automatic means of mitigating events.

(4) A digital-based CCF of any oxygen gas analyzer sets may lead to spurious actuations with production impacts but no adverse safety impacts.

(5) A digital-based CCF of any oxygen gas analyzer may cause failure to initiate protective actions; however, for each set, there exists alternate means for either the operator to identify, initiate, and assess protective actions, or alternate automatic means of mitigating events.

The NRC staff confirmed that the D3 assessment supports the description in SHINE FSAR section 7.4.5.2.4. The staff concludes that there is reasonable assurance that the TRPS and ESFAS designs have adequate diversity features that are commensurate with the safety significance of the systems. See section 7.4.2.2.4 of this SER.

The NRC staff evaluated the overall diversity strategy and audited the supporting assessment and finds that the TRPS contains sufficient attributes that are commensurate with the low likelihood of potential CCFs of safety functions concurrent with the design basis scenarios and events in SHINE FSAR chapters 4 and 13, and the potential consequences and large safety margins described in chapter 13 of this SER.

<u>Protection System Failure Modes</u>

NUREG-1537, Part 1, section 7.2.1, states, in part, that “I&C systems should be designed to fail into a safe state on loss of electrical power or exposure to extreme adverse environments.”

Consistent with this guidance, the SHINE FSAR includes SHINE Design Criterion 17, which is as follows, and states that it is applicable to the TRPS.

> SHINE Design Criterion 17 – The protection systems are designed to fail into a safe state if conditions such as disconnection of the system, loss of energy (e.g., electric power, instrument air), or postulated adverse environments are experienced.

TS LCO 3.2.1 states that each division of the TRPS has two 5V power supplies. TS Bases for LCO 3.6.1 states that the 24V power supplies for the TRPS and ESFAS cabinets are also within the scope of LCO 3.6.1 for the UPSS distribution system. The power for the actuated components originates from other sources, but can be controlled (i.e., removed) by the TRPS.

SHINE FSAR section 7.4.3.8, "Loss of External Power," states that on a loss of power to the TRPS, the TRPS deenergizes actuation components and that controlled components associated with safety actuations are designed to go to their safe states when deenergized.

SHINE FSAR sections 7.4.2.1.5 and 7.4.3.5 state that the TRPS equipment is qualified for the environments in which it is required to operate.

Based on this information provided in these SHINE FSAR sections, the NRC staff concludes that the TRPS meets SHINE Design Criterion 17.

Separation of Protection and Control Systems

SHINE Design Criteria 18 addresses the separation of protection and control systems for the TRPS.

> Criterion 18 – Separation of protection and control systems
>
> The protection system is separated from control systems to the extent that failure of any single control system component or channel, or failure or removal from service of any single protection system component or channel that is common to the control and protection systems leaves intact a system satisfying all reliability, redundancy, and independence requirements of the protection system. Interconnection of the protection and control systems is limited to assure that safety is not significantly impaired.

Generally, facilities that are designed to meet the single failure criterion (as the SHINE Design Criteria require) are required to protect against certain initiating events concurrent with a single failure (and all associated cascading failures) in the protection system. When the design of the facility has a control system and a separate and independent protection systems that meets the single failure criterion, then the facility can withstand a failure of the control system that causes an initiating event that is assumed as a design basis accident, and then subsequent failure of the protection system.

When the control system and the protection system share components in a 2-out-of-3 trip system, then measures are appropriate to provide separation of protection and control as provided in SHINE Design Criterion 18. The redundancy and independence requirements stated in SHINE Design Criterion 15 and referred to in SHINE Design Criterion 18 are equivalent to requiring that a system must meet the single failure criterion. In a 2-out-of-3 system, a failure of a shared component would result in a 2-out-of-2 system, which can protect against the event (i.e., the failure that has occurred), but not in the presence of a single failure in the protection system.

A facility that has three sensors that are shared between protection and control systems and where the protection system uses 2-out-of-3 logic cannot meet the criteria as stated in SHINE Design Criterion 18, but it can be safe by protecting against the two failures of concern by using other means besides redundancy. In its response to NRC staff RAI 7-9(c) (ML22318A178), the applicant stated that SHINE FSAR section 7.4.2.1.6 was revised to enhance the description of how TRPS meets this criterion. The revised section states that there is no shared equipment. Since there is no shared equipment or sensors among the protection and control systems, the staff concludes that the SHINE facility meets SHINE Design Criterion 18.

Protection Against Anticipated Transients

SHINE Design Criteria 19 addresses protection against anticipated transients and is as follows:

> Criterion 19 – Protection against anticipated transients
>
> The protection systems are designed to ensure an extremely high probability of accomplishing their safety functions in the event of anticipated transients.

The safety functions of the TRPS are evaluated in section 7.4.4.2.1, "Protection System Functions," of this SER. The arrangement of HIPS modules in the TRPS is the same for each safety function; therefore, the evaluation in this section addresses the "extremely high probability" aspect of this criterion.

SHINE FSAR section 7.4.2.1.7, "Protection Against Anticipated Transients," states that the TRPS is extremely reliable because of its: independence, redundancy, and diversity. The NRC staff considered the reliability of the HIPS equipment of the TRPS as evaluated in section 7.4.2 of this SER.

As noted above, power and pressure transients are analyzed in SHINE FSAR chapters 4, 5, and 13, but the NRC staff could not independently identify and distinguish a set of "anticipated transients" apart from "design basis accidents" with respect to the specific accident-initiating events and scenarios described in SHINE FSAR chapter 13. Therefore, the staff reviewed SHINE FSAR chapters 4, 5, and 13 to identify the TRPS functions credited by these chapters regardless of its treatment as either a potential transient or a potential accident. Section 7.4.2.2 and 7.4.2.3 of this SER describes the HIPS design attributes and design process that provide reasonable assurance of TRPS reliability; and chapter 13 of this SER further describes the TRPS protection functions that are credited for transients. Based on the TRPS having adequate reliability for protecting against upset conditions in the subcritical aqueous solution environment of the TSV and the significant safety margins described in chapter 13 of this SER, the staff has reasonable assurance that the TRPS meets SHINE Design Criterion 19.

Monitoring Radioactivity Releases

SHINE Design Criteria 38 addresses monitoring radioactivity releases and is as follows:

> Criterion 38 – Monitoring radioactivity releases
>
> Means are provided for monitoring the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material. Potential effluent discharge paths and the plant environs are monitored for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents.

SHINE FSAR section 7.7, "Radiation Monitoring Systems," describes the SHINE facility radiation monitoring systems. SHINE FSAR table 7.4-1, "TRPS Monitored Variables," identifies only one radiation monitoring sensor (i.e., radiological ventilation zone 1 exhaust (RVZ1e) IU cell radiation) as initiating a TRPS safety function. Therefore, the NRC staff concludes that the TRPS supports the SHINE facility meeting SHINE Design Criterion 38. The radiation monitoring system is further evaluated in section 7.4.6 of this SER.

Hydrogen Mitigation

SHINE Design Criteria 39 addresses hydrogen mitigation and is as follows:

> Criterion 39 – Hydrogen mitigation
>
> Systems to control the buildup of hydrogen that is released into the primary system boundary and tanks or other volumes that contain fission products and produce significant quantities of hydrogen are provided to ensure that the integrity of the system and confinement boundaries is maintained.

SHINE FSAR section 4a2.8, "Gas Management System," describes how the TOGS, the vacuum transfer system (VTS), the process vessel vent system (PVVS), the PICS, and the operator work together to control the buildup of hydrogen.

The NRC staff did not evaluate the adequacy of the PICS and operators to control the build-up of hydrogen. The TRPS monitors key parameters of the TOGS system to ensure that it is working properly (e.g., per SHINE FSAR section 4a2.8.6: minimum TOGS mainstream flow, minimum TOGS dump tank flow, and minimum oxygen concentration). The TRPS initiates the protective functions evaluated in SHINE FSAR section 7.4.2.1.2 for IU Cell Nitrogen Purge when setpoints are exceeded for these parameters. Therefore, the staff concludes that the TRPS supports the SHINE facility meeting SHINE Design Criterion 39.

7.4.4.2.2 TRPS System Design Criteria

SHINE FSAR section 7.4.2.2 outlines several TRPS system-specific design criteria for protective actions, single failure, independence, communication, prioritization, setpoints, bypass and permissives, equipment qualification, surveillance, human factors, access control, software requirements development, and quality. The NRC staff's evaluation of the safety-significant TRPS system-specific design criteria is documented in section 7.4.4.2.1 of this SER as a part of the SHINE facility design criteria evaluation and in section 7.4.2 of this SER as a part of the HIPS design evaluation. While the staff evaluated the analysis of selected equipment design criteria as subsidiary elements of the broader SHINE Design Criteria, the staff did not independently confirm each TRPS system design criterion and is not specifically making a finding for the TRPS system design criteria.

7.4.3.3 Design Basis

The design bases (defined in 10 CFR 50.2) include the specific functions to be performed by SSCs and the specific values or ranges of values chosen for controlling parameters as reference bounds for the design.

Other SHINE FSAR chapters demonstrate that the design of the SHINE facility provides reasonable assurance of safety. SHINE FSAR chapter 3 provides the design criteria for the facility, SHINE FSAR chapter 4 discusses the intended operations of the facility including I&C, and SHINE FSAR chapter 13 describes accident and transient scenarios that assume the protective functions of the TRPS within specified analytical limits. The SHINE FSAR chapter 13 accident analyses and transient scenarios are based on certain required behavior of the TRPS, as described in SHINE FSAR chapter 7.4. Therefore, this NRC staff evaluation determines whether SHINE FSAR section 7.4 describes the features, credited in other SHINE FSAR chapters, needed for the reasonable assurance of public health and safety. This review focused on:

- the safety functions to be performed,
- the prioritization for commands,
- the facility parameter monitored to determine when a safety function is needed,
- the value assumed in the analysis at which the safety function is initiated,
- the time assumed in the analysis to achieve the safety function,
- the conditions under which the I&C equipment described in SHINE FSAR chapter 7 (i.e., the TRPS and NFDS) must be able to operate, and
- whether the TRPS equipment reliably and predictably performs the functions as described in SHINE FSAR chapter 7.

7.4.4.3.1 Safety Functions

Generally, the term safety function is used to refer to those design bases functions performed by the safety systems and credited in the safety analysis.

NUREG-1537, Part 1, section 3.1, states: “general design criteria should include … Design to cope with anticipated transients and potential accidents, including those discussed in chapter 13, “Accident Analyses,” of the [FSAR].”

NUREG-1537, Part 2, section 7.4 states: “the applicant should thoroughly discuss and describe the [protection system], listing the protective functions performed by the [protection system] ….”

SHINE FSAR section 7.4.2.1.2 includes specific acceptance criteria for two types of design basis events: (1) anticipated transients and (2) accidents, and states: “There are no anticipated transients that would result in target solution design limits being exceeded.”

The SHINE FSAR explicitly identifies the safety functions of the TRPS and the safety analyses credits these functions for demonstrating reasonable assurance of protection of public health and safety. The adequacy of the safety analyses is addressed in other chapters of this SER.

The NRC staff reviewed SHINE FSAR chapters 4, 5, and 13 to identify the TRPS functions credited in these chapters, and the staff concluded that SHINE FSAR section 7.4.3.1, “Safety Functions,” includes the TRPS functions credited in these SHINE FSAR chapters, and that SHINE FSAR section 7.4 references the SHINE FSAR chapter 13 analyses where these functions are credited. The staff performed an audit to confirm how specific functions were addressed. Based on this evaluation, the staff has reasonable assurance that SHINE FSAR section 7.4 describes the TRPS safety functions explicitly credited in SHINE FSAR chapters 4, 5, and 13; therefore, the staff finds that SHINE FSAR section 7.4 includes the appropriate safety functions to meet the applicable principal design criteria of the facility to cope with anticipated transients and potential accidents, including those discussed in the accident analyses.

7.4.4.3.2 Prioritization

NUREG-1537, Part 1, section 3.1, states: “general design criteria should include … design to cope with anticipated transients and potential accidents [which] should include malfunction of any control function ….”

The SHINE facility uses the same actuated components for normal operational purposes (e.g., for normal operational control) and for implementing the safety functions of the safety-related systems (e.g., TRPS-initiated safety functions) for some processes. In these instances, the design must ensure that the commands from the safety system (e.g., to implement a safety function) have priority over the commands from the nonsafety operational or control systems. This prioritization is necessary to ensure that the safety systems are designed to address failures in the control systems, as described by the preceding paragraph.

SHINE FSAR section 7.4.2.2.6 contains a design criterion for prioritization and states: “Priority is provided to automatic and manual safety-related actuation signals over nonsafety-related signals as described in Subsection 7.4.3.12.” Based on this description, the NRC staff has reasonable assurance that TRPS actuation commands have priority over control system commands.

7.4.4.3.3 Parameters Monitored

NUREG-1537, Part 1, section 7.1, “Summary Description,” states: “The general description of each category of I&C subsystem should include … the types of parameters monitored, both nuclear and non-nuclear, the number of channels designed to monitor each parameter, the actuating logic that determines the need for actions to change … conditions and that takes these actions ….”

NUREG-1537 Part 2, section 7.4, states: “the applicant should thoroughly discuss and describe the [protection system], listing … the parameters monitored to detect the need for protective action.”

SHINE FSAR section 7.4.4.1 identifies the parameters monitored to determine when to initiate each safety function, and points to the SHINE FSAR chapter 13 analyses where these monitored variables are credited for initiating each safety function. SHINE FSAR table 7.4-1 identifies the number of sensors used to monitor each parameter. SHINE FSAR figure 7.4-1, "TRPS Logic Diagrams," depicts the actuation associated logic. The NRC staff sampled scenarios in SHINE FSAR chapters 4 and 13 to confirm that the TRPS monitored variables include the TRPS facility process parameters credited in SHINE FSAR chapters 4 and 13. Based on this, the staff finds that the SHINE FSAR adequately describes the parameters monitored by the TRPS.

7.4.4.3.4 Values Assumed in the Analysis

Section 50.36(c) of 10 CFR states: "Technical specifications will include items in the following categories: (1) Safety limits, limiting safety system settings … (2) Limiting conditions for operation ...."

NUREG-1537, Part 2, section 7.4, states: "The [FSAR] should contain … Proposed trip setpoints, time delays, accuracy requirements, and actuated equipment response to verify that the [protection system] is consistent with the [FSAR] analyses of safety limits, [LSSS], and [LCOs], and that this information is adequately included in the technical specifications …."

SHINE FSAR chapters 4 and 13 include an analysis of events that is evaluated by the NRC staff to ensure that the analyzed events demonstrate reasonable assurance of public health and safety. Each event that is addressed by a protective action in the safety systems is analyzed assuming that a protective action is initiated at a certain value. The staff considers this value to be the "analytical limit" for purposes of determining the adequacy of I&C systems. The limiting setpoints in the TSs are determined by starting with the analytical limit and accounting for known uncertainties and drift between surveillances.

The safety limits of the SHINE facility are documented in TS 2.1, "Safety Limits." The LSSS are documented in TS 2.2, "Limiting Safety System Settings (LSSS)," and the lowest functional capability or performance levels of equipment are in the TS LCOs. The limiting process parameter value assumed in the analysis, where an automatic protective action is initiated, is generally called the analytic limit (AL). SHINE FSAR chapter 13 analyses provide justification for the adequacy of the AL for protecting the safety limit. SHINE FSAR setpoint chapters describe that the LSSS values in the TS LCOs are chosen to be more conservative than the AL by at least the amount associated with uncertainties in the process measurements. Generally, SHINE FSAR section 7.4.4.1 includes a subsection for each TRPS-variable monitored, and each of these subsections identifies the SHINE FSAR chapter 13 subsection(s) and scenario(s) that credit(s) that particular monitored variable for performing a TRPS safety function. Furthermore, SHINE FSAR table 7.4-1 includes the AL(s) for each variable monitored. Based on this, the NRC staff finds that the SHINE FSAR provides safety ALs for which the TRPS is designed to protect.

7.4.4.3.5 Response Time

Subparagraph 50.34(b)(2) of 10 CFR requires that an FSAR include:

> A description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, with technical justification

> therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

NUREG-1537, Part 2, section 7.4, states, in part: “The [FSAR] should contain … time delays … and actuated equipment response to verify that the [protection system] is consistent with the [FSAR] analyses of safety limits, [LSSS], and [LCOs], and that this information is adequately included in the technical specifications ….”

The implementation of a safety function requires that certain protective actions are achieved within a particular time period. To support this need, certain response times should be included in the SHINE FSAR. SHINE FSAR section 7.4.2.1.1, “Instrumentation and Controls,” states (SHINE FSAR section 7.4.4.1 also has a similar statement.): “The TRPS monitored variables for performance of design basis functions are presented in Table 7.4-1 and include … the response time ….”

Chapter 13 of this SER discusses the determination of overall response time, as appropriate, to ensure that target solution limits are not exceeded as a result of transients and accidents. Therefore, the NRC staff finds that the TRPS design meets SHINE Design Criterion 14.

7.4.4.3.6 Seismic, Tornado, Flood

SHINE FSAR section 7.4.3.6, “Seismic, Tornado, Flood,” states that (1) the TRPS equipment is installed in the seismically qualified portion of the main production facility where it is protected from earthquakes, tornadoes, and floods and (2) the TRPS equipment is Seismic Category I, designed in accordance with section 8 of IEEE Standard 344-2013. The ability of the TRPS to withstand seismic, tornado, and flood conditions is evaluated in section 3.4 of this SER.

7.4.4.4 Technical Specifications

Section 7.4.10.2, “TRPS Technical Specifications,” of this SER provides the NRC staff review of the SHINE TSs related to the TRPS.

7.4.4.5 Conclusion

The NRC staff has reasonable assurance that the SHINE TRPS is designed to (1) mitigate the consequences of design basis events within the main production facility, (2) provide sense, command, and execute functions necessary to maintain the facility confinement strategy, (3) provide process actuation functions required to shut down processes and maintain processes in a safe condition, and (4) provide system status and measured process variable values to the PICS for viewing, recording, and trending. The staff has reasonable assurance that the NFDS is adequately described in SHINE FSAR section 7.8. The NFDS is adequately designed for measurement of the neutron flux signal, signal processing, indication, and interfacing with other systems, including providing analog input to the TRPS. The staff also finds that the TRPS design meets SHINE Design Criteria 1 through 6, 13 through 19, 38, and 39. The staff review of the lifecycle development process for HIPS is described in section 7.4.2 of this SER and the adequacy of HIPS and TRPS-related TSs is evaluated in section 7.4.10 of this SER. Therefore, the staff concludes that the TRPS is capable of performing the allocated design basis safety function under postulated conditions.

7.4.5 Engineered Safety Features Actuation System

The NRC staff evaluated the sufficiency of the SHINE facility ESFAS, as described in SHINE FSAR section 7.5, "Engineered Safety Features Actuation System," using the applicable guidance and acceptance criteria from section 7.5, "Engineered Safety Features Actuation Systems," of NUREG-1537, Parts 1 and 2, and section 7b.4, "Engineered Safety Features Actuation Systems," of the ISG augmenting NUREG-1537, Part 2.

7.4.5.1 System Description

The applicant describes the ESFAS in SHINE FSAR section 7.5.1, and the NRC staff audited SHINE TECRPT-2020-0002 to confirm the information in SHINE FSAR section 7.5.1. SHINE FSAR figure 6a2.1-1 is a block diagram of the engineered safety features for the IF and SHINE FSAR figure 6b.1-1 is a block diagram of the engineered safety features for the RPF. The ESFAS is built using the HIPS digital I&C platform. Section 7.4.2 of this SER evaluates the HIPS design for implementation of the ESFAS. A general architecture of the ESFAS is shown in SHINE FSAR figure 7.1-3, "Engineered Safety Feature Actuation System Architecture."

The SHINE facility has a safety-related ESFAS I&C system that provides monitoring and actuation functions credited in the safety analysis described in chapter 13 of the SHINE FSAR to prevent the occurrence or mitigate the consequences of design basis events within the SHINE facility. If a monitored variable exceeds its predetermined limits, the ESFAS automatically initiates the associated safety function. The ESFAS monitors variables important to the safety functions for confinement of fission products and tritium, and for criticality safety to perform the following functions:

- Radiologically Controlled Area (RCA) Isolation
- Supercell Isolation
- Carbon Delay Bed Isolation
- VTS Safety Actuation
- TPS Train Isolation
- TPS Process Vent Actuation
- IU Cell Nitrogen Purge
- RPF Nitrogen Purge
- Molybdenum Extraction and Purification System (MEPS) Heating Loop Isolation
- Extraction Column Alignment Actuation
- Iodine and Xenon Purification and Packaging (IXP) Alignment Actuation
- Dissolution Tank Isolation

The ESFAS also provides nonsafety-related system status and measured process variable values to the PICS for viewing, recording, and trending.

7.4.5.2 Design Criteria

SHINE FSAR section 7.5.2.1, "SHINE Facility Design Criteria," states that the generally applicable SHINE Design Criteria 1 through 6 and SHINE Design Criteria 13 through 19 and 37 through 39 apply to the ESFAS. The subsections below therefore include an evaluation of the ESFAS against each of the applicable SHINE Design Criteria to the extent that the ESFAS supports the ability of the overall facility to demonstrate adequate protection against the hazards present.

This section of the SER documents the NRC staff's review and evaluation of the ESFAS system design to perform its safety functions based on the appropriate design criteria to satisfy the 10 CFR 50.34(a)(3) and 10 CFR 50.34(b) requirements. The staff's evaluation of the design of the ESFAS is based on acceptance criteria in section 7.5 of NUREG-1537, Part 2, including acceptance criteria from the guidance and industry standards referenced by NUREG-1537.

7.4.5.2.1 SHINE Facility Design Criteria

Each of the SHINE Design Criteria applicable to the ESFAS are addressed in a separate subsection below.

<u>Quality Standards and Records</u>

> <u>SHINE Design Criterion 1</u> – Safety-related structures, systems, and components (SSCs) are designed, fabricated, erected, and tested to quality standards commensurate with the safety functions to be performed. Where generally recognized codes and standards are used, they are identified and evaluated to determine their applicability, adequacy, and sufficiency and are supplemented or modified as necessary to ensure a quality product in keeping with the required safety function.
>
> A quality assurance program is established and implemented in order to provide adequate assurance that these SSCs satisfactorily perform their safety functions.
>
> Appropriate records of the design, fabrication, erection and testing of safety-related SSCs are maintained by or under the control of SHINE throughout the life of the facility.

SHINE FSAR section 7.5.2.2.15, "Quality," states that the ESFAS design, fabrication, installation, and modification is performed in accordance with a quality assurance program that conforms to the guidance of ANSI/ANS-15.8-1995 as endorsed by Regulatory Guide 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors" (ML093520099), and in accordance with the HIPS platform vendor's project quality assurance plan described in SHINE FSAR section 7.4.5.4. SHINE is responsible for oversight of the vendor and maintaining the vendor as an approved supplier on the approved supplier list. SHINE FSAR section 7.5.3.12 outlines the codes and standards applicable to the ESFAS design, fabrication, installation, and testing. Therefore, the NRC staff finds that the safety-related ESFAS meets SHINE Design Criterion 1.

Natural Phenomena Hazards

> SHINE Design Criterion 2 – The facility structure supports and protects safety-related SSCs and is designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches as necessary to prevent the loss of capability of safety-related SSCs to perform their safety functions.
>
> Safety-related SSCs are designed to withstand the effects of earthquakes without loss of capability to perform their safety functions.

SHINE FSAR section 7.5.3.5 states that the ESFAS equipment is installed in the seismically qualified portion of the main production facility where it is protected from earthquakes, tornadoes, and floods. The ESFAS equipment is Seismic Category I, tested using biaxial excitation testing and triaxial excitation testing, in accordance with section 8 of IEEE Standard 344-2013. Based on the NRC staff's evaluation in chapter 3 of this SER for natural phenomena, and SHINE FSAR section 7.5.3.4 for seismic events, the staff finds that the safety-related ESFAS meets SHINE Design Criterion 2.

Fire Protection

> SHINE Design Criterion 3 – Safety-related SSCs are designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.
>
> Noncombustible and heat resistant materials are used wherever practical throughout the facility, particularly in locations such as confinement boundaries and the control room.
>
> Fire detection and suppression systems of appropriate capacity and capability are provided and designed to minimize the adverse effects of fires on safety-related SSCs. Firefighting systems are designed to ensure that their rupture or inadvertent operation does not significantly impair the safety capability of these SSCs.

SHINE FSAR section 7.5.3.8, "Fire Protection," states that the ESFAS design uses physical separation to minimize the effects from fire or explosion. ESFAS equipment in different divisions is located in separate fire areas except for the facility control room and in other locations where end devices are installed. Physical separation is used to achieve separation of redundant sensors. Wiring for redundant divisions uses physical separation and isolation to provide independence for circuits. Separation of wiring is achieved using separate wireways and cable trays for each of Divisions A, B, and C. Field instruments are located in separate fire areas. Within the facility control room, Divisions A and C ESFAS cabinets are separated by a minimum of 4 feet and are located on the opposite side of the facility control room from where Division B cabinets are located. Nonsafety-related ESFAS inputs and outputs are routed in non-divisional cable raceways and are segregated from safety-related inputs and outputs. Spatial separation between cable and raceway groups is in accordance with IEEE Standard 384-2008, "Standard Criteria for Independence of Class 1E Equipment and Circuits." Portable Class A and Class C fire extinguishers are located in the control room to extinguish fires originating within a cabinet, console, or connecting cables. Noncombustible and heat resistant materials are used whenever practical in the ESFAS design, particularly in locations such as confinement boundaries and the facility control room. Additional information on fire protection can be found in SHINE FSAR section 9a2.3, "Fire Protections Systems and Programs." Therefore, the NRC staff finds that the

ESFAS design meets SHINE Design Criterion 3.

Environmental and Dynamic Effects

> SHINE Design Criterion 4 – Safety-related SSCs are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility.

SHINE FSAR section 7.5.2.2.11 states that the ESFAS rack mounted equipment is installed in a mild operating environment and is designed for the facility control room environmental parameters outlined in SHINE FSAR table 7.2-2. Rack mounted ESFAS equipment is tested to appropriate standards to show that the effects of EMI/RFI and power surges are adequately addressed. This testing includes emissions testing, susceptibility testing, and surge withstand testing. Appropriate grounding of the ESFAS is performed in accordance with section 5.2.1 of IEEE Standard 1050-2004. SHINE FSAR section 7.5.3.4 states that the cables for the ESFAS are routed through the radiologically controlled area to the process areas. The routed cables have the potential to be exposed to more harsh conditions than the mild environment of the facility control room. The sensors are located inside the process confinement boundary; therefore, the terminations of the cables routed to the sensors are exposed to the high radiation environment. During normal operation, the ESFAS equipment will operate in the applicable normal radiation environments identified in SHINE FSAR table 7.2-1 for up to 20 years, replaced at a frequency sufficient such that the radiation qualification of the affected components is not exceeded. The radiation qualification of the affected components is based upon the total integrated dose identified in SHINE FSAR table 7.2-1 being less than the threshold values identified in industry studies. The environmental conditions for ESFAS components are outlined in SHINE FSAR tables 7.2-1 through 7.2-3. Therefore, the NRC staff finds that the ESFAS design meets SHINE Design Criterion 4.

Sharing of Structures, Systems, and Components

> SHINE Design Criterion 5 – Safety-related SSCs are not shared between irradiation units unless it can be shown that such sharing will not significantly impair their ability to perform their safety functions.

SHINE FSAR section 7.5.2.1 states that the ESFAS does not share components between IUs. SHINE FSAR section 7.5.2.1.6, “Separation of Protection and Control Systems,” states that there are no sensor outputs that have both an ESFAS safety-related protection function and a nonsafety-related control function. Based on its review of ESFAS monitored variables in SHINE FSAR table 7.5-1, “ESFAS Monitored Variables,” and ESFAS logic diagrams in SHINE FSAR figure 7.5-1, the NRC staff finds that the ESFAS does not share components between IUs. Therefore, the staff finds that the ESFAS design meets SHINE Design Criterion 5.

Control Room

> SHINE Design Criterion 6 - A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

SHINE FSAR section 7.5.2.2.14, “Human Factors,” states that the ESFAS design provides capability for manual actuation of ESFAS safety function in the facility control room. ESFAS logic diagrams in SHINE FSAR figure 7.5-1 show the logic for manual actuation of ESFAS safety functions. The ESFAS includes redundantly isolated outputs for each safety-related instrument channel to provide monitoring and indication information to the PICS, which includes indication of ESFAS actuation device status. This supports operator actions under postulated accident conditions. Therefore, the NRC staff finds that the ESFAS design meets SHINE Design Criterion 6.

Instrumentation and Controls

> SHINE Design Criterion 13 – Instrumentation is provided to monitor variables and systems over their anticipated ranges for normal operation, for anticipated transients, and for postulated accidents as appropriate to ensure adequate safety, including those variables and systems that can affect the fission process, the integrity of the primary system boundary, the primary confinement and its associated systems, and the process confinement boundary and its associated systems. Appropriate controls are provided to maintain these variables and systems within prescribed operating range.

In its response to RAI 7-13, the applicant stated that each division of the ESFAS transmits monitoring and indication information to the PICS. The following information from the ESFAS is displayed in the FCR:

- Mode and Fault status for each HIPS module
- Status and value of the monitored variables identified in SHINE FSAR table 7.5-1
- Trip/Bypass switch status
- Divisional partial trip determination status
- Divisional full trip determination status
- TRPS IU cell operational mode status
- Actuation output and fault status
- Actuated component position feedback status

The ESFAS monitoring and indication information is available to the operators in the FCR at the PICS operator workstations. A subset of the ESFAS monitoring and indication information is displayed at the main control board in the FCR near the manual control switches for actuating ESFAS safety functions. The ESFAS provides redundant outputs to the PICS. The PICS receives the outputs from the ESFAS onto a fault-tolerant server comprised of internal redundant physical servers. The use of redundant outputs from the ESFAS to redundant internal physical servers on the PICS ensures that a failure would not prevent the operator from obtaining or resolving conflicting information. By displaying ESFAS monitoring and indication information at multiple locations in the FCR, including near manual controls for actuating ESFAS equipment, the design ensures that the operator has sufficient information to operate the facility and take manual operator action, as necessary. SHINE FSAR section 7.4.5.2.4

provides a description of the information available to the operators in the FCR. SHINE FSAR section 7.5.4.1, “Monitored Variables and Response,” provides a discussion of the ESFAS response to each monitored variable (signal input). SHINE FSAR table 7.5-1 provides the instrument range, accuracy, response time, and a specified analytical limit. The NRC staff did not review specific design information or performance data for the sensors/instruments listed in SHINE FSAR table 7.5-1 and, therefore, did not specifically confirm the validly of performance parameters assigned to each instrument. SHINE will test and qualify the instrumentation in accordance with TSs and SHINE FSAR section 12.11.2, “Startup Tests.”

Based on the above, the NRC staff confirmed that the variables listed in SHINE FSAR table 7.5-1 are used for display and to initiate defined actuation of the applicable engineered safety feature. Further, these variables have operable protection capability in all operating modes and conditions, as analyzed in the SHINE FSAR for the complete range of normal facility operating conditions and to cope with anticipated transients and potential accidents evaluated. Therefore, the staff finds that the ESFAS design meets SHINE Design Criterion 13. The adequacy of the PICS, consoles, and displays in meeting SHINE Design Criterion 13 is addressed separately in section 7.4.6 of this SER.

Protection System Functions

SHINE Design Criterion 14 – The protection systems are designed to:

1) initiate, automatically, the operation of appropriate systems to ensure that specified acceptable target solution design limits are not exceeded as a result of anticipated transients; and

2) sense accident conditions and to initiate the operation of safety-related systems and components.

SHINE FSAR section 7.5.2.1.2, “Protection System Functions,” states that there are no anticipated transients that require the initiation of the ESFAS to ensure that specified acceptable target solution design limits are not exceeded and refers to SHINE FSAR section 7.5.3.1, “Safety Functions,” that describes the ESFAS safety functions that are relied upon for specific accident scenarios. Based on its review of these SHINE FSAR sections and the ESFAS logic diagrams depicted in SHINE FSAR figure 7.5-1, the NRC staff finds that the ESFAS is designed to perform the safety functions for transients and accidents credited by SHINE FSAR chapter 13 necessary to maintain the facility confinement strategy and provides process actuation functions required to shut down processes and maintain processes in a safe condition. The SHINE FSAR does not appear to describe the total system response time assumed or credited for all event scenarios in chapter 13 or how the instrument response time specified in SHINE FSAR table 7.5-1 relates to any associated analyses assumed in the total system response time. The staff also reviewed selected calculations to confirm that the response time in SHINE FSAR table 7.5-1 is consistent with the total response time assumed in the accident analysis for instrument response time, HIPS response time, and actuation time. The staff audited SHINE CALC-2019-0045, Revision 1, “MEPS heating Loop Radiation Extraction Area A/B/C,” to confirm the basis for the response time values listed in SHINE FSAR table 7.5-1, which are verified during factory acceptance and start-up testing. Chapter 13 of this SER provides the evaluation of overall response times, as appropriate, to ensure that target solution limits are not exceeded as a result of transients and accidents. Therefore, the staff finds that the ESFAS design meets SHINE Design Criterion 14.

Protection System Reliability and Testability

> SHINE Design Criterion 15 – The protection systems are designed for high functional reliability and inservice testability commensurate with the safety functions to be performed. Redundancy and independence designed into the protection systems are sufficient to ensure that:
>
> 1) no single failure results in loss of the protection function, and
>
> 2) removal from service of any component or channel does not result in loss of the required minimum redundancy unless the acceptable reliability of operation of the protection system can be otherwise demonstrated.
>
> The protection systems are designed to permit periodic testing, including a capability to test channels independently to determine failures and losses of redundancy that may have occurred.

SHINE FSAR section 7.5.2.1.3 states that the HIPS platform design for the ESFAS supports high functional reliability by:

- Incorporating predictability and repeatability principles to ensure an extremely high probability of accomplishing safety functions.

- ESFAS contains capabilities for inservice testing for those functions that cannot be tested while the associated equipment is out of service. The HIPS maintenance bypass function allows for an individual SFM to be removed from service in accordance with the technical specifications, for the purpose of performing required technical specification surveillance testing to verify the operability of ESFAS components during system operation, which supports in-service testability.

- SSCs that comprise a division are physically separated to retain the capability of performing the required safety functions during a design basis accident.

- Redundancy within the ESFAS consists of two or three divisions of input processing and trip determination and two divisions of actuation logic arranged such that no single failure can prevent a safety actuation when required. An ESFAS channel can be taken out of service without an adverse impact on redundancy.

- Self-test features are provided for the HIPS components that do not have setpoints or tunable parameters. Self-testing capabilities provide indication of component degradation and failure, which allows action to be taken to ensure that no single failure results in the loss of the protection function.

The NRC staff’s evaluation of the HIPS platform design for the TRPS and ESFAS in section 7.4.2, “HIPS Design,” of this SER finds that the high functional reliability features discussed above have been adequately implemented in the HIPS platform. Specifically, the staff’s evaluation in sections 7.4.2.1.4, “HIPS Diagnostics and Self-testing,” 7.4.2.1.5, “Operational and Maintenance Bypass,” 7.4.2.2.1, “Independence,” 7.4.2.2.2, “Redundancy,” and 7.4.2.2.3, “Predictability and Repeatability,” of this SER finds that the HIPS platform design for the TRPS and ESFAS provides for high functional reliability and testability. Therefore, the staff finds that the ESFAS design meets SHINE Design Criterion 15.

Protection System Independence

> SHINE Design Criterion 16 – The protection systems are designed to ensure that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions on redundant channels, do not result in loss of the protection function or are demonstrated to be acceptable on some other defined basis. Design techniques, such as functional diversity or diversity in component design and principles of operation, are used to the extent practical to prevent loss of the protection function.

SHINE FSAR section 7.5.2.1.4, "Protection System Independence," states that the ESFAS control and logic functions operate inside of the facility control room where the environment is mild, not exposed to the irradiation process, and is protected from earthquakes, tornadoes, and floods. The ESFAS SSCs that comprise a division are physically separated to retain the capability of performing the required safety functions during a design basis accident. Division independence is maintained throughout, extending from the sensor to the devices actuating the protective function. Functional allocation of different process parameters on different SFMs and diversity in component design are used to prevent loss of the protection function. SHINE FSAR section 7.5.3.4 states that the ESFAS components are qualified to the environmental and radiological parameters provided in SHINE FSAR tables 7.2-1 through 7.2-3. SHINE FSAR section 7.5.3.5 states that the ESFAS equipment is installed in the seismically qualified portion of the main production facility where it is protected from earthquakes, tornadoes, and floods. The ESFAS equipment is Seismic Category I, tested using biaxial excitation testing and triaxial excitation testing, in accordance with section 8 of IEEE Standard 344-2013. SHINE FSAR section 7.5.2.2.11 states that the rack mounted ESFAS equipment is tested to appropriate standards to show that the effects of EMI/RFI and power surges are adequately addressed. This testing includes emissions testing, susceptibility testing, and surge withstand testing. Appropriate grounding of the ESFAS is performed in accordance with section 5.2.1 of IEEE Standard 1050-2004.

Based on the above and the NRC staff's evaluation in section 7.4.2.1.3, "Equipment Qualification," and section 7.4.2.2.4, "Diversity," of this SER, the staff finds that the ESFAS design meets SHINE Design Criterion 16, considering the potential consequences and large safety margins described in chapter 13 of this SER. This ensures that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions on redundant channels do not result in loss of the protection function.

Protection System Failure Modes

> SHINE Design Criterion 17 – The protection systems are designed to fail into a safe state if conditions such as disconnection of the system, loss of energy (e.g., electric power, instrument air), or postulated adverse environments are experienced.

SHINE FSAR section 7.5.2.1.5, "Protection System Failure Modes," states that controlled components associated with safety actuations are designed to go to their safe state when deenergized. SHINE FSAR table 7.5-2 identifies the fail-safe positions of the ESFAS safety actuation components on a loss of power. SHINE FSAR section 7.5.3.4 states that the ESFAS equipment is qualified for radiological and environmental hazards present during normal operation and postulated accidents. During normal operation, the ESFAS equipment will operate in the applicable normal radiation environments identified in SHINE FSAR table 7.2-1 for up to 20 years, replaced at a frequency sufficient such that the radiation qualification of the affected components, which is based upon the total integrated dose identified in SHINE FSAR table 7.2-1, is not exceeded.

Based on the above, the NRC staff's evaluation of equipment qualification and protection system reliability and testability in sections 7.4.2.1.3 and 7.4.5.2.1 of this SER, and evaluation of the ESFAS logic diagrams in SHINE FSAR figure 7.5-1, Sheets 1 through 27, the staff finds that the ESFAS is designed to fail into a safe state and will perform its protective actions upon loss of power, loss of an ESFAS component, or adverse environmental conditions. Therefore, the staff concludes that the ESFAS is designed to perform the required protective actions in the presence of any single failure or malfunction and meets SHINE Design Criterion 17, the design acceptance criterion in NUREG-1537, Part 2, for single failure, and the design acceptance criteria in sections 5.1 and 5.4 of ANSI/ANS-15.15-1978 for single failure and fail-safe.

Separation of Protection and Control Systems

> SHINE Design Criterion 18 – The protection system is separated from control systems to the extent that failure of any single control system component or channel, or failure or removal from service of any single protection system component or channel that is common to the control and protection systems leaves intact a system satisfying all reliability, redundancy, and independence requirements of the protection system. Interconnection of the protection and control systems is limited to assure that safety is not significantly impaired.

SHINE FSAR section 7.5.2.1.6 states that there are no sensor outputs that have both an ESFAS safety-related protection function and a nonsafety-related control function. There are no inputs to the ESFAS from the PICS that are used in the determination of protective actions. Nonsafety-related inputs to the ESFAS from the PICS are limited to those for controls and monitoring and indication only variables. SHINE FSAR section 7.5.3.3 states that the nonsafety control signals from the PICS are implemented through a hardwired parallel interface that requires the PICS to send a binary address associated to the output state of the EIM along with a mirrored complement address. The mirrored complement address prevents any single incorrectly presented bit from addressing the wrong EIM output state. The ESFAS contains an enable nonsafety switch that controls when the hardwired parallel interface within the APL is active, thus controlling when the PICS inputs can operate ESFAS components. When the enable nonsafety switch is not active, the nonsafety-related control signal is ignored. If the enable nonsafety is active, and no automatic or manual safety actuation command is present, the nonsafety-related control signal can control the ESFAS component. The hardwired module provides isolation for the nonsafety-related signal path.

Based on the above and the NRC staff's evaluation in section 7.4.2.2.1, "Independence," section 7.4.2.2.2, "Redundancy," and section 7.4.2.2.6, " Prioritization of Functions," of this SER, the staff finds that the ESFAS is adequately separated from the PICS such that the failure of any single PICS component, or the failure or removal from service of any single ESFAS component or channel, leaves intact a system satisfying all reliability, redundancy, and independence requirements of the ESFAS. Interconnection of the ESFAS and the PICS is designed to ensure that safety is not significantly impaired. Therefore, the staff concludes that the ESFAS design meets SHINE Design Criterion 18.

Protection Against Anticipated Transients

> SHINE Design Criterion 19 – The protection systems are designed to ensure an extremely high probability of accomplishing their safety functions in the event of anticipated transients.

SHINE FSAR section 7.5.2.1.7 states that the HIPS platform's implementation of the ESFAS ensures an extremely high probability of accomplishing the required safety functions by applying the attributes of independence, redundancy, and predictability and repeatability. Collectively, these attributes ensure that the ESFAS functions in a highly consistent manner with high reliability. Independence principles contribute to ensuring an extremely high probability of accomplishing safety functions by ensuring that SSCs that comprise a division are physically separated. Redundancy principles contribute to ensuring an extremely high probability of accomplishing safety functions by ensuring that no single failure can prevent a safety actuation. Predictability and repeatability principles contribute to ensuring an extremely high probability of accomplishing safety functions by ensuring that the ESFAS produces the same outputs for a given set of input signals within well-defined response time limits.

Based on the above and the NRC staff's evaluation in section 7.4.2.2.1, "Independence," section 7.4.2.2.2, "Redundancy," and section 7.4.2.2.3, "Predictability and Repeatability," of this SER, the staff finds that the ESFAS is designed to ensure an extremely high probability of accomplishing its safety functions in the event of anticipated transients. Therefore, the staff finds that the ESFAS meets SHINE Design Criterion 19 and the acceptance criterion in NUREG-1537, Part 2, for single failure, and the design acceptance criteria in sections 5.1 and 5.4 of ANSI/ANS-15.15-1978 for single failure and fail-safe.

Criticality Control in the Radioisotope Production Facility

> SHINE Design Criterion 37 – Criticality in the radioisotope production facility is prevented by physical systems or processes and the use of administrative controls. Use of geometrically safe configurations is preferred. Control of criticality adheres to the double contingency principle.
>
> A criticality accident alarm system to detect and alert facility personnel of an inadvertent criticality is provided.

SHINE FSAR section 7.5.2.1.8, "Criticality Control in the Radioisotope Production Facility," states that the ESFAS provides the following two safety functions as required by the SHINE criticality safety program described in SHINE FSAR section 6b.3, "Nuclear Criticality Safety."

- VTS Safety Actuation - This safety function stops the transfer of target solution or other radioactive solutions upon indication of potential upset conditions. The VTS vacuum header liquid detection signal protects against an overflow of the vacuum lift tanks to prevent a potential criticality event as described in SHINE FSAR section 6b.3.2.5, "Vacuum Transfer System."

- Target Solution Preparation System (TSPS) Dissolution Tank Isolation - Dissolution tank isolation is relied upon as a safety-related control for preventing a criticality event as described in SHINE FSAR section 6b.3.2.4, "Target Solution Preparation System." This safety function protects against a criticality event due to excess fissile material in a non-favorable geometry system and prevents overflow of the dissolution tank into the uranium handling glovebox or ventilation system.

SHINE FSAR section 6b.3.1.4, “Nuclear Criticality Safety Evaluations,” states that for the purposes of nuclear criticality safety evaluations (NCSEs), criticality events are always considered to be high consequence, with a strict emphasis on the selection of controls to prevent criticality, and where the double contingency principle (DCP) is employed. The NCSE contains a description of its implementation. SHINE FSAR section 6b.3.2, “Criticality Safety Controls,” describes the criticality safety controls and states that the failure of a single nuclear criticality safety (NCS) control which maintains two or more controlled parameters is considered a single process upset when determining whether the DCP is met. Passive engineered geometry controls are the most preferred type of NCS controls. Otherwise, the preferred hierarchy of NCS controls is (1) passive engineered, (2) active engineered, (3) enhanced administrative, and (4) administrative. Generally, control on two independent criticality parameters is preferred over multiple controls on a single parameter. If redundant controls on a single parameter are used, a preference is given to diverse means of control on that parameter. SHINE FSAR section 6b.3.2 describes the following systems that require active engineered criticality safety control:

- SHINE FSAR section 6b.3.2.4: TSPS – High level within the dissolution tanks requires application of the DCP to prevent criticality accidents. The dissolution tanks are equipped with high level controls that are interlocked with isolation valves on cooling and ventilation lines.

- SHINE FSAR section 6b.3.2.5: VTS – The inadvertent transfer of solution to a non-fissile system requires application of the DCP to prevent criticality accidents. The VTS piping design and features prevent transfer of target solution to non-favorable geometry components within the VTS. The vacuum headers are equipped with liquid detection that stops transfers upon detection of liquid.

- SHINE FSAR section 6b.3.2.8: Radioactive Drain System (RDS) – Precipitation of solids requires application of the DCP to prevent criticality accidents. The hold tanks are equipped with level instrumentation to detect a leak of solution transferred to RDS. FSAR section 7.3.1.3.3, “Radioactive Drain System,” states that drains from vaults, trenches, and other areas where uranium-bearing solutions may be present are part of the RDS. The PICS is used to provide indication of leakage and the presence of liquid in the RDS sump tanks to alert the operator of abnormal situations.

The NRC staff’s evaluation of the NCSEs and CAAS is documented in section 6b.3.3 of this SER.

Based on the above, the NRC staff finds that the TSPS dissolution tank level signals protect against a criticality event due to excess fissile material in a non-favorable geometry system since the TSPS dissolution tank level signal is received by the ESFAS and on “high level” in either dissolution tank, it initiates TSPS dissolution tank isolation. Additionally, the staff finds that the VTS vacuum header liquid detection signal protects against an overflow of the vacuum lift tanks to prevent a potential criticality event because VTS vacuum header liquid detection signal is received by the ESFAS and upon detection of liquid in the VTS vacuum header, a VTS safety actuation is initiated. Further, the staff finds that the RDS liquid detection signal detects leakage or overflow from other tanks and piping since the RDS liquid detection signal is received by the ESFAS and upon detection of liquid in the RDS, a VTS safety actuation is initiated. Therefore, the staff finds that the ESFAS design meets SHINE Design Criterion 37.

Monitoring Radioactivity Releases

> SHINE Design Criterion 38 – Means are provided for monitoring the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material. Potential effluent discharge paths and the plant environs are monitored for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents.

SHINE FSAR section 7.5.2.1.9, "Monitoring Radioactivity Releases," states that the ESFAS monitors for potential radioactivity releases from the following various areas of the main production facility:

- Radiological Ventilation Zones – SHINE FSAR section 7.5.3.1.24, "RCA Isolations," states that the ESFAS monitors radiation in the radiological ventilation zone 1 (RVZ1) and RVZ2 exhaust for an RCA isolation actuation.

- Super Cell Areas – SHINE FSAR sections 7.5.3.1.1 through 7.5.3.1.10 state that the ESFAS monitors radiation at the outlet of each supercell area 1 through area 10 for respective supercell area(s) isolation actuation.

- TPS Confinement – SHINE FSAR sections 7.5.3.1.18 through 7.5.3.1.20 state that the ESFAS monitors TPS confinement tritium for the respective TPS train isolation actuation.

SHINE FSAR section 7.4.4.1.15, "High RVZ1e IU Cell Exhaust Radiation," states that the high RVZ1e IU cell exhaust radiation is measured on the exhaust of the PCLS expansion tank located in each IU cell. High RVZ1e IU cell exhaust radiation signal is generated by the TRPS when an RVZ1e IU cell exhaust radiation input exceeds the high level setpoint.

SHINE FSAR section 7.7.2, "Nonsafety-Related Process Radiation Monitoring," states that nonsafety-related process radiation monitoring is provided as part of various systems to provide information to the operator on the status and effectiveness of processes. They may be used to diagnose process upsets but are not relied upon to prevent or mitigate accidents.
SHINE FSAR section 7.7.3, "Area Radiation Monitoring," states that the area radiation monitoring within the facility is provided by the RAMS. Area radiation monitors are in areas where personnel may be present and where radiation levels could become significant. The monitors provide local and remote indication of radiation levels and provide local alarms to notify personnel of potentially hazardous conditions.

SHINE FSAR section 7.7.4, "Continuous Air Monitoring," states that continuous airborne contamination monitoring within the facility is provided by the CAMS. Each CAMS unit samples air and provides real time alpha and beta activities or tritium activity to alert personnel when airborne contamination is above preset limits. CAMS units are in areas where personnel may be present and where contamination levels could become significant. Each CAMS unit provides local and remote indication of airborne radiation levels and alarm capabilities.

SHINE FSAR section 7.7.5, “Effluent Monitoring,” states that effluent monitoring for the facility is provided by the SRMS. The SRMS is composed of two monitoring units: the main facility stack release monitor and the carbon delay bed effluent monitor (CDBEM). The stack release monitor is used to demonstrate that gaseous effluents from the main production facility are within regulatory limits and does not have an accident mitigation or personnel protection function. The stack release monitor performs its function by drawing a representative air sample from the stack and providing a means to measure the air sample for noble gases (continuous measurement) and capturing particulates, iodine, and tritium for collective measurement. The CDBEM monitors for noble gases at the exhaust of the PVVS carbon delay beds to provide information about the health of the PVVS carbon delay beds and to provide the ability to monitor the safety-related exhaust point effluent release pathway when it is in use. The CDBEM is used on an as-needed basis to demonstrate that gaseous effluents from the main production facility are within regulatory limits (e.g., during a loss of off-site power when the normal heating, ventilation, and air conditioning (HVAC) systems and the PVVS are not operating) and do not have an accident mitigation or personnel protection function. Two particulate and iodine filters (redundant configuration) are provided for in-line capturing and collective measurement when the safety-related exhaust point is in use.

Based on the above, the NRC staff finds that means are provided for monitoring the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material. Potential effluent discharge paths and the plant environs are monitored for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents. Therefore, the staff finds that the SHINE facility, including the ESFAS, meets SHINE Design Criterion 38.

Hydrogen Mitigation

> SHINE Design Criterion 39 – Systems to control the buildup of hydrogen that is released into the primary system boundary and tanks or other volumes that contain fission products and produce significant quantities of hydrogen are provided to ensure that the integrity of the system and confinement boundaries are maintained.

SHINE FSAR section 7.5.2.1.10 states that the ESFAS monitors variables and provides actuations to protect against hydrogen deflagration in various areas in the SHINE main production facility.

SHINE FSAR section 7.5.4.1.14 states that the TRPS IU cell nitrogen purge signal protects against a loss of hydrogen mitigation capabilities in the IUs. Upon receipt of a TRPS IU cell nitrogen purge initiation signal, the ESFAS initiates IU cell nitrogen purge.

SHINE FSAR section 7.5.4.1.15 states that the PVVS flow signal protects against loss of hydrogen mitigation capabilities in the RPF. The ESFAS initiates an RPF nitrogen purge based on low PVVS flow.

SHINE FSAR section 7.5.4.1.19, “UPSS Loss of External Power,” states that the loss of external power signal protects against an anticipatory loss of hydrogen mitigation in the IU cell. The ESFAS provides an ESFAS loss of external power actuation signal to the TRPS subsystem associated with each IU cell upon receipt of an UPSS loss of external power signal to initiate an IU Cell Nitrogen Purge within the TRPS. The ESFAS-initiated IU Cell Nitrogen Purge signal is provided to each of the eight TRPS subsystems as an ESFAS loss of external power signal.

Based on the above, the NRC staff finds that the ESFAS is designed to initiate nitrogen purge to control the buildup of hydrogen that is released into the primary system boundary and tanks or other volumes that contain fission products and produce significant quantities of hydrogen to ensure that the integrity of the system and confinement boundaries is maintained. Therefore, the staff finds that the ESFAS design meets SHINE Design Criterion 39.

7.4.5.2.2 ESFAS System Design Criteria

SHINE FSAR section 7.5.2.2, "ESFAS System Design Criteria," outlines several ESFAS system-specific design criteria for protective actions, single failure, independence, communication, prioritization, setpoints, bypass and permissives, equipment qualification, surveillance, human factors, access control, software requirements development, and quality. The NRC staff's evaluation of the safety-significant ESFAS system design features and attributes is documented in section 7.4.5.2.1 of this SER as a part of the SHINE Design Criteria evaluation and in section 7.4.2 of this SER as a part of the HIPS design evaluation. While the staff evaluated the analysis of selected equipment design criteria as subsidiary elements of the broader SHINE Design Criteria, the staff did not independently confirm each ESFAS system-specific design criterion and is not specifically making a finding for the ESFAS system-specific design criteria.

7.4.5.3 Design Basis

The ESFAS is a safety-related system designed to monitor process variables and provide automatic initiating signals in response to off-normal conditions, providing protection against unsafe conditions in the main production facility. The HIPS digital I&C platform is used to implement the ESFAS logic and the design bases associated with the HIPS platform are evaluated in section 7.4.2 of this SER. Following is the NRC staff's evaluation of the ESFAS-specific design basis.

7.4.5.3.1 Safety Functions

SHINE FSAR section 7.5.3.1 describes the safety functions performed by the ESFAS to mitigate the consequences of design basis events credited in SHINE FSAR chapter 13. The ESFAS monitors variables associated with the safety functions for confinement of radiation and tritium within the IF and the RPF and for criticality safety. For each ESFAS safety function, this SHINE FSAR section identifies the components that actuate based on monitored variables and associated system actuation. SHINE FSAR section 7.5.3.6, "Human Factors," states that the ESFAS provides manual actuation capabilities for the ESFAS safety functions via the manual push buttons located on the main control board. To support the use of manual safety actuations and reset of protective actions, the ESFAS provides monitored process parameters information, ESFAS actuated components status, and ESFAS actuation function status to the PICS. Based on its review of these SHINE FSAR sections and the ESFAS logic diagrams depicted in SHINE FSAR figure 7.5-1, the NRC staff finds that the ESFAS is design to perform the safety functions credited by the safety analysis in SHINE FSAR chapter 13 as necessary to maintain the facility confinement strategy and provides process actuation functions required to shut down processes and maintain processes in a safe condition.

7.4.5.3.2 Completion of ESFAS Protective Actions

SHINE FSAR section 7.5.3.2 states that the ESFAS is designed so that once initiated, protective actions will continue to completion. Only deliberate operator action can be taken to reset the ESFAS following a protective action.

Based on its review of the ESFAS logic diagrams in SHINE FSAR figure 7.5-1, the NRC staff finds that the ESFAS latches in a protective action and maintains the state of a protective action until operator input is initiated to reset the output of the ESFAS to normal operating conditions. If there is no signal present from the automatic safety actuation or manual actuation, then the enable nonsafety switch would allow an operator, after the switch has been brought to enable, to control the output state of the ESFAS with a control signal from the nonsafety-related PICS. Therefore, the staff finds that the ESFAS design allows the initiated protective actions to continue to completion and to only be manually reset by an operator in the absence of a safety actuation signal.

7.4.5.3.3 Single Failure

SHINE FSAR section 7.5.3.3 states that no single failure within the ESFAS results in the loss of the protective function. The HIPS digital I&C platform is used to implement the ESFAS and the ESFAS single failure criterion associated with the HIPS platform is evaluated in section 7.4.2 of this SER. The following is the NRC staff's evaluation of single failures in the ESFAS design where a passive check valve is credited as a redundant component.

Based on SHINE FSAR sections 7.5.3.1.17, "VTS Safety Actuation," 7.5.3.1.18, "TPS Train A Isolation," 7.5.3.1.19, "TPS Train B Isolation," 7.5.3.1.20, "TPS Train C Isolation," 7.5.3.1.23, "RPF Nitrogen Purge," and 7.5.3.3, "Single Failure," and ESFAS Logic Diagram SHINE FSAR figure 7.5-1, Sheets 13, 14, 15, 18, 19, 20, the ESFAS is designed to actuate only the Division A component for the following select safety functions where a passive check valve is credited as a redundant component:

- A check valve is provided in series with each of the following components to support isolation during a VTS Safety Actuation:
  - MEPS A/B/C extraction column wash supply valve
  - MEPS A/B/C extraction column eluent valve
  - MEPS A/B/C wash supply valve
  - MEPS A/B/C effluent valve
  - IXP recovery column wash supply valve
  - IXP recovery column effluent valve
  - IXP wash supply valve
  - IXP effluent valve
  - IXP facility nitrogen handling system supply valve
  - IXP liquid nitrogen supply valve
- A TPS helium supply check valve is provided in series with the TPS train A/B/C helium supply isolation valve to support isolation during a TPS Train A/B/C Isolation.

- An RLWI PVVS check valve is provided in series with the RLWI PVVS isolation valve to support isolation during an RPF Nitrogen Purge.

The NRC staff finds that using a respective passive check valve in series will prevent backflow should any of the valves fail to close due to a single failure. Therefore, staff finds that in each of the above instances, sufficient redundancy is provided such that no single failure results in the loss of the protective function.

7.4.5.4 Technical Specifications

Section 7.4.10, "Proposed Technical Specifications," of this SER provides the NRC staff review of the SHINE TSs related to the ESFAS.

7.4.5.5 Conclusion

The NRC staff has reasonable assurance that the SHINE ESFAS is designed to (1) mitigate the consequences of design basis events within the main production facility, (2) provide sense, command, and execute functions necessary to maintain the facility confinement strategy, (3) provide process actuation functions required to shut down processes and maintain processes in a safe condition, and (4) provide system status and measured process variable values to the PICS for viewing, recording, and trending. The staff also finds that the ESFAS design meets SHINE design criteria 1 through 6, 13 through 19, and 37 through 39. The staff review of the lifecycle development process for HIPS is described in section 7.4.2 of this SER and the adequacy of HIPS and ESFAS-related TS is included in section 7.4.10 of this SER. Therefore, the staff concludes that the ESFAS is capable of performing the allocated design basis safety function under postulated conditions.

7.4.6 Control Console and Display Instruments

The control room, containing the control consoles and other status display instruments, is the hub for facility operation. It is the location to which all information necessary and sufficient for safe and effective operation of the facility is transmitted, and the primary location from which control and safety devices are actuated either manually or automatically. The control console and display instruments contain most of the hardware for organizing and processing the information and routing signals to display devices or automatic action of other subsystems.

The NRC staff evaluated the sufficiency of the SHINE facility control console and display instruments as described in SHINE FSAR section 7.6, "Control Console and Display Instruments," using the applicable guidance and acceptance criteria from section 7.6, "Control Console and Display Instruments," of NUREG-1537, Parts 1 and 2, and section 7b.5, "Control Console and Display Instruments," of the ISG augmenting NUREG-1537, Part 2.

As described in section 7.4.3 of this SER, the NRC staff evaluated the control console and display instruments as part of the PICS, as appropriate. Therefore, findings for the PICS are applicable to the control console and display instrument equipment, as appropriate. In addition, the findings for the human factors engineering (HFE) development of the computer displays and arrangement of discrete indications and controls are also applicable to the control console and display instruments. The staff has reasonable assurance that the control console and display instruments are adequately described in SHINE FSAR section 7.8 and that nuclear and process parameters important to safe and effective operation of the facility will be displayed at the control consoles. Therefore, the staff concludes that the applicant has shown that all nuclear and process parameters important to the safe and effective operation of the SHINE facility will be displayed at the control console and display instruments. The staff finds that the display devices for these parameters will be easily understood and readily observable by an operator positioned at the controls. The control console design and operator interface will be sufficient to promote safe facility operation.

7.4.7 Radiation Monitoring Systems

The NRC staff evaluated the sufficiency of the SHINE facility RMS, as described in SHINE FSAR section 7.7, "Radiation Monitoring Systems," using the applicable guidance and acceptance criteria from section 7.7, "Radiation Monitoring Systems," of NUREG-1537, Parts 1 and 2, and section 7b.6, "Radiation Monitoring Systems," of the ISG augmenting NUREG-1537, Part 2.

SHINE FSAR section 7.7 states that the SHINE facility uses the RMS to perform radiation monitoring functions within the facility and that it includes the following safety-related and nonsafety-related equipment:

- Safety-related process radiation monitors as a part of the ESFAS, TRPS, and TPS;
- Nonsafety-related process radiation monitors as a part of other facility processes;
- Nonsafety-related RAMS;
- Nonsafety-related CAMS; and
- Nonsafety-related SRMS for effluent monitoring, which is comprised of:
  - Main facility stack release monitor
  - Carbon delay bed effluent monitor (CDBEM).

SHINE FSAR section 7.7 states that the ESFAS and TRPS receive analog signals from the safety-related process radiation monitors for performing their intended safety functions whereas the non-safety related equipment monitors several areas of the facility and provides information to the operator on the status and effectiveness of processes and effluent monitoring. Nonsafety-related process radiation monitors may be used to diagnose process upsets and are not used to control personnel or environmental radiological exposures. The RAMS provide local and remote indication of radiation levels and provide local alarms to notify personnel of potentially hazardous conditions. Each CAMS unit samples air and provides real time alpha and beta activities or tritium activity to alert personnel when airborne contamination is above preset limits. Both the RAMS and CAMS provide a nonsafety-related defense-in-depth as low as is reasonably achievable function of alerting personnel of the need to evacuate an area if required. The stack release monitor is used to demonstrate that gaseous effluents from the main production facility are within regulatory limits and do not have an accident mitigation or personnel protection function. The CDBEM monitors for noble gases at the exhaust of the PVVS carbon delay beds to provide information about the health of the PVVS carbon delay beds and to provide the ability to monitor the safety-related exhaust point effluent release pathway when it is in use. Although the CDBEM monitors a safety-related point in the PVVS system, the CDBEM is not required to perform a safety function. The CDBEM is used on an as-needed basis to demonstrate that gaseous effluents from the main production facility are within regulatory limits (e.g., during a loss of off-site power when the normal HVAC systems and the PVVS are not operating) and does not have an accident mitigation or personnel protection function.

In this section, the NRC staff's evaluation of the RMS is primarily focused on the safety-related process radiation monitors that are used for actuating safety functions performed by the ESFAS and TRPS. The evaluation of the non-safety related RMS for radiation protection is addressed in chapter 11, "Radiation Protection Program and Waste Management," of this SER.

7.4.7.1 Safety-Related Process Radiation Monitors

7.4.7.1.1 System Description

SHINE FSAR section 7.7.1 states that the safety-related process radiation monitors monitor radiation and actuate safety and protection systems if defined radiation levels are reached. There are different radiation monitors to detect fission products or tritium. The monitors detecting beta and gamma-ray radiation send signals to the TRPS and/or ESFAS to perform safety actuations when abnormal situations within the facility ventilation systems are presented. In addition, radiation monitors will send a signal to the TRPS for interlocking the operation of the neutron driver. The radiation monitors detecting tritium are part of the TPS. If tritium releases to a defined level, then the TPS provides inputs to the ESFAS and provides interlock inputs to the TRPS. SHINE FSAR table 7.7-1 identifies the safety-related radiation monitors, and SHINE FSAR section 7.7.1.4.2 refers to SHINE FSAR tables 7.4-1 and 7.5-1 for the instrument ranges, accuracies, and response times of these radiation monitors.

Safety-related process radiation monitors provide analog signals to the ESFAS and TRPS that are then used to generate actuation signals when radiation levels exceed pre-determined setpoints. SHINE FSAR section 7.7.1.4.1 describes the safety-related radiation signals processed to generate the different actuation signals.

7.4.7.1.2 Safety-Related Process Radiation Monitors Design Criteria

SHINE FSAR section 7.7.1.2 states that the generally applicable SHINE Design Criteria 1, 2, and 4 apply to the safety-related process radiation monitors. In addition, SHINE Design Criteria 13 and 38 also apply to the safety-related process radiation monitors. The following discussion includes an evaluation of the safety-related process radiation monitors against each applicable SHINE Design Criterion.

This section of the SER documents the NRC staff's review and evaluation of the RMS design to perform its safety functions based on the appropriate design criteria to satisfy the 10 CFR 50.34(a)(3) and 10 CFR 50.34(b) requirements. The staff's evaluation of the RMS design is based on acceptance criteria in section 7.5 of NUREG-1537, Part 2, including acceptance criteria from the guidance and industry standards referenced by NUREG-1537.

Quality Standards and Records

> SHINE Design Criterion 1 – Safety-related structures, systems, and components (SSCs) are designed, fabricated, erected, and tested to quality standards commensurate with the safety functions to be performed. Where generally recognized codes and standards are used, they are identified and evaluated to

determine their applicability, adequacy, and sufficiency and are supplemented or modified as necessary to ensure a quality product in keeping with the required safety function.

A quality assurance program is established and implemented in order to provide adequate assurance that these SSCs satisfactorily perform their safety functions.

Appropriate records of the design, fabrication, erection and testing of safety-related SSCs are maintained by or under the control of SHINE throughout the life of the facility.

SHINE FSAR section 7.7.1.3.9 states that the safety-related process radiation monitors are designed, procured, fabricated, erected, and tested in accordance with the SHINE quality assurance program description and all associated quality records are maintained. The following codes and standards are invoked for design of the safety-related process radiation monitors:

- IEEE Standard 323-2003 for environmental qualification;
- IEEE Standard 344-2013, section 8 for seismic qualification;
- IEEE Standard 384-2008 for separation of safety-related and nonsafety-related cables and raceways; and
- IEEE Standard 1050-2004, section 5.2.1 to support electromagnetic compatibility qualification for digital I&C equipment.

Based on the above, the NRC staff has reasonable assurance that the safety-related process radiation monitors meet SHINE Design Criterion 1.

Natural Phenomena Hazards

SHINE Design Criterion 2 – The facility structure supports and protects safety-related SSCs and is designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches as necessary to prevent the loss of capability of safety-related SSCs to perform their safety functions.

Safety-related SSCs are designed to withstand the effects of earthquakes without loss of capability to perform their safety functions.

SHINE FSAR section 7.7.1.3.8 states that the safety-related process radiation monitors are installed in the seismically qualified portion of the main production facility where they are protected from earthquakes, tornadoes, and floods. The radiation monitors are Seismic Category I, designed and tested using triaxial testing in accordance with section 8 of IEEE Standard 344-2013. Based on the above and the NRC staff's evaluation in chapter 3 of this SER for natural phenomena, the staff finds that the safety-related process radiation monitors meet SHINE Design Criterion 2.

Environmental and Dynamic Effects

SHINE Design Criterion 4 – Safety-related SSCs are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility.

SHINE FSAR sections 7.7.1.3.2 and 7.7.1.4 state that the safety-related process radiation monitors are designed to operate under normal environmental conditions for an expected 20-year lifetime of the equipment, and under transient conditions until the associated protective function has continued to completion. These radiation monitors are qualified to the environmental parameters provided in SHINE FSAR tables 7.2-1, 7.2-3, and 7.2-6 in accordance with the guidance of IEEE Standard 323-2003, sections 4.1, 5.1, 6.1, and 7. EMI/RFI qualification testing has been performed on these radiation monitors through emissions, susceptibility, and surge withstand capability testing. The radiation monitors are grounded in accordance with IEEE Standard 1050-2004, section 5.2.1. Therefore, the NRC staff finds that the safety-related process radiation monitors meet SHINE Design Criterion 4.

Instrumentation and Controls

SHINE Design Criterion 13 – Instrumentation is provided to monitor variables and systems over their anticipated ranges for normal operation, for anticipated transients, and for postulated accidents as appropriate to ensure adequate safety, including those variables and systems that can affect the fission process, the integrity of the primary system boundary, the primary confinement and its associated systems, and the process confinement boundary and its associated systems. Appropriate controls are provided to maintain these variables and systems within prescribed operating range.

SHINE FSAR section 7.7.1.2.1 states that the safety-related process radiation monitors are designed to function during normal operation, anticipated transients, and design basis accidents to a level required to detect accident conditions and provide safety-related inputs to the ESFAS and TRPS to initiate protective actions, which are evaluated in sections 7.4.4 and 7.4.5 of this SER. Setpoints are selected based on analytical limits and calculated to account for known uncertainties in accordance with the setpoint methodology and these radiation monitors are periodically functionally tested and maintained. SHINE FSAR table 7.7-1 identifies the safety-related process radiation monitors and the corresponding analytical limits, ranges, accuracies, and response times are identified in SHINE FSAR tables 7.4-1 and 7.5-1. Therefore, the NRC staff finds that the safety-related process radiation monitors meet SHINE Design Criterion 13.

Monitoring Radioactivity Releases

SHINE Design Criterion 38 – Means are provided for monitoring the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material. Potential effluent discharge paths and the plant environs are monitored for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents.

SHINE FSAR section 7.7.1.2.2 states that the safety-related process radiation monitors provide radiation monitoring for the primary confinement boundary, hot cell, and glovebox atmospheres, and monitor effluent release paths. SHINE FSAR section 7.7.1.4.1 and SHINE FSAR table 7.7-1 identify the location for these related radiation monitors. The radiation monitors send an analog signal to the TRPS and ESFAS, which is then sent to the PICS for monitoring and alarming purposes. Based on the above and the NRC staff's evaluation in section 7.4.5.2.1 of this SER, the staff finds that the safety-related process radiation monitors meet SHINE Design Criterion 38.

7.4.7.1.3 Safety-Related Process Radiation Monitors Design Bases

Each safety-related process radiation monitor provides an analog signal proportional to the monitored radiation levels to the ESFAS or TRPS for performing the associated safety function. The TRPS and ESFAS are safety-related systems designed to monitor process variables and provide automatic initiating signals in response to off-normal conditions, providing protection against unsafe conditions. The HIPS digital I&C platform is used to implement the TRPS and ESFAS logic and the design bases associated with the HIPS platform are evaluated in section 7.4.2.5 of this SER. The TRPS and ESFAS specific design bases are evaluated in sections 7.4.4.3 and 7.4.5.3 of this SER, respectively. The following is the NRC staff's evaluation of the safety-related process radiation monitors specific design bases.

Design Bases Functions

SHINE FSAR section 7.7.1.3.1 states that the safety-related process radiation monitors are selected based on the presence of radiation materials in the different areas of the facility. As determined by the safety analysis, each location that requires process radiation monitoring is equipped with a safety-related process radiation monitor. SHINE FSAR table 7.7-1 contains a list of safety-related process radiation monitors along with the monitored location, number of sensing channels, and operability requirements. Process radiation monitors are selected for compatibility with the normal and postulated accident environmental and radiological conditions. The safety-related process radiation monitors are designed to function during normal operation, anticipated transients, and design basis accidents to a level required to detect accident conditions and provide safety-related inputs to the ESFAS and TRPS for initiating protective actions. If the measured radiation field goes above the full-scale, the analog output from the safety-related process radiation monitor will be equivalent to the full-scale reading. The TRPS or ESFAS will process this signal as a valid, full-scale value. For defense-in-depth, the RCA exhaust, general area radiation levels, and airborne particulates are monitored by stack release, radiation area, and continuous area monitors, respectively.

Single Failure

SHINE FSAR section 7.7.1.3.3 states that two or three redundant and independent safety-related process radiation monitors are provided for each protection function input parameter, each providing input to the associated division of the TRPS or ESFAS. Channel A safety-related process radiation monitors are powered by UPSS Division A, Channel B safety-related process radiation monitors are powered by UPSS Division B, and Channel C safety-related process radiation monitors, when provided, receive auctioneered power from both UPSS Divisions A and B. On a loss of power to a safety-related process radiation monitor, analog output to the TRPS or ESFAS fails low, and a trip or a partial trip signal is initiated for the associated safety function.

Based on the above, the NRC staff's evaluation of single failure of the TRPS and ESFAS in sections 7.4.4.2.1 and 7.4.5.3.3 of this SER, respectively, and the staff's evaluation of the HIPS design in section 7.4.2 of this SER, the staff finds that a single failure of a safety-related process radiation monitor will not adversely impact the associated safety function.

Independence

SHINE FSAR section 7.7.1.3.4 states that physical separation is maintained between divisions of safety-related process radiation monitors, and division independence is maintained from the safety-related process radiation monitors through the TRPS and ESFAS. The safety-related process radiation monitors provide analog signals directly to the TRPS and ESFAS and do not interface electrically with any nonsafety-related system. Safety-related process radiation monitors from separate divisions are independently powered from the associated UPSS division.

Based on the above, the NRC staff finds that the design of the safety-related process radiation monitors demonstrates adequate independence such that a failure in a redundant channel or in a nonsafety-related system would not adversely impact any associated safety function.

Technical Specifications

Section 7.4.10.4, “Radiation Monitoring Technical Specifications,” of this SER provides the NRC staff’s review of the SHINE TSs related to radiation monitoring.

7.4.7.2 Conclusion

Based on the above, the NRC staff finds that the SHINE RMS is designed to perform radiation monitoring functions within the facility that include safety-related and nonsafety-related radiation monitoring equipment. Each safety-related process radiation monitor provides an analog signal proportional to the monitored variable to the ESFAS or TRPS for performing the associated safety function. Nonsafety-related process radiation monitors, RAMS, CAMS, and SRMS monitor several areas of the facility and provide information to the operator on the status and effectiveness of processes and effluent monitoring. Nonsafety-related process radiation monitors may be used to diagnose process upsets but do not perform an accident mitigation or personnel protection function. The evaluation of the nonsafety-related RMS for radiation protection is in section 11.4.1.4, “Radiation monitoring and Surveying,” of this SER. The staff also finds that the design of the safety-related process radiation monitors meets SHINE Design Criteria 1, 2, 4, 13, and 38. Therefore, the staff concludes that the RMS is capable of performing the allocated design basis function under postulated conditions.

7.4.8 Neutron Flux Detection System

The NRC staff evaluated the sufficiency of the SHINE facility NFDS, as described in SHINE FSAR section 7.8, “Neutron Flux Detection System,” using the applicable guidance and acceptance criteria from chapter 7, “Instrumentation and Control Systems,” of NUREG-1537, Parts 1 and 2, and chapter 7, “Instrumentation and Control Systems,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

7.4.8.1 System Description

SHINE FSAR section 7.8 states that the NFDS will measure, monitor, and indicate the neutron flux levels in the TSV during filling and irradiation of the target solution. The NFDS consists of three divisions. Each division consists of watertight detectors located in the light water pool and an NFDS amplifier mounted in the RPF or IF. The NFDS provides data to the TRPS for safety functions, monitoring, and indication, and also interfaces with the PICS for nonsafety-related functions.

SHINE FSAR section 7.8 states that the NFDS covers the entire range of neutron flux levels. There are three different ranges provided from the NFDS: source range, wide range, and power range. Source range covers the low levels expected while the TSV is being filled and power range covers the higher flux levels anticipated while the neutron driver is on and irradiating. The wide range monitors the flux levels between the source and power range with a minimum of a one-decade overlap with the high end of the source range and a two-decade overlap with the low end of the power range. SHINE FSAR table 7.4-1 identifies the instrument range, accuracy, response time, logic, and analytical limit. SHINE TS table 3.2.3-a identifies the setpoints for the monitored variables. When any neutron channel reaches its defined setpoint for action, the TRPS will generate and output a signal to isolate the IU Cell.

As summarized above, the SHINE FSAR describes the variables monitored by the NFDS. In the SHINE TSs, the applicant identified the neutron flux to maintain LSSS 2.2.1, 2.2.2, and 2.2.3. These LSSSs were established to protect the primary system boundary pressure safety limit.

The three detectors for the NFDS are positioned around the SASS at approximately 120-degree intervals to the TSV.

7.4.8.2 Conclusion

As described in section 7.4.4 of this SER, the NRC staff evaluated the NFDS as part of its evaluation of the TRPS as instrumentation inputs to the TRPS. Therefore, the findings for the TRPS are applicable to the NFDS as appropriate. The staff has reasonable assurance that the NFDS is adequately described in SHINE FSAR section 7.8. The staff finds that the NFDS is adequately designed for measurement of the neutron flux signal, signal processing, indication, and interfacing with other systems, including providing analog input to the TRPS. The staff's review of the lifecycle development process for HIPS is described in section 7.4.2 of this SER, and the adequacy of HIPS and the TRPS and NFDS related TSs is evaluated in section 7.4.10 of this SER. Therefore, the staff concludes that the TRPS and NFDS are capable of performing the allocated design basis safety function under postulated conditions.

7.4.9 Human Factors Engineering

The NRC staff evaluated the sufficiency of SHINE's HFE, as described in SHINE FSAR chapter 3, "Design of Structures, Systems, and Components," chapter 7, "Instrumentation and Control Systems," chapter 12, "Conduct of Operations," and chapter 13, "Accident Analysis," using the applicable guidance and acceptance criteria from NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The NRC staff reviewed the HFE-related portions of SHINE FSAR chapters 3, 7, 12, and 13 to assess the sufficiency of the HFE-related design aspects and programmatic considerations for the SHINE facility. To allow for the appropriate scoping and grading of its HFE review, the staff considered the credited operator role in facility safety, including for defense-in-depth (DID), within the context of the SHINE facility design and operational concept. As part of this review, the staff evaluated the sufficiency of the SHINE Design Criterion for the control room, as well as the ability of the control room to meet that design criterion. Additionally, the staff evaluated whether the control console and display system final design incorporates HFE principles in accordance with relevant guidance. Finally, the staff evaluated whether HFE-related aspects of the administrative controls and management measures programs are sufficient to support the operator role in the safe operation of both the IF and RPF portions of the SHINE facility.

7.4.9.1 SHINE Design Criterion 6

SHINE uses design criteria to ensure that the SSCs within the SHINE facility demonstrate adequate protection against the hazards present. The design criterion that is within the scope of the NRC staff's HFE review is Criterion 6, "Control room," which states:

> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

As part of its HFE review, the NRC staff evaluated the sufficiency of SHINE Design Criterion 6 for the SHINE facility control room, as well as the ability of the control room to, in turn, meet SHINE Design Criterion 6.

In its response to NRC staff RAI HFE-8 (ML21288A050), SHINE clarified that it developed SHINE Design Criterion 6 using General Design Criterion (GDC) 19, "Control room," of Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 as a basis. GDC 19 states, in part, that "[a] control room shall be provided from which actions can be taken to operate the nuclear power unit safely under normal conditions and to maintain it in a safe condition under accident conditions …." SHINE explained that the scope of GDC 19 is limited to a nuclear power unit and that SHINE's IUs represent the closest analog to a nuclear power unit for the SHINE facility. However, SHINE further stated that the scope of SHINE Design Criterion 6, which refers specifically to the IUs, does not limit the scope of the control room functions that are incorporated into the final design of the SHINE facility and that the control room allows for the operation of systems and components related both to the IUs in the IF and to the RPF.

Regulatory Guide 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors" (ML17325A611), contains guidance on how the GDC in Appendix A to 10 CFR Part 50 may be adapted for non-light-water reactor designs. This regulatory guide includes Advanced Reactor Design Criterion (ARDC) 19, which is comparable to SHINE Design Criterion 6 and states, in part, that "[a] control room shall be provided from which actions can be taken to operate the nuclear power unit safely under normal conditions and to maintain it in a safe condition under accident conditions …."

The NRC staff compared SHINE Design Criterion 6 to GDC 19 and ARDC 19 and determined that it is consistent with the HFE aspects of these criteria with appropriate changes based on differences in technology. Therefore, the staff finds that SHINE Design Criterion 6 is sufficient to support the safe operation of the SHINE facility with respect to HFE.

7.4.9.2 The Operator's Role in SHINE Facility Safety

The SHINE FSAR includes the following characterizations concerning the role of humans at the SHINE facility:

- Manual actuations of automated safety functions are not required to ensure adequate safety of the facility (SHINE FSAR section 7.6.1.1);

- There are no time constrained operator-required responses (SHINE FSAR section 7.6.2.2.3);

- Operator action inside the facility is not required to stabilize accident conditions (SHINE FSAR section 13a2.2);

- Safe shutdown conditions are capable of being achieved without operator actions (SHINE FSAR section 13b.2.3);

- The main control board, PICS, and NDAS operator workstations and supervisor workstation are not credited with performing safety functions and only assist operators in performance of normal operations or diverse actuations to the safety systems (SHINE FSAR section 7.6);

- The TRPS and ESFAS are the safety-related control systems for the main production facility (SHINE FSAR section 7.3.1.3.11);

- Preventative or mitigative controls are identified to reduce the overall risk of the evaluated scenarios to within acceptable limits (SHINE FSAR section 13b.1.2); and

- The radiological consequences of criticality accidents are not included in the accident analysis because preventative controls are used to ensure criticality events are highly unlikely (SHINE FSAR section 13b.1.2.4).

In its response to NRC staff RAI HFE-1 (ML21288A050), SHINE clarified that certain operator actions are credited to prevent or mitigate specific accident sequences and that those credited operator actions (referred to as specific administrative controls (SACs)) occur during routine activities within the facility. SHINE stated that the operator role in facility safety is supported by HFE via implementation of the SHINE HFE Program. This program ensures that the control room and human system interfaces conform to specific style guidance via the use of a checklist that is used to verify that SHINE's HFE design guidelines are met and that the physical installation of systems and components adhere to the HFE design guidelines. SHINE also stated that the operator role in facility safety is supported by procedure development and training programs. Additionally, SHINE FSAR section 12.1.3 states that there are no postulated accident sequences that credit operator action to mitigate the consequences of the event after initiation of the event and that should an initiating event of a postulated accident sequence occur, operator actions provide a DID, nonsafety-related, diverse means of actuating components. SHINE FSAR section 7.6.3.3 further states that modifications to safety-related I&C systems after the SHINE facility is in operation will include human factors considerations and that issues related to human factors will be identified and tracked to resolution using the corrective action program.

The NRC staff assessed and confirmed that the role of operators with respect to safety at the SHINE facility is associated with (1) DID actions and (2) the implementation of administrative controls, with the administrative controls themselves not involving mitigative actions for event response. This information was applied to scope the review used to make the regulatory findings in sections 7.4.9.3, 7.4.9.4, and 7.4.9.5 of this SER.

7.4.9.3 Application of Human Factors Engineering Principles to the SHINE Facility Control Room

The NRC staff evaluated the HFE-related acceptance criteria in section 7.6, of NUREG-1537, Part 2 as they relate to the specifics of the SHINE facility's design and equipment configuration. The staff's interpretation of these acceptance criteria within the context of the SHINE facility and their evaluation from an HFE perspective is detailed in sections 7.4.9.3.1 through 7.4.9.3.3 of this SER. Additionally, SHINE's HFE Program, which is also relevant to the evaluation of these acceptance criteria, is evaluated in section 7.4.9.3.4 of this SER.

7.4.9.3.1 Outputs and Display Devices Observability Acceptance Criterion

The NRC staff evaluated the following acceptance criterion in section 7.6 of NUREG-1537, Part 2 as it relates to the specifics of the SHINE facility's design and equipment configuration:

> The outputs and display devices showing … nuclear status should be readily observable by the operator while positioned at the … control and manual protection systems.

As explained below, the NRC staff determined that within the context of the SHINE facility, the "control" systems are the PICS and the NDAS and the "protection" systems are the TRPS and the ESFAS. The staff then evaluated whether outputs and display devices showing parameters related to SHINE facility safety would be readily observable by the operator while positioned at the SHINE facility control room operator PICS and NDAS workstations and the main control board TRPS and ESFAS manual actuation controls.

The NRC staff reviewed the description of outputs and display devices for parameters related to SHINE facility safety provided in the SHINE FSAR. SHINE FSAR section 7.6 describes the SHINE facility control room as containing a main control board, two PICS operator workstations, two NDAS workstations, and a supervisor workstation. The operator workstations consist of display screens and human interface equipment, and the main control board consists of a console, static display screens, and manual actuation interfaces.

SHINE FSAR section 7.6.1.1 states that the main control board static display screens, which show the variables important to the safety functions of the IUs and other facility processes, are located on the upper half of the main control board, aligned in three rows of displays. SHINE FSAR section 7.6.2.2.3 states that the main control board is readily accessible by operators normally located at either PICS operator workstation. SHINE FSAR section 7.6.2.2.3 also states that the parameters required to be displayed for the TRPS and ESFAS are displayed on the main control board and are accessible from the operator and supervisor workstations. TRPS and ESFAS indications and manual actuation controls are further evaluated in section 7.4.9.3.2 of this SER.

SHINE FSAR section 7.6.3.3 further states that the design of the SHINE facility control room, display screens, and operator interfaces incorporates HFE principles by means of the implementation of the SHINE HFE Program. The layout of screens presenting the same set of information at multiple locations is identical at each location (i.e., PICS operator workstation, supervisor workstation, local control station, or main control board). The displays and controls are generally grouped by system to aid the operator in the recognition and operation of the controls. The supervisor workstation is placed and arranged so that the supervisor has a visual of both operator workstations, the displays that the operators are working from, and the main control board. Operator workstations are oriented such that the main control board static display screens are directly in front of the operator workstation. During its audit, the NRC staff verified these SHINE FSAR statements in part through observing that the HFE design guidelines in SHINE's TECRPT-2020-0018, "Human Factors Engineering (HFE) Design Guidelines," include guidelines related to the observability, content, readability, and arrangement of displays. Additionally, the staff observed that those guidelines were based, in part, on portions of NUREG-0700, Revision 2, "Human-System Interface Design Review Guidelines" (ML021700337). The results of the staff's audit are documented in the audit report (ML22124A073).

Based on the above, the NRC staff finds that the applicant has demonstrated that the outputs and display devices observability acceptance criterion in section 7.6 of NUREG-1537, Part 2 is satisfied because outputs and display devices showing parameters related to SHINE facility safety are readily observable by the operator while positioned at the SHINE facility control room PICS and NDAS operator workstations and at the main control board TRPS and ESFAS manual actuation controls. This finding is further supported by SHINE's HFE Program, which is evaluated in section 7.4.9.3.4 of this SER.

7.4.9.3.2 Accessibility/Understandability of Important Controls and Displays Acceptance Criterion

The NRC staff evaluated the following acceptance criterion in section 7.6 of NUREG-1537, Part 2 as it relates to the specifics of the SHINE facility's design and equipment configuration:

> Other controls and displays of important parameters that the operator should monitor to keep parameters within a limiting value, and those which can affect the reactivity of the core should be readily accessible and understandable to the reactor operator.

As explained below, the NRC staff determined that within the context of the SHINE facility, other controls and displays of important parameters that the operator should monitor to keep parameters within a limiting value, and those that can affect reactivity, are readily accessible and understandable to the operator.

<u>Other Controls and Displays (Not Specific to Manual Protective Actions)</u>

The NRC staff reviewed the description in the SHINE FSAR of other SHINE facility control room controls and displays of important parameters. SHINE FSAR section 7.6.2.2.7 states that the design of the SHINE facility control room, display screens, and operator interfaces incorporates HFE principles. Displays that an operator may use to perform a task are placed such that they are visible from the operator workstation, with the displays most frequently used placed closest to the operator. The supervisor workstation is placed and arranged so that the supervisor can see both operator workstations, the displays that the operators are working from, and the main control board. SHINE FSAR section 7.6.3.1 describes the supervisor workstation as providing displays so that the supervisor can select and monitor the appropriate screen applicable to the current tasks being performed by the operator. SHINE FSAR section 7.6.1.2 describes that there are four desks that make up the main operator workstations, centrally located in front of the main control board, which has TRPS and ESFAS indications and manual actuation controls; the two outermost desks are designated as PICS workstations and the two inner desks are NDAS control stations. SHINE FSAR section 7.6.4.1 describes what displays of information related to the operation of the main production facility are available to the operator on the workstations and the main control board. The displays at each of the operator workstations, supervisor workstation, and main control board are digital displays. Displays are programmed such that the range of the displayed information includes the expected range of variation of the monitored variable.

SHINE FSAR section 7.1.1 describes the PICS as a nonsafety-related, distributed digital control system that provides monitoring and control of the various processes throughout the SHINE facility. The PICS includes system controls, both automated and manual, and human system interfaces necessary to provide the operator interaction with the necessary process control mechanism. The functions of the PICS enable the operator to perform irradiation cycles, transfer target solution to and from the IUs, as well as throughout the RPF, and interface with the TPS, processes in the supercell, waste handling operations, and the auxiliary systems. SHINE FSAR section 7.6.4.1 states that values on each PICS display screen are automatically updated as more current data becomes available. Section 7.6.4.1 also states that each PICS display screen presented on the operator workstation has a title or header and unique identification to distinguish each display page. SHINE FSAR section 7.6.4.3 states that manual controls are provided on both of the PICS operator workstations (via input to the PICS) and on the main control board, with controls for normal operation provided at the operator workstations. Multiple equipment control displays are set up at each operator workstation for operators to select the PICS (or NDAS) display screen that coincides with the task that the operator is currently performing. Operators interface with the equipment control displays through a keyboard and mouse provided at each operator workstation. SHINE FSAR section 7.6.4.3 also states that on a failure of one PICS operator workstation, the control functions assigned to that station can be transferred to the remaining PICS operator workstation or to the supervisor workstation.

SHINE FSAR section 7.6.4.3 states that an enable nonsafety switch is in each main control board section next to the manual push buttons to allow the operator to control actuation components or to reset the safety-related control systems using the PICS following the actuation of a protective function. The enable nonsafety switch is described as a two-position switch with Enable and Disable positions. Additionally, a single manual key switch is located at the facility process section of the main control board below the static display screens to provide the operators the ability to place the facility into the Facility Secure state. This switch is described as having two positions of operation: Secured and Operating.

Additionally, SHINE FSAR section 7.6.4.1 states that each of the variables associated with the TRPS and ESFAS are continuously displayed on the static displays of the main control board. The position indication of actuation components associated with TRPS and ESFAS are also available on the static display screens. Variables available to the PICS, including variables associated with the TRPS and ESFAS, are available for display on the various PICS displays at the operator workstations and supervisor workstation. Display of interlock and bypass status is available on each of the PICS displays of the equipment control display screens for the equipment or instrument channel that has been bypassed. Bypassed channels for the safety systems are also visible on the maintenance workstation. Additionally, the variables displayed at the PICS operator workstation displays include both those that would be associated with a breach of the primary system boundary and those that would be used in determining and assessing the magnitude of a radioactive material release.

SHINE FSAR section 7.6.3.1 describes the NDAS control stations as displaying variables associated with the neutron drivers located in each IU. SHINE FSAR section 7.3.1.1.5 states that the NDAS control system also allows the operator to manually adjust the deuterium beam, control the ion source, manually start and stop various system auxiliaries, and open and close

NDAS system valves. The operator uses the PICS to provide signals to manually open or close the neutron driver high voltage power supply breakers to meet TRPS mode transition criteria and allow the beam to be energized. The operator is able to use the PICS to manually open and close individual valves that are capable of being actuated by the TRPS. SHINE FSAR section 7.6.4.3 states that while the NDAS control stations can each provide control of any of the eight neutron drivers, each NDAS control station can only provide control commands to one neutron driver at any given time.

SHINE FSAR section 7.3.1.1.6 states that the NFDS monitors the neutron flux in the IU during TSV fill and irradiation. Furthermore, SHINE FSAR section 7.8.3.9 states that the NFDS provides source range, wide range, and power range neutron flux signals to the TRPS to transmit to the PICS for display to the operator. SHINE FSAR section 7.8.1 states that the NFDS performs the task of monitoring and indicating the neutron flux to determine the multiplication factor and power level during filling of the TSV and irradiating the target solution. The NFDS also provides continuous indication of the neutron flux during operation, from filling through maximum power during irradiation.

Finally, SHINE FSAR section 7.6.4.1 states that radiation monitoring information is conveyed from the radiation monitoring instruments to the PICS and displayed in the SHINE facility control room, where it is available on demand at the operator workstations. SHINE FSAR section 7.7.1.1 further states that information from safety-related process radiation monitors is displayed in the SHINE facility control room on the operator workstations via the PICS. SHINE FSAR section 7.7.1.3.6 states that selection and display of safety-related process radiation monitor variables are designed with consideration of HFE principles.

During its audit, the NRC staff verified these FSAR statements in part through observing that the HFE design guidelines in SHINE's TECRPT-2020-0018 include guidelines related to the accessibility of controls and displays, as well as guidelines associated with the understandability of displays. Additionally, the staff observed that those guidelines were based, in part, on portions of NUREG-0700, Revision 2.

Other Controls and Displays (Specific to Manual Protective Actions)

The NRC staff also considered controls used for the manual initiation of protective actions under the accessibility and understandability acceptance criterion in section 7.6 of NUREG-1537, Part 2. SHINE FSAR section 7.3.1.3.11 states that the TRPS and ESFAS are the safety-related control systems for the main production facility. Therefore, the staff evaluated the applicant's description of how the SHINE human system interface (HSI) supports the operator's role in DID by implementing the manual initiation of protective actions that are automatically actuated by the TRPS and ESFAS.

SHINE FSAR section 7.4.3.7 states that the TRPS provides manual actuation capabilities via individual manual push buttons for each TRPS subsystem (i.e., IU Cell Safety Actuation, IU Cell Nitrogen Purge, and Driver Dropout). Both TRPS divisions (i.e., A and B) respond to the activation of a push button. Furthermore, a manual IU Cell TPS actuation on all eight TRPS subsystems is initiated via the manual TPS Isolation push button located on the ESFAS main control board panel. To support the use of manual safety actuations, the TRPS subsystem associated with each IU cell includes outputs for each safety-related instrument channel to provide monitoring and indication information to the PICS. To facilitate operator indication of mode control status, TRPS actuation function status, manual initiation, and reset of protective actions, the TRPS, at the division level, includes indication of TRPS variable values, parameter values, logic status, equipment status, actuation device status, and mode. SHINE FSAR section 7.4.2.2.14 states that human factors are a design consideration for the development of the TRPS and that changes to the design throughout the lifecycle process include human factors considerations. The TRPS provides manual safety actuation capability that is supported by human factors design and to support the use of manual safety actuations, the TRPS associated with each IU includes isolated outputs for each safety-related instrument channel to provide monitoring and indication information to the PICS.

SHINE FSAR section 7.5.3.6 states that the ESFAS provides manual actuation capabilities for safety functions (i.e., RCA Isolation, Supercell Isolation, VTS Actuation, TPS Isolation, Carbon Delay Bed 1, 2, and 3 Isolations, Extraction Column A, B, and C Alignment Actuations, Iodine and Xenon Purification Alignment Actuation, RPF Nitrogen Purge, and Dissolution Tank Isolation) via manual push buttons located on the main control board. To support the use of manual actuations, the ESFAS includes isolated outputs for each safety-related instrument channel to provide monitoring and indication information to the PICS. To facilitate operator indication of ESFAS actuation function status, manual initiation, and reset of protective actions, the ESFAS, at the division level, includes indication of ESFAS variable values, parameter values, logic status, equipment status, and actuation device status. SHINE FSAR section 7.5.2.2.14 states that human factors are a design consideration for the development of the ESFAS and that changes to the design throughout the lifecycle process include human factors considerations. SHINE FSAR section 7.5.2.2.14 also states that the ESFAS provides manual safety actuation capability that is supported by human factors design and that to support the use of manual safety actuations, the ESFAS includes isolated outputs for each safety-related instrument channel to provide monitoring and indication information to the PICS.

Additionally, SHINE FSAR section 7.6.3.1 states that each IU-specific set of static display screens on the main control board indicates variables important for verifying proper operation of safety systems following automatic actuation of the TRPS. Similarly, the facility process set of static display screens indicates variables important for verifying proper operation of safety systems used in other facility systems following automatic actuation of the ESFAS. Each set of static display screens on the main control board is used to support an operator in performing manual actuation of a safety function. Manual actuations are performed from the main control board, where the static display screens are visible from the manual actuation push buttons. SHINE FSAR section 7.6.4.1 states that each of the variables associated with the TRPS and ESFAS is continuously displayed on the static displays of the main control board, with the position indication of actuation components associated with the TRPS and ESFAS also being available on the static display screens.

In its response to RAI 7-13, SHINE stated, in part, that the TRPS and ESFAS information displayed in the SHINE facility control room includes mode and fault status for each HIPS module, the status and value of the monitored variables identified in SHINE FSAR tables 7.4-1 and 7.5-1, Trip/Bypass switch status, divisional partial and full trip determination status, TRPS IU cell operational mode status, actuation output and fault status, and actuated component position feedback status. SHINE stated that this will enable operators to determine if manual actuation of a safety function is necessary by providing information on TRPS and ESFAS monitored variables, as well as on the status of those systems themselves. Additionally, SHINE stated that TRPS and ESFAS information will be provided to operators via the PICS workstations in the SHINE facility control room, with a subset of the TRPS and ESFAS monitoring and indication information also being displayed at the main control board, thus providing this information at multiple locations in the control room (including near the manual controls for actuating TRPS and ESFAS equipment). SHINE described this as being intended to ensure that operators have the information needed to support manual actions.

Furthermore, SHINE FSAR section 7.6.4.3 states that manual controls for the safety-related TRPS and ESAFS protective functions are located at the main control board and that these nonsafety manual push buttons provide a diverse actuation to the automatically generated safety actuations. SHINE FSAR section 7.6.3.3 states that the manual actuation push buttons are located directly below the static display screens so that the operator can be directly monitoring the variables important to the safe operation of the facility when the manual actuation is performed. SHINE stated that the use of push buttons of the same product line ensures consistency in look and function. These push buttons also include a positive position indication and a protective guard to prevent inadvertent actuation.

The NRC staff finds that the applicant has demonstrated that the HSI will be capable of supporting the manual initiation of protective actions because displays and controls will be available in the SHINE facility control room for the manual, system-level actuation of safety functions and for monitoring those parameters that support them.

<u>Conclusion on Other Controls and Displays</u>

Based on the above, the NRC staff finds that the applicant has demonstrated that the accessibility and understandability of other controls and displays acceptance criterion in section 7.6 of NUREG-1537, Part 2 is satisfied because SHINE facility control room controls and displays of important parameters that the operator should monitor to keep parameters within a limiting value, and those that can affect reactivity, are readily accessible and understandable to the operator. This finding is further supported by SHINE’s HFE Program, which is evaluated in section 7.4.9.3.4 of this SER.

7.4.9.3.3 Control Console Annunciators and Alarms Acceptance Criterion

The NRC staff evaluated the following acceptance criterion in section 7.6 of NUREG-1537, Part 2 as it relates to the specifics of the SHINE facility’s design and equipment configuration:

> Annunciators or alarms on the control console should clearly show the status of systems such as operating systems, interlocks, [engineered safety features] initiation, radiation fields and concentration, and confinement or containment status.

As explained below, the NRC staff determined that within the context of the SHINE facility, the annunciators and alarms on the control console clearly show the status of systems such as operating systems, interlocks, TRPS and ESFAS initiation, radiation fields and concentration, and confinement.

SHINE FSAR section 7.6.4.2 states that alarms are integrated into the PICS display systems. The operator workstations provide detailed visual alarms to the operator to represent unfavorable status of the facility systems. Indications at the operator workstation are provided as visual feedback as well as visual features to indicate that systems are operating properly. Indication of alarms present is also provided for each IU and for the facility process systems at the main control board.

Additionally, SHINE FSAR section 7.6.3.1 states that the PICS operator workstations have multiple equipment control display screens available to support normal control functions and to provide indication of alarms. SHINE FSAR section 7.6.1.2 states that one of the screens at the PICS workstation is used to display the alarms present in the facility. This screen is designated as monitoring only so that, when an alarm is present, the screen automatically changes the content displayed to the current alarms that are present without interrupting a control process. The remaining screens can be used for control or monitoring as the operator tasks demand. SHINE FSAR section 7.3.1.3.11 states that the PICS receives input from the TRPS and ESFAS and provides alarms related to the status and functionality of the safety-related control systems (e.g., communication errors, faulted modules, failed power supplies).

Furthermore, SHINE FSAR section 7.1.6 states that radiation monitoring is used to monitor radiation levels within, and airborne effluent streams from, the SHINE facility and provides alarms for personnel within the facility and the control room. Area radiation monitoring and local alarms within the general areas of the facility RCA are provided by the RAMS, which provides signals to the control room to inform operators of abnormal conditions within the facility. Airborne contamination monitoring within general areas of the RCA is performed by the CAMS, which provides both local alarms and signals to the control room to inform operators of the occurrence and approximate location of abnormal conditions. SHINE FSAR section 7.6.1.5 states that the control room also contains a CAAS panel for processing alarms and monitoring the status of the CAAS, as well as a fire control panel for monitoring facility fire alarms from the facility fire protection system.

In its response to RAI HFE-3, SHINE clarified that stacklights, which produce audible alarm sounds and are programmed to represent both IU and non-IU alarms, are part of the control room and are evaluated with respect to HFE design guidelines both as part of initial installation and during future modifications. SHINE identified the following conditions as causing audible alarms: ESFAS actuation, TRPS actuation, high radiation or contamination levels, loss of electrical power, and improper transfer of target solution. SHINE also revised SHINE FSAR section 7.6.4.2 to provide additional description of control room alarms. Specifically, SHINE described that configurable stacklights are mounted above the main control board to provide audible and visual alarm indications. Alarms are provided to inform the operator of off-normal operating system status, interlocks, engineered safety feature initiations, confinement status, and radiation fields and concentration.

During its audit, the NRC staff verified these applicant statements in part through observing that the HFE design guidelines in SHINE's TECRPT-2020-0018 include guidelines related to the design of alarms. Additionally, the staff observed that those guidelines were based, in part, on portions of NUREG-0700, Revision 2.

Based on the above, the NRC staff finds that the applicant has demonstrated that the control console annunciators and alarms acceptance criterion in section 7.6 of NUREG-1537, Part 2 is satisfied because annunciators and alarms on the control console clearly show the status of systems such as operating systems, interlocks, TRPS and ESFAS initiation, radiation fields and concentration, and confinement. This finding is further supported by SHINE's HFE Program, which is evaluated in section 7.4.9.3.4 of this SER.

7.4.9.3.4 SHINE's Human Factors Engineering Program

The NRC staff evaluated SHINE's HFE Program and the way in which it is utilized. To support this evaluation, a regulatory audit was used to supplement the staff's understanding of the scope and nature of SHINE's HFE Program.

During its audit, the NRC staff verified the assertion in the SHINE FSAR that SHINE has an HFE program. The staff considered various aspects of SHINE's HFE Program that provide programmatic evidence that SHINE facility control room HSIs have been designed and evaluated in accordance with accepted human factors methods. Specifically, the staff noted that SHINE's HFE Program both establishes HFE design guidelines and implements a checklist-based process for verifying specific HFE attributes during equipment design, and then again following equipment installation. Further observations made regarding the specific content of SHINE's HFE Program, design guidelines, and associated checklists are documented in an audit report (ML22124A073).

SHINE FSAR section 7.6.3.3 states that human factors is a design consideration for the TRPS and ESFAS, that modifications to safety-related I&C systems after the SHINE facility is in operation will include human factors considerations, and that human factors issues are identified and tracked to resolution using the corrective action program.

The NRC staff finds that SHINE has elected to incorporate certain programmatic elements that include comparing the characteristics of HSIs with HFE guidelines, determining whether the HSI is acceptable according to those guidelines, and tracking and evaluating identified discrepancies. The use of an HFE style guide and checklists helps ensure that HSIs are designed, manufactured, and installed consistent with appropriate human factors principles, thereby supporting the ability of operators to safely operate the facility as required by SHINE Design Criterion 6. The staff also finds that these programmatic elements will be applicable to changes that are made to the safety-related TRPS and ESFAS throughout the lifecycle of the facility.

Based on its evaluations described in sections 7.4.9.3.1 through 7.4.9.3.4 of this SER, the NRC staff finds that the applicant has demonstrated that the applicable acceptance criteria in section 7.6 of NUREG-1537, Part 2 for the observability of outputs and display devices, for the accessibility and understandability of important controls and displays, and for control console annunciators and alarms are satisfied. Furthermore, the staff finds that SHINE's HFE Program supports the satisfaction of these acceptance criteria. Therefore, the staff concludes that SHINE has appropriately applied HFE principles to the SHINE facility control room.

7.4.9.4 Review Findings for Sections 7.4.9.1 through 7.4.9.3

In sections 7.4.9.1 through 7.4.9.3 of this SER, the NRC staff evaluated the sufficiency of SHINE Design Criterion 6 for the SHINE facility control room, as well as the ability of the control room to meet this criterion, and whether the control console and display system final design incorporates HFE principles in accordance with relevant guidance. Based on these evaluations, the staff finds that:

- The applicant has shown that all nuclear and process parameters important to the safe and effective operation of the SHINE facility will be displayed at the control console. The display devices for these parameters are easily understood and readily observable by an operator positioned at the facility controls and the controls are readily accessible.

- The annunciator and alarm panels on the control console provide assurance of the operability of systems important to safe facility operation.

- The HSI supports the manual initiation of protective actions at the system level for safety systems and provides displays and controls in the SHINE facility control room for manual, system-level actuation of safety functions, and for monitoring those parameters that support them.

The NRC staff therefore finds that the SHINE operators' DID role of manually actuating safety-related systems is reasonably supported by HFE principles and, furthermore, that the HFE-related aspects of SHINE Criterion 6 are met.

7.4.9.5 Administrative Controls Review

The NRC staff also evaluated the HFE-related aspects of SHINE's administrative controls. SHINE FSAR section 13b.1.2 states that accident scenarios that presented potential consequences above the appropriate evaluation guidelines for worker or public exposure were subjected to preventative or mitigative controls to reduce the overall risk to within acceptable limits. SHINE FSAR section 13b.1.2.4 states that nuclear criticality safety in the RPF is accomplished by using criticality safety controls to prevent criticality during normal and abnormal conditions and, furthermore, that the radiological consequences of criticality accidents are not included in the accident analysis because preventative controls are used to ensure that criticality events are highly unlikely. To adequately evaluate the applicable acceptance criteria of NUREG-1537, Part 2 and the ISG augmenting NUREG-1537, Part 2 for management measures that support the reliability of administrative controls, the staff determined that it was appropriate to supplement these criteria with relevant guidance from NUREG-1520, Revision 2. Specifically, section 11, "Management Measures," of NUREG-1520 was consulted for general guidance regarding appropriate areas for evaluation.

During its audit, the NRC staff verified the SHINE FSAR statements regarding administrative controls related to HFE in part through observing that the SACs and enhanced SACs identified by the applicant generally appeared to be comprised of activities in which procedures and training would constitute important, as well as cross-cutting, considerations. The staff noted that the SACs appeared to take place in a variety of plant locations and as such would not commonly be associated with any given HSI. Therefore, the staff determined that a scoped and graded review approach that focuses on the general ability of the applicant's procedures and training programs to support the reliable implementation of the administrative controls was appropriate. In implementing this review, the staff considered the guidance of NUREG-1520 in conjunction with the acceptance criteria of NUREG-1537, Part 2 and the ISG augmenting NUREG-1537, Part 2, sections 12.1 and 12.3. Sections 7.4.9.5.1 and 7.4.9.5.2 of this SER present the staff's evaluation, from an HFE perspective, of SHINE's administrative controls by procedures and training, respectively.

7.4.9.5.1 Procedures Management Program Support of Administrative Controls

The NRC staff evaluated whether the ability of SHINE operators to reliably implement administrative controls was adequately supported by SHINE's program for managing procedures. The staff informed this evaluation using areas described in NUREG-1520, section 11.3 and considered the following:

- The process for the preparation, use, and management control of written procedures;
- The method for verifying and validating procedures before use; and
- The method for ensuring that current procedures are available to personnel.

In its response to NRC staff RAI HFE-6 (ML21288A050), SHINE provided clarification that SACs are specifically defined, safety-related, administrative controls that are credited within the SHINE safety analysis. The SACs themselves are incorporated into facility procedures. SHINE further clarified that the SHINE HFE Program does not address programmatic administrative controls (i.e., management measures), but that programmatic administrative controls, such as procedures and training, serve to ensure that operators are provided with procedures and trained as needed to ensure the reliability of SACs.

SHINE FSAR section 12.3 states that procedures for the operation and use of the SHINE facility are written, reviewed, and approved by appropriate management and are controlled and monitored to ensure that the content is technically correct and that the wording and format are clear and concise. The process required to make changes to procedures, including substantive and minor permanent changes, and temporary deviations to accommodate special or unusual circumstances during operation, conforms to ANSI/ANS-15.1-2007, “The Development of Technical Specifications for Research Reactors.” Additionally, SHINE will prepare, review, and approve written procedures for topics including administrative controls for operations and maintenance and for the conduct of irradiations that could affect nuclear safety. The extent of detail in a procedure is dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error. The process for making changes and revisions to procedures is documented; a controlled copy of all operations procedures is maintained in the control room; and tasks are performed in accordance with approved implementing procedures.

In its response to NRC staff RAI HFE-6, SHINE also clarified that procedures are written and reviewed by operations personnel under the SHINE operating procedure development process. Procedures that include SACs are specifically reviewed by the Review and Audit Committee (described in SHINE FSAR section 12.2). Following these review processes, procedures are also verified and validated prior to issuance for use within the facility. Procedures that implement SACs are verified and validated to be technically accurate, comprehensive, explicit, and easy to use, such that assumptions made about the reliability of SACs in the SHINE safety analysis are supported via these processes.

Based on the above, the NRC staff finds that the applicant has demonstrated that the combination of processes used for the preparation, use, and management control of written procedures, the methods used for verifying and validating procedures before use, and the methods used for ensuring that current procedures are available to personnel supports the ability of SHINE operators to reliably implement administrative controls. Therefore, the staff concludes that the applicant’s procedures management program adequately supports the implementation of administrative controls.

7.4.9.5.2 Training and Qualification Program Support of Administrative Controls

The NRC staff evaluated whether the ability of SHINE operators to reliably implement administrative controls was adequately supported by SHINE's training and qualification program. The staff informed this evaluation using areas described in NUREG-1520, section 11.3 and considered the following:

- Provisions for the initial training of personnel;
- Personnel qualifications; and
- Provisions for the retraining of personnel.

SHINE FSAR section 12.10 states that the initial training program for operators was developed to conform to the requirements of 10 CFR Part 55, as it pertains to non-power facilities, following the guidance of ANSI/ANS 15.4-2016, "Selection and Training of Personnel for Research Reactors." The initial training program also contains, in part, the additional topics of criticality control features and management measures required for processes involving special nuclear material (SNM). During its audit, the NRC staff verified the SHINE FSAR statements regarding operator training in part through observing that both the operator initial and requalification training programs included training within the areas of design features (e.g., theory and principles of the radioisotope production process involving SNM, theory and principles of the radioisotope extraction and purification process, criticality control features and management measures required for each process involving SNM), reactivity, alterations and control systems, and uranium handling.

In its response to NRC staff RAI HFE-6, SHINE clarified that the operator training program ensures that individuals are trained in the knowledge, skills, and abilities needed to conduct assigned activities. The operator training program utilizes a systems approach to training, with the implementation and evaluation of the program including elements of self-study, classroom, mentoring, and simulation.

Based on the above, the NRC staff finds that the applicant has demonstrated that the combination of provisions for the initial training of personnel, personnel qualifications, and the retraining of personnel supports the ability of SHINE operators to reliably implement administrative controls. Therefore, the staff concludes that the applicant's training and qualification program adequately supports the implementation of administrative controls.

7.4.9.6 Conclusion

The NRC staff finds that the applicant has demonstrated that SHINE Design Criterion 6 is sufficient to support the safe operation of the SHINE facility with respect to HFE and that the HFE-related design aspects and programmatic considerations for the SHINE facility meet the HFE-related aspects of SHINE Design Criterion 6 because, within the specific context of the operator role in safety at the SHINE facility, operators will reasonably be able to take actions to control the facility; be provided with controls designed to support safe actions; have sufficient knowledge about the status of the facility; be able to make decisions about the appropriate course of action given a particular operating circumstance; and be provided with indications, displays, alarms, and controls that are designed to reflect cognitive needs.

The NRC staff finds that the applicant has demonstrated that the HFE-related design aspects of the SHINE facility control console and display instruments are acceptable because all nuclear and process parameters important to safe and effective operation of the SHINE facility will be displayed at the control console, the display devices for these parameters are easily understood and readily observable by an operator positioned at the facility controls, the controls are readily accessible, and the annunciator and alarm panels on the control console provide assurance of the operability of systems important to safe facility operation. Furthermore, within the specific context of the operator role in safety at the SHINE facility, the applicant has demonstrated that the HSI supports the manual initiation of protective actions for safety systems and provides displays and controls for manual actuation of safety functions and for monitoring those parameters that support them. Therefore, the staff concludes that the requirement of 10 CFR 50.34(b) for an operating license application to include a final analysis and evaluation of the SSCs of the facility showing that safety functions will be accomplished is met within the context of the HFE-related aspects of SHINE Design Criterion 6.

The NRC staff finds that the applicant has demonstrated that the HFE-related programmatic considerations for the SHINE facility, specifically the programs for procedures management and training and qualification, are acceptable, within the specific context of the operator role in safety at the SHINE facility, because they reasonably support the ability of SHINE operators to reliably implement administrative controls at the facility. Therefore, the staff concludes that the requirement of 10 CFR 50.57(a)(3) for reasonable assurance that activities authorized by the operating license can be conducted without endangering the health and safety of the public is supported by the application of HFE measures within the context of administrative controls.

7.4.10 Proposed Technical Specifications

As part of its application, SHINE submitted TSs as required by 10 CFR 50.34(b)(6)(vi) that are stated to be prepared in accordance with the requirements of 10 CFR 50.36. In this section, the NRC staff evaluates the sufficiency of the proposed TSs for the SHINE facility related specifically to SHINE FSAR chapter 7 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria. SHINE also provided proposed TS 1.4 to explain the meaning of logical connectors and completion times used throughout the TSs. The logical connectors and completion times are reviewed and found acceptable in section 14 of this SER. The SHINE reactivity control mechanisms are evaluated in section 4a.4.2.2 of this SER. The control console and display instruments are evaluated in sections 7.4.6 and 7.4.9, respectively, of this SER. Access control and cyber security are evaluated in sections 7.4.2.2.7, 7.4.3.2.2.1, and 12.4.14 of this SER.

7.4.10.1 Setpoint Methodology used for Safety System Setpoints

SHINE FSAR section 7.2.1 states that SHINE uses a documented methodology for establishing and calibrating setpoints for safety-related I&C functions. Instrument drift between calibrations is accounted for in the setpoint methodology. SHINE safety limits will not be exceeded if required actions are initiated before analytical limits are exceeded. Analytical limits are chosen to include a conservative margin between the analytical limit and the safety limit. The LSSS is the least conservative value that the instrument setpoint can be and still ensure that the analytical limits are not exceeded and that the safety limits are protected. The LSSS is separated from the analytical limit by an amount not less than the total loop uncertainty (TLU) for the setpoint determined by the SHINE setpoint methodology.

During its audit of the SHINE TSs, as documented in the NRC staff's audit report (ML22220A261), the staff reviewed several setpoint calculations to confirm that the results included conservative margin between the analytical limit and the limiting trip setpoints that accounted for the instrument TLU. SHINE established usage rules in TS SR 3.0.1.8 to ensure that during SRs the instrument setpoint is left within the as-left tolerance determined using the setpoint methodology, but in no cases less conservative than the instrument setpoint provided in the LCO. This bounds the equipment performance after calibration and helps ensure that a trip will occur before the AL is reached.

Based on the information provided in the SHINE FSAR, as supplemented, and reviewed during the NRC staff's audits, the staff finds that the SHINE methodology for establishing and calibrating setpoints is consistent with the guidance in ANSI/ISA-67.04.01-2006, "Setpoints for Nuclear Safety-Related Instrumentation," in establishing procedures for determining setpoints, setpoint margins, and test routines in safety-related instrument channels. Therefore, the staff finds SHINE's setpoint methodology used for safety system setpoints acceptable.

7.4.10.2 TRPS Technical Specifications

SHINE FSAR section 7.4.4.5, "Technical Specifications and Surveillance," states that LCOs and SRs are established for TRPS logic, voting, and actuation divisions and instrumentation monitored by TRPS as input to safety actuations. LCOs are established for components of the safety-related I&C systems that perform safety functions to ensure that the system will remain available to perform safety functions when required. SRs are performed at a frequency to ensure that LSSSs are not exceeded. Startup-testing conditions and first use of the instrumentation and the TRPS is discussed in SHINE FSAR section 12.11.2

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed TSs for the SHINE TRPS as described in SHINE FSAR chapter 7. The TRPS is addressed in the SHINE TSs at TS 2.2, "Limiting Safety System Settings (LSSS)," TS 3.2, "Instrumentation and Control Safety Systems," and TS 3.8, "Facility-Specific." TS 2.2 was reviewed and found acceptable in section 4a.4.9 of this SER. The staff's review of the TRPS is discussed in section 7.4.4 of this SER.

The proposed LCO 3.2.1 and SR 3.2.1 help ensure that the TRPS is able to perform its designed safety function. They state the following:

LCO 3.2.1	Divisions A, B, and C of the TRPS shall be Operable. Each TRPS Division A or B is Operable if: 3. Three scheduling, bypass and voting modules (SBVMs) are Operable 4. Two 5V power supplies are Operating 5. Two equipment interface modules (EIMs) for each TRPS actuation device are Operable TRPS Division C is Operable if: • Three scheduling and bypass modules (SBMs) are Operable • Two 5V power supplies are Operating Note – Actions 1, 2, 3, 4, 5, and 6 in Table 3.2.1 may be applied separately to each Division of TRPS associated with each IU. Note – Action 7 in Table 3.2.1 may be applied separately to each IU.
Applicability	Associated IU in Mode 1, 2, 3, or 4
Action	According to Table 3.2.1
SR 3.2.1	3. Check that the TRPS self-diagnostics indicate no failed modules prior to entering Mode 1. 4. Simulated automatic and manual actuation priority logic testing shall be performed every five years. Note – This SR cannot be deferred. 5. SBVM hardwired communications shall be tested quarterly. 6. Power supply voltages shall be tested semi-annually.

The proposed TS table 3.2.1, “TRPS Logic and Actuation Actions,” states the following:

	Condition and Action	Completion Time
1.	If one SBVM or SBM in a single Division is inoperable, Confirm that the SBVM or SBM is in the “tripped” state AND Restore the module to Operable.	 Immediately 72 hours
2.	If one 5V power supply in a single Division is inoperable, Restore the power supply to Operable.	 72 hours

3.	If one EIM in a single Division is inoperable, Restore the module to Operable OR Enter the corresponding action(s) for the inoperable component according to LCOs 3.1.5, 3.4.1, or 3.6.2.	 72 hours 72 hours
4.	If two EIMs associated with a single actuation component in a single Division are inoperable (and not actuating), Enter the corresponding action(s) for the inoperable component according to LCOs 3.1.5, 3.4.1, or 3.6.2.	 Immediately
5.	If two or more SBVMs in a single Division A or B are inoperable, OR If two 5V power supplies in a single Division A or B are inoperable, OR Action and associated completion time of Condition 1 or 2 not met for a Division A or B SBVM, Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 6 hours [[PROP/ECI]]
6.	If two or more SBMs in Division C are inoperable, OR If two 5V power supplies in Division C are inoperable, OR Action and associated completion time of Condition 1 or 2 not met for a Division C SBM, Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 12 hours [[PROP/ECI]]

7.	If two or more Divisions for an IU are inoperable, Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 1 hour [[PROP/ECI]]

LCO 3.2.1 specifies that all three divisions (Divisions A, B, and C) must be operable during Modes 1, 2, 3, and 4 (startup, irradiation, post-irradiation (shutdown), and transfer to the RPF). Operability for each division is specified in the LCO. Divisions A and B require the operability of the SBVMs, the EIMs, and the associated 5-volt power supplies and Division C requires the operability of the SBMs and the associated 5-volt power supplies. The LCO 3.2.1 required equipment is consistent with SHINE FSAR section 7.4.3.1 because the SFMs and the input channels are addressed in LCO 3.2.3 and the actuated components are addressed in LCO 3.4.1 (for primary confinement and primary system boundary components) and LCO 3.6.2 (for safety-related breakers). Similarly, the 24-volt power to the 5-volt power supplies are addressed in LCO 3.6.1 for the TRPS cabinets in each division. The proposed TS table 3.2.1 provides the deviations from LCO 3.2.1 that may be allowed under specified conditions, while restoring the system to operation. The completion times allow for the replacement of failed components, while limiting the amount of time that an IU is allowed to operate with reduced TRPS reliability. The 72-hour duration of the completion time for a single failed SBVM, SBM, 5-volt power supply, or EIM within a single division is acceptable because the output is received as a trip signal by the associated EIMs, and the output of a failed SBM is received as a trip signal by the Division A and B SBVMs, preserving the single failure criterion for the remaining operable modules. If more than one module or power supply fails or if the 72-hour completion time to restore operability will be exceeded, TS table 3.2.1 provides the additional times and steps to place the IU in a condition of applicability where the TRPS safety functions are not required (i.e., Mode 3 then Mode 0). The completion time for these transitions is based on the minimum time specified in LCO 3.1.8 to transfer target solution out of the IU to achieve Mode 0 (solution removed), which is acceptable because the redundant TRPS Division(s) are still available to sense adverse conditions. If two or more divisions for an IU are inoperable, actions are taken to place the IU in Mode 3 within an hour. This minimal time provides for an orderly IU shutdown. Based on the above, the NRC staff finds that the LCO 3.2.1 and the associated TS table 3.2.1 actions provide the conditions and actions required to help ensure that the TRPS is able to perform its safety functions specified by the SHINE safety analysis that are necessary to ensure that the IU is maintained in a safe state. Therefore, the staff finds LCO 3.2.1 and TS table 3.2.1 acceptable.

SR 3.2.1.1 requires checks for TRPS faults monitored by the end-to-end self-testing that covers each module from sensor input to the output switching logic prior to initiating IU startup. The discrete circuitry of the actuation and priority logic is not tested by self-testing, so SR 3.2.1.2 requires testing the priority logic for automatic and manual actuation and SR 3.2.1.3 and SR 3.2.1.4 verify operability of the hardwired communications and power supplies. The NRC staff finds that SR 3.2.1 prescribes the frequency and scope of required surveillances to demonstrate the performance of the TRPS logic and actuation and that the maximum allowable surveillance intervals are consistent with the guidance in ANSI/ANS-15.1-2007, section 4, “Surveillance requirements.” Therefore, the staff finds SR 3.2.1 acceptable.

The proposed LCO 3.2.3 and SR 3.2.3 help ensure that the input devices and the trip determination portions of the TRPS SFMs are able to initiate safety functions specified by the SHINE safety analysis, as described in SHINE FSAR subsection 7.4.3.1. They state the following:

LCO 3.2.3	TRPS input channels listed in Table 3.2.3-a shall be Operable. Note – Any single safety function module (SFM) associated with the wide, power, or source range neutron flux channels may be bypassed for up to 2 hours while the neutron flux variable(s) associated with the SFM is in the condition of applicability for the purpose of performing a Channel Calibration.
Applicability	Associated IU in Mode 1, 2, 3 or 4, according to Table 3.2.3-a
Action	According to Table 3.2.3
SR 3.2.3	1. Check that the TRPS self-diagnostics indicate no failed modules prior to entering Mode 1. 2. A Channel Check shall be performed on each channel listed in Table 3.2.3-a weekly. 3. A Channel Test shall be performed on TRPS instrument channels listed in Table 3.2.3-a quarterly. 4. A Channel Calibration shall be performed on each channel listed in Table 3.2.3-a annually.

The proposed TS table 3.2.3-a, "TRPS Instrumentation," states the following:

	Variable	Setpoint	Required Channels	Applicability (per IU)	Action	SR
a.	Wide range neutron flux	≤ 176% power	3	Modes 1 and 2	1, 2, 6	2, 4
b.	Power range neutron flux	≤ 85% power; averaged over ≤ 45 seconds [[PROP/ECI]]	3	Modes 1 and 2	1, 2, 6	2, 4

c.	Source range neutron flux	≤ 1.5 times the nominal flux at 95% volume of the critical fill height	3	Mode 1	1, 4, 6	2, 4
d.	TSV fill isolation valve position indication	Not Closed	2	Mode 2	5	3
e.	PCLS flow	[[PROP /ECI]]; IU Cell Safety Actuation delayed by ≤ 180 seconds	3	Modes 1 and 2	1, 2, 6	2, 4
f.	PCLS temperature	≤ 72.9°F; IU Cell Safety Actuation delayed by ≤ 180 seconds ≥ 63.5°F	3	Modes 1 and 2	1, 2, 6	2, 4
g.	Low-high TSV dump tank level	High level	3	Modes 1 and 2	1, 2, 6	3
h.	High-high TSV dump tank level	High level	3	Modes 1, 2, 3, and 4	1, 3, 7	3
i.	TOGS mainstream flow	[[PROP /ECI]]	3 (per train)	Modes 1, 2, 3, and 4	1, 3, 7	2, 4

The scope of LCO 3.2.3 is for each channel beginning at the input devices and including the associated SFMs and HWMs up to the inputs to the SBVMs or SBMs addressed in LCO 3.2.1. The proposed TS table 3.2.3-a provides the list of TRPS input channels required by LCO 3.2.3 and the applicable mode when each input channel variable is required to be operable. The NRC staff finds that, consistent with NUREG-1537, Part 1, appendix 14.1, this table specifies the setpoints, the minimum number of channels, and the operating mode when the channels are required. The TS table 3.2.3-a setpoints are evaluated in sections 7.4.4 and 7.4.5 of this SER. The staff finds that the setpoints are selected based on analytical limits and calculated to account for known uncertainties in accordance with the setpoint methodology and that the variables are periodically functionally tested as required by SR 3.2.3. TS table B-3.2.3, “TRPS Input Variable Allocation,” provided in the bases for LCO 3.2.3, shows the input device that provides a signal to each SFM or HWM for each division.

In addition to LCO 3.2.3, the NRC staff also reviewed proposed TS table 3.2.3, “TRPS Input Channel Actions.” TS table 3.2.3, which is very similar to proposed TS table 3.2.1, provides actions and completion times for when LCO 3.2.3 is not met and provides the deviations from LCO 3.2.3 that may be allowed under specified conditions, while restoring the system to operation. The completion times allow for the replacement of failed components, while limiting the amount of time that an IU is allowed to operate with reduced TRPS reliability. More than one input device provides a signal to each SFM or HWM. Each SFM can be placed in maintenance bypass or in a trip state by use of the OOS switch and an associated trip/bypass switch located below the SFM, as described in SHINE FSAR section 7.4.4.3. Normal actuation of the safety function occurs on 2-out-of-3 voting logic. However, when any single channel is inoperable (except for the TSV fill isolation valve), the SFM associated with the inoperable channel is required to be placed in trip within 2 hours, which changes the voting logic to 1-out-of-2, preserving single failure protection. If one or more TSV fill valve position indication is inoperable, TS table 3.2.3 requires shutting a TSV fill isolation valve or placing the IU In Mode 3 (shutdown). Based on the above, the staff finds that LCO 3.2.3, table 3.2.3, and table 3.2.3-a provide the conditions and actions required to help ensure that the TRPS is able to perform its safety functions specified by the SHINE safety analysis that are necessary to ensure that the IU is maintained in a safe state. Therefore, the staff finds LCO 3.2.3, table 3.2.3, and table 3.2.3-a acceptable.

SR 3.2.3.1 requires checks for TRPS faults monitored by the end-to-end self-testing that covers each module from sensor input to the output switching logic prior to initiating IU startup. SR 3.2.3.2, SR 3.2.3.3, and SR 3.2.3.4 provide for weekly checks, quarterly tests, and annual calibrations of the channels listed in TS table 3.2.3-a. To allow the performance of these SRs during IU operation, LCO 3.2.3 allows placing any single SFM in bypass for up to 2 hours during performance of a required SR calibration on a channel associated with that SFM, effectively changing the voting logic to 2-out-of-2 (with two other channels Operable) or 1-out-of-1 (with one other channel Operable). The NRC staff finds this 2-hour time constraint acceptable based on the presence of operations and maintenance personnel performing the test, the operability of the redundant channel(s), and the relatively short time period to perform the testing. Additionally, LCO 3.0.1.6 applies to SR 3.2.3.4 since entry into the mode of applicability (Mode 1) is required to perform the SR. This is a known and accepted deviation for calibrating flux monitoring equipment that is acceptable to the staff because of the minimal time a single SFM is bypassed and because the safety function of the operable channels or channel is not compromised. The staff finds that SR 3.2.3 prescribes the frequency and scope of required surveillances to demonstrate the continued operability of the process variable instrument channels and that the maximum allowable surveillance intervals are consistent with the guidance in ANSI/ANS-15.1, section 4. Therefore, the staff finds SR 3.2.3 acceptable.

The proposed LCO 3.8.5 and SR 3.8.5 for the NDAS help minimize the possibility of inadvertent personnel exposure during IU operations and are a part of the TS 1.3, “Definitions,” definition for “Facility Secured.” They state the following:

LCO 3.8.5	The NDAS two-key interlocks shall be in the “open” position.
Applicability	Personnel present in the associated IU cell containing an NDAS unit or in the neutron driver service cell (NSC)

SR 3.8.5	1. The function of the NSC driver interlock shall be tested quarterly. Note – This SR cannot be deferred. 2. The function of the IU cell driver interlock shall be tested prior to removal of the IU cell plug, and quarterly thereafter, while the IU cell plug is removed.

The NDAS is the accelerator-based assembly that accelerates a deuterium ion beam into a gas target chamber producing neutrons from the resulting fusion reaction. The NDAS two-key interlock disables the beam to prevent inadvertent exposure when personnel are present in the IU cell or neutron driver service cell. The NRC staff finds that the proposed LCO 3.8.5 and SR 3.8.5 help to protect personnel and ensure that the interlock is operable when required by the SHINE safety analysis, as described in SHINE FSAR section 13a2.1.12. The staff also finds that LCO 3.8.5 and SR 3.8.5 are an appropriate and acceptable means to protect personnel when they are in the IU cell. The staff finds that the incorporation of the NDAS two-key interlocks is an important aspect of when the facility is secured consistent with NUREG-1537, Part 1, appendix 14.1 that is appropriately adapted for the SHINE facility. The staff also finds that the requirements to test the interlocks are consistent with the periodicity recommendations of ANSI/ANS-15.1-2007. Therefore, the staff finds LCO 3.8.5 and SR 3.8.5 acceptable.

Although not specifically discussed in this section of the SER, the NRC staff also reviewed proposed LCO 3.4.1 and SR 3.4.1, LCO 3.9.1 and SR 3.9.1, LCO 3.9.2 and SR 3.9.2, and LCO 3.9.3 and SR 3.9.3 in relation to the TRPS. LCO 3.4.1 and SR 3.4.1 monitor the operability of the safety-related valves and dampers that are verified to stroke upon demand from the TRPS annually. TS 3.9 is related to specific deviations to the normal LCOs and SRs during startup testing as discussed in SHINE FSAR section 12.11.2. LCO 3.9.1 and LCO 3.9.2 permit specific deviations from LCO 3.2.3 and LCO 3.9.3 provides special conditions to permit the initial channel calibration of the NFDS power and wide range neutron flux channels. Based on information provided and reviewed, the staff finds these TSs acceptable.

Based on its review of the SHINE TSs applicable to the TRPS, the NRC staff finds that the LCOs and SRs help to ensure the operability of the TRPS, including the TRPS logic, voting, actuation divisions, and instrumentation monitored by the TRPS as input to safety actuations. The staff also finds that the setpoint values of the SHINE TSs for the TRPS are based on the SHINE setpoint calculations for the applicable process variables. Therefore, the staff finds the TSs related to the TRPS acceptable.

7.4.10.3 ESFAS Technical Specifications

SHINE FSAR section 7.5.4.6, “Technical Specifications and Surveillance,” states that LCOs and SRs are established for ESFAS logic, voting, and actuation divisions and instrumentation monitored by ESFAS as input to safety actuations. LCOs are established for components of the safety-related I&C systems that perform safety functions to ensure that the system will remain available to perform safety functions when required. SRs are performed at a frequency to ensure that LSSSs are not exceeded. SHINE FSAR section 7.2.1 states that SHINE uses a documented methodology for establishing and calibrating setpoints for safety-related I&C functions. Instrument drift between calibrations is accounted for in the setpoint methodology. SHINE safety limits will not be exceeded if required actions are initiated before analytical limits are exceeded. Analytical limits are chosen to include a conservative margin between the analytical limit and the safety limit. The LSSS is the least conservative value that the instrument setpoint can be and still ensure that the analytical limits are not exceeded and the safety limits are protected. The LSSS is separated from the analytical limit by an amount not less than the TLU for the setpoint determined by the SHINE setpoint methodology. Startup-testing conditions and first use of the instrumentation and the ESFAS is discussed in SHINE FSAR section 12.11.2. The loss of external power signal from ESFAS as an input to TRPS is addressed in LCO 3.2.1. The ESFAS loss of external power signal protects against the expected loss of TOGS blowers and recombiners after the required runtime on the UPSS is exceeded. The staff evaluated the UPSS in chapter 8 of this SER.

The ESFAS is required to perform safety functions as described in SHINE FSAR section 7.5.3.1. In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed TSs for the SHINE ESFAS as described in SHINE FSAR chapter 7. The ESFAS is addressed in the SHINE TSs at LCO 3.2.2 and SR 3.2.2, LCO 3.2.4 and SR 3.2.4, LCO 3.4.3 and SR 3.4.3, LCO 3.4.4 and SR 3.4.4, LCO 3.6.2 and SR 3.6.2, LCO 3.8.9 and SR 3.8.9, and LCO 3.8.10 and SR 3.8.10. The staff's review of the ESFAS is discussed in section 7.4.5 of this SER.

The proposed LCO 3.2.2 and SR 3.2.2 address the logic, voting, and actuation portions of the ESFAS to help ensure that the system is able to generate an appropriate actuation signal when required. They state the following:

LCO 3.2.2	Divisions A, B, and C of the ESFAS shall be Operable. Each ESFAS Division A or B is Operable if: 1. Three SBVMs or SBMs are Operable 2. Two 5V power supplies are Operating 3. Two EIMs for each ESFAS actuation device are Operable ESFAS Division C is Operable if: 1. Three SBMs are Operable 2. Two 5V power supplies are Operating Note – Actions 1, 2, 3, 4, 5 and 6 in Table 3.2.2 may be applied separately to each division of ESFAS.
Applicability	Facility not Secured
Action	According to Table 3.2.2
SR 3.2.2	1. Check that the ESFAS self-diagnostics indicate no failed modules weekly. 2. Simulated automatic and manual actuation priority logic testing shall be performed every five years. Note – This SR cannot be deferred. 3. SBVM hardwired communications shall be checked quarterly. 4. Power supply voltages shall be checked semi-annually.

The proposed TS table 3.2.2, “ESFAS Logic and Actuation Actions,” states the following:

	Condition and Action	Completion Time
1.	If one SBVM or SBM in a single Division is inoperable, Confirm that the SBVM or SBM is in the “tripped” state AND Restore the module to Operable.	 Immediately 72 hours
2.	If one 5V power supply in a single Division is inoperable, Restore the power supply to Operable.	 72 hours
3.	If one EIM in a single Division is inoperable, Restore the module to Operable OR Enter the corresponding action(s) for the inoperable component according to LCOs 3.4.3, 3.4.4, 3.6.2, 3.8.9, or 3.8.10.	 72 hours 72 hours
4.	If two EIMs associated with a single actuation component in a single Division are inoperable (and not actuating), Enter the corresponding action(s) for the inoperable actuation device according to LCOs 3.4.3, 3.4.4, 3.6.2, 3.8.9, or 3.8.10.	 Immediately

5.	If two or more SBVMs in a single Division A or B are inoperable, OR If two 5V power supplies in a single Division A or B are inoperable, OR Action and associated completion time of Condition 1 or 2 not met for a Division A or B SBVM,	
	Place all IUs undergoing irradiation in Mode 3	6 hours
	AND	
	Open the vacuum transfer system (VTS) vacuum pump breakers	12 hours
	AND	
	Open at least one VTS vacuum break valve	12 hours
	AND	
	Suspend all work involving special nuclear material	12 hours
	AND	
	Place tritium in all three trains of TPS process equipment in its storage location	12 hours
	OR	
	Initiate a TPS Train Isolation for gloveboxes containing tritium.	12 hours

6.	If two or more SBMs in Division C are inoperable, OR If two 5V power supplies in Division C are inoperable, OR Action and associated completion time of Condition 1 or 2 not met for a Division C SBM, Place all IUs undergoing irradiation in Mode 3 AND Open the VTS vacuum pump breakers AND Open at least one VTS vacuum break valve AND Suspend all work involving special nuclear material AND Place tritium in all three trains of TPS process equipment in a storage location OR Initiate a TPS Train Isolation for gloveboxes containing tritium.	 12 hours 24 hours 24 hours 24 hours 24 hours 24 hours
7.	If two or more Divisions are inoperable, Place all IUs undergoing irradiation in Mode 3 AND Open the VTS vacuum pump breakers AND Open at least one VTS vacuum break valve AND Initiate a TPS Train Isolation for gloveboxes containing tritium. AND Suspend all work involving special nuclear material	 1 hour 1 hour 1 hour 1 hour 1 hour

LCO 3.2.2 specifies that all three divisions (Divisions A, B, and C) must be operable whenever the SHINE facility is not secured. Operability for each division is specified in the LCO. Divisions A and B require the operability of three SBVMs or SBMs, two EIMs, and the associated two 5-volt power supplies. Division C requires the operability of three SBMs and the two associated 5-volt power supplies. The LCO 3.2.2 required equipment is consistent with SHINE FSAR section 7.5.3.1 because the SFMs and the input channels are addressed in LCO 3.2.4 and the actuated components are addressed in LCO 3.4.3 (for tritium confinement boundary components), LCO 3.4.4 (for supercell confinement dampers), LCO 3.6.2 (for safety-related breakers), LCO 3.8.9 (for RCA isolation dampers), and LCO 3.8.10 (for facility-specific safety-related valves and dampers). Additionally, LCO 3.2.2 addresses the two redundant 5-volt power supplies per ESFAS division and LCO 3.6.1 discusses the 24-volt power to the 5-volt power supplies for each division of ESFAS cabinets.

The proposed TS table 3.2.2, “ESFAS Logic and Actuation Actions,” provides the deviations from LCO 3.2.2 that may be allowed under specified conditions, while restoring the system to operation. The completion times allow for the replacement of failed components, while limiting the amount of time an IU is allowed to operate with reduced ESFAS capability. The 72-hour completion time duration is acceptable for a single failed SBVM, SBM, 5-volt power supply, or EIM within one division because the output of a failed SBVM is received as a trip signal by the associated EIMs, and the output of a failed SBM is received as a trip signal by the Division A and B SBVMs, preserving the single failure criterion for the remaining operable modules. For a failed EIM, the time allows adequate time to diagnose, repair, and retest the inoperable module while having continued availability of the redundant actuation component (or redundant check valve) to perform the required function. In the case of a failed power supply, the 72 hour duration is deemed acceptable while conducting restoration due to the ability of the redundant ESFAS division(s) to sense adverse conditions and actuate equipment in response to an event. If more than one EIM for a single actuation component in a single division are inoperable, table 3.2.2 requires that the corresponding action(s) from LCO(s) 3.4.3, 3.4.4, 3.6.2, 3.8.9, or 3.8.10 be entered immediately using the new completion times for the associated actions stated in the applicable LCO(s). If more than one SBVM, or both power supplies in a single division, or two or more SBMs in Division C are inoperable or if the 72-hour completion time to restore operability will be exceeded, the ESFAS is deemed inoperable and the actions in table 3.2.2 must be completed to shut down the facility and systems in an orderly manner, including suspending all work involving special nuclear material within 12 hours. The NRC staff finds the actions and completion times to be acceptable based on the continued availability of the redundant ESFAS division(s) to sense adverse conditions (two remaining divisions) and actuate equipment (one remaining division) in response to an event. In the unlikely event that two or more divisions are inoperable, the TS table 3.2.2 requires that all IUs undergoing irradiation be placed in Mode 3 (shutdown) within one hour and that actions are taken to remove the potential for an event by placing facility systems in a condition of applicability where the functionality of the ESFAS is no longer required, including isolating any gloveboxes containing tritium.

The NRC staff finds that LCO 3.2.2 and the associated TS table 3.2.2 provide the conditions and actions required to help ensure that the ESFAS is able to perform its safety function specified by the SHINE safety analysis to ensure that the facility is maintained in a safe condition. Therefore, the staff finds LCO 3.2.2 and TS table 3.2.2 acceptable.

SR 3.2.2.1 requires checks for ESFAS faults monitored by the end-to-end self-testing that covers each module from sensor input to the output switching logic (except for the discrete circuitry of the actuation and priority logic) weekly. The HIPS platform self-tests and integral LEDs, as described in SHINE FSAR section 7.5.4.5 and evaluated by the NRC staff in section 7.4.2 of this SER, evaluate the state of the module latches, the operational state of the module, and the presence of any faults to determine if the platform is functioning correctly. The discrete circuitry of the actuation and priority logic is not tested by self-testing, so SR 3.2.2.2 requires testing of the priority logic for automatic and manual actuation. SR 3.2.2.3 verifies operability of the SBVM hardwired communications and SR 3.2.2.4 checks power supply voltages semi-annually. The staff finds that SR 3.2.2 prescribes the frequency and scope of required surveillances to demonstrate the performance of the TRPS logic, actuation, and power supply voltages and that the maximum allowable surveillance intervals are consistent with the guidance in ANSI/ANS-15.1-2007, section 4. Therefore, the staff finds SR 3.2.2 acceptable.

The proposed LCO 3.2.4 and SR 3.2.4 help ensure that the input devices and the trip determination portions of the ESFAS SFMs are able to initiate safety functions specified by the SHINE safety analysis, as described in SHINE FSAR subsection 7.4.3.1. They state the following:

LCO 3.2.4	ESFAS input Channels listed in Table 3.2.4-a shall be Operable. Note – Any single SFM may be bypassed for up to 2 hours while the variable is the condition of applicability for the purpose of performing a Channel Test or Channel Calibration.
Applicability	According to Table 3.2.4-a when the Facility is not Secured
Action	According to Table 3.2.4
SR 3.2.4	1. Check that the ESFAS self-diagnostics indicate no failed modules weekly. 2. A Channel Check shall be performed on ESFAS instrument Channels listed in Table 3.2.4-a quarterly. 3. A Channel Calibration shall be performed on ESFAS instrument Channels listed in Table 3.2.4-a annually. 4. A Channel Test shall be performed on ESFAS instrument Channels listed in Table 3.2.4-a quarterly.

The scope of LCO 3.2.4 is for each channel beginning at the input devices and the trip determination portions of the ESFAS, including the associated SFMs and HWMs up to the inputs to the SBVMs or SBMs addressed in LCO 3.2.2. Radiation monitors that provide inputs to the ESFAS are addressed in LCO 3.7.1.

The proposed TS table 3.2.4-a, “ESFAS Process Instrumentation,” provides the list of ESFAS instrument channels, the associated setpoints for each variable, and the minimum number of required channels. The ESFAS process variable instrumentation listed in TS table 3.2.4-a is required to initiate the safety functions described in SHINE FSAR section 7.5.3.1. The table also provides a cross reference to the action steps detailed in TS table 3.2.4, “ESFAS Process

Instrumentation Actions," for any process variable deemed inoperable and to the applicable SR for each variable. TS table 3.2.4-a states the following:

	Variable	Setpoint	Required Channels	Applicability	Action	SR
a.	PVVS carbon delay bed exhaust temperature	≤ 219°F	2 (per delay bed)	Associated carbon delay bed Operating	5, 6	2, 3
b.	VTS vacuum header liquid detection	Liquid detected	2	Solution transfers using VTS in-progress	3, 4	4
c.	RDS liquid detection	Liquid detected	2	Solution transfers using VTS in-progress	3, 4	4
d.	PVVS flow	≥ 7.1 SCFM	3	RPF Nitrogen Purge not Operating when the Facility is not Secured	1, 2	2, 3
e.	Target solution preparation system (TSPS) dissolution tank level	High level	2	Dissolution tank or TSPS glovebox contains uranium	7, 8	4
f.	UPSS loss of external power	Loss of Power; actuation delayed by ≤ 180 seconds	2	Any IU in Mode 1 or 2	9, 10	4
g.	Molybdenum extraction and purification system (MEPS) three-way valve position indication	Supplying	2 (per valve)	Target solution present in the associated hot cell	11, 12	4
h.	IXP three-way valve position indication	Supplying	2 (per valve)	Target solution present in the IXP hot cell	11, 12	4
i.	TPS target chamber supply pressure	≤ 7.7 psia	2 (per IU)	Tritium present in associated TPS process equipment and not in storage	13, 14	2, 3
j	TPS target chamber exhaust pressure	≤ 7.7 psia	2 (per IU)	Tritium present in associated TPS process equipment and not in storage	13, 14	2, 3

The NRC staff finds that, consistent with NUREG-1537, Part 1, appendix 14.1, TS table 3.2.4-a specifies the setpoints, the minimum number of channels, and the operating mode when the channels are required. The TS table 3.2.4-a setpoints are evaluated in sections 7.4.5 of this SER. The staff finds that the setpoints are selected based on analytical limits and calculated to account for known uncertainties in accordance with the setpoint methodology and that the variables are periodically functionally tested as required by SR 3.2.4. TS Table B-3.2.4, “ESFAS Input Variable Allocation,” provided in the bases for LCO 3.2.4, shows that more than one input device provides a signal to each SFM.

Although not specifically discussed in this section of the SER, the NRC staff also reviewed proposed LCO 3.4.3 and SR 3.4.3, LCO 3.4.4 and SR 3.4.4, LCO 3.6.2 and SR 3.6.2, LCO 3.8.9 and SR 3.8.9, and LCO 3.8.10 and SR 3.8.10 related to the ESFAS. LCO 3.4.3 and SR 3.4.3 ensure the operability of the safety-related tritium confinement boundary isolation valves actuated on demand by the ESFAS. LCO 3.4.4 and SR 3.4.4 are related to the operability of the supercell confinement dampers verified to close on demand from the ESFAS annually. LCO 3.6.2 and SR 3.6.2 ensure the operability of the safety-related breakers required to support the ESFAS safety functions. LCO 3.8.9 and SR 3.8.9 monitor the operability of the safety-related isolation dampers to ensure that they are capable of closing on demand from the ESFAS and LCO 3.8.10 and SR 3.8.10 monitor the operability of the safety-related valves to ensure that they are capable of opening or closing on demand from the ESFAS. Based on information provided and reviewed, the staff finds these LCOs and SRs acceptable.

Based on its review of SHINE TSs applicable to the ESFAS, the NRC staff finds that the LCOs and SRs discussed above help to ensure the operability of the ESFAS, including the ESFAS logic, voting, actuation divisions, and instrumentation monitored by the ESFAS as input to safety actuations. The staff also finds that the setpoint values of the SHINE TSs for the ESFAS are based on the SHINE setpoint calculations for the applicable process variables. Therefore, the staff finds the TSs related to the ESFAS acceptable.

7.4.10.4 Radiation Monitoring Technical Specifications

SHINE FSAR section 7.7.1.4.3 states that the safety-related process radiation monitors are periodically functionally tested and maintained in accordance with the TSs to verify operability. The surveillance frequencies for the safety-related process radiation monitoring instruments included in the TSs were selected consistent with the guidance provided in ANSI/ANS-15.1-2007. The SRs for the safety-related process radiation monitoring instruments included in the TSs verify the operability of the channel from the safety-related process radiation monitor to the inputs to the SBVM or SBM located in the TRPS or ESFAS. Safety-related process radiation monitors located in a low background area are equipped with a check source to be able to verify proper operation. Startup-testing conditions and first use of safety-related RMS instrumentation is discussed in SHINE FSAR section 12.11.2 and the startup plan is evaluated in chapter 12, “Conduct of Operations,” of this SER.

SHINE TS 3.7, “Radiation Monitoring Systems and Effluents,” identifies the LCOs and SRs for the safety-related process radiation monitoring instruments and gaseous effluents.

LCO 3.7.1 and SR 3.7.1 address the safety-related radiation monitors used to detect elevated levels of radiation that may result in unwanted radiation exposure to workers or individual members of the public in excess of allowable limits, as described in SHINE FSAR section 7.7.1.

These radiation monitors also provide input to initiate safety functions specified by the SHINE safety analysis, as described in SHINE FSAR sections 7.4.3.1 and 7.5.3.1.

The scope of LCO 3.7.1 begins at the radiation monitoring input devices (SFMs) up to the inputs to the SBVMs or SBMs, to help ensure that radiation levels within the SHINE facility and radiation released to the environment remain below the limits of 10 CFR Part 20. LCO 3.7.1 and SR 3.7.1 state the following:

LCO 3.7.1	Radiation monitoring instruments listed in Table 3.7.1-a shall be Operable. Note – Any single SFM may be bypassed for up to 2 hours while in the condition of applicability for the purpose of performing a Channel Calibration.
Applicability	According to Table 3.7.1-a when the Facility is not Secured
Action	According to Table 3.7.1
SR 3.7.1	1. A Channel Check shall be performed for radiation monitors monthly. 2. A Channel Calibration shall be performed for radiation monitors annually.

At least two channels of safety-related radiation monitors are provided for each monitored location with some locations having three channels, as stated in SHINE FSAR table 7.7-1 and listed in TS table 3.7.1-a, “Safety-Related Radiation Monitoring Instruments.” Additionally, table B-3.7.1, “Safety-Related Radiation Monitoring Input Allocation,” identifies the SFMs assigned to each monitored location. TS table 3.7.1-a states the following:

	Monitored Location	**Setpoint and Monitored Material**	**Required Channels**	**Applicability (per IU, TPS train, or monitored location)**	**Action**
a.	RVZ1 supercell exhaust ventilation (PVVS hot cell)	≤ 7.6E-05 µCi/cc Fission products	3	RPF Nitrogen Purge not Operating when the Facility is not Secured	1, 2, 3
b.	RVZ1 supercell exhaust ventilation (Extraction and IXP hot cells)	≤ 7.6E-05 µCi/cc Fission products	2 (per hot cell)	Target solution or radioactive process fluids present in the associated hot cell	4, 5
c.	RVZ1 supercell exhaust ventilation (Purification and Packaging hot cells)	≤ 7.6E-05 µCi/cc Fission products	2 (per hot cell)	Radioisotope products or radioactive process fluids present in the associated hot cell	4, 5
d.	RVZ1 RCA exhaust	≤ 1.3E-05 µCi/cc Fission products	3	Facility not Secured	1, 6, 7

e.	RVZ2 RCA exhaust	≤ 9.1E-07 μCi/cc Fission products	3	Facility not Secured	1, 6, 7
f.	RVZ1e IU cell exhaust	≤ 9.6E-03 μCi/cc Fission products	3 (per IU)	Associated IU in Mode 1, 2, 3, or 4	1, 8
g.	TPS confinement A/B/C	≤ 927 Ci/m^3 Tritium	2 (per TPS train)	Tritium present in associated TPS process equipment and not in storage	9
h.	TPS exhaust to facility stack	≤ 0.96 Ci/m^3 Tritium	3	Tritium present in any TPS process equipment and not in storage	1, 10
i.	MEPS heating loop extraction area A/B/C	≤ 1110 mR/hr Fission products	2 (per hot cell)	Target solution or radioactive process fluids present in the associated hot cell	11, 12

SHINE proposed TS table 3.7.1-a provides the list of radiation monitoring points required by LCO 3.7.1 and the applicable mode when each input channel variable is required to be operable. The NRC staff finds that, consistent with NUREG-1537, Part 1, appendix 14.1, this table specifies the setpoints, the minimum number of channels, and the operating mode when the channels are required. The TS table 3.7.1-a setpoints are evaluated in sections 7.4.7 of this SER. The staff finds that the setpoints are selected based on analytical limits and calculated to account for known uncertainties in accordance with the setpoint methodology and that the variables are periodically functionally tested as required by SR 3.7.1. Table B-3.7.1, provided in the bases for LCO 3.7.1, shows the input device that provides a signal to each SFM for each division consistent with the guidance in NUREG-1537, Part 2, section 7.7 to show the I&C radiation detectors and monitors applicable to the anticipated sources of radiation.

The NRC staff also reviewed proposed TS table 3.7.1, “Safety-Related Radiation Monitor Actions.” This table provides actions and completion times for when LCO 3.7.1 is not met and provides the deviations from LCO 3.7.1 that may be allowed under specified conditions, while restoring the system to operation. The staff finds that the completion times specified in TS table 3.7.1 allow for replacement of failed components, while limiting the amount of time equipment protected by the TRPS or ESFAS is allowed to operate with reduced safety system reliability.

Each safety-related radiation monitoring input has two or three required radiation monitoring instruments (SHINE TS table 3.7.1-a) and each monitoring input has two or three SFMs (SHINE TS table B-3.7.1). When any single radiation monitoring channel is inoperable for variables provided with three channels, the inoperable channel is required to be placed in trip within 2 hours, effectively changing the voting logic to 1-out-of-2 and preserving the single failure protection. For variables provided with only two channels, actuation of the safety function occurs on 1-out-of-2 voting logic. Each SFM can be placed in maintenance bypass or in a trip state by the use of the OOS switch and an associated trip/bypass switch located below the SFM, as described in SHINE FSAR section 7.4.4.3. Normal actuation of the safety function occurs on 2-out-of-3 voting logic; however, when any single channel is inoperable, the SFM associated with the inoperable channel is required to be placed in trip within 2 hours, which changes the voting logic to 1-out-of-2 and preserving the single failure protection.

The NRC staff reviewed the completion times of 72 hours to restore any one channel, which decrease when (a) the number of channels inoperable increases (i.e., 12 hours for 2 inoperable channels and 1 hour for three inoperable channels) or (b) if the prior condition completion time will not be met, and finds that the completion times appropriately address the various failure/testing conditions. TS table 3.7.1 states the required actions and a reasonable completion time for when a channel is declared inoperable due to an inoperable radiation monitor or when a channel is declared inoperable due to an SFM. TS table 3.7.1 also permits rendering radiation monitoring channels inoperable in accordance with LCO 3.0.1.4 to facilitate resetting the TRPS or ESFAS to perform recovery actions or to satisfy required actions of an LCO. This functionality is evaluated by the staff in section 7.4.2.1 of this SER.

The NRC staff finds that LCO 3.7.1, table 3.7.1, and table 3.7.1-a provide the conditions and actions required to help ensure that radiation levels within the facility and radiation released to the environment remain below the applicable limits specified by the SHINE safety analysis. Therefore, the staff finds LCO 3.7.1, table 3.7.1, and table 3.7.1-a acceptable.

SR 3.7.1.1 provides for monthly checks and SR 3.7.1.2 for annual calibrations of the channels listed in TS table 3.7.1-a. Per LCO 3.7.1, the radiation monitors are required to be operable continuously when the facility is not secured according to TS table 3.7.1-a. To allow the performance of SRs during operation, LCO 3.7.1 allows any single channel for any of the radiation monitoring instruments to be placed in bypass for up to two hours during the performance of the required SR. The NRC staff finds the 2-hour time limit acceptable based on the small amount of time the channel is out of service and the fact that the voting logic is changed to 2-out-of-2 (with two other channels operable) or 1-out-of-1 (with one other channel operable), which continues protection under the LCO. The staff finds that SR 3.7.1 prescribes the frequency and scope of surveillance to demonstrate the continued operability of the process variable instrument channels and that the maximum allowable surveillance intervals are consistent with the guidance in ANSI/ANS-15.1-2007, section 4. Therefore, the staff finds SR 3.7.1 acceptable.

The NRC staff evaluated LCO 3.7.2 and SR 3.7.2 in section 11.4.4, “Proposed Technical Specifications” of this SER and found LCO 3.7.3 and SR 3.7.2 acceptable.

Based on its review of SHINE TSs applicable to the radiation monitoring equipment, the NRC staff finds that the LCOs and SRs discussed above help to ensure the operability of the TRPS/ESFAS, including the logic, voting, actuation divisions, and instrumentation monitored by the TRPS/ESFAS as input to safety actuations. The staff also finds that the setpoint values of the SHINE TSs for the TRPS/ESFAS are based on the SHINE setpoint calculations for the applicable process variables. Therefore, the staff finds TS 3.71 related to radiation monitoring acceptable.

7.4.10.5 Conclusion

TS are required by 10 CFR 50.34(b)(6)(vi) to be prepared in accordance with the requirements of 10 CFR 50.36. Under 10 CFR 50.36, the SHINE operating license application is required to include TSs that will include LSSSs, LCOs, SRs, and other requirements for facility operation to protect the environment and preserve the health and safety of the public.

The NRC staff reviewed the proposed TSs submitted by SHINE for the TRPS, the ESFAS, and the radiation monitoring instrumentation. Based on its above evaluation of the information presented, the staff concludes:

- The SHINE TSs for the TRPS, the ESFAS, and the radiation monitoring equipment satisfy 10 CFR 50.34 and 10 CFR 50.36 because they adequately provide reasonable assurance that the TRPS, the ESFAS, and the radiation monitoring equipment will be operable and will perform their design functions as analyzed in the SHINE FSAR.

- The SHINE TSs and surveillance tests for the TRPS, the ESFAS, and the radiation monitoring equipment appropriately address the guidance format and content of ANSI/ANS-15.1-2007, as supplemented in NUREG-1537, Part 1, appendix 14.1 for nonpower production and utilization facilities.

- The SHINE TSs and surveillance tests for the TRPS, the ESFAS, and the radiation monitoring equipment, including SRs and intervals, are based on analyses in the SHINE FSAR and help establish the necessary confidence in the availability and the reliable operation of the detection channels and control elements and devices.

7.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE I&C systems, as described in SHINE FSAR chapter 7, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the I&C systems and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE I&C systems are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

8.0 ELECTRICAL POWER SYSTEMS

Electrical power systems are designed for operation of the SHINE Medical Technologies, LLC (SHINE, the applicant) irradiation facility (IF) and radioisotope production facility (RPF) (together, the SHINE facility). In addition to normal electrical service, emergency electrical service ensures that, given a loss of normal electric service, sufficient power will be available to mitigate accidents in order to: (1) shut down the facility and maintain it in a safe shutdown condition and (2) prevent or minimize the offsite release of radioactivity in excess of applicable regulatory requirements and guidance.

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE IF and RPF electrical power systems, as presented in Chapter 8, “Electrical Power Systems,” of the SHINE Final Safety Analysis Report (FSAR) and supplemented by the applicant’s response to staff requests for additional information (RAIs).

8a Irradiation Facility Electrical Power Systems

Section 8a, “Irradiation Facility Electrical Power Systems,” of this SER provides an evaluation of the final design of SHINE’s IF electrical power systems as presented in SHINE FSAR section 8a2, “Irradiation Facility Electrical Power Systems,” within which the applicant described the irradiation unit (IU) normal electrical power systems and emergency electrical power systems.

8a.1 Areas of Review

The NRC staff reviewed SHINE FSAR Section 8a2 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design of the SHINE IF electrical power systems. The staff assessed the final analysis of the normal electrical power systems to ensure the safe operation and shutdown of the SHINE IUs, including the response of the facility to interruptions of normal electrical service, and the ability of the facility to be maintained in a safe condition with and without the availability of normal electrical service. The staff examined the ranges of power required, schematic diagrams, design and performance specifications, deviations from guidance and their justifications, and SHINE’s proposed technical specifications (TSs).

The NRC staff also assessed the final design and analysis of the SHINE emergency electrical power systems, including the design and functions of the emergency electrical power systems and their support of related systems required for protecting the health and safety of the public.

As described in SHINE FSAR sections 8b.1, “Normal Electrical Power Systems,” and 8b.2, “Emergency Electrical Power Systems,” respectively, the SHINE facility has one common normal electrical power system and one common emergency electrical power system, which serve both the IF and the RPF. Therefore, the areas of review described below are applicable to both the SHINE IF and RPF.

8a.2 <u>Summary of Application</u>

As described in SHINE FSAR sections 8b.1 and 8b.2, the SHINE facility has one common normal electrical power system and one common emergency electrical power system, which serve both the IF and the RPF. Therefore, the summary provided below applies to both the SHINE IF and RPF.

8a.2.1 Normal Electrical Power Supply System

SHINE FSAR section 8a2.1, "Normal Electrical Power Supply System," and section 8a2.1.3, "Normal Electrical Power Supply System Description," provide details for the normal electrical power supply system (NPSS). This system is comprised of normal power service entrances from the electric utility at 480Y/277 volts alternating current (VAC) into separate feeds that provide power to the distribution system providing three utilization voltages, 480Y/277, 400Y/277, and 208Y/120 VAC, 3-phase, 60 hertz. The NPSS is used for normal operation and normal shutdown of the SHINE facility. SHINE FSAR figure 8a2.1-1, "Electrical Distribution System (Simplified)," provides a one-line diagram of the electrical power system of the SHINE facility, including the NPSS and the emergency electrical power system.

SHINE FSAR section 8a2.1.3 states, in part, that the "NPSS operates as five separate branches, each receiving utility power at 480Y/277 VAC. The branches automatically physically disconnect from the utility by opening the associated utility power (UP) supply breaker … on a loss of phase, phase reversal, or sustained overvoltage or undervoltage as detected by protection relays for each utility transformer." This function is not required for safe shutdown, as described in SHINE FSAR section 8a2.1.6, "Loss of Off-Site Power." The two branches serving loads in the main production facility and the nitrogen purge system (N2PS) structure can be cross-connected by manually opening one of the UP supply breakers and manually closing both bus tie breakers in the event of the loss of a single utility 480Y/277 VAC feed. This cross-connection would be administratively controlled to ensure that the remaining utility feed is not overloaded.

8a.2.2 Emergency Electrical Power Systems

SHINE FSAR section 8a2.2, "Emergency Electrical Power Systems," provides details for the emergency electrical power system. This system is comprised of a safety-related uninterruptible electrical power supply system (UPSS), a non-safety-related standby generator system (SGS), and non-safety-related local power supplies and unit batteries. The UPSS consist of a 125-volt direct current (VDC) battery subsystem, inverters, bypass transformers, distribution panels, and other distribution equipment. The UPSS provides power to both safety-related loads and non-safety-related loads.

The non-safety-related SGS consist of a natural gas-driven generator and associated circuit breakers and distribution equipment that provides power for the UPSS loads and emergency power to SHINE's facility physical security control systems and information and communications systems.

SHINE FSAR section 8a2.2.3, "Uninterruptible Electrical Power Supply System Description," states, in part, that the "safety-related UPSS provides a reliable source of power to the redundant divisions of AC [alternating current] and DC [direct current] components on the safety-related power buses. Each division of the UPSS consists of a 125 VDC battery subsystem, 125 VDC to 208Y/120 volts alternating current (VAC) inverter, rectifier (battery charger), bypass transformer, static switch and a manual bypass switch, and 208Y/120 VAC and 125 VDC distribution panels." Each of the components of the UPSS are safety-related. SHINE FSAR figure 8a2.2-1, "Uninterruptible Power Supply System," provides a one-line diagram of the UPSS and connections with safety-related and non-safety-related loads. SHINE FSAR table 8a2.2-1, "UPSS Load List," provides the list of the loads connected to the UPSS, and table 8a2.2-2, "UPSS Battery Sizing," provides the Amp-hours required to provide power to the loads connected to the UPSS.

8a.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR sections 8a2, and 8b, "Radioisotope Production Facility Electrical Power Systems," against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE electrical power systems for the issuance of an operating license.

8a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE electrical power systems are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.57, "Issuance of operating license."
- 10 CFR Part 20, "Standards for Protection Against Radiation."

8a.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power

Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, "References," of this SER.

In addition, the SHINE design criteria discussed in section 8a.4.1 of this SER are applicable to the SHINE electrical power systems.

8a.4 <u>Review Procedures, Technical Evaluation, and Evaluation Findings</u>

The NRC staff performed a review of the technical information presented in SHINE FSAR sections 8a2 and 8b, as supplemented by the applicant's response to staff RAIs dated December 15, 2020 (Agencywide Documents Access and Management System Accession No. ML21011A264, January 29, 2021 (ML21029A101), and July 2, 2021 (ML21183A125) to assess the sufficiency of the final design and performance of the SHINE electrical power systems for the issuance of an operating license. The sufficiency of the final design and performance is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 8a.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in section 8a.5, "Review Findings," of this SER.

As described in SHINE FSAR sections 8b.1 and 8b.2, the SHINE facility has one common normal electrical power system and one common emergency electrical power system that serve both the IF and the RPF.

8a.4.1 Normal Electrical Power Systems

The NRC staff evaluated the sufficiency of the final design of the SHINE normal electrical power systems, as presented in SHINE FSAR section 8a2.1, using the guidance and acceptance criteria from section 8.1, "Normal Electrical Power Systems," of NUREG-1537, Parts 1 and 2, and section 8a2, "Aqueous Homogeneous Reactor Electrical Power Systems," and section 8b, “Radioisotope Production Facility Electrical Power Systems,” of the ISG augmenting NUREG-537, Parts 1 and 2.

Section 8.1 of NUREG-1537, Part 2, provides the applicable acceptance criteria. The guidance states, in part, that, “Normal electrical power systems at non-power reactors are designed for safe operation and shutdown of the reactor, and to provide for reactor use.” It also states that, “The reactor design should use high-quality, commercially available components and wiring in accordance with applicable codes in the normal electrical systems.” The NRC staff evaluated the SHINE normal electrical power systems against the following acceptance criteria:

- The design and functional characteristics should be commensurate with the design bases.

- The facility should have a dedicated substation or a shared system designed to provide reasonable assurance that other uses could not prevent safe shutdown.

- The system should be designed to permit safe shutdown and to prevent uncontrolled release of radioactive material if offsite power is interrupted or lost.

- Electrical power circuits should be isolated sufficiently to avoid electromagnetic interference with safety-related instrumentation and control functions.

- Technical specifications should be provided to ensure operability commensurate with power requirements for shutdown and to prevent uncontrolled release of radioactive material.

The SHINE design criteria are provided in SHINE FSAR section 3.1, “Design Criteria,” table 3.1-3, “SHINE Design Criteria.” The following design criteria are applicable to the normal electrical power systems:

- Criterion 4, “Environmental and dynamic effects.”

  Safety-related SSCs [structures, systems, and components] are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility.

- Criterion 27, “Electric power systems.”

  An on-site electric power system and an off-site electric power system are provided to permit functioning of safety-related SSCs. The safety functions are to provide sufficient capacity and capability to assure that:

  1) target solution design limits and primary system boundary design limits are not exceeded as a result of anticipated transients, and

  2) confinement integrity and other vital functions are maintained in the event of postulated accidents.

The onsite uninterruptible electric power supply and distribution system has sufficient independence, redundancy, and testability to perform its safety functions assuming a single failure.

Provisions are included to minimize the probability of losing electric power from the uninterruptible power supply as a result of or coincident with, the loss of power from the off-site electric power system.

- Criterion 28, “Inspection and testing of electric power systems.”

  The safety-related electric power systems are designed to permit appropriate periodic inspection and testing of important areas and features, such as wiring, insulation, connections, and switchboards, to assess the continuity of the systems and the condition of their components. The systems are designed with a capability to test periodically:

  1) the operability and functional performance of the components of the systems, such as on-site power sources, relays, switches, and buses; and

  2) the operability of the systems as a whole and, under conditions as close to design as practical, the full operation sequence that brings the systems into operation, including operation of applicable portions of the protection system, and the transfer of power among the on-site and off-site power supplies.

The NRC staff reviewed the information in SHINE FSAR section 8a2.1 to verify the functional characteristics of the normal electrical power system. SHINE FSAR section 8a2.1.1, “Design Basis,” states, in part, that the “design of the NPSS provides sufficient, reliable power to facility and site electrical equipment as required for operation of the SHINE facility and to comply with applicable codes and standards.” SHINE applies National Fire Protection Association (NFPA) 70-2017, “National Electrical Code,” as adopted by the State of Wisconsin (Chapter SPS 316 of the Wisconsin Administrative Code, Electrical), for the design of the normal electrical power system.

In its response to NRC staff RAIs, SHINE provided clarification regarding the portions of NFPA 70-2017 that were used for the design of the electrical systems, including the NPSS, the UPSS, and the SGS. In addition, SHINE incorporated standards from the IEEE for the design of the NPSS. Safety-related breakers in the NPSS are designed in accordance with IEEE Standard C.37.13-2015, “Standard for Low-Voltage AC Power Circuit Breakers Used in Enclosures.” The staff finds that the use of appliable portions of these standards provides reasonable assurance that SHINE’s final design and the functional characteristics of the normal electrical power system are commensurate with the design bases of the facility.

SHINE FSAR section 8a2.1 states, in part, that the “NPSS is sized for safe operation of the facility. The largest loads on the NPSS are the process chilled water system (PCHS), neutron driver assembly system (NDAS), and the facility chilled water system (FCHS); however, those loads are not required for safe shutdown of the facility.” For the sizing of the NPSS, SHINE used applicable portions of NFPA 70-2017, as described in its response to NRC staff RAI 8-10 (ML21183A125), Enclosure 2 (ML21183A128). In addition, in its response to NRC staff RAI 8-1 (ML21029A101), Enclosure 1 (ML21029A103), SHINE stated that, “Equipment sizing studies for the NPSS are not performed by SHINE, as there is no explicit requirement for SHINE to perform such studies. NPSS equipment sizing is based on wire and bus sizing minimums established in NFPA 70-2017." The NRC staff performed a regulatory audit and confirmed that the electrical system design assumptions align with the recommended practices of NFPA 70-2017, as discussed in the audit report. Based on the above, the NRC staff concludes that the electrical system final design meets Criteria 27 and 28 of the SHINE design criteria.

SHINE FSAR section 8a2.1.1 states, in part, that the NPSS is designed such that it:

- Does not prevent the ability of safety-related SSCs to perform their safety functions;
- Provides for the separation or isolation of safety-related circuits from nonsafety-related circuits, including the avoidance of electromagnetic interference with safety-related instrumentation and control functions;
- Fails to a safe configuration upon a loss of offsite power (LOOP);
- Provides the normal source of power supply to the safety-related electrical buses;
- Provides the safety-related function of removing power from select components when demanded by the safety-related engineered safety features actuation system (ESFAS) or target solution vessel (TSV) reactivity protection system (TRPS); and
- Is able to be inspected, tested, and maintained to meet the above design bases.

The NRC staff reviewed other sections of the SHINE FSAR to confirm consistency with SHINE FSAR Chapter 8, such as Chapter 4, "Irradiation Unit and Radioisotope Production Facility Description," Chapter 5, "Cooling Systems," Chapter 7, "Instrumentation and Control Systems," Chapter 9, "Auxiliary Systems," and Chapter 13, "Accident Analysis." The staff performed a regulatory audit to confirm that the final design and functional characteristics are commensurate with the design bases. Based on the above, the staff finds that the final design of the components within each of the systems in these chapters is commensurate with the design bases and functional characteristics of the NPSS.

As described in section 8.1 of NUREG-1537, Part 2, the SHINE facility should have a dedicated substation or a shared system designed to provide reasonable assurance that other uses could not prevent safe shutdown. SHINE FSAR Section 8a2.1.2, "Off-Site Power Supply Description," provides a description of the SHINE facility substation. It states, in part, that the "SHINE facility is connected to two single power circuits from the off-site transmission electric network. The power circuits are shared with other utility customers. The two power circuits feed five local outdoor 12.47 kilovolt (kV) – 480Y/277 VAC 3-phase transformers." The NRC staff finds that the final design of the dedicated substation meets the related acceptance criterion in NUREG-1537, Part 2.

SHINE FSAR section 8a2.1.3 provides a list of safety-related equipment in the NPSS, which are the following:

- Two safety-related breakers for each instance of the NDAS to provide the redundant ability to disconnect power.
- Two safety-related breakers per vacuum pump to provide the redundant ability to disconnect power from each vacuum pump in the vacuum transfer system (VTS).
- Two safety-related breakers per extraction feed pump to provide the redundant ability to disconnect power from each (of three) extraction feed pumps in the molybdenum extraction and purification system (MEPS).
- Two safety-related breakers providing the redundant ability to disconnect power from the radiological ventilation zone 1 (RVZ1) exhaust fans, radiological ventilation zone 2 (RVZ2) exhaust fans, and RVZ2 supply air handling units.

SHINE FSAR section 8a2.1.3 states, in part, that the safety functions performed by the specified breakers are related to preventing actions that could initiate or increase the consequences of an accident. The equipment tied to these breakers does not perform an active safety function. Redundant breakers are provided to ensure that the safety function of the breakers can still be performed in the event of a single active failure. The NRC staff reviewed applicable portions of SHINE FSAR Chapter 13, to verify that the classification of the safety-related equipment supports the mitigation of an accident. SHINE FSAR section 13b.2.2, “Loss of Electrical Power,” evaluates in the accident analysis an initiating event for a number of critical equipment malfunction scenarios. SHINE FSAR section 13b.2.2 states that, “A facility-wide LOOP results in automatic actuation of multiple facility engineered safety features, which act to ensure the risk associated with radiological or chemical releases is reduced to within acceptable limits. The facility-wide LOOP does not result in system or component failures within the RPF that result in unacceptable radiological or chemical consequences.”

In its response to NRC staff RAI 8-2 (ML21011A2640), Enclosure 3 (ML21011A240), SHINE stated that, “The NDAS breakers are opened as part of the sequence to reach a safe shutdown condition in an IU, as the unit is transitioned to Mode 3. The VTS, MEPS, and RVZ breakers are not involved in reaching a safe shutdown condition.” SHINE stated that the safety function performed by the safety-related breakers is to prevent actions that could initiate or increase the consequences of an accident and that the equipment tied to these breakers does not perform an active safety function. The staff finds that the proposed safety-related breakers provide reasonable assurance that the final design will permit safe shutdown and prevent uncontrolled release of radioactive material if offsite power is interrupted or lost. Therefore, the staff finds that the final design of the normal electrical power systems provides reasonable assurance that use or malfunction of electrical power systems and controls for experiments could not cause IU damage or prevent safe shutdown.

SHINE applied the guidance in sections 6.1.2.1, 6.1.2.2, and 6.1.2.3 of IEEE Standard 384-2008, “Standard Criteria for Independence of Class 1E Equipment and Circuits,” for isolation and the guidance in section 5.1.1.2, table 1 of section 5.1.3.3, and table 2 of section 5.1.4 of IEEE Standard 384-2008 for physical separation between non-safety-related circuits and safety-related circuits. In its responses to NRC staff RAIs, SHINE explained that it has committed to portions of specific IEEE standards that are applicable to its facility in order to meet Criteria 27 and 28 of the

SHINE design criteria. The staff reviewed the standards to verify whether the portions committed to are sufficient to meet the isolation and physical separation necessary to permit safe shutdown and to prevent uncontrolled release of radioactive material if offsite power is interrupted or lost to the electrical equipment. Based on the acceptance criteria in NUREG-1537, Part 2 and the portions of IEEE Standard 384-2008 used, the staff finds that SHINE's commitments are sufficient to meet the isolation and physical separation necessary for the NPSS.

SHINE FSAR section 8a2.1.5, "Raceway and Cable Routing," provides the design and location of the electrical wiring, stating that there are four separation groups for cables and raceways for the SHINE facility: Group A, Group B, Group C, and Group N. Spatial separation between groups is in accordance with section 5.1.1.2, table 1 of section 5.1.3.3, and table 2 of section 5.1.4 of IEEE Standard 384-2008. Group A and Group B contain safety-related power circuits for UPSS Division A and Division B, respectively. Group C contains safety-related control circuits from TRPS and ESFAS Division C. SHINE provides electrical isolation between non-safety-related circuits and safety-related circuits by isolation devices in accordance with sections 6.1.2.1, 6.1.2.2, and 6.1.2.3 of IEEE Standard 384-2008. The NRC staff finds that meeting these sections of IEEE Standard 384-2008 provides reasonable assurance that isolation between safety-related and non-safety-related circuits is achieved. Therefore, the staff finds that the final design and location of the electrical wiring will prevent inadvertent electromagnetic interference between the electrical power service and safety-related instrumentation and control circuits and is acceptable.

The NRC staff reviewed SHINE FSAR section 8a2.1 to verify that the NPSS final design is commensurate with SHINE Design Criterion 4. SHINE follows applicable portions of IEEE Standard 323-2003, "Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations," to ensure that the NPSS is in conformance with Design Criterion 4. SHINE FSAR section 8a2.1.3 states that safety-related NPSS equipment is located in a mild environment, is not subject to harsh environmental conditions during normal operation or transient conditions, and has no significant aging mechanisms. This equipment is designed and qualified by applying the guidance of sections 4.1, 5.1, 6.1, and 7 of IEEE Standard 323-2003 and is qualified to the environmental parameters provided in SHINE FSAR tables 7.2-2, "Facility Control Room Design Environmental Parameters," and 7.2-3, "RPF and IF General Area Design Environmental Parameters." SHINE FSAR Tables 7.2-2 and 7.2-3 provide the environmental parameters to be considered for the qualification of the NPSS electrical equipment.

The NRC staff evaluated the information related to SHINE's approach for considerations for environmental and dynamic effects and finds that the use of the specific portions of IEEE Standard 323-2003 provides reasonable assurance that the NPSS is in conformance with SHINE Design Criterion 4. The NPSS is located in a mild environment, and qualifying equipment for the specific environmental parameters provided in SHINE FSAR tables 7.2-2 and 7.2-3 provides reasonable assurance that SHINE Design Criterion 4 is met.

8a.4.2 Emergency Electrical Power Systems

The NRC staff evaluated the sufficiency of the final design of the SHINE emergency electrical power systems, as presented in SHINE FSAR section 8a2.2, as supplemented, using the guidance and acceptance criteria from section 8.2, "Emergency Electrical Power Systems," of NUREG-1537, Parts 1 and 2, and Section 8a2, "Aqueous Homogeneous Reactor Electrical Power Systems," and section 8b, "Radioisotope Production Facility Electrical Power Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

The SHINE emergency electrical power systems are described in SHINE FSAR section 8a2.2. section 8.2 of NUREG-1537, Part 2, provides the applicable acceptance criteria for the emergency electrical power systems for non-power reactors. This guidance states, in part, that emergency electrical power systems will be required to ensure that power is available to maintain safe shutdown, to support operation of a required engineered safety feature, or to protect the public from release of radioactive effluents. The NRC staff evaluated the SHINE emergency electrical power systems against the following acceptance criteria:

- The functional characteristics of the emergency power system should be commensurate with the design bases, which are derived from analyses presented in other chapters of the SAR [safety analysis report]. In general, the minimum requirement of an emergency electrical power system should be to ensure and maintain safe facility shutdown and to prevent uncontrolled release of radioactive material.

- The source of electrical power (generator, batteries, etc.) should be capable of supplying power for the duration required by the SAR analysis.

- The system should be designed for either automatic or manual startup and switchover.

- The emergency electrical power system should not interfere with or prevent safe facility shutdown.

- Malfunctions of the emergency electrical power system during … operation with normal electrical power should not interfere with normal … operation or prevent safe facility shutdown.

- Any non-safety-related uses of an emergency electrical power system should not interfere with performance of its safety-related functions.

- Technical specifications should be based on the accident analyses, should include surveillance and testing, and should provide reasonable assurance of emergency electrical power system operability. The discussions in the SAR should identify the minimum design requirements, the minimum equipment required, and the power and duration of operation required.

The NRC staff reviewed SHINE FSAR section 8a2.2 to verify that the functional characteristics of the SHINE emergency electrical power systems are commensurate with the design bases. The safety-related portion of the SHINE emergency electrical power systems is comprised of the UPSS. In addition, the design provides defense-in-depth with a non-safety-related SGS that will provide power to the UPSS upon a LOOP. The staff finds that the UPSS design provides the necessary power to the safety-related loads in order to ensure safe shutdown of the SHINE facility. Therefore, the staff finds that the SGS is not required to ensure safe shutdown of the facility.

The NRC staff evaluated the final design of the UPSS as described in SHINE FSAR section 8a2.2.1, “Uninterruptible Electrical Power Supply System Design Basis,” and section 8a2.2.3, “Uninterruptible Electrical Power Supply System Description.” SHINE stated that the UPSS provides power at a sufficient capacity and capability to allow safety-related SSCs to perform their safety functions. Further, SHINE used NFPA 70-2017 and portions of

IEEE Standard 384-2008 for the design of the UPSS. Although IEEE Standard 384-2008 provides the criteria for independence of Class 1E equipment, the SHINE UPSS safety-related equipment is not classified as Class 1E.

SHINE FSAR section 8a2.2.3 states that the safety-related UPSS provides a reliable source of power to the redundant divisions of AC and DC components on the safety-related power buses. Each division of the UPSS consists of a 125 VDC battery subsystem, 125 VDC to 208Y/120 VAC inverter, rectifier (battery charger), bypass transformer, static switch and a manual bypass switch, and 208Y/120 VAC and 125 VDC distribution panels. Each division of UPSS is normally powered by an emergency 480 VAC NPSS transfer bus via a division-specific battery charger. The emergency 480 VAC NPSS transfer buses can also be powered by the SGS, providing an alternate source of power to the UPSS.

In its response to NRC staff RAI 8-7 (ML21011A264), Enclosure 3 (ML21011A240), SHINE stated, "SHINE does not classify the UPSS as a Class 1E system. The NRC has not endorsed conformance with IEEE standards related to Class 1E power systems in satisfying the NRC's regulations with respect to the design, operation, and testing of safety-related power systems at non-power production and utilization facilities, like the NRC has for nuclear power plants." Additionally, the applicant stated, "While SHINE does not classify the UPSS as a Class 1E system and apply the full-scope of Class 1E-related standards to the UPSS, portions of Class 1E-related standards are applied to the design of the UPSS in order to satisfy applicable SHINE design criteria." SHINE FSAR section 8a2.2.3 provides details of the applicable portions of IEEE Standard 384-2008, such as sections 6.1.2.1, 6.1.2.2, and 6.1.2.3 for isolation of each UPSS division, and section 5.1.1.2, table 1 of section 5.1.3.3, and table 2 of section 5.1.4 for the physical separation of the electrical system. The staff finds that applying applicable portions of IEEE Standard 384-2008 for the design of safety-related electrical equipment within the UPSS provides reasonable assurance that the system is capable of providing the required power to perform the safety-related functions.

Section 8.2 of NUREG-1537, Part 2 provides that the emergency electrical power system source of electrical power should be capable of supplying power for the duration required by the FSAR analysis and that any malfunctions of the emergency electrical power system during facility operation with normal electrical power should not interfere with normal operation or prevent safe facility shutdown. Malfunctions that could impact the operation of the emergency system can be created by subcomponents, such as cables and connectors, associated with the emergency system. The SHINE UPSS is designed using applicable portions of IEEE Standard 384-2008. The NRC staff reviewed SHINE FSAR Chapter 8 to verify that SHINE provides a description of the safety classification of subcomponents used as part of the UPSS safety-related system to provide assurance that a malfunction of a subcomponent does not affect the operation of the facility. The staff confirmed by a request for confirmatory information that the UPSS subcomponents that support safety-related functions are classified as safety-related.

Sections 5.2, 6.2, 6.5, 7.1, 7.3, table 2 of 7.4, 7.6, and 7.9 of IEEE Standard 946-2004, "Recommended Practice for the Design of DC Auxiliary Power Systems for Generating Stations," are used for the design of the battery and the battery chargers for the UPSS. In its response to NRC staff RAI 8-9 (ML21183A125), Enclosure 2 (ML21183A128), SHINE stated that it follows "specific sections of IEEE standards to meet SHINE's facility-specific Design Criteria 4, 27, and 28. The specific portions of the standards used by SHINE are for the design, qualification, testing, installation, and maintenance of safety related electrical equipment."

SHINE provided justification of how the specific portions of the standard are sufficient to meet SHINE Design Criteria 27 and 28.

The NRC staff reviewed SHINE FSAR table 8a2.2-1 and compared the loads provided in the list with the design calculations and documents provided for the UPSS during the staff's regulatory audit to ensure that the emergency electrical power systems are designed in accordance with the applicable portions of IEEE Standard 384-2008. The staff reviewed the documentation to ensure that the UPSS is designed to provide the capacity and capability to perform its intended safety function. The staff finds that the safety-related load list is comprehensive and that the UPSS system is capable of providing the necessary range of safety-related services. In addition, the design and operating characteristics of the safety-related UPSS are reliable, ensuring availability if needed.

The safety-related UPSS is environmentally qualified in accordance with IEEE Standard 323-2003. IEEE Standard 323-2003 provides an acceptable methodology to provide qualification of the equipment within the UPSS. SHINE stated that safety-related UPSS equipment is located in a mild environment, is not subject to harsh environmental conditions during normal operation or transient conditions, and has no significant aging mechanisms. This equipment is designed and qualified by applying the guidance of sections 4.1, 5.1, 6.1, and 7 of IEEE Standard 323-2003 and is qualified to the environmental parameters provided in SHINE FSAR tables 7.2-2 and 7.2-3. The NRC staff determined that the SHINE facility does not have electrical equipment located in a harsh environment and, therefore, the staff finds that the applicable portions of IEEE Standard 323-2003 mentioned above provide an acceptable method to environmentally qualify the UPSS and meet SHINE Design Criterion 4.

The safety-related UPSS is seismically qualified in accordance with IEEE Standard 344-2013, "Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations." SHINE FSAR section 8a2.2.3 states that the UPSS is required to perform its safety function before, during, and after a seismic event, and is qualified by one of the testing methods described in sections 8 and 9.3 of IEEE Standard 344-2013. Regulatory Guide 1.100, Revision 4, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants" ML19312C677), endorses IEEE Standard 344-2013 as an acceptable method for meeting the seismic qualification requirements. Therefore, the NRC staff finds that SHINE's use of IEEE Standard 344-2013 provides an acceptable method for the seismic qualification of safety-related equipment. The staff concludes that the seismic qualification of the UPSS meets SHINE Design Criterion 4 and is acceptable.

SHINE FSAR section 8a2.2.3 states that the UPSS is isolated from the NPSS and SGS by isolating breakers feeding the battery chargers and the bypass transformers. Additionally, SHINE stated that the breakers monitor incoming power for voltage, phase, and frequency, and will trip when monitored variables are out of limits. SHINE used specific portions of IEEE Standard 384-2008 for the independence and separation of the safety-related electrical equipment. Regulatory Guide 1.75, Revision 3, "Criteria for Independence of Electrical Safety Systems" (ML043630448), endorses IEEE Standard 384-1992, "Criteria for Independence of Class 1E Equipment and Circuits," which provides acceptable methods for independence of safety-related electrical equipment. The NRC staff reviewed IEEE Standard 384-2008 and finds that the content in section 4.5.2 of the 2008 version of the standard is consistent with section 5.5.2 of the endorsed 1992 version of the standard. Therefore, the staff finds SHINE's use of IEEE Standard 384-2008 acceptable. The staff finds that the final design of the emergency electrical power systems will not interfere with safe facility shutdown or lead to damage if the systems malfunction during normal operation since the design meets the applicable portions of IEEE Standard 384-2008.

The NRC staff reviewed the separation of the safety-related bus from the non-safety-related bus connected to the UPSS. Each of the DC and AC safety-related loads and non-safety-related buses are described in SHINE FSAR section 8a2.2.3. The DC safety-related bus is separated using isolation overcurrent devices. SHINE categorized DC non-safety-related loads as associated equipment, as defined in section 4.5.2 of IEEE Standard 384-2008. For AC safety-related buses that provide power to non-safety-related loads, isolation from the safety-related portion of the bus is accomplished by isolation overcurrent devices. The staff finds SHINE's use of the applicable portions of IEEE Standard 384-2008 for the isolation and separation between safety-related and non-safety-related loads connected to the UPSS acceptable because the content in the 2008 version of the standard is consistent with the endorsed 1992 version of the standard.

The NRC staff evaluated the non-safety-related SGS as a defense-in-depth for the SHINE emergency electrical power systems. The SGS is described in SHINE FSAR section 8a2.2.4, "Standby Generator System Design Basis." SHINE stated that "the purpose of the SGS is to provide a temporary source of nonsafety-related alternate power to the UPSS and selected additional loads for operational convenience and defense-in-depth." The SGS functions are as follows:

- Will provide for the separation or isolation of safety-related circuits from nonsafety-related circuits, including the avoidance of electromagnetic interference with safety-related I&C [instrumentation and control] functions;
- Will provide an alternate source of power for the safety-related electrical buses;
- Will provide an alternate source of power to systems required for life-safety or important for facility monitoring;
- Will automatically start and supply loads upon a loss of off-site power; and
- Permits appropriate periodic inspection and testing to assess the continuity of the system and the condition of components.

The SGS is designed in accordance with article 700 of NFPA 70-2017. In its response RAI 8-10, SHINE described the specific portions within article 700 of NFPA 70-2017 used for the design of the SGS.

SHINE FSAR section 8a2.2.6, "Standby Generator System Description," states that, "The SGS consists of a 480Y/277 VAC, 60 Hertz (Hz) natural gas-driven generator, a 480 VAC switchgear, and transfer switches to allow the SGS switchgear to be connected to either or both 480 VAC NPSS transfer buses. Upon a loss of off-site power (LOOP) (i.e., undervoltage or overvoltage sensed on utility service), the SGS automatically starts, both non-vital breakers (NV BKR 1 and NV BKR 2) automatically open, and the transfer switches operate to provide power to the associated 480 VAC NPSS transfer bus." Although the SGS provides power upon LOOP, it is not required to provide safe shutdown of the SHINE facility. Based on the above, the NRC staff finds that the SGS provides additional defense-in-depth to the emergency electrical power systems of the SHINE facility.

8a.4.3 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed technical specifications (TSs) for the SHINE electrical power systems as described in SHINE FSAR Chapter 8.

The proposed TS 3.6, "Emergency Power," limiting condition for operation (LCO) 3.6.1 and surveillance requirement (SR) 3.6.1 state the following:

LCO 3.6.1	Two Divisions of the UPSS shall be Operable. A Division of UPSS is considered Operable if: 1. The battery, battery charger, inverter, alternating current (AC) distribution panel, and direct current (DC) distribution panel are Operable, 2. The inverter is supplied by the DC distribution panel and is supplying power to the AC distribution panel, and 3. The battery and battery charger are connected to the DC distribution panel.
Applicability	Facility not Secured
Action	According to Table 3.6.1
SR 3.6.1	1. UPSS battery voltage and specific gravity shall be checked semi-annually. 2. UPSS battery charger and inverter voltage shall be checked semi-annually. 3. UPSS AC and DC distribution panels shall be verified to be energized semi-annually. 4. UPSS discharge test shall be performed every five years.

The proposed TS Table 3.6.1, "UPSS Actions," states the following:

	Condition and Action	**Completion Time**
1.	If one Division of UPSS is inoperable, Restore the Division to Operable.	 72 hours
2.	If both Divisions of UPSS are inoperable, OR Associated action and completion time of Condition 1 not met Place all IUs undergoing irradiation in Mode 3 AND Suspend all work involving special nuclear material AND Open the VTS vacuum pump breakers	 1 hour 12 hours 12 hours

	AND Open at least one VTS vacuum break valve	12 hours
	AND Place tritium in all three trains of TPS process equipment in its storage location	12 hours
	OR Initiate a TPS Train Isolation for gloveboxes containing tritium.	12 hours

LCO 3.6.1 requires that two divisions of the UPSS be operable. Additionally, LCO 3.6.1 provides the conditions for the UPSS to be considered operable and the actions to be taken with completion times if one or two divisions are inoperable. The basis for the LCO 3.6.1 states, in part, "One Division of UPSS may be inoperable 72 hours to perform corrective or preventative maintenance. The 72-hour completion time is based on the availability of off-site power and the SGS. This provides a reasonable time to restore the UPSS to Operable status with an acceptably low risk. It also provides sufficient time to prepare and implement an orderly and safe facility shutdown if the UPSS is not restored to Operable status." The NRC staff finds that LCO 3.6.1 would ensure that the UPSS can supply power to safety-related loads upon loss of the normal electrical power systems. The staff also finds that the completion times would allow for corrective or preventative maintenance based on the availability of the normal electrical power systems and the SGS. Therefore, the staff finds that LCO 3.6.1 is acceptable.

SR 3.6.1 requires that the UPSS battery voltage and specific gravity be checked semi-annually, the UPSS battery charger and inverter voltage be checked semi-annually, the UPSS AC and DC distribution panels be verified to be energized semi-annually, and an UPSS discharge test be performed every five years. The NRC staff finds that SR 3.6.1 is consistent with section 4.6.2 of ANSI/ANS 15.1-2007, "The Development of Technical Specifications for Research Reactors." In addition, SHINE's UPSS batteries are maintained in accordance with section 5 of IEEE Standard 450-2010, "Recommended Practice for Maintenance, Testing, and Replacement of Vented Lead- Acid batteries for Stationary Applications." The staff finds that these surveillances would ensure that the UPSS is operable to perform its safety function when the SHINE facility is not secured and, therefore, the staff finds SR 3.6.1 acceptable.

The proposed TS 3.6, LCO 3.6.2 and SR 3.6.2 state the following:

LCO 3.6.2	Safety-related breakers listed in Table 3.6.2-a shall be Operable. A breaker is considered Operable if: 1. The breaker is capable of tripping on demand from TRPS or ESFAS
Applicability	According to Table 3.6.2-a
Action	According to Table 3.6.2
SR 3.6.2	1. Safety-related breakers listed in Table 3.6.2-a shall be verified to trip on demand from TRPS or ESFAS, as applicable, annually.

The proposed TS Table 3.6.2, “Safety-Related Breakers Actions,” states the following:

	Action	Completion Time
1.	If one Division of breakers for a single load listed in Table 3.6.2-a is inoperable, Open at least one redundant breaker.	12 hours
2.	If both Divisions of breakers for a single load listed in Table 3.6.2-a are inoperable, Open at least one redundant breaker.	1 hour

The proposed TS Table 3.6.2-a, “Safety-Related Breakers,” states the following:

	Component	Required Divisions	Applicability
a.	RVZ1 exhaust blower breakers	2 (per train)	Associated RVZ1 exhaust train operating
b.	RVZ2 exhaust blower breakers	2 (per train)	Associated RVZ2 exhaust train operating
c.	RVZ2 supply blower breakers	2 (per train)	Associated RVZ2 supply train operating
d.	VTS vacuum transfer pump breakers	2 (per pump)	Solution transfers using VTS in-progress
e.	MEPS extraction feed pump breakers	2 (per train)	Target solution present in the associated MEPS extraction hot cell
f.	NDAS HVPS breakers	2 (per IU)	Associated IU in Mode 1, 2, 3, or 4

LCO 3.6.2 requires that safety-related breakers be operable by ensuring that the TRPS and ESFAS are capable of opening all safety-related breakers listed in TS table 3.6.2-a. TRPS and ESFAS are evaluated in Chapter 7 of this SER. The NRC staff finds that LCO 3.6.2 would ensure that the TRPS and ESFAS would perform their safety functions to secure the components in TS table 3.6.2-a. For a single division inoperable, the staff finds that the completion time of 12 hours is acceptable because the redundant breaker remains operable and remains capable of securing the load. For both divisions inoperable, the staff finds that 1 hour is a reasonable time to promptly secure the equipment. Therefore, the staff finds LCO 3.6.2 acceptable.

SR 3.6.2 requires that the safety-related breakers listed in TS Table 3.6.2-a be verified to trip on demand from TRPS or ESFAS, as applicable, annually. The functions of the safety-related breakers are described in SHINE FSAR sections 7.4, “Target Solution Vessel Reactivity Protection System,” and 7.5, “Engineered Safety Features Actuation System.” SHINE’s safety-related breakers are designed in accordance with IEEE C.37.13-2015. The NRC staff determined that this surveillance would ensure that the safety-related breakers listed in TS table 3.6.2-a are capable of securing the components in TS table 3.6.2-a upon demand from the TRPS or ESFAS and is consistent with section 4.2.9 of ANSI/ANS 15.1-2007 to test control and safety system interlocks annually, therefore, the staff finds SR 3.6.2 acceptable.

8a.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE electrical power systems, as described in SHINE FSAR Chapter 8, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. The staff determined that the final design and functional characteristics of the NPSS and the emergency electrical power systems are commensurate with SHINE Design Criteria 4, 27, and 28. The NPSS provides reasonable assurance that in the event of a loss or interruption of electrical power, the facility can be safely shutdown. In addition, the emergency electrical power systems provide reasonable assurance that in the event of a loss of the NPSS, the UPSS can maintain the SHINE facility in a safe shutdown condition. The staff finds that the applicant's use of specific codes and standards provides reasonable assurance that the NPSS and the emergency electrical power systems meet SHINE Design Criteria 4, 27, and 28.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the facility electrical power systems and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE electrical power systems are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

8b Radioisotope Production Facility Electrical Power Systems

Section 8b, "Radioisotope Production Facility Electrical Power Systems," of this SER provides an evaluation of the final design of SHINE's RPF electrical power systems, as presented in SHINE FSAR section 8b, "Radioisotope Production Facility Electrical Power Systems."

8b.1 Areas of Review

As described in SHINE FSAR sections 8b.1 and 8b.2, respectively, the SHINE facility has one common normal electrical power system and one common emergency electrical power system, which serve both the IF and the RPF. Therefore, the areas of review described in section 8a.1, "Areas of Review," of this SER are applicable to both the SHINE IF and RPF.

8b.2 Summary of Application

As described in SHINE FSAR sections 8b.1 and 8b.2, respectively, the SHINE facility has one common normal electrical power system and one common emergency electrical power system, which serve both the IF and the RPF. Therefore, the summary of these systems provided in section 8a.2, "Summary of Application," of this SER is applicable to both the SHINE IF and RPF.

8b.3 Regulatory Basis and Acceptance Criteria

As described in SHINE FSAR sections 8b.1 and 8b.2, respectively, the SHINE facility has one common normal electrical power system and one common emergency electrical power system, which serve both the IF and the RPF. Therefore, the regulatory basis and acceptance criteria provided in section 8a.3, "Regulatory Basis and Acceptance Criteria," of this SER are applicable to both the SHINE IF and RPF.

8b.4 Review Procedures, Technical Evaluation, and Evaluation Findings

As described in SHINE FSAR sections 8b.1 and 8b.2, respectively, the SHINE facility has one common normal electrical power system and one common emergency electrical power system, which serve both the IF and the RPF. While the technical evaluation of these systems provided in section 8a.4, "Review Procedures, Technical Evaluation, and Evaluation Findings," of this SER is specific to the SHINE IF, the NRC staff's review considered the interface of these systems between the IF and the RPF as part of a comprehensive technical evaluation. The staff notes that SHINE FSAR section 8b has no unique content. The staff evaluated the content of SHINE FSAR section 8a2 as it pertains to the final design of functions and equipment necessary for RPF electrical power loads.

8b.4.1 Normal Electrical Power Systems

The NRC staff evaluated the sufficiency of the final design of the SHINE normal electrical power systems in the RPF, as presented in SHINE FSAR section 8a2.1, using the guidance and acceptance criteria from Section 8.1 of NUREG-1537, Parts 1 and 2, and Section 8a2 and section 8b of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff review included the offsite power service; power distribution system; standby diesel generator and supported loads; distribution equipment; facility grounding system; lightning protection system; cathodic protection system; freeze protection; and cable and raceway components and routing. The technical evaluation provided in section 8a.4.1, “Normal Electrical Power Systems,” of this SER applies to both the IF and RPF.

8b.4.2 Emergency Electrical Power Systems

The NRC staff evaluated the sufficiency of the final design of the SHINE emergency electrical power systems in the RPF, as presented in SHINE FSAR section 8a2.2, in part, by reviewing the UPSS; 250–VDC battery subsystem; nonsafety-related loads, maintenance, and testing; surveillance methods; seismic qualification; independence; single-failure criterion; and monitoring systems on the UPSS using the guidance and acceptance criteria from section 8.2 of NUREG-1537, Parts 1 and 2, and section 8a2 and section 8b of the ISG augmenting NUREG-1537, Parts 1 and 2. The technical evaluation provided in section 8a.4.2, of this SER “Emergency Electrical Power Systems,” applies to both the IF and RPF.

8b.4.3 Proposed Technical Specifications

As stated above and described in SHINE FSAR sections 8b.1 and 8b.2, respectively, the SHINE facility has one common normal electrical power system and one common emergency electrical power system, which serve both the IF and the RPF. Therefore, the evaluation of proposed technical specifications provided in section 8a.4.3, “Proposed Technical Specifications,” of this SER is applicable to both the SHINE IF and RPF.

8b.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE electrical power systems in the RPF, including proposed technical specifications, as described in SHINE FSAR section 8a2. The review findings provided in section 8a.5, “Review Findings,” of this SER are applicable to both the SHINE IF and RPF.

9.0 AUXILIARY SYSTEMS

The final design description of the auxiliary systems in the SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR) focuses on those structures, systems, and components (SSCs) and associated equipment that constitute the auxiliary safety systems and includes the overall design bases, system classifications, functional requirements, and system architecture. The auxiliary systems are designed for the operation of the SHINE irradiation facility (IF) and radioisotope production facility (RPF) (together, the SHINE facility).

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE facility auxiliary systems, as presented in Chapter 9, "Auxiliary Systems," of the SHINE FSAR and supplemented by the applicant's response to staff requests for additional information (RAIs).

9a Irradiation Facility Auxiliary Systems

Section 9a, "Irradiation Facility Auxiliary Systems," of this SER provides an evaluation of the final design of SHINE's IF auxiliary systems as presented in SHINE FSAR section 9a2, "Irradiation Facility Auxiliary Systems."

9a.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 9a2 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of SHINE's IF auxiliary systems. The final design of SHINE's IF auxiliary systems' control systems was evaluated to ensure that the design bases and functions of the systems and components are presented in sufficient detail to allow a clear understanding of the facility and that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the operating staff and the public. Drawings and diagrams were evaluated to ensure that they present a clear and general understanding of the physical facility features and of the processes involved. In addition, the staff evaluated the sufficiency of SHINE's proposed technical specifications (TSs) for the facility.

Areas of review for this section include a summary description of the IF auxiliary systems' control systems, as well as a detailed description of the IF confinement and radiologically controlled area (RCA) isolation. Within these review areas, the NRC staff assessed, in part, the design bases and functional descriptions of the required mitigative features of the auxiliary systems; drawings, schematic drawings, and tables of important design and operating parameters and specifications for the auxiliary systems; description of control and safety instrumentation, including locations and functions of sensors, readout devices, monitors, and isolation components, as applicable; and the required limitations on the release of confined effluents to the environment.

9a.2 Summary of Application

SHINE FSAR section 9a2 includes a summary of the auxiliary systems in the IF, including the design bases, a system description, operational analysis and safety function, instrumentation and control, and relevant TSs. The IF auxiliary systems include the heating, ventilation, and air conditioning (HVAC) systems, handling and storage of target solution, fire protection systems and programs, communication systems, possession and use of byproduct, source, and special nuclear material (SNM), cover gas control in closed primary coolant systems, and other auxiliary systems.

9a.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR section 9a2 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE IF auxiliary systems for the issuance of an operating license.

9a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's IF auxiliary systems are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.48, "Fire protection."
- 10 CFR 50.57, "Issuance of operating license."
- 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix A, "General Design Criteria for Nuclear Power Plants," Criterion 3, "Fire protection."
- 10 CFR Part 20, "Standards for Protection Against Radiation."

9a.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power

Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, "References," of this SER.

In addition, the following SHINE design criteria, located in SHINE FSAR Chapter 3, "Design of Structures, Systems, and Components," are applicable to various IF auxiliary systems:

- Criterion 29 - Confinement design
- Criterion 30 - Confinement design basis
- Criterion 31 - Fracture prevention of confinement boundary
- Criterion 32 - Provisions for confinement testing and inspection
- Criterion 33 - Piping systems penetrating confinement
- Criterion 34 - Confinement isolation
- Criterion 35 - Control of releases of radioactive materials to the environment
- Criterion 36 - Target solution storage and handling and radioactivity control
- Criterion 37 - Criticality control
- Criterion 38 - Monitoring radioactivity releases
- Criterion 39 - Hydrogen mitigation

9a.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR section 9a2, as supplemented, to assess the sufficiency of the final design and performance of SHINE's IF auxiliary systems for the issuance of an operating license. The sufficiency of the final design and performance of SHINE's IF auxiliary systems is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 9a.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in section 9a.5, "Review Findings," of this SER.

9a.4.1 Heating, Ventilation, and Air Conditioning Systems

The NRC staff evaluated the sufficiency of SHINE's HVAC systems, as presented in SHINE FSAR section 9a2.1, "Heating, Ventilation, and Air Conditioning Systems," using the guidance and acceptance criteria from section 9.1, "Heating, Ventilation, and Air Conditioning Systems," of NUREG-1537, Parts 1 and 2, and Section 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

9a.4.1.1 Radiologically Controlled Area Ventilation System

SHINE FSAR section 9a2.1.1, "Radiologically Controlled Area Ventilation System," states that the radiological ventilation (RV) systems include supply air, recirculating, and exhaust subsystems to condition the air and provide confinement and isolation. There are three ventilation systems in the RCA: Radiological Ventilation Zone 1 (RVZ1), RVZ2, and RVZ3. The FSAR also states the design basis of the RV systems as follows:

- Provide confinement at ventilation zone 1 confinement boundaries.
- Provide isolation at the RCA boundary.
- Confine airborne radiological materials in an accident scenario.
- Provide ventilation and makeup air and condition the RCA environment for workers and process equipment.
- Filter exhaust streams prior to them being exhausted out of the RCA.
- Maintain occupational exposure to radiation as low as is reasonably achievable (ALARA) and to ensure compliance with the requirements of 10 CFR Part 20.
- Exhaust hazardous chemical fumes.

<u>Radiological Ventilation Zone 1</u>

SHINE FSAR section 9a2.1.1.2, "System Description," states that RVZ1 consists of two subsystems, the RVZ1 recirculating subsystem (RVZ1r) and the RVZ1 exhaust subsystem (RVZ1e). SHINE FSAR figures 9a2.1-2, "Radiological Ventilation Zone 1 Recirculating Cooling Subsystem (RVZ1r) Flow Diagram," and 9a2.1-3, "Radiological Ventilation Zone 1 Exhaust Subsystem (RVZ1e) Flow Diagram," provide flow diagrams for these subsystems.

RVZ1r consists of two recirculation cooling units for each set of irradiation unit (IU) and target solution off-gas system (TOGS) cells, one providing cooling for the systems within the IU cell and one providing cooling for the TOGS cell. The two units are located in a common cooling room for each IU unit, thus there are a total of 16 recirculation units for the 8 IU units. Each RVZ1r unit consists of a high efficiency particulate air (HEPA) filter, carbon adsorbers, and cooling coil, aided by a blower and dampers to recirculate the air from the cell served by the unit. The cooling water of the cooling coils is provided by the non-safety-related RPF cooling system (RPCS), which in turn is cooled by the non-safety-related process chilled water system (PCHS). Condensate collected from the drip pan serving the IU cell is routed to the light water pool. In its response to NRC staff RAI 9-1(c) (Agencywide Documents Access and Management System Accession No. ML21095A241), Enclosure 2 (ML21095A229), SHINE stated that condensate from the cooling coil serving the TOGS cell is not expected because the TOGS cell cooling coil removes sensible heat only; however, the cooling coil is provided with a drip pan and drip pan heating elements in the event that small amounts of condensate were to form.

RVZ1e areas draw ambient supply air from adjacent ventilation zone 2 spaces, except for the supercell. The supercell is supplied air directly from RVZ2r. The air supplied to the supercell is exhausted by RVZ1e. During normal operation, areas ventilated by RVZ1e are maintained at negative pressure with respect to their surrounding ventilation zone 2 spaces. RVZ1e contains redundant fans, with one fan operating while the other fan is on standby. If the operating fan fails, the standby fan will start automatically.

The exhaust from both RVZ1e is drawn through a single filter bank consisting of HEPA filters and carbon adsorbers, connected to redundant exhaust fans. Figure 9a2.1-8, “Radiological Ventilation Zone 1 Exhaust Subsystem (RVZ1e) and Radiological Ventilation Zone 2 Exhaust Subsystem (RVZ2e) Mezzanine,” shows an isolable line to bypass the filter bank. The filter bank is located in the RCA mezzanine and the exhaust fans are located in the non-RCA mezzanine. Safety-related, automatic, bubble tight isolation dampers controlled by the engineered safety features actuation system (ESFAS) are located at the RCA boundary. Downstream of the dampers, also at the RCA boundary, is a tornado damper to protect the RCA from tornadoes. The filters and adsorbers are equipped with differential pressure monitoring equipment and are periodically monitored by operations personnel. The exhaust fans discharge to an exhaust stack that is shared with the process vessel vent system (PVVS). The NRC staff finds that the downstream safety-related, automatic isolation dampers controlled by ESFAS provide reasonable assurance that that the proposed systems are adequate to control the release of airborne radioactive effluents during the full range of facility operations.

In its response to NRC staff RAI 9-1(a) (ML21095A241), Enclosure 2 (ML21095A229), SHINE stated that the occupational dose requirements of 10 CFR Part 20 will be met during normal operations and maintenance by following the radiation protection practices and the radiation protection program described in SHINE FSAR section 11.1, “Radiation Protection.” The NRC staff evaluated SHINE’s radiation protection program in Chapter 11, “Radiation Protection Program and Waste Management,” of this SER.

Radiological Ventilation Zone 2

SHINE FSAR section 9a2.1.1.2 states that RVZ2 consists of three subsystems: the RVZ2 supply subsystem (RVZ2s), RVZ2r, and RVZ2e, as depicted in flow diagrams in SHINE FSAR figures 9a2.1-5, “Radiological Ventilation Zone 2 Supply Subsystem (RVZ2s) Air Handling Units,” 9a2.1-6, “Radiological Ventilation Zone 2 Supply Subsystem (RVZ2s) and Radiological

Ventilation Zone 2 Recirculating Cooling Subsystem (RVZ2r) Flow Diagram," and 9a2.1-4, "Radiological Ventilation Zone 2 Exhaust Subsystem (RVZ2e) Flow Diagram," respectively.

RVZ2s supplies conditioned outside air into the RCA to provide ventilation and cooling, and to make up for the air quantities exhausted by RVZ1e and RVZ2e subsystems. The system includes two air handling units (AHUs) containing filters, cooling and heating coils, a humidifier, and dampers. RVZ2s provides cooling, heating, and humidification for all areas within ventilation zone 2 and maintains the quality control lab and analytical labs at positive pressure with respect to the ventilation zone 2 general area. The AHUs are located in the non-RCA mezzanine with a tornado damper at the RCA boundary, including two redundant bubble tight dampers downstream of the tornado damper located within Zone 2 of the RCA.

RVZ2r recirculates, filters, and conditions air within the RCA. The system includes several AHUs, filters, ductwork, and dampers. The RVZ2r units are located within the RCA. RVZ2r units provide additional cooling for systems within ventilation zone 2. RVZ2r is also used to cool air supplied to the supercell, which reduces the flow rate required to cool the equipment within the supercell. In its response to NRC staff RAI 9-1(d) (ML21095A241), Enclosure 2 (ML21095A229), SHINE stated that condensate is not generated by RVZ2r units because the RVZ2r units function to remove sensible heat only, at temperatures above the dew point. SHINE also stated that the RVZ2s AHUs condition outside air by removing moisture prior to supply into the RCA.

The RVZ2e train contains HEPA filters and carbon adsorbers to remove airborne contaminants from the ventilation air stream. Figure 9a2.1-8 also shows an isolable line to bypass the filter bank in RVZ2e. The filter bank is located in the RCA mezzanine and the exhaust fans are located in the non-RCA mezzanine. Safety-related, automatic, bubble tight isolation dampers controlled by ESFAS are located at the RCA boundary. Downstream of the dampers, also at the RCA boundary, is a tornado damper to protect the RCA from tornadoes. The filters and adsorbers are equipped with differential pressure monitoring equipment and are periodically monitored by operations personnel. The exhaust fans discharge to an exhaust stack that is shared with the PVVS. The NRC staff finds that the downstream safety-related, automatic isolation dampers controlled by ESFAS provide reasonable assurance that that the proposed systems are adequate to control the release of airborne radioactive effluents during the full range of reactor operations.

<u>Radiological Ventilation Zone 3</u>

SHINE FSAR section 9a2.1.1.2 states that during normal operations, RVZ3 transfers air from ventilation zone 4 to ventilation zone 3 then from ventilation zone 3 to ventilation zone 2 via engineered pathways as depicted in SHINE FSAR figure 9a2.1-7, "Radiological Ventilation Zone 3 (RVZ3) Flow Diagram." Under accident conditions, bubble tight dampers in the pathways close, isolating ventilation zone 2 from ventilation zone 3. The design of RVZ3 includes a backdraft damper in the engineered pathways, which inhibits backflow within ductwork that could spread contamination to outside of ventilation zone 2. Transfer ductwork from ventilation zone 3 to ventilation zone 2 is provided for several areas of ingress/egress to and from the RCA, including emergency exits to the IF and RPF general areas.

In its response to NRC staff RAI 9-1(b) (ML21095A24), Enclosure 2 (ML21095A229), SHINE stated that the design of the engineered pathways, which includes backflow prevention by backdraft dampers in the pathways from RVZ3 to RVZ2 and from RVZ4 to RVZ 3, prevents the transfer of contaminated air from RVZ2 to ventilation zone 4 during entry and exit through

RVZ3. SHINE further stated that non-RCA areas are included in the surveys required by 10 CFR 20.1501 in the event of an inadvertent release of radioactive airborne material into non-RCA areas from a ventilation system or component failure.

RVZ1, RVZ2, and RVZ3 System Operation

SHINE FSAR section 9a2.1.1.3, “System Operation,” states that system operation between RVZ1e, RVZ2e, and RVZ2s is coordinated such that the overall airflow and pressure gradients are maintained. The pressure gradients create flow patterns that direct air towards areas of increasing contamination potential, maintained by the variable frequency drives on the exhaust fans. Minimum airflow will be maintained during normal system operation.

The building isolation dampers are safety-related automatic isolation dampers controlled by ESFAS. These dampers are located at the RCA boundary, upstream of the exhaust fans and exhaust stack. During upset conditions, affected sections of the RVZ1e, RVZ2s, and RVZ2e ventilation systems are isolated as required for the specific event or indication. Bubble tight dampers close, based on the detection of radiation at a predetermined level that is more than normal background radiation levels. Upon loss of power, loss of signal, or ESFAS initiation of confinement, dampers seal the affected confinement areas within 30 seconds. The NRC staff evaluated SHINE’s instrumentation and control system, including ESFAS, in Chapter 7, “Instrumentation and Control Systems,” of this SER.

RVZ2e exhausts the various normally occupiable rooms within the RCA, filters the air via HEPA filter banks, and discharges to the facility stack. Exhaust headers are maintained at a negative pressure by the variable frequency drives on the exhaust fans. Negative pressure is maintained in the ductwork to control contamination and maintain pressure gradients. The exhaust from RVZ2 areas collects in the RVZ2 system duct header and then is drawn through final HEPA filters and carbon adsorbers prior to discharge to the exhaust stack.

During normal operation, ventilation zone 2 areas are maintained at negative pressure with respect to RVZ3 airlocks. The speed of the RVZ2e exhaust fans is controlled to maintain a negative pressure setpoint in the RVZ2e exhaust header.

Ventilation zone 2 areas are directly supplied air by the RVZ2s AHUs. The AHUs supply conditioned air sourced completely from outside. Each AHU contains filters, pre-heat and cooling coils, and supply fans. The AHUs normally supply a constant volume of conditioned air to RVZ2 areas. The RVZ2 supply duct contains safety-related automatic isolation dampers located at the RCA boundary and controlled by ESFAS.

SHINE FSAR section 9a2.1.1.4, “Instrumentation and Control,” states that the process integrated control system (PICS) monitors the radiological ventilation system equipment, flow rates, pressures, and temperatures. Instrumentation monitors the ventilation systems for off-normal conditions and signals alarms as required. The PICS starts, shuts down, and operates the RVZ1r in normal operating modes. The building automation system starts, shuts down, and operates the RVZ1e and RVZ2 systems in normal operating modes. Coordinated controls maintain negative pressurization to create flow patterns that direct air toward areas of increasing contamination potential.

SHINE FSAR section 9a2.1.1.5, “Inspection and Testing,” states that the ventilation systems (RVZ1, RVZ2, and RVZ3) are balanced upon installation. Control systems are tested to ensure that control elements are calibrated and properly adjusted. Safety-related isolation dampers are inspected and tested as required by, and in accordance with, Section DA of American Society of Mechanical Engineers (ASME) AG-1, “Code on Nuclear Air and Gas Treatment.” Safety-related ductwork will be inspected and tested as required by, and in accordance with, Section SA of ASME AG-1.

Design Criteria

As stated in SHINE FSAR section 3.1, “Design Criteria,” the nuclear safety classification of safety-related SSCs at SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public; and to control or mitigate the consequences of such accidents. SHINE FSAR table 3.1-1, “Safety- Related Structures, Systems, and Components,” identifies the SSCs at SHINE that are classified as safety-related. The list includes the ventilation system features and all of its supporting structures and systems. SHINE FSAR table 3.1-3, “SHINE Design Criteria,” provides the generically applicable design criteria for the SHINE facility. The NRC staff focused on the design criteria applicable to the ventilation system features, namely criteria 29, 32, 35, and 39. For instance, many criteria shown in SHINE FSAR table 3.1-1 applicable to confinements are addressed in Chapter 6, “Engineered Safety Features,” of this SER. The applicable criteria are listed in section 9a.3.2 of this SER.

For criterion 29, the NRC staff finds that SHINE appropriately identified passive RCA boundaries and active components for the establishment of the fourth class of confinement boundaries (i.e., RCA ventilation isolations). The staff finds that the ventilation system RCA boundaries for the RCA ventilation zones are addressed in sufficient detail in SHINE FSAR section 9a2.1 and SHINE FSAR figures 9a2.1-5, 9a2.1-7, and 9a2.1-8.

For criterion 32, the NRC staff finds that periodic inspection, surveillance, and testing are satisfied by the proposed TSs.

For criterion 35, the NRC staff finds that the facility is equipped with isolation provisions in the ventilation system at the RCA boundary and that they are subject to the TSs.

For criterion 39, the NRC staff finds that the applicant has described systems to control the buildup of hydrogen that is released into the primary system boundary and ensure that the integrity of the system is maintained during normal operating conditions.

Based on the above, the NRC staff finds that the applicant provided final analysis and evaluation of the design and performance of SSCs as it relates to confinement and, therefore, satisfies 10 CFR 50.34(b)(4).

Conclusion

Based on its review, the NRC staff finds that the level of detail provided on the Radiologically Controlled Area Ventilation System for SHINE demonstrates an adequate description for its performance and, therefore, concludes that SHINE’s operating license application satisfies 10 CFR 50.34(b)(2).

The NRC staff evaluated the descriptions and discussions of SHINE’s Radiologically Controlled Area Ventilation System, including proposed TSs, as described in SHINE FSAR section 9a2.1, and finds that the final design of SHINE’s Radiologically Controlled Area Ventilation System, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9a.4.1.2 Non-Radiological Area Ventilation System

SHINE FSAR section 9a2.1.2, “Non-Radiological Area Ventilation System,” states that facility ventilation zone 4 (FVZ4) consists of areas that are located within the main production facility, but outside of the RCA, and is completely independent of the RVZ systems described in SHINE FSAR section 9a2.1.1. The FVZ4 system is non-safety related. FVZ4 exhausts directly to the outside of the main production facility with no radiation detectors present in the exhaust path, as contamination is not expected to be present in the FVZ4 system.

The design bases for the FVZ4 system are to provide environmental conditions suitable for personnel and equipment, maintain positive pressure with respect to the RCA, provide outside makeup air for ventilation, exhaust, and pressurization, maintain hydrogen concentration within acceptable limits (less than 2 percent) in the uninterruptible power supply (UPS) battery rooms, and remove hazardous chemical fumes from applicable spaces. The FVZ4 also provides transfer air into the RVZ3 system airlocks. The FVZ4 system consists of three subsystems: the FVZ4 supply and transfer air subsystem (FVZ4s), the FVZ4 exhaust subsystem (FVZ4e), and the FVZ4 room cooling recirculation subsystem (FVZ4r).

FVZ4s provides conditioned air for workers and equipment in the non-RCA portion of the facility, makeup air from outside to compensate for exhaust air systems in RVZ4, and to maintain positive pressure with respect to the RCA. The supply air distribution diagram of FVZ4s is provided in SHINE FSAR figure 9a2.1.9, “Facility Ventilation Zone 4 Supply and Transfer Air Subsystem (FVZ4s) Distribuiton.” The flow diagram of the return air associated with the FVZ4s is provided in SHINE FSAR figure 9a2.1-10, “Facility Ventilation Zone 4 Supply and Transfer Air Subsystem (FVZ4s) Return Air Flow Diagram.” The flow diagram of FZV4s subsystem AHUs is provided in SHINE FSAR figure 9a2.1-11, “Facility Ventilation Zone 4 (FVZ4) Air Handling Units (AHUs) (Typical).”

The FVZ4s consists of two 100 percent capacity AHUs and a single return air fan, with each AHU equipped with filters, heating and cooling coils, and supply fans. The AHUs are capable of providing a variable volume of conditioned air to FVZ4 areas, with a minimum flow determined by ventilation requirements. The FVZ4s supplies air to and the FVZ4e exhausts air from each battery and UPS room and each room can be independently isolated by dampers on an initiation signal from each location’s fire suppression system.

FVZ4e maintains hydrogen concentration below 2 percent in each battery and UPS room. Dedicated fans powered by the standby generator system are provided to exhaust the battery and UPS rooms during loss of power. The FVZ4e flow diagram is provided in SHINE FSAR figure 9a2.1-12, “Facility Ventilation Zone 4 Exhaust subsystem (FVZ4) Distribution Flow Diagram.”

FVZ4r recirculates and cools air within the electrical/telecommunication rooms. The subsystem is made up of two split systems that cool the server space. The FVZ4r subsystem provides equipment status to PICS. The supply air subsystem HVAC controls operate through the building automation system. The FVZ4 system is designed such that the building automation system monitors and controls the recirculation air subsystem ventilation equipment, flow rates, pressures, and temperatures. Instrumentation monitors the ventilation systems for off-normal conditions and signals alarms as required. In addition, the building automation system can perform start, shutdown, and operational functions of FVZ4 during normal operating modes, monitor supply and return air temperatures from the AHUs, and monitor pressure differential across the filters.

The FVZ4 system will be balanced and the HVAC control systems tested to ensure that control elements are calibrated, adjusted, and in proper working condition.

The NRC staff evaluated the descriptions and discussions of SHINE's Non-Radiological Area Ventilation System, as described in SHINE FSAR section 9a2.1, and finds that the final design of SHINE's Non-Radiological Area Ventilation System, including the design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9a.4.1.3 Facility Chilled Water System

SHINE FSAR section 9a2.1.3, "Facility Chilled Water System," states that the facility chilled water system (FCHS) is a closed-loop, forced circulation system which provides chilled water (CW) to the cooling coils of the RVZ2s subsystem AHUs. The FCHS also provides CW to the cooling coils of the FVZ4 AHUs. The FCHS rejects heat to the atmosphere via air-cooled chillers. The FVZ4 AHUs, RVZ2s AHUs, chillers, and CW pumps are located external to the RCA.

The FCHS is non-safety related. Primary components of the FCHS include air-cooled chillers, CW pumps, system piping and valves, makeup water and water treatment equipment, and an expansion tank. The CW pumps are equipped with variable frequency drives, and the CW supply lines to RVZ2s and FVZ4 contain a modulating flow control valve capable of a fully-open or fully-closed valve position. AHU system flow, temperature, and differential pressure are utilized by an FCHS controller to signal valves, pumps, and chillers to come online, vary speed, or secure as necessary to meet system setpoints during normal system operation.

PICS monitors the RVZ2s and FVZ4 airstream delivery temperatures. An FCHS controller monitors flow control valve position and delivers a signal to individual valves to adjust cooling water flow rates in response to signals sent to the load instrumentation. A flow control valve is maintained on the system bypass line and is controlled by input signals from FCHS controller inputs made by chiller supply, RVZ2s, and FVZ4 modulating flow control valves. When the FCHS controller registers that a pump is not running, and a stop command has not been issued from the control panel, an alarm is generated at the control panel and the standby pump is automatically started.

Local chiller equipment monitors differential pressure across each chiller and the chillers' running status. Upon communication of a fault alarm, an FCHS controller isolates that chiller's modulating flow control valve and issues a start command to the backup chiller. System pumps respond accordingly to the loading of the chillers via a local controller.

The system maintains alarms monitored by the building automation system and displays them in the control room. All FCHS controls are non-safety related.

The FCHS testing requirements for water piping, pipe supports, and valves are in accordance with ASME B31.9, "Building Services Piping." Hydrostatic tests are performed in accordance with Section 937.3 of ASME B31.9. Visual welding inspections are performed on piping and piping supports in accordance with ASME B31.9.

The NRC staff evaluated the descriptions and discussions of SHINE's FCHS, as described in SHINE FSAR section 9a2.1, and finds that the final design of SHINE's FCHS, including the design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9a.4.1.4 Facility Heating Water System

SHINE FSAR section 9a2.1.4, "Facility Heating Water System," states that the design bases of the facility heating water system (FHWS) are to supply heated water to the RVZ2s and the FVZ4 system, as well as other heating coils outside of the RCA, and be able to maintain system operation in the event of a single pump or single boiler failure. The FHWS is non-safety related.

The FHWS consists of equipment required to deliver heating hot water to the RVZ2 and FVZ4 AHUs in non-RCA portions of the main production facility. The primary components of the FHWS are three 50 percent natural gas-fired boilers, three 50 percent centrifugal hot water pumps, eight 100 percent centrifugal pumps for heating coil freeze protection, an air separator, and an expansion tank. Two pumps each are provided on the FVZ4s and the RVZ2s to maintain freeze protection. If one pump is down for maintenance, the other can ensure freeze protection.

The flow through the system is varied by modulating the pump speed based upon maintaining the pressure differential across the pumps. A bypass valve is installed at the end of the coil loop piping to maintain the minimum flow required to operate the pumps.

The FHWS provides the necessary output signal to PICS for the monitoring of heating water temperatures, pressures, and flow rates. Low water cutoff controls and flow sensing controls are provided, which automatically stop the combustion operation of the boiler when the water level drops below the lowest acceptable water level or when water circulation stops.

FHWS piping design, installation, inspection, and testing are in accordance with ASME B31.9. Hydrostatic tests are performed in accordance with Section 937.3 of ASME B31.9. Visual welding inspections are performed on piping and piping supports in accordance with ASME B31.9.

The NRC staff evaluated the descriptions and discussions of SHINE's FHWS, as described in SHINE FSAR section 9a2.1, and finds that the final design of SHINE's FHWS, including the design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9a.4.2 Handling and Storage of Target Solution

The NRC staff evaluated the sufficiency of SHINE's handling and storage of the target solution, as presented in SHINE FSAR section 9a2.2, "Handling and Storage of Target Solution," using the guidance and acceptance criteria from section 9.2, "Handling and Storage of Reactor Fuel," of NUREG-1537, Parts 1 and 2, and Section 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 9a2.2.2, "Irradiation Facility Target Solution Storage and Handling," states that target solution is transferred from the target solution hold tank to the target solution vessel (TSV) via the TSV fill lift tank by using the vacuum transfer system. The target solution in the TSV fill lift tank gravity drains into the TSV. Upon completion of filling the TSV, any remaining target solution in the TSV lift tank is drained back into the target solution hold tank. After filling the TSV with target solution, the TSV is isolated from the TSV fill lift tank and the target solution hold tank by closing two fill valves in series. SHINE FSAR section 9a2.2.3, “Irradiation Facility Target Solution Handling Equipment,” states that the major equipment that interacts with the target solution in the IF are eight TSVs and eight connected TSV dump tanks. Both the TSV and TSV dump tanks are located within the IU cell. SHINE FSAR section 9a2.2.6, “Biological Shielding,” states that the irradiation cell biological shield ensures that projected radiation dose rates and accumulated doses in occupied areas within the IF do not exceed the limits of 10 CFR Part 20 and supports SHINE’s radiation exposure goal described in SHINE’s ALARA program. The IF biological shield is evaluated in section 4a.4.5, “Irradiation Facility Biological Shield,” of this SER. Reactivity control mechanisms for the TSV are evaluated in section 4a.4.2.2, “Reactivity Control Mechanisms,” of this SER. SHINE’s ALARA program is evaluated in section 11.4.1.3 and the nuclear criticality safety program is evaluated in section 6b.4.3 of this SER.

The NRC staff finds that methods for handling, moving, and storing target solution in the IF provide reasonable assurance that potential personnel doses from irradiated target solution will not exceed regulatory limits in 10 CFR Part 20 and support SHINE’s ALARA program.

9a.4.3 Fire Protection Systems and Programs

The NRC staff evaluated the sufficiency of SHINE’s fire protection systems and programs, as presented in SHINE FSAR section 9a2.3, “Fire Protection Systems and Programs,” using the guidance and acceptance criteria from section 9.3, “Fire Protection Systems and Programs,” of NUREG-1537, Parts 1 and 2, and Section 9a2, “Aqueous Homogeneous Reactor Auxiliary Systems,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 9a2.3.1, “Fire Protection Plan and Program,” states that the applicant’s Fire Protection Program (FPP) ensures, through the application of the defense-in-depth (DID) concept, that a fire will not prevent the performance of necessary safety-related functions and that radioactive releases to the environment, in the event of fire, will be minimized. The SHINE FPP describes the overall program and references individual program elements, including the fire hazard analysis (FHA), the safe shutdown analysis (SSA), administrative controls, pre-fire plans, implementing procedures, etc.

SHINE FSAR section 9a2.3.2, “Design Bases,” states that fire protection DID for the SHINE facility is designed to do the following:

- Prevent fires from starting, including limiting combustible materials;
- Detect, control, and extinguish those fires that do occur to limit consequences; and
- Provide protection for SSCs important to safety so that a continuing fire will not prevent the safe shutdown of the IUs or cause an uncontrolled release of radioactive material to the environment.

During the NRC staff’s review, the need for additional information was identified, resulting in an RAI dated June 23, 2021 (ML21162A318). In response, SHINE submitted letters dated December 30, 2021 (ML21364A055), and February 28, 2022 (ML22059A017). The additional information requested is intended to ensure that the operating license applicant has provided and developed sufficient analyses applicable to and commensurate with the risks of releases of radioactive material associated with fire hazards in the unrestricted environment at the site, and that any doses received by members of the public are within the regulatory limits of 10 CFR Part 20. Additionally, the RAI sought to confirm that SHINE's fire protection plan includes the applicable elements of 10 CFR 50.48 and satisfies SHINE's principal design criteria. As part of the staff's evaluation, its RAI and the applicant's responses are summarized below.

In NRC staff RAI 9-3(a), the staff requested that the applicant discuss firefighting procedures for use in a moderation-controlled area and evaluate the use of moderator material (i.e., water) as an extinguishing agent. In its response to RAI 9-3(a) (ML21364A055), the applicant stated that use of moderation as a controlled parameter, including firefighting procedure evaluation, is described in SHINE FSAR section 6b.3, "Nuclear Criticality Safety," and is in accordance with ANSI/ANS-8.22-1997, "Nuclear Criticality Safety Based on Limiting and Controlling Moderators." The applicant further stated that subsection 9a2.3.8 of the FSAR states, "Fire response using water-based extinguishants [in the target solution preparation system (TSPS) and uranium receipt and storage system (URSS) rooms] is prohibited; elevated floors of the URSS and TSPS fire area are provided to prevent flooding of these rooms," and that pre-fire plans, developed in accordance with the FPP, note where water use is restricted due to a criticality hazard.

Based on the information provided by the applicant, the NRC staff concludes that the applicant satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant has established firefighting procedures for use in a moderation-controlled area and has evaluated the use of moderator material.

In NRC staff RAI 9-3(b), the staff requested that the applicant discuss specific guidance in the Rock County 911 Communications Center's SHINE-specific response information binder on the use of firefighting foam at the SHINE facility. In its response to RAI 9-3(b) (ML21364A055), the applicant stated, in part, that:

> [T]he SHINE specific response information binder to be provided to the Rock County 911 Communications Center will provide specific guidance on the use of firefighting foam at the SHINE facility. The response information binder will be developed and provided to the Communication Center as part of the development and implementation of the SHINE Emergency Plan Implementing Procedures (EPIPs). The SHINE EPIPs will be submitted to the NRC no less than 180 days before the scheduled issuance of the SHINE operating license in accordance with Section V of Appendix E to 10 CFR Part 50.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant stated that the Rock County 911 Communications Center response information binder will be developed and provided to the Communications Center as part of the development and implementation of the SHINE EPIPs and that the SHINE EPIPs will be submitted to the NRC no less than 180 days before the scheduled issuance of the SHINE operating license in accordance with Section V of Appendix E to 10 CFR Part 50.

In NRC staff RAI 9-4(a), the staff requested that the applicant discuss its fire protection organization, its staffing, and their responsibilities. In its response to RAI 9-4(a) (ML21364A055), the applicant provided the requested information including discussions regarding responsibilities of the Safety Analysis Manager, the Operations Manager, the

Maintenance Manager, the Fire Protection Staff, and the Fire Response Team. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant described its fire protection organization, including its staffing and responsibilities, which provides reasonable assurance that the applicant has an acceptable organization, appropriate administrative controls, and qualified key management positions to satisfy the regulatory requirements for a license to possess and use radioactive material.

In NRC staff RAI 9-4(b), the staff requested that the applicant discuss fire protection engineering design bases. In its response to RAI 9-4(b) (ML21364A055), the applicant stated that Appendix A to 10 CFR Part 50, General Design Criterion 3, has been adopted and revised for application to the SHINE facility to define the design bases for fire protection engineering, and that SHINE Design Criterion 3 is defined in table 3.1-3 of the FSAR. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant has adopted General Design Criterion 3, which ensures that the FPP is based on evaluation of potential fire hazards throughout the facility and the effect of postulated design basis fires relative to maintaining the ability to perform safe shutdown functions, to protect SSCs from fire and minimize radioactive releases to the environment.

In NRC staff RAI 9-4(c), the staff requested that the applicant provide a description of electrical cable construction. In its response to RAI 9-4(c) (ML21364A055), the applicant stated that electrical cables selected for use, to the extent practicable, are constructed to recognized flame spread test criteria and that plant cabling is selected and routed to minimize its contribution to combustible loading. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant stated that the electrical cables are constructed to recognized flame spread test criteria and that cable trays are routed to minimize its contribution to combustible loading.

In NRC staff RAI 9-4(d), the staff requested that the applicant discuss the fire brigade and fire brigade training program. In its response to RAI 9-4(d) (ML21364A055), the applicant stated that it does not employ a fire brigade, and consequently, does not have a fire brigade training program. Additional information regarding the applicant's manual fire-fighting capability can be found in the discussions for RAIs 9-4(f), 9-4(g), and 9-7(e).

In NRC staff RAI 9-4(e), the staff requested that the applicant discuss its general employee fire protection training program. In its response to RAI 9-4(e) (ML21364A055), the applicant stated that as part of the implementation of the FPP, general employee fire protection training will be provided to facility employees upon initial hire with refresher training performed periodically. The applicant further stated that this training covers general fire protection awareness, FPP introduction, fire prevention, fire reporting, and response to fire alarms. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant's general employee fire protection training program covers the appropriate topics.

In NRC staff RAI 9-4(f), the staff requested that the applicant discuss pre-fire planning and emergency planning considerations. In its response to the RAI 9-4(f) (ML21364A055), the applicant stated:

Pre-Fire Plans are developed for the main production facility to provide information for trained facility personnel and responding professional firefighters. Pre-Fire Plans are designed to aid firefighting personnel in their response to fires through identification of hazards, process activities, access routes, and available firefighting equipment. Pre-Fire Plans provide the basis for development of firefighting strategies for responder training and incident command. Pre-Fire Plans contain the following information, as appropriate:

- Area Identification
- Fire Hazards
- Radiation Hazards
- Electrical Information (electrical disconnect)
- Hazardous Substances
- Physical Hazards
- Communications
- Access/Egress Routes
- Fixed Fire Systems
- Portable Firefighting Equipment
- Safe Shutdown Guidance

Off-site fire support is requested to respond to fires that progress beyond the incipient stage. SHINE has developed a memorandum of understanding (MOU) with the Rock County Sheriff's Office – Emergency Management Bureau, for incident response at the SHINE facility. This MOU is designed to facilitate periodic training, fire and emergency incident command protocol, and to identify key SHINE Emergency Response contacts, in accordance with the SHINE Emergency Plan.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant demonstrated that it has developed adequate pre-fire plans and emergency planning considerations.

In NRC staff RAI 9-4(g), the staff requested that the applicant discuss manual firefighting capability. In its response to RAI 9-4(g) (ML21364A055), the applicant stated that manual firefighting is not credited for safe shutdown or the protection of safety-related equipment in the event of a fire. The applicant further stated that the SHINE facility does have portable fire extinguishers throughout the facility for use by SHINE personnel in the suppression of incipient-stage fires and that in the RCA there are Class I standpipes where firefighters responding to an emergency can get water for their hoses. The applicant further stated that exterior to the SHINE buildings, there are fire hydrants arranged around the fire water loop. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant demonstrated that it has developed adequate manual fire-fighting capability to control or mitigate a fire.

In NRC staff RAI 9-4(h), the staff requested that the applicant discuss lighting and communications for operator actions. In its response to RAI 9-4(h) (ML21364A055), the applicant stated that operator actions are not required to put the facility in a safe shutdown state in the case of a fire and that lighting, including emergency lighting, is provided to illuminate means of egress in accordance with the International Code Council, “International Building Code” (IBC), and National Fire Protection Association (NFPA) 101-2012, “Life Safety Code.” The applicant further stated that fire alarms throughout the facility will notify occupants of a detected fire and that alarm response is initiated by facility operators in accordance with site procedures. The applicant stated that additional communication systems in the facility include a public announcement system and sound-powered telephones for communication among operators in the facility. Based on the information provided by the applicant, the NRC staff concludes that the applicant’s response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant demonstrated that operator actions are not needed to achieve safe shutdown in the event of fire and because emergency lighting is provided in accordance with applicable codes and standards.

In NRC staff RAI 9-4(i), the staff requested that the applicant discuss its fire protection corrective action program and compensatory measures. In its response to RAI 9-4(i) (ML21364A055), the applicant stated that its corrective action program applies to the FPP and fire protection related operations; and that identified failures, malfunctions, deficiencies, deviations, defective components, uncontrolled combustibles, and non-conformances are promptly identified and corrected in accordance with the corrective action program. The applicant further stated that compensatory measures are used to provide an added level of safety for areas where fire protection systems or equipment are out of service or degraded and that compensatory measures, such as fire watches, are intended to be temporary measures and may not be permanently relied on for fire protection. Based on the information provided by the applicant, the NRC staff concludes that the applicant’s response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant demonstrated that its corrective action program applies to its FPP and fire protection related operations and that its fire protection compensatory measures program is intended to be temporary and not permanently relied on for fire protection.

In NRC staff RAI 9-4(j), the staff requested that the applicant discuss fire testing, qualification reports, and data for fire-rated systems, barriers, and assemblies. In its response to RAI 9-4(j) (ML21364A055), the applicant stated:

> Installations of fire protection equipment are inspected by qualified personnel to validate critical parameters and provide assurance of construction/installation with design requirements. Personnel, independent of the activity performed are assigned inspection duties to verify:
>
> - Installation, maintenance, or modification of fire protection features, systems, or equipment.
> - Installation, maintenance, or modification of electrical raceway fire barrier systems, fire barrier features, fire barrier segments, penetration seals, fire retardant coatings.

> Acceptance procedures/instructions are documented in design control packages. Periodic inspection/surveillance, preventive maintenance, and system testing is conducted in accordance with approved plant administrative and maintenance procedures. Plant inspection and surveillance schedules are documented to demonstrate required surveillance, testing, and preventive maintenance is conducted within appropriate timeframes. These inspection, surveillance, maintenance, and system testing activities will be performed and documented in accordance with the requirements of the IBC and NFPA 801, Standard for Facilities Handling Radioactive Materials.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant demonstrated that its acceptance, inspection, testing, and maintenance programs provide a reasonable level of assurance that adequate fire protection quality assurance is maintained for fire protection systems and features.

In NRC staff RAI 9-4(k), the staff requested that the applicant discuss fire protection features of the facility's emergency diesel generator room and battery room. In its response to RAI 9-4(k) (ML21364A055), the applicant stated that the uninterruptible power supply system (UPSS) battery rooms and equipment rooms are separated from the rest of the facility by walls with a fire resistance rating of 3 hours and that these rooms are protected by an automatic clean-agent fire detection and suppression system. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3, because the facility does not have an emergency diesel generator room and because the UPSS battery rooms and equipment rooms are provided with adequate fire barriers and fire protection systems.

In NRC staff RAI 9-4(l), the staff requested that the applicant confirm that SHINE will follow 10 CFR 50.59, "Changes, tests, and experiments," as the change control process for making changes to its fire protection features and program. In its response to RAI 9-4(l) (ML21364A055), the applicant stated that it will follow 10 CFR 50.59 as the change control process for making changes to its fire protection features and program. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant will follow an acceptable change process for making changes to its FPP.

In NRC staff RAI 9-5(a), the staff requested that the applicant describe the facility construction elements related to the FPP. In its response to RAI 9-5(a) (ML21364A055), the applicant stated:

> The SHINE facility consists of non-combustible construction, of IBC Type II-B …. Fire-rated barriers separate the individual fire areas within the SHINE facility. Fire barriers in the SHINE facility have fire resistance ratings of 1, 2, or 3 hours. The fire resistance rating is determined by the Fire Hazards Analysis (FHA), and considers regulatory requirements (e.g., IBC fire barrier requirements) as well as assessments of fire area contents, means of egress considerations, and equipment separation considerations. The RCA is separated from the non-RCA portion of the building by a 3-hour-rated fire barrier. Exit stairways are protected by 2-hour-rated fire barriers. Fire barrier design and construction is in accordance with the IBC and NFPA 801 ….

> Where fire-rated barriers are penetrated by pipes, ducts, conduits, raceways or other such penetrations, fire barrier penetration material is placed in and around the penetrations to maintain the fire-resistance rating of the barrier.
>
> Fire doors and dampers are rated commensurate with the fire barrier in which they are installed and comply with the requirements of NFPA 80, Standard for Fire Doors and Other Opening Protectives … and NFPA 90A, Standard for the Installation of Air-Conditioning and Ventilating Systems ….

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant described the facility construction elements related to the FPP and demonstrated that these elements were designed in accordance with applicable codes and standards.

In NRC staff RAI 9-5(b), the NRC staff requested that the applicant discuss facility life safety features related to the FPP. In its response to RAI 9-5(b) (ML21364A055), the applicant stated:

> The SHINE facility life safety features are designed in accordance with NFPA 101, Life Safety Code … and the IBC ….
>
> Automatic fire detectors are installed where required. In addition, manual pull stations are installed to allow personnel to activate the fire alarm system. Upon actuation of the fire alarm system, audible and visual indicating devices will provide notification to personnel to evacuate the building.
>
> Emergency exits are available from all areas of the facility within the IBC allowed maximum travel distance of 200 feet. Common path of travel does not exceed the allowed maximum of 100 feet per the IBC. Dead-end corridors do not exceed the allowed maximum of 50 feet per the IBC.
>
> The illumination of means of egress is provided in accordance with the life safety code and IBC.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant described the facility life safety features related to the FPP and demonstrated that these features were designed in accordance with applicable codes and standards.

In NRC staff RAI 9-5(c), the staff requested that the applicant describe facility fire protection water supply systems. In its response to RAI 9-5(c) (ML21364A055), the applicant stated:

> The fire water distribution subsystem provides firefighting water to the main production facility and those outbuildings requiring fire water service. The system draws water from the municipal water supply and directly supplies water to the building sprinkler systems, and fire hydrants. The municipal water supply provides suction for two 100 percent capacity fire pumps that supply water to a fire water distribution loop and water-based fire suppression systems installed in the facility, including the fire hose standpipes in the RCA and automatic fire sprinklers in the administrative areas. Multiple hydrants are arranged around the main production

> facility, and fire water supply is sufficient to supply the greatest single suppression system demand plus a 500 gallons per minute (gpm) hose stream allowance for a period of 1-1/2 hours.
>
> The fire water distribution supply loop is designed such that individual legs of the loop may be isolated for system maintenance or testing without interruption of supply to unaffected portions of the system. Fire hydrants are provided around the facility structures.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant described the facility fire protection water supply system and demonstrated that the system was designed to meet the fire protection design demands.

In NRC staff RAI 9-5(d), the staff requested that the applicant discuss fire protection active and passive fire suppression systems. In its response to RAI 9-5(d) (ML21364A055), the applicant stated:

> The main production facility contains a water-based, wet-pipe fire sprinkler subsystem, a standpipe subsystem, and a gaseous suppression subsystem.
>
> Automatic water-based, wet-pipe fire sprinkler systems are designed to provide fire suppression in several general/administrative areas of the facility. The system piping contains water provided by the fire water distribution subsystem at the static system pressure for the water distribution system. These systems maintain fire suppression water available at each sprinkler, with water spray provided immediately upon activation of a sprinkler ….
>
> The standpipe system is provided to facilitate manual firefighting capability in the RCA by responding professional firefighters. A Class I standpipe system is installed to provide 2-1/2 inch (in.) (65 millimeter [(mm)]) hose line connections for fire use by fire department personnel. This system allows distribution of firefighting water to the interior of the RCA from the fire water distribution subsystem. Manual dry standpipes are arranged to allow admission of firefighting water to be piped into the RCA, as necessary, to support manual firefighting in these areas ….
>
> Gaseous suppression systems are used for fire hazards where a clean agent or inert gas is needed to protect sensitive electronic equipment or in areas where nuclear criticality or other hazards preclude the use of water for fire suppression. These areas include the URSS and TSPS rooms, the Supercell, the radioactive liquid waste immobilization (RLWI) enclosure, the facility control room, the uninterruptible power supply equipment and battery rooms, and certain small rooms containing electrical and information technology (IT) equipment. These systems discharge a gaseous fire suppression agent from pressurized storage tanks into the protected volume/room achieving a predetermined concentration of agent required to accomplish fire suppression. The system can be activated by a signal from the area fire detection and alarm system and/or manually. Local pre discharge alarm and delay allow personnel evacuation before the suppression system actuates ….

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3

because the applicant described its active and passive fire suppression systems and demonstrated that they provide reasonable assurance to detect and control a fire and minimize radiological contamination in areas where fissile material is handled.

In NRC staff RAI 9-5(e), the staff requested that the applicant discuss facility fire detection and alarm/signaling systems. In its response to RAI 9-5(e) (ML21364A055), the applicant stated:

> The main production facility fire detection and alarm subsystems are designed to detect and provide early warning/notification of fire. These systems detect fire through the placement of signal initiating devices (e.g., smoke/heat detectors, manual pull boxes, supervisory switches) throughout the protected portions of the facility. Detection devices communicate via a communications loop and local fire alarm panels with the master fire alarm panel located in the facility control room. Alarm, supervisory, and trouble signals are received at the facility control room and alarms are annunciated within the protected space for occupant notification. Alarm response is initiated by facility operators in accordance with site emergency or standard operating procedures.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant described its facility fire detection and alarm/signaling systems and demonstrated that they provide reasonable assurance to detect and provide notification of a fire.

In NRC staff RAI 9-5(f), the staff requested that the applicant discuss the codes of record for the facility lightning protection system, including justification for the choice of code and any deviations. In its response RAI 9-5(f) (ML21364A055), the applicant stated that the facility grounding and lightning protection system adheres to the requirements of NFPA 780-2014, "Standard for the Installation of Lightning Protection Systems," without deviation and that adherence to NFPA 780-2014 is consistent with the guidance provided in section 5.12 of NFPA 801. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant demonstrated that its lightning protection system is designed in accordance with applicable codes and standards.

In NRC staff RAI 9-6, the staff requested that the applicant:

a. Summarize the safe shutdown performance goals and the safe shutdown analysis methodology.

b. Identify the functions required for safe shutdown. Such functions may include inventory control, process monitoring, and reactivity control. Include any auxiliary equipment or cables required to support a safe shutdown function (e.g., room cooling).

c. Identify any required safe shutdown function that has only a single train and justify how such a configuration can ensure safe shutdown in the event of a fire.

d. Describe the separation criteria for redundant trains of a safe shutdown function located in the same fire area.

e. Describe and justify any deviations from the separation criteria described in item (d).

f. Identify the fire area(s) that contain equipment or cables from all trains of a required safe shutdown function. If such area(s) exist, describe how safe shutdown is ensured for a fire occurring in that fire area(s).

g. Identify any fire areas where fire damage could prevent safe shutdown. If such areas exist, justify how safe shutdown is ensured for a fire occurring in those fire areas.

h. Identify the entry conditions for the facility fire safe shutdown procedure.

i. Identify the guidance used to perform any safe shutdown-related circuit analysis.

In its response to RAI 9-6 (ML22059A017), Enclosure 2 (ML22059A020), the applicant provided additional details regarding its fire SSA.

The applicant identified the following safe shutdown criteria and goals in the event of a fire:

Safe Shutdown Criteria	Safe Shutdown Goal
Reactivity control	maintain the target solution subcritical
Combustible gas control	maintain the functionality of the combustible gas control system
Target solution cooling	maintain the target solution cooling system to prevent boiling
Radioactive material barriers	prevent the uncontrolled release of radiation

The applicant also identified the following safe shutdown functions that support the identified safe shutdown criteria:

Reactivity Control

The applicant identified that reactivity control is achieved using the IU Cell Safety Actuation system, which is initiated by the TSV reactivity protection system (TRPS). This involves the opening of the TSV dump valves and the closing of the TSV fill valves.

Combustible Gas Control

The applicant identified that combustible gas control is achieved using the active function of TOGS and nitrogen purge via the nitrogen purge system (N2PS), initiated by the TRPS and ESFAS. SHINE further stated that to maintain hydrogen concentrations at acceptable levels TOGS must be powered for 5 minutes after an IU Cell Safety Actuation. The UPSS is the safety-related source of this power.

Target Solution Cooling

The applicant identified that target solution cooling is achieved using natural convection cooling of the TSV dump tank through the dump tank wall via the passive light water pool system.

Radioactive Material Barriers

The applicant identified that the uncontrolled release of radioactive material to the environment is prevented by the IU Cell Safety Actuation initiated by the TRPS and RCA isolation initiated by ESFAS. These actuations move appropriate valves, ventilation dampers, and circuit breakers to their safe positions.

The applicant stated that none of these safe shutdown functions rely on a single train of equipment.

The applicant described its safe shutdown strategy in its response to RAI 9-6. Based on this description, the NRC staff identified the following key aspects of SHINE's safe shutdown strategy:

- Reliance on redundant or fail-safe components to perform safe shutdown functions;
- Automatic fire suppression and fire detection systems;
- Spatial separation of redundant cables and equipment by at least 20 feet where automatic fire suppression is provided and at least 40 feet where automatic fire suppression is not provided;
- Where separation cannot be provided, the use of fire modeling analysis to determine whether both trains of components can be damaged by a single fire;
- Cables in conduit embedded in structural concrete;
- Consideration of levels of fire area occupancy (continuous/restricted/none); and
- Administrative controls.

The applicant stated that there are no fire areas where the separation criteria could not be met.

For fire areas that contain only a single train of safe shutdown components for a safe shutdown function, the opposite train is available to achieve the safe shutdown function.

The applicant identified seven areas that contain more than one train of safe shutdown components for at least one safe shutdown function.

Fire Area 1 – RPF General Area

The applicant stated that based on the separation of Divisions A and B cables, the Division A cables being mostly embedded in concrete, and the limited combustible loading in the area, a single fire would not damage both redundant trains. The applicant further stated that this conclusion was supported by modeling results for hot gas layer temperatures for potential fire scenarios and that each redundant component in this area moves to the safe position on loss of power and has a redundant component in the opposite train that can fulfil the function in the case the first is spuriously powered.

Fire Area 2 – IU and TOGS Cells (8 Cells Each)

The applicant stated that the physical and fire protection features of this area (limited oxygen supply due to the sealed nature of each cell, limited combustible load, and early warning fire detection capabilities in each cell exhaust duct) would prevent a single fire from damaging components in redundant TOGS trains. Regarding the other (non-TOGS) redundant safe shutdown components, the applicant stated that they each move to the safe position on loss of power and each has a redundant component in the opposite train that can fulfil the function in the case the first is spuriously powered.

Fire Area 2 – IF General Area Mezzanine

The applicant stated that the fire protection features of this area (limited combustible load, very early smoke detection, manual fire suppression capability, and transient combustible controls) would keep a single fire from damaging components in redundant trains. The applicant further stated that each redundant component in this area moves to the safe position on loss of power and has a redundant component in the opposite train that can fulfil the function in the case the first is spuriously powered.

Fire Area 2 – Tritium Purification System Room

The applicant stated that the fire protection features of this area (limited combustible load, very early smoke detection, manual fire suppression capability, and transient combustible controls) would keep a single fire from damaging components in redundant trains. The applicant further stated that each redundant component in this area moves to the safe position on loss of power and has a redundant component in the opposite train that can fulfil the function in the case the first is spuriously powered.

Fire Area 2 – TOGS Motor Control Center Hallway

The applicant stated that fire modeling demonstrates that both trains of TOGS motor control center (MCC) cannot be damaged by a single fire and that all train A TOGS cables are imbedded in concrete.

Fire Area 15 – Facility Control Room

The applicant stated that based on the spatial separation of redundant systems (UPSS, ESFAS, and TRPS panels), continuous occupancy leading to prompt fire detection and suppression, and the installed automatic clean agent suppression system, a single fire would not damage both trains of a redundant safe shutdown function.

Fire Area 19 – Ship/Receive Alcove

The applicant stated that this area has transient and combustible controls in place and installed smoke detection and that each redundant component in this area moves to the safe position on loss of power and has a redundant component in the opposite train that can fulfil the function in the case the first is spuriously powered.

Safe Shutdown Procedure Entry

The applicant stated that procedures and training will direct operators to manually actuate (if not already automatically actuated) the TRPS and ESFAS systems under any of several conditions, including a fire that cannot be controlled or requires offsite assistance, deteriorating control room habitability, or at the discretion of the operator in the event of loss of control of the facility, power loss, erratic indication, or evidence of spurious operation.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response to RAI 9-6 satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3, because the applicant appropriately addressed safe shutdown of the facility by establishing safe shutdown criteria and goals, identifying safe shutdown functions and equipment, developing a safe shutdown strategy, evaluating fire areas containing redundant components of safe shutdown functions, and identifying safe shutdown procedure entry conditions.

In NRC staff RAI 9-7(a), the staff requested that the applicant discuss fire protection systems design criteria. In its response to RAI 9-7(a) (ML21364A055), the applicant stated:

a. Design criteria for the facility fire protection systems include:

- Fire water loop system flow requirement: 1,500 gpm at 100 pounds per square inch (psi)

- Manual dry standpipes are located such that they will provide 100 percent coverage of the RCA assuming a 100-foot (ft.) (30.5 meter [m]) hose and 30-ft. (9.1 m) hose stream.

- Minimum Density for Automatic-Sprinkler Piping Design:

  - Light-Hazard Occupancy: 0.10 gpm over 1500 square foot (sq. ft.) area.
  - Ordinary-Hazard, Group 1 Occupancy: 0.15 gpm over 1500-sq. ft. area.

In addition:

- The fire detection and alarm systems are designed, installed, tested, and maintained in accordance with NFPA 72, National Fire Alarm and Signaling Code ….

- The automatic wet-pipe fire sprinkler system is designed, installed, tested and maintained in accordance with NFPA 13, Standard for the Installation of Sprinkler Systems ….

- The standpipe system is designed, installed, tested, and maintained in accordance with NFPA 14, Standard for the Installation of Standpipe and Hose Systems ….

- The automatic gas-based fire suppression systems are designed, installed, tested, and maintained in accordance with NFPA 2001, Standard on Clean Agent Fire Extinguishing Systems ….

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3, because the applicant described its fire protection systems design criteria, which is in accordance with applicable codes and standards.

In NRC staff RAI 9-7(b), the staff requested that the applicant discuss control of ignition sources. In its response to RAI 9-7(b) (ML21364A055), the applicant stated:

> Administrative controls are established to manage hot work (i.e., welding, cutting, grinding, and open flames) in facility areas that are not designated for such operations. These controls are developed in accordance with NFPA 51B, Standard for Fire Prevention During Welding, Cutting, and Other Hot Work …. The procedure for hot work is designed to ensure hot work is adequately controlled to mitigate the potential for ignition of combustibles and to provide immediate response if a fire does occur.
>
> Locations designated for the performance of hot work are designated as permanent hot work locations in accordance with the ignition control procedures. Hot work performed outside of designated locations is conducted under permit and in accordance with the ignition control procedures.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3, because the applicant described its control of ignition sources program and demonstrated that it is in accordance with applicable codes and standards.

In NRC staff RAI 9-7(c), the staff requested that the applicant discuss fire prevention methods intended to control handling, use, and disposal of combustible materials. In its response to RAI 9-7(c) (ML21364A055), the applicant stated:

> Combustible loading of fire areas and fire zones that contain safety-related equipment are carefully managed to maintain combustible loading as low as reasonable without impeding normal facility operations. In accordance with SHINE Design Criterion 3, noncombustible and heat resistant materials are used wherever practical throughout the facility and particularly in locations containing safety-related equipment.
>
> Combustible loading control is managed in accordance with FHA-assigned fire load limits. Combustible loading for each area containing safety-related equipment is

tracked in the combustible loading calculation. This calculation is used to determine the baseline (in-situ) combustible loading for each affected fire area or zone. The difference in the baseline loading and the maximum allowable loading for the fire loading category assigned in the FHA identifies the maximum available transient combustible loading for the area under consideration.

The combustible control procedure identifies requirements and restrictions for the use, handling, storage, and disposal of combustible materials, including:

- Spacing and separation requirements for transient combustible storage;
- Housekeeping requirements, including disposal requirements for combustible wastes (supplementing the housekeeping procedure);
- Requirements for the use, handling, and storage of lumber and plastic;
- Requirements for the use, handling, and storage of combustible and flammable liquids and gases; and
- Requirements for the use of transient combustible permits.

The combustible control procedure requires an engineering evaluation to be performed when a variance from procedure requirements is needed, or work activities require significant amounts of flammable or combustible liquids outside of approved storage rooms or storage cabinets.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant described adequate fire prevention methods intended to control handling, use, and disposal of combustible materials.

In NRC staff RAI 9-7(d), the staff requested that the applicant discuss fire protection procedures, instructions, and design drawings. In its response to RAI 9-7(d) (ML21364A055), the applicant stated:

The FPP elements are controlled by administrative, engineering, maintenance, and operations procedures. The topics of these procedures include:

- Ignition control;
- Control of combustibles;
- Housekeeping;
- Surveillance, inspection, maintenance, and testing of fire protection systems;
- Compensatory measures for out of service or degraded fire protection systems;
- Fire watches; and

- Fire protection training, including general employee fire protection program awareness, fire watch personnel training, and SHINE Fire Response Team training.

> General area drawings are prepared to depict important fire protection information. These fire protection drawings document general arrangement of fire areas, fire zones, fire barriers and ratings, extinguishers, fire suppression system coverage, fire detection system coverage, hose connections, fire doors, fire dampers, fire hydrants, and other key fire protection equipment. In addition to general area drawings, information on individual fire protection systems and components is depicted on detailed drawings (e.g., component drawings, piping and instrumentation diagrams [(P&IDs)]).

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant described adequate fire protection procedures, instructions, and design drawings.

In NRC staff RAI 9-7(e), the staff requested that the applicant discuss manual fire suppression actions. In its response to RAI 9-7(e) (ML21364A055), the applicant stated that incipient stage fire suppression is provided by trained SHINE personnel using fire extinguishers and that for fires beyond the incipient stage, firefighting by professional firefighters is managed via pre-fire planning and interface with on-shift operations personnel. Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant demonstrated appropriate manual fire suppression actions.

In NRC staff RAI 9-8(a), the staff requested that the applicant provide a list of the building and fire codes and standards that it considered in the design of the facility as related to the development of the FPP and implementing procedures, including identification of the edition (year). For codes and standards where more than one edition is used, the staff requested that the applicant identify which edition pertains to which areas of the facility. In its response to RAI 9-8(a)(ML21364A055), the applicant stated:

> SHINE applies the following building and fire codes and standards in the design of the SHINE facility, as related to the development of the FPP and implementing procedures:

- [IBC], 2015 Edition …, and codes listed therein, as amended by the Wisconsin Administrative Code

- International Fire Code (IFC), 2015 Edition …, as amended by the Wisconsin Administrative Code

- NFPA 1, Fire Code, 2012 Edition …, as amended by Wisconsin Administrative Code

- NFPA 801, Standard for Fire Protection for Facilities Handling Radioactive Materials, 2014 Edition …, and codes listed therein

> There are no instances where SHINE applies more than one edition of a code or standard to the design of the SHINE facility, as related to the development of the FPP and implementing procedures.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant identified the building and fire codes and standards that it considered in the design of the facility and also identified other applicable codes of record in its FHA.

In NRC staff RAI 9-8(b), the staff requested that the applicant identify and justify any deviations from the codes and standards for the design and installation of fire protection systems identified in RAI 9-8(a). In its response to RAI 9-8(b) (ML22178A032), Enclosure 2 (ML22178A035), the applicant identified the following deviations and provided the following justifications:

> Deviation: Section 903.2.4 of the IBC … requires an automatic sprinkler system for group F-1 occupancies; however, the SHINE facility does not provide an automatic sprinkler system in the radiologically controlled area (RCA).
>
> Justification: SHINE will not install an automatic sprinkler system in the RCA because the release of water into the RCA could cause a nuclear criticality hazard or lead to the spread of radioactive contamination. Section 903.3.1.1.1 of the IBC provides exemption from the automatic sprinkler system requirements for certain rooms or areas protected by an approved automatic fire detection system where, in part, application of water, or flame and water, constitutes a serious life or fire hazard. SHINE will seek approval of the exempted condition for the RCA as part of the fire protection plan review for the SHINE facility by the Wisconsin Department of Safety and Professional Services.
>
> Deviation: Section 5.13.1 of NFPA 801-2014 … requires less-hazardous dielectric fluids to be used in place of hydrocarbon-based insulating oils for transformers and capacitors located inside buildings or where they are an exposure hazard to important facilities. SHINE uses a hydrocarbon-based insulating oil within the high-voltage power supply (HVPS) transformers.
>
> Justification: SHINE has determined that the use of a hydrocarbon-based insulating oil within the HVPS transformer does not present an exposure hazard. Each HVPS is installed with an oil catchment assembly installed around the transformer. The HVPS oil catchment is designed to contain the entire contents of the transformer oil and contain any spray or leaking under pressure. Additionally, a worst-case fire for an HVPS was evaluated in a fire modeling calculation, and the calculation determined the worst-case fire involving an HVPS will not cause structural failure of the facility roof trusses or bridge cranes.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3

because the applicant justified the code deviations by demonstrating that the use of water in the RCA has the potential to create a nuclear criticality hazard and spread radioactive contamination, and that the use of hydrocarbon-based insulating oil in the HVPS transformers does not present an exposure hazard and will not cause structural failure of the facility roof trusses or bridge cranes.

In NRC staff RAI 9-9, the staff requested that the applicant do the following:

a. Discuss means of egress for fire areas and zones and means of egress protection.

b. Describe the types of combustibles found in each fire area.

c. Describe combustible loading in fire areas and zones.

d. Discuss fire hazards and ignition sources that were considered for facility fire areas.

e. Describe the types of fire-resistant coatings and electric raceway fire barriers systems used for the protection of electrical cables and structural steel.

f. Identify the fire modeling tools or methods used in the development of the fire hazard analysis including how these tools or methods were applied. Describe the process to validate and verify the fire models, including any calculational and numerical methods used, used in support of fire hazard analysis. Discuss how the fire modeling uncertainties were accounted in the fire modeling calculations.

g. Describe how the installed cabling in the fire areas was characterized. Specifically, describe the critical damage threshold temperatures and heat fluxes for thermoset and thermoplastic cables consistent with the use of these cables in the facility. Include an explanation of how exposed temperature-sensitive equipment was treated in the fire modeling and justify the damage criteria that was used for such equipment. Alternatively, justify why this information is not necessary.

In its response to RAI 9-9 (ML22178A032), Enclosure 2 (ML22178A035), the applicant:

a. Discussed means of egress for fire areas and zones and means of egress protection;

b. Described the types of combustibles found in each fire area;

c. Described combustible loading in fire areas and zones;

d. Discussed fire hazards and ignition sources that were considered for facility fire areas;

e. Described the types of fire-resistant coatings and electric raceway fire barriers systems used for the protection of electrical cables and structural steel;

f. Identified the fire modeling tools or methods used in the development of the FHA including how these tools or methods were applied, discussed the process to validate and verify the fire models used in support of the FHA, and discussed how the fire modeling uncertainties were accounted for in the fire modeling calculations; and

g. Described how the installed cabling in the fire areas was characterized including specifically describing the critical damage threshold temperatures and heat fluxes for thermoset and thermoplastic cables consistent with the use of these cables in the facility and included an explanation of how exposed temperature-sensitive equipment was treated in the fire modeling and justified the damage criteria that was used for such equipment.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant adequately responded to each question and demonstrated that its answers were in accordance with applicable codes and standards and standards of good practice for fire protection.

In NRC staff RAI 9-10, the staff requested that the applicant describe that:

- The plans for preventing fires ensure that the facility meets local and national fire and building codes;

- The systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time;

- The potential for radiological consequences of a fire will not prevent safe shutdown, and any fire-related release of radioactive material from the facility to the unrestricted environment has been adequately addressed in the appropriate sections of the facility emergency plan; and

- Any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20.

In its response to RAI 9-10 (ML21364A055), the applicant stated:

> Accident scenarios related to fire and internal flooding due to fire water are described in Subsections 13a2.1.11 and 13a2.2.11 of the FSAR. These scenarios are prevented or mitigated to an acceptable level of risk, in accordance with the SHINE Safety Criteria, including the limit on the total effective dose equivalent to an individual member of the public not exceeding 1 rem over the duration of the event.
>
> A description of the internal flooding event is provided in Section 3.3 of the FSAR. Liquid firefighting related effluents are prevented from exiting the RCA through the use of 2-inch berms or ramps at each exit from the RCA.
>
> The radiological ventilation (RV) systems include isolation dampers that close on radiation detection through the engineered safety features actuation system (ESFAS) and target solution vessel (TSV) reactivity protection system (TRPS). If the gaseous firefighting related effluents contain radiological materials, these systems

automatically initiate an RCA Isolation, Supercell Area Isolation, Tritium Purification System (TPS) Process Vent Actuation, TPS Train Isolation, or Irradiation Unit (IU) Cell Actuation depending on the impacted region of the facility. These isolations provide confinement of gaseous effluents, including contaminated smoke, for as long as postulated accident conditions require. In this way, gaseous firefighting effluents, including smoke, that contain radiological materials are contained within facility boundaries and prevent accident consequences from exceeding the SHINE Safety Criteria.

> The RV systems also contain smoke detectors downstream of the air filters and ahead of any branch connections in air supply systems, per NFPA 90A, Standard for the Installation of Air-Conditioning and Ventilating Systems …. These smoke detectors automatically stop their respective fan(s) on detecting the presence of smoke.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant adequately responded to each question and demonstrated that its answers were in accordance with applicable codes and standards and standards of good practice for fire protection.

In its response to RAI 9-10, the applicant also described how contaminated gaseous and liquid fire-fighting effluents will be contained within the facility. The applicant described the automatic isolation feature of the radiological ventilation system, which will provide the containment of contaminated gaseous effluents to within the RCA. The applicant further stated that the ramps and berms will confine any fire-fighting water to within the RCA, and that because contaminated effluents are confined within the RCA, the public radiological exposure will be bounded by the design-basis accident (DBA) fire scenarios.

Based on the information provided by the applicant, the NRC staff concludes that the applicant's response satisfies the acceptance criteria described in NUREG-1537, Part 2, section 9.3 because the applicant demonstrated that it has a program in place to contain contaminated gaseous and liquid fire-fighting effluents.

Based on the information contained in the SHINE FSAR and RAI responses, the NRC staff finds that there is reasonable assurance that a release of radioactive material as a result of fire will not cause radiation exposures that exceed the requirements of 10 CFR Part 20.

Conclusion

The NRC staff reviewed the fire protection portion of the applicant's operating license application; the procedures for maintaining an acceptable level of fire protection; and the design basis of fire protection systems and their components including the safety function, system descriptions, safety assessments, and other related information that the applicant provided to demonstrate that it is prepared to prevent and/or control or extinguish fires. The NRC staff's review also encompassed design basis considerations, such as redundancy, independence, reliability, and quality. The NRC staff used section 9.3 of NUREG-1537, Parts 1 and 2, as guidance in performing the review and various nationally recognized codes and standards, as appropriate, in evaluating the reasonable assurance of the facility's fire protection systems and programs.

The NRC staff reviewed the applicant's design basis for fire protection, its SSA, its FHA, and fire-related administrative control procedures as described in the operating license application. The NRC staff concludes that fire protection-related SSCs and DID controls are designed, constructed, and used consistent with good engineering practice, which dictates that certain minimum requirements be applied as design and safety considerations for any new nuclear material process or facility. Based on its evaluation, the NRC staff concludes that there is reasonable assurance that the applicant's fire protection systems and programs are in conformance with the guidelines of NUREG-1537, Parts 1 and 2, and that there is reasonable assurance that the facility meets the requirements of 10 CFR 50.48(a) and Criterion 3 of Appendix A to 10 CFR Part 50 with respect to fire protection. In addition, the NRC staff concludes that there is reasonable assurance that a fire in any plant area during any operational mode and plant configuration will not prevent the plant from achieving safe shutdown and maintaining a safe and stable condition and will also not cause radiation exposures that exceed the requirements of 10 CFR Part 20.

Based on the above, the Commission concludes that (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner; (2) there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations; and (3) the issuance of the operating license will not be inimical to the common defense and security or to the health and safety of the public.

9a.4.4 Communication Systems

The NRC staff evaluated the sufficiency of SHINE's communication systems, as presented in SHINE FSAR section 9a2.4, "Communication Systems," using the guidance and acceptance criteria from section 9.4, "Communication Systems" of NUREG-1537, Parts 1 and 2, and Section 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR Section 9a2.4 describes the facility data and communication system (FDCS) that provides the ability to communicate during both normal and emergency conditions between different areas of the production facility and the main facility, support buildings, and remote locations to the SHINE site. SHINE Emergency Plan, section 9.1, "Control Room," states that the control room is provided with communications equipment to communicate within and outside the SHINE facility, which includes commercial telephones, sound-powered phones, base station radios, and the ability to broadcast information on the public address system. FSAR section 9b.4, "Communication Systems," states that the communication systems for the SHINE facility are common to both the IF and the RPF.

SHINE FSAR section 9a2.4.1, "Telephones," describes the general design of the telephone communication system. The FSAR states that the SHINE facility uses a commercial telephone communication system that provides for onsite two-way communication, paging and public address, and party-line-type voice communications for the main facility and outbuildings. The system is provided power from the standby generator system (SGS), as described in SHINE FSAR section 8a2.2, "Emergency Electrical Power Systems," should a loss of offsite power occur.

SHINE FSAR section 9a2.4.3, "Sound-Powered Phones," describes the general design and operation of the sound-powered phone system. The FSAR states that the sound-powered phones supplement the commercial telephone communication system. These phones plug into local terminal jacks where critical operations and response activities are anticipated to occur within the site. Because the sound-powered phones operate independent of any electrical power source, the system provides uninterrupted communications in the event of a loss of power to the facility. The NRC staff finds that the sound-powered phones provide two-way communications between different locations throughout the facility. SHINE Emergency Plan, section 9.8.3, “Sound Powered Phones,” states that a sound-powered phone is located in the control room.

Based on the information in SHINE FSAR sections 9a2.4.1 and 9a2.4.3, the NRC staff finds that both the telephone communication system and the sound-powered phone system are designed to provide two-way communications between the control room and other locations to support safe operation of the facility.

SHINE FSAR section 9a2.4.2, “Public Address System,” describes the general design and operation of the public address (PA) system. The FSAR states that the PA system, using the commercial telephone communication system, is designed to make announcements site-wide or to specified predefined areas. Specifically, the PA system is designed to be audible in occupiable areas in the RCA, normally occupied areas of the facility and support buildings, hallways and corridors of the facility and support buildings, and outdoor areas within the controlled access area fence. The PA system includes a prioritization such that announcements from the control room override any other use of the PA system. The PA system has a battery backup to ensure system reliability during any loss of power.

Based on the information in SHINE FSAR section 9a2.4.2, the NRC staff finds that the PA system is designed to announce emergency information to the entire facility and support buildings.

SHINE FSAR section 9a2.4.4, “Radio System,” describes the general design and operation of the hand-held portable radios. The FSAR states that hand-held portable radios, powered by rechargeable battery packs, are provided to communicate with offsite emergency support organizations. This system allows for communication with the Janesville Fire and Police Departments using P25 transmission protocols. In the case of loss of offsite electrical power, backup power is provided by the SGS, as described in FSAR section 8a2.2. SHINE Emergency Plan, section 9.8.4, “Radio,” states that the handheld portable radios are located in the control room and available for use by facility emergency organization personnel as an additional onsite backup communication device. Additionally, SHINE Emergency Plan, section 9.8.5, “Mobile Telephones,” states that a mobile telephone is stored in the control room and serves as a back-up onsite and offsite communication system.

The design of the telephone system, as described in SHINE FSAR section 9a2.4.1, provides facility personnel the ability to contact or receive calls from any outside telephone number to ensure that offsite personnel can be contacted for assistance in case of an emergency. Further, designated emergency cell phones located in the control room, emergency support center (ESC), and backup ESC can be used to contact offsite personnel in case of an emergency.

Based on the information in the FSAR, sections 9a2.4.4 and 9a2.4.1, the NRC staff finds that the facility communication systems are designed to contact both onsite and offsite emergency personnel for assistance.

SHINE FSAR section 9a2.4.8, “Technical Specifications,” states that there are no TSs associated with the communication systems. The NRC staff reviewed NUREG-1537, Part 1, appendix 14.1, “Format and Content of Technical Specifications for Non-Power Reactors,” and

ANSI/ANS-15.1-2007, "The Development of Technical Specifications for Research Reactors," for guidance on the inclusion of the communication systems in TSs. The staff didn't identify any specific guidance for including a communication system in TSs. Further, the staff reviewed the TSs of several non-power reactors to identify whether communication systems were included within the facilities' TSs. The staff did not identify any TS requirements for a communication system. Based on the staff's review of similar facilities' TSs and the guidance in NUREG-1537, Part 1, and ANSI/ANS-15.1-2007, the staff finds that no TSs are necessary for the communication systems. Therefore, the staff finds that the lack of a TS requiring SHINE's communication systems is acceptable.

The NRC staff finds that the design of the SHINE communications systems provides effective two-way communication between locations essential for safe operation of the facility, allows for a facility-wide announcement of an emergency, and has provisions for contacting offsite personnel for assistance in case of an emergency. Therefore, the staff finds that the SHINE communication systems, as described in SHINE FSAR section 9a2.4, meet all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9a.4.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

The NRC staff evaluated the sufficiency of SHINE's program for possession and use of byproduct, source, and SNM in the IF, as described in SHINE FSAR section 9a2.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," using the guidance and acceptance criteria from section 9.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," of NUREG-1537, Parts 1 and 2, and Section 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 9a2.5 states that the IF is designated as an RCA and that radiation protection program controls and procedures, including the ALARA program, apply to the IF as described in SHINE FSAR Section 11.1. SHINE FSAR figure 1.3-1, "Main Production Facility Building General Arrangement," identifies the areas and rooms that constitute the IF and the RPF.

SHINE FSAR section 9a2.5.1, "Byproduct Material," states that the SHINE facility is designed to generate byproduct material, such as molybdenum-99 (Mo-99) for use as medical isotopes, fission and activation products, and tritium within the neutron driver assembly. Additionally, the FSAR states that up to eight neutron sources are used, one in each IU, for startup operations.

SHINE FSAR section 9a2.5.2, "Source Material," states that the IF includes depleted uranium within the tritium purification system and natural uranium within the neutron multiplier. By letter dated April 29, 2021 (ML21119A165), as supplemented on August 20, 2021, and December 2, 2021 (ML21242A028 and ML21336A193, respectively), SHINE requested to amend its construction permit for the SHINE facility to allow the receipt and possession of certain radioactive materials during the construction of the facility. On December 2, 2021 (ML21320A224), the NRC issued Amendment No. 2 to the construction permit to authorize SHINE to receive and possess sealed neutron sources. Further, the amendment authorized SHINE to receive and possess natural uranium in the form of neutron multipliers and depleted uranium in the form of tritium storage beds.

SHINE FSAR section 9a2.5.3, "Special Nuclear Material," states that the IF includes low enriched uranium (LEU) within the TSV. The LEU is irradiated to Mo-99 by fission within the IF. Further, the FSAR states that plutonium is generated in the target solution and the neutron multiplier. The FSAR also states the total amount of LEU used in the IF to support facility operation. By letter dated October 15, 2021 (ML21288A543), SHINE notified the NRC of the submission date for a planned request to license certain byproduct, source, and SNM to support initial facility operations.

Based on the above information, the NRC staff finds that SHINE has radiation protection controls, procedures, and an ALARA program to help ensure that potential radiation exposures to workers are within the limits of 10 CFR Part 20. The staff finds that the authorized spaces for the use of material have been sufficiently described. Further, the staff finds that the use of controls and procedures provides reasonable assurance that an uncontrolled release of radioactive material to the unrestricted environment will not occur. The staff notes that SHINE will submit a separate request for a license to use and possess certain byproduct, source, and SNM to support initial facility operations.

9a.4.6 Cover Gas Control in Closed Primary Coolant Systems

The NRC staff evaluated the sufficiency of SHINE's cover gas control in the primary coolant systems, as presented in SHINE FSAR section 9a2.6, "Cover Gas Control in Closed Primary Coolant Systems," using the guidance and acceptance criteria from section 9.6, "Cover Gas Control in Closed Primary Coolant Systems," of NUREG-1537, Parts 1 and 2, and Section 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 9a2.6 states that the Primary Closed Loop Cooling System (PCLS) is the closed loop cooling system that provides cooling to the TSV. Buildup of radiolysis products in the PCLS is controlled by the ventilation of the PCLS expansion tank by RVZ1. Cover gas control for the PCLS is described in SHINE FSAR section 5a2.2, "Primary Closed Loop Cooling System," and depicted in SHINE FSAR figure 5a2.2-1.

The PCLS cooling water leaves the subcritical assembly system (SCAS) and enters the PCLS air separator, which allows entrained radiolytic gas to separate from the cooling water. In addition to hydrogen and oxygen, the headspace contains air, water vapor, and small amounts of Nitrogen-16 and Argon-41. An interface between the RVZ1e and the expansion tank allows radiolytic gases to be purged to RVZ1e, preventing the buildup of hydrogen gas. Ambient air from within the primary confinement boundary is drawn through a flame arrestor and filter for sweeping of the expansion tank headspace. SHINE FSAR section 5a2.2.7, "Hydrogen Limits," states that radiolysis of the primary cooling water and the light water pool results in the generation of hydrogen and oxygen gases. The RVZ1 draws air from the primary confinement and through the PCLS expansion tank, and SHINE provided figures to support that the nominal flow rate provided by RVZ1e is significantly greater than the combined quantity of hydrogen gas calculated from the primary cooling water and light water pool.

Deuterium source gas is also exhausted to the facility ventilation. In its response to NRC staff RAI 9-1(e) (ML21095A241), Enclosure 2 (ML21095A229), SHINE discussed the potential for a combustible deuterium-air mixture. SHINE stated that during normal ventilation system conditions, the formation of flammable mixtures of deuterium source gas and other sources of hydrogen is prevented by the forced RVZ1e ventilation, which maintains hydrogen concentration in the IU cell atmosphere and RVZ1e exhaust stream below 1 percent hydrogen by volume. SHINE also stated that ignition of deuterium source gas and hydrogen in the PCLS expansion tank and RVZ1e ductwork is prevented by the PCLS flame arrestor.

The NRC staff evaluated the descriptions and discussions of SHINE's cover gas control, as described in SHINE FSAR section 9a2.6, and finds that the final design of SHINE's cover gas control, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9a.4.7 Other Auxiliary Systems

The NRC staff evaluated the sufficiency of SHINE's other auxiliary systems in the IF, as presented in SHINE FSAR section 9a2.7, "Other Auxiliary Systems," using the guidance and acceptance criteria from section 9.7, "Other Auxiliary Systems," of NUREG-1537, Parts 1 and 2, and Section 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

9a.4.7.1 Tritium Purification System

SHINE FSAR section 9a2.7.1, "Tritium Purification System," states that the function of the TPS is to separate the deuterium-tritium gas mixture from the neutron driver assembly system (NDAS) into pure deuterium and tritium gas streams and remove other impurities from the gas. The TPS supplies purified deuterium and tritium gas streams to the NDAS to achieve the desired target mixture fractions. There are three trains of the TPS, and all components of the system are located in the TPS room. Each train independently serves a fixed set of IUs. The TPS limits the amount of tritium in waste streams that are exhausted to the facility ventilation system. The TPS also provides storage for tritium in depleted uranium as a metal hydride. There are external supplies of deuterium, helium, and liquid nitrogen for use in the TPS. Only deuterium from the external tank supply is used for the NDAS ion source. The liquid nitrogen is used to cool the cryopumps that are part of the isotope separation system. The system has redundant valves that can isolate the system if a tritium leak is detected. The processes associated with the TPS are performed within gloveboxes to minimize tritium exposure to the workers.

SHINE FSAR section 9a2.7.1.1, "Tritium Purification System Subsystems," describes the subsystems of the TPS. The subsystems of the TPS are the isotope separation system (ISS), the TPS-NDAS interface lines, the TPS gloveboxes, the secondary enclosure cleanup subsystem (SEC), the vacuum impurity treatment subsystems (VAC/ITS), the NDAS secondary enclosure cleanup (NDAS SEC), and the TPS room. The ISS receives the gas mixture from the NDAS units, removes impurities from the gas, and separates the tritium from the deuterium so that it can supply high purity tritium to each NDAS. The ISS also flushes and evacuates process lines before and after maintenance activities. The TPS-NDAS interface lines are used to transfer the tritium to the NDAS. The lines run through subgrade penetrations, and the lines are protected from impact in the run between the subgrade penetrations and the TPS gloveboxes. There is also monitoring of the lines to detect tritium leaks. The lines can be isolated to minimize releases during DBAs. The TPS gloveboxes are confinement gloveboxes that enclose the isotope separation equipment. The gloveboxes have gloveports and windows to support operator access to the equipment in the gloveboxes. The gloveboxes are maintained at a negative pressure relative to the TPS room and have a recirculating helium atmosphere. An external helium tank provides any makeup helium that is necessary. The gloveboxes and associated redundant isolation valves minimize the release of tritium to the facility and the environment. The secondary enclosure cleanup system maintains low levels of tritium and oxygen in the glovebox atmosphere. The operator is notified of high tritium concentration in the glovebox by an alarm. There are three gloveboxes to service the three TPS trains (one per train). Each train independently serves a subset of the NDAS units. The volumes of the gloveboxes are large enough that a release of the tritium and deuterium in the glovebox would not cause it to exceed the lower flammability limit.

The SEC removes tritium and oxygen from the recirculating helium TPS glovebox atmosphere. The SEC minimizes the amount of tritium in the glovebox atmosphere. It can remove both elemental tritium and tritiated water. The SEC removes tritium from the glovebox atmosphere before it is exhausted to RVZ1e. There are alarms to notify the operator of high tritium levels in the glovebox. The VAC/ITS evacuates the TPS process lines and removes tritium from process waste streams to support operations and maintenance. The waste streams are monitored for tritium before being exhausted to the facility ventilation system. When the NDAS is evacuated for maintenance, it is treated by the VAC/ITS system before exhausting it to the ventilation system. The NDAS SEC removes tritium resulting from leakage and permeation to the NDAS secondary enclosures during operation of the NDAS. The TPS room houses the equipment that is part of the TPS including the TPS gloveboxes, the VAC/ITS equipment, the NDAS secondary enclosure cleanup equipment, TPS fume hoods, SEC equipment, and supporting control and process equipment. The TPS fume hoods and the overall ventilation of the TPS room exhaust to RVZ2.

SHINE FSAR section 9a2.7.1.7, “Instrumentation and Controls,” states that PICS provides normal process control and monitoring of components not important to the safe operation of the TPS. The TPS exhaust and the TPS confinements are monitored by ESFAS for high tritium concentration. The ESFAS initiates a TPS Process Vent Actuation if the TPS exhaust exceeds 1 Curie (Ci) per cubic meter. The ESFAS initiates a TPS Train Isolation if the tritium concentration in a train confinement exceeds 1,000 Ci per cubic meter. The ESFAS also initiates a TPS Train Isolation if the TPS target chamber supply or exhaust pressure in an IU cell connected to the train exceeds 8 pounds per square inch atmosphere (psia) because this indicates a breach of the low-pressure tritium boundary.

SHINE FSAR table 3.1-1 identifies the TPS as safety-related and includes the applicable design criteria. SHINE FSAR table 3.1-3, “SHINE Design Criteria,” describes the applicable design criteria. The NRC staff finds that the TPS meets the applicable design criteria of 29–36 and 38. The staff finds that the TPS is designed to detect and minimize leakage from the TPS confinement boundary during normal operations and DBAs through a combination of multiple barriers, cleanup systems, and isolations initiated by the ESFAS. The staff also finds that the TPS prevents leakage from the primary confinement boundary in the IUs by isolating the interface process lines from the NDAS during and after a design basis seismic event through the TRPS. The staff evaluated SHINE’s instrumentation and control system and DBAs in Chapter 7 and Chapter 13, “Accident Analysis,” of this SER, respectively.

9a.4.7.2 Neutron Driver Assembly System Service Cell

SHINE FSAR section 9a2.7.2, “Neutron Driver Assembly System Service Cell,” states that the “NDAS Service Cell (NSC is a dedicated work area provided to support the staging, commissioning, maintenance, and disposal of a single NDAS unit.” The FSAR further describes the NSC as a roofless room with four walls. Within the NSC area, a directed airflow system is used for the reduction of residual tritium contamination of NDAS components. The airflow system interfaces with the facility’s Zone 2 exhaust system. The NSC shield walls consist of 24-inch-thick concrete walls with reinforced carbon steel rebar. Local shielding can be added to the NSC area to help reduce occupation exposure to workers within the area. SHINE FSAR section 9a2.7.2.3, “Radiological Protection,” states that the calculated dose rates during accelerator operation in the NSC are estimated to be 8 millirem per hour outside the NSC walls. The NCS is designed with an interlock to prevent operation of the NDAS while the service door is open. The NSC is also designed with a radiation interlock button inside the NCS that prevents or stops operation of the NDAS when actuated. FSAR figure 4a2.5-1, “Irradiation Facility Biological Shielding,” provides a general layout of the NSC. The NSC is a nonsafety-related system.

Based on the above information, the NRC staff finds that the design of the NSC will minimize the possibility of tritium contamination and keep radiation exposures to workers consistent with ALARA principles with the use of permanent shielding (i.e., NSC concrete walls), local shielding, and interlocks. The staff evaluated SHINE’s ALARA program and radiation protection program in Chapter 11of this SER.

9a.4.8 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant’s proposed TSs for the SHINE IF auxiliary systems as described in SHINE FSAR Chapter 9.

The proposed TS 3.8, “Facility-Specific,” limiting condition for operation (LCO) 3.8.7 and surveillance requirement (SR) 3.8.7 state the following:

LCO 3.8.7	Each TPS glovebox shall have a helium atmosphere with dew point ≤ -4°F. Note – This LCO is applied to each TPS train independently; actions are only applicable to the TPS train(s) that fail to meet the LCO.
Applicability	Associated TPS glovebox tritium present in TPS process equipment and not in storage
Action	According to Table 3.8.7
SR 3.8.7	6. TPS glovebox atmosphere dew point shall be verified to be within the limit daily.

The proposed TS table 3.8.7, “TPS Glovebox Atmosphere Actions,” states the following:

	Condition and Action	Completion Time
1.	If the TPS glovebox dew point is above the allowable limit, Initiate actions to purge the associated TPS glovebox with helium	6 hours

LCO 3.8.7 specifies the helium atmosphere dew point temperature limit for the TPS gloveboxes and the actions to be taken if it is not below or equal to the limit. The NRC staff finds that the limit would minimize the flammability risk and minimize oxygen exposure to TPS process equipment. The staff finds that if the temperature is above the allowable limit, purging the glovebox with helium will return the glovebox atmosphere to within allowable parameters. The

staff also finds that the completion time of 6 hours would minimize the risk of a fire. Therefore, the staff finds the LCO acceptable.

SR 3.8.7 requires verification of the TPS glovebox dew point limit daily. The NRC staff finds that this SR 3.8.7 is performed more frequently compared in with guidance in ANSI/ANS-15.1-2007 for leak-tightness tests following modification or repeat. Therefore, the staff finds the SR acceptable.

The proposed TS 3.8, LCO 3.8.8 and SR 3.8.8 state the following:

LCO 3.8.8	Each TPS secondary enclosure cleanup (SEC) shall be Operable. An SEC is considered to be Operable if: 1. The circulating blower is Operating, 2. At least 1 molecular sieve bed is Operating, and 3. The hydride bed is Operating. Note – This LCO is applied to each TPS train independently; actions are only applicable to the TPS train(s) that fail to meet the LCO.
Applicability	Tritium present in the associated train of TPS process equipment and not in storage.
Action	According to Table 3.8.8
SR 3.8.8	1. Verify each SEC is Operating daily.

The proposed TS table 3.8.8, "TPS SEC Actions," states the following:

	Condition and Action	**Completion Time**
1.	If an SEC is inoperable, Place tritium in the associated train of TPS process equipment in its storage location.	12 hours

LCO 3.8.8 specifies that each TPS SEC should be operable, provides the conditions for the TPS SECs to be considered operable, and provides the actions to be taken if they are not operable. The NRC staff finds that requiring the TPS SEC to be operable would prevent the accumulation of tritium in its associated glovebox which minimizes the leakage of tritium and prevents excessive dosage to workers. The staff finds that if an SEC is inoperable, the completion time of 12 hours would allow for minor repairs and adequate time to store the tritium in its storage location. Therefore, the staff finds the LCO acceptable.

SR 3.8.8 requires verification that each SEC is operating daily. The NRC staff finds that this frequency would ensure continued operability of the system. Therefore, the staff finds the SR acceptable.

The proposed TS 3.8, LCO 3.8.9 and SR 3.8.9 state the following:

LCO 3.8.9	Each RCA isolation damper listed in Table 3.8.9-a shall be Operable. A damper is considered Operable if: 1. The damper is capable of closing on demand from ESFAS Note – A single Division of required components may be inoperable for up to 2 hours during the performance of required surveillances.
Applicability	Facility not Secured
Action	According to Table 3.8.9
SR 3.8.9	1. Dampers listed in Table 3.8.9-a shall be verified to close on demand from ESFAS annually.

The proposed TS table 3.8.9, "RCA Isolation Damper Actions," states the following:

	Condition and Action	**Completion Time**
1.	If one isolation damper in one or more flow path(s) is inoperable, Close at least one damper in the affected flow path.	72 hours
2.	If two redundant isolation dampers in one or more flow path(s) are inoperable, Close at least one damper in the affected flow path.	12 hours

The proposed TS table 3.8.9-a, "RCA Isolation Dampers," states the following:

	Component	**Number Provided perFlow Path**
a.	RVZ1 RCA exhaust isolation dampers	2
b.	RVZ2 RCA exhaust isolation dampers	2
c.	RVZ2 RCA supply isolation dampers	2
d.	RVZ3 RCA transfer isolation dampers 1. Shipping/receiving IF 2. Shipping/receiving RPF 3. RPF emergency exit 4. IF emergency exit 5. Mezzanine emergency exit	2 (per location)

e.	RVZ2 TPS room supply and exhaust isolation dampers	2 (per location)
f.	RVZ2 main RCA ingress/egress supply isolation dampers	2
g.	RVZ2 main RCA ingress/egress exhaust isolation dampers	2

LCO 3.8.9 specifies that each RCA isolation damper listed in TS table 3.8.9-a shall be operable when the facility is not secured and provides the actions to be taken if they are not operable. The NRC staff finds that this LCO would ensure that the RCA is automatically isolated to prevent the inadvertent release of radioactive material. The staff also finds that if the isolation dampers listed in table 3.8.9-a are inoperable, the flow path is isolated by closing at least one damper. The staff finds that the completion time allows for investigation and the performance of minor repairs and is based on the continued availability of the redundant isolation damper in the flow path. Therefore, the staff finds the LCO acceptable.

SR 3.8.9 requires that the isolation dampers listed in TS table 3.8.9-a be verified to close on demand from ESFAS annually. Section 4.4.2, “Confinement,” of ANSI/ANS-15.1-2007 states that a functional test should be performed NUREG-1431, “Standard Technical Specifications: Westinghouse Plants,” Volume 1, “Specifications” (ML21259A155), SR 3.8.3.8 states, in part, that a test to verify that automatic containment isolation valves actuate to the isolation position on an actual or simulated signal be performed every 18 months. As described in Chapter 14, “Technical Specifications,” of this SER, the NRC staff used guidance in NUREG-1431 to review SHINE’s proposed TSs. Based on the foregoing, the staff finds that the verification of closure from ESFAS of SR 3.8.9 is an appropriate functional test and that its frequency is adequate to confirm the operability of the RCA isolation boundary. Therefore, the staff finds SR 3.8.9 acceptable.

9a.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE IF auxiliary systems, as described in SHINE FSAR section 9a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the IF auxiliary systems and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF auxiliary systems are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

9b Radioisotope Production Facility Auxiliary Systems

Section 9b, “Radioisotope Production Facility Auxiliary Systems,” of this SER provides an evaluation of the final design of SHINE’s RPF auxiliary systems, as presented in SHINE FSAR section 9b.

9b.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 9b against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of SHINE’s RPF auxiliary systems. The final design of SHINE’s RPF auxiliary systems’ control systems was evaluated to ensure that the design bases and functions of the systems and components are presented in sufficient detail to allow a clear understanding of the facility and that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the operating staff and the public. Drawings and diagrams were evaluated to ensure that they present a clear and general understanding of the physical facility features and of the processes involved. In addition, the staff evaluated the sufficiency of SHINE’s proposed TSs for the facility.

Areas of review for this section include a summary description of the RPF auxiliary systems’ control systems, as well as a detailed description of the RPF confinement and RCA isolation. Within these review areas, the NRC staff assessed, in part, the design bases and functional descriptions of the required mitigative features of the auxiliary systems; drawings, schematic drawings, and tables of important design and operating parameters and specifications for the auxiliary systems; description of control and safety instrumentation, including locations and functions of sensors, readout devices, monitors, and isolation components, as applicable; and the required limitations on the release of confined effluents to the environment.

9b.2 Summary of Application

SHINE FSAR section 9b includes a description of the auxiliary systems in the RPF, including the design bases, a system description, operational analysis and safety function, instrumentation and control, and relevant TSs. The RPF auxiliary systems include the HVAC systems, handling and storage of target solution, fire protection systems and programs, communication systems, possession and use of byproduct, source, and SNM, cover gas control in the RPF, and other auxiliary systems.

9b.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR section 9b against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE RPF auxiliary systems for the issuance of an operating license.

9b.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's RPF auxiliary systems are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.48, "Fire protection."
- 10 CFR 50.57, "Issuance of operating license."
- 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix A, "General Design Criteria for Nuclear Power Plants," Criterion 3, "Fire protection."
- 10 CFR Part 20, "Standards for Protection Against Radiation."

9b.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

As stated in the ISG augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, IEEE standards, ANSI/ANS standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, "References," of this SER.

In addition, the following SHINE design criteria, located in SHINE FSAR Chapter 3, "Design of Structures, Systems, and Components," are applicable to various RPF auxiliary systems:

- Criterion 29 – Confinement design
- Criterion 30 – Confinement design basis
- Criterion 31 – Fracture prevention of confinement boundary
- Criterion 32 – Provisions for confinement testing and inspection
- Criterion 33 – Piping systems penetrating confinement
- Criterion 34 – Confinement isolation
- Criterion 35 – Control of releases of radioactive materials to the environment
- Criterion 36 – Target solution storage and handling and radioactivity control
- Criterion 37 – Criticality control
- Criterion 38 – Monitoring radioactivity releases
- Criterion 39 – Hydrogen mitigation

9b.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR section 9b, as supplemented, to assess the sufficiency of the final design and performance of SHINE's RPF auxiliary systems for the issuance of an operating license. The sufficiency of the final design and performance of SHINE's RPF auxiliary systems is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 9b.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in section 9b.5, "Review Findings," of this SER.

9b.4.1 Heating, Ventilation, and Air Conditioning Systems

The review and evaluation described in section 9a.4.1, "Heating, Ventilation, and Air Conditioning Systems," of this SER is applicable to both the SHINE IF and RPF.

9b.4.2 Handling and Storage of Target Solution

The NRC staff evaluated the sufficiency of SHINE's handling and storage of the target solution, as presented in SHINE FSAR section 9b.2, "Handling and Storage of Target Solution," using the guidance and acceptance criteria from section 9.2, "Handling and Storage of Reactor Fuel," of NUREG-1537, Parts 1 and 2, and section 9b.2, "Handling and Storage of Reactor Fuel," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 9b.2.1, "Target Solution Lifecycle," describes the different RPF systems that contain target solution during and after it is preprepared. These systems include the uranium receipt and storage system, target solution preparation system, target solution staging system (TSSS), molybdenum extraction and purification system (MEPS), radioactive liquid waste storage (RLWS) system, radioactive liquid waste immobilization (RLWI) system and iodine and xenon purification and packing (IXP) system.

SHINE FSAR section 9b.2.5, "Vacuum Transfer System," describes the method of transporting radioactive liquids, including target solution, throughout the RPF. The design bases of the vacuum transfer system (VTS) are to prevent inadvertent criticality in accordance with the SHINE criticality safety evaluation and to relieve the VTS to atmospheric pressure upon actuation of ESFAS to terminate transfers of target solution. The ESFAS is evaluated in chapter 7 of this SER. The VTS operates by applying a vacuum to a lift tank or directly to a destination tank. The VTS is designed with two separate headers based on the liquid, which contains fissile or non-fissile material, being transferred. The NRC staff finds that the use of two separate headers ensures that fissile material is maintained separate from non-fissile liquids preventing cross contamination.

The VTS is located in the hot cells and in below-grade vaults to minimize radiation exposure to workers. Automatic flow isolation valves and liquid level instruments in the VTS prevent solution from entering the knockout pots. If liquid is detected in the knockout pots, the ESFAS system actuates to break the vacuum in the system and turn off the vacuum pumps. All solution in the knockout pots drains to the favorable geometry tanks in the RLWS system. The VTS is classified as Seismic Category I. Criticality safety controls are evaluated in section 6b, "Radioisotope Production Facility Engineered Safety Features," of this SER. Accident scenarios involving the VTS are evaluated in Chapter 13 of this SER.

By locating the VTS in the hot cells and in below-grade vaults, the NRC staff finds that there is reasonable assurance that potential personnel doses from radiological materials will not exceed regulatory limits and supports SHINE's ALARA program. By the use of favorable geometry tanks and ESFAS to terminate solution transfers, the staff also finds that the VTS, as described in SHINE FSAR section 9b2.5, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

The NRC staff finds that the methods for handling, moving, and storing target solution in the RPF provide reasonable assurance that potential personnel doses will not exceed regulatory limits in 10 CFR Part 20 and support SHINE's ALARA program.

9b.4.3 Fire Protection Systems and Programs

The review and evaluation described in section 9a.4.3, "Fire Protection Systems and Programs," of this SER is applicable to both the SHINE IF and RPF.

9b.4.4 Communication Systems

The review and evaluation described in section 9a.4.4, "Communication Systems," of this SER is applicable to both the SHINE IF and RPF.

9b.4.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

The NRC staff evaluated the sufficiency of SHINE's program for possession and use of byproduct, source, and SNM in the RPF, as described in SHINE FSAR section 9b.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," using the guidance and acceptance criteria from section 9.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," of NUREG-1537, Parts 1 and 2, and section 9b.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," of the ISG augmenting NUREG-1537, Parts 1 and 2.

As discussed in SHINE FSAR section 9b.5, the RPF is designated as an RCA and the SHINE Radiation Protection Program controls and procedures, including the ALARA Program, apply to the RPF. SHINE FSAR section 9b.5.1, "Byproduct Material," describes the various RPF systems that may contain byproduct material. SHINE identifies that a batch of Mo-99 can be up to 5,000 Ci and that up to 8 batches of Mo-99 may be produced in a week. The maximum amount of Iodine-131 (I-131) and Xenon-133 (Xe-133) shipped in a week is 2,000 Ci per isotope. Source material is not normally processed in the RPF, however, SHINE describes in section 9b.5.2, "Source Material," that there is a potential for source material to be processed as waste within the RPF in the form of IF components, such as the tritium beds or neutron multipliers that contain source material. The NRC staff evaluated SHINE's waste management in section 11.4.2, "Radioactive Waste Management," of this SER. As described in SHINE FSAR section 9b.5.3, "Special Nuclear Material," the RPF includes LEU in the form of target solution (i.e., uranyl sulfate solution). The SHINE FSAR describes the systems within the RPF that may contain SNM. SHINE FSAR Section 9b.5.3 states that the total inventory of LEU in the RPF used to support facility operations is up to 6,600 pounds (lbs) of LEU. SHINE FSAR section 9b.5.4, "Quality Control and Analytical Testing Laboratories," describes the use of two labs to provide analytical laboratory support for the production of Mo-99, I-131, and Xe-133. The wet lab is used for sample preparations and the instrument lab is used for detailed sample analysis. SHINE FSAR section 9b.5.4.3, "Operational Analysis and Safety Functions," states that the labs perform no safety functions.

Based on the above information, the NRC staff finds that SHINE has radiation protection controls, procedures, and an ALARA program to help ensure that potential radiation exposures to workers are within the limits of 10 CFR Part 20. The staff finds that the authorized spaces for the use of material have been described. Further, the staff finds that the use of controls and procedures provides reasonable assurance that an uncontrolled release of radioactive material to the unrestricted environment will not occur.

9b.4.6 Cover Gas Control in the Radioisotope Production Facility

The NRC staff evaluated the sufficiency of SHINE's radiolytic gas management systems located in the RPF, as presented in SHINE FSAR section 9b.6, "Cover Gas Control in the Radioisotope Production Facility," using the guidance and acceptance criteria from section 9.6, "Cover Gas Control in Closed Primary Coolant Systems," of NUREG-1537, Parts 1 and 2, and section 9b.6, “Cover Gas Control in Closed Primary Coolant Systems,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

9b.4.6.1 Process Vessel Vent System

SHINE FSAR section 9b.6.1.1, “Design Bases,” provides the design basis of the PVVS as:

- Mitigate radiolytic hydrogen generation in the headspace of RPF tanks and vessels;
- Capture radioiodine from the off-gas stream;
- Delay the release of radioactive noble gases in gaseous effluents to the environment;
- Filter radioactive particulates from the gaseous effluents;
- Maintain RPF tanks and vessels at a negative pressure;
- Accept VTS vacuum pump discharge;
- Accept TOGS pressure relief discharge;
- Accept purges of TOGS, resulting from either a loss of TOGS capability to mitigate radiolytic hydrogen generation or maintenance requirements;
- Accept any sweep gases from TOGS used to purge gas analyzer instrumentation;
- Condition collected off-gas to improve reliability and performance of filtration equipment; and
- Discharge off-gases to the facility stack.

The PVVS provides radiolytic hydrogen mitigation capability for the RPF by ventilating the process tanks and vessels and accepting flow gases discharged from VTS and TOGS. Flows from VTS and TOGS include vacuum pump discharge, sweep gas from gas analyzer instruments, nitrogen purges, and pressure relief. PVVS blowers upstream of the facility stack induce flow through the ventilation system. Flow rate requirements for PVVS are constant for nominal ventilation in the RPF but increase when tanks are sparged for mixing, when VTS is operating, or during TOGS transients such as a purge during fill or maintenance, or pressure relief. PVVS equipment is designed for the maximum off-gas flow rate that could require processing at any one time.

SHINE FSAR table 9b.6-2, “Process Vessel Vent System Process Equipment,” identifies the principal components of the PVVS. SHINE FSAR figure 9b.6-1 provides a flow diagram for the PVVS.

The off-gases are processed to remove or delay iodine, noble gases, and radioactive particulates prior to the gas being discharged to the facility stack. The PVVS blower placement ensures that the system is maintained at a negative pressure relative to ventilation zone 2. Intakes within ventilation zone 2 are the nominal air source for the PVVS. Air flows from the intake, across the tank headspace, to the PVVS headers and the combined quantity is passed thorough conditioning and filtration equipment. Gases pass through condensers, cooled with chilled water from the RPCS to remove excess heat and reduce absolute humidity of the off-gas.

Condensate can either be collected in the PVVS condensate tank within the PVVS hot cell, located within the supercell, or can be returned to the TSSS tanks as makeup water or to the RLWS system for waste processing. An in-line heater, the PVVS reheater, downstream of the condenser heats the off-gas back to ambient temperature to reduce the relative humidity. Gases discharged by TOGS from the primary system boundary, which contain noble gases and iodine, are also processed by the PVVS. The off-gas may also contain radioactive particulates such as cesium. HEPA filters are used to remove entrained particulates from the air flow. Carbon filters are used to capture iodine and carbon beds are employed to delay the release of xenon and krypton isotopes. The NRC staff finds that the design ensures that 10 CFR Part 20 limits are met. The off-gas then flows through acid adsorber beds, HEPA filters, and the guard beds to neutralize entrained acid droplets or gases, filter particulates, and capture iodine. The gas flows from the hot cell to a below-grade, shielded vault, passing through a series of delay beds packed with carbon to delay the release of fission product noble gases. The eight delay beds are organized into three groups as shown in SHINE FSAR figure 9b.6-1. Group 1 includes Delay Beds 1 and 2; Group 2 includes Delay Beds 3, 4, and 5; and Group 3 includes Delay Beds 6, 7, and 8.

The ESFAS automatically isolates affected delay bed groups when carbon monoxide concentrations in the effluent gas exceed 50 parts per million (ppm). The arrangement facilitates bypassing any combination of beds to facilitate maintenance. A final set of HEPA filters removes any entrained carbon fines upstream of the blowers, and the treated gases are discharged to the facility stack.

The PVVS processes are performed within the production facility biological shield (PFBS) hot cells and below-grade vaults, thus complying with the ALARA objectives and 10 CFR Part 20 dose limits.

<u>Instrumentation and Control</u>

Safety-related PVVS instrumentation has redundant channels and provides output to ESFAS. Non-safety-related PVVS instrumentation provides output signals to PICS.

Temperature instrumentation is used to monitor the performance of the condensers, heaters, and acid adsorbers as well as the guard beds and delay beds.

Carbon monoxide gas analyzers are used to monitor the operation of the delay beds and to monitor carbon monoxide concentrations in the bed effluent.

Flow instrumentation is used to monitor the flow rate of air from ventilation zone 2 into the RPF tanks and vessels ventilated by the PVVS. The PICS alerts operators on low flow. Flow instrumentation is used to monitor the flow rate of air from the RPF tanks and vessels to the condensers. The system is designed to maintain this flow rate above the minimum required to maintain hydrogen levels below the LFL.

The NRC staff evaluated SHINE’s instrumentation and control system, including ESFAS and PICS, in Chapter 7 of this SER.

Design Criteria

As stated in SHINE FSAR section 3.1, the nuclear safety classification of safety-related SSCs at SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents. SHINE FSAR table 3.1-1 identifies the SSCs at SHINE that are classified as safety-related. The list includes the PVVS. SHINE FSAR table 3.1-3 provides the generically applicable design criteria to the SHINE facility. The NRC staff focused on the design criteria directly applicable to the PVVS, namely criteria 35 and 39.

For criterion 35, the NRC staff finds that the PVVS includes means to suitably control the release of radioactive materials due to the condensers and filtration equipment (carbon adsorbers, HEPA filters, and delay beds) included in the design of the systems. The staff also finds that the delay beds provide holdup capacity of the system effluents.

For criterion 39, the NRC staff finds that the PVVS is designed to control the buildup of hydrogen that is released into the primary system boundary and tanks. The PVVS is also capable of controlling buildup of hydrogen during normal operating conditions.

Based on the above, the NRC staff finds that the applicant provided final analysis and evaluation of the design and performance of SSCs as it relates to cover gas control in the PVVS and, therefore, satisfies 10 CFR 50.34(b)(4).

Conclusion

Based on its review, the NRC staff finds that the level of detail provided on the PVVS demonstrates an adequate description of its performance and, therefore, concludes that SHINE's operating license application satisfies 10 CFR 50.34(b)(2).

The NRC staff evaluated the descriptions and discussions of SHINE's PVVS, including proposed TSs, as described in SHINE FSAR section 9b.6.1, and finds that the final design of the PVVS, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9b.4.6.2 Nitrogen Purge System

SHINE FSAR section 9b.6.2.1, "Design Bases," states the design bases of the N2PS as:

- Ensure safe shutdown by preventing detonations or deflagrations from potential hydrogen accumulation in the IUs and RPF processes during deviations from normal conditions; and

- Remain functional during and following design basis events.

The N2PS provides a backup supply of sweep gas to each IU and to all tanks normally ventilated by the PVVS during a loss of normal power or loss of normal sweep gas flow. Upon PVVS flow dropping below a preset minimum amount, the ESFAS automatically initiates RPF nitrogen purge to mitigate hydrogen generation in RPF tanks. The RPF header valves from the N2PS actuate open and the PVVS header valves actuate closed. In addition, the PVVS isolation valve at the RLWI interface actuates closed to prevent nitrogen backflow. The off-gas resulting from the nitrogen purge is treated by passive PVVS filtration equipment (e.g., delay beds) prior to being discharged to the facility stack, as discussed in SHINE FSAR section -9b.6.1.2, “System Description.” Active PVVS components such as the condensers, RPCS supply to the condensers, and heaters are bypassed. The nitrogen supply pressure is regulated to overcome the pressure drop through pipe fittings, PVVS filtration components, and the facility stack. Thus, the N2PS is safety-related and Seismic Category I.

The N2PS system interfaces are described in SHINE FSAR table 9b.6-3. The N2PS process flow diagram is provided in SHINE FSAR figure 9b.6-2.

Nitrogen supply is from pressurized nitrogen stored gas. As described above, during the nitrogen purge, the PVVS equipment and piping continues to provide the flow path for the off-gas through the RPF, except that safety-related bypasses are provided around filtration equipment in the hot cell that could contribute to a blocked pathway and an alternate, safety-related exhaust point to the roof is opened. The branch to the alternate exhaust point is upstream of the PVVS blowers.

The N2PS provides back-up sweep gas flow. Downstream pressure is controlled with self-regulating pressure reducing valves with overpressure protection from pressure relief valves. On actuation of the N2PS, nitrogen flows through the IF and RPF equipment to ensure that the hydrogen concentration is below the lower flammability limit. The nitrogen purge flows through the normal PVVS path and the delay beds. After exiting the delay beds in the PVVS, the nitrogen purge is diverted to a safety-related alternate vent path in case of a downstream blockage. Valves configured to fail open allow the diversion to the alternate vent path. After actuation of the N2PS, the pressurized storage tubes can be refilled by truck deliveries.

Purge of an IU or RPF equipment

Upon loss of normal power as determined by ESFAS and after a delay or upon loss of normal sweep gas flow in the IU as determined by TRPS, solenoid valves on the nitrogen discharge manifold actuate open, releasing nitrogen into the IU cell supply header. Upon loss of sweep gas flow in any IU cell, nitrogen solenoid isolation valves for the given cell actuate open releasing nitrogen purge gas into the TSV dump tank, and valves in the TOGS actuate open to allow the nitrogen purge gas to flow to the PVVS. The nitrogen purge gas flows through the TSV dump tank, TSV, and TOGS equipment before discharging into the PVVS. A flow switch provides indication that nitrogen is flowing to the IU cell.

Upon loss of normal power or loss of normal sweep gas flow through the PVVS, as determined by the ESFAS, solenoid valves on the ventilation zone 2 air supply to the PVVS fail close and isolate the sweep gas air flow to the RPF tanks. At the same time, solenoid valves on the nitrogen discharge manifold actuate open, releasing nitrogen into the RPF distribution piping. The nitrogen flows through the RPF equipment in parallel before discharging into the PVVS. A flow switch provides indication that nitrogen is flowing to the RPF distribution piping.

Processes that receive ventilation air from the PVVS during normal conditions are also ventilated by the N2PS during deviations from normal operation. In the RPF, the N2PS ventilates tanks in the TSSS, RLWS system, radioactive drain system (RDS), MEPS, IXP system, and VTS.

Tanks containing irradiated target solution in the RPF are supplied with a self-regulating pressure reducing valve with overpressure protection provided by a pressure relief valve. TSV dump tanks are supplied with a self-regulating pressure reducing valve. The N2PS piping, valves, and in-line components are designed to ASME B31.3, “Process Piping.”

The high-pressure nitrogen gas storage is contained in integrally forged pressure vessels (i.e., high-pressure nitrogen gas tubes) designed to meet the requirements of ASME Boiler and Pressure Vessel Code, Section VIII, Rules for Construction of Pressure Vessels. The high-pressure nitrogen gas tubes and associated piping, manual isolation valves, high point vents, low point drains, self-regulating pressure reducing valves, relief valves, check valves, and pressure instrumentation for the supply system are housed in the N2PS structure, an above-grade reinforced concrete structure adjacent to the main production facility. The N2PS structure and equipment are designed to remain functional during and following a seismic event. In addition, the N2PS structure is designed to withstand the impact of tornado missiles.

The high-pressure nitrogen gas tubes are manifolded so that they will act in unison and they have a common remote fill connection to allow refill by tanker truck delivery. One redundant nitrogen gas tube provides service in the event of the loss of a tube or failure of the associated valves upstream of the common manifold. Each nitrogen gas tube and the downstream piping and equipment is protected from overpressure by relief valves discharging to atmosphere above the roof of the structure, through a nonsafety-related vent path.

The N2PS is sized to provide three days of sweep gas flow to tanks containing irradiated target solution in the RPF during a loss of normal power or a loss of sweep gas flow. The N2PS also provides three days of sweep gas flow to each TSV dump tank.

Instrumentation and Control

The N2PS includes pressure instrumentation to monitor the function of the self-regulating pressure reducing valves. The nitrogen tube pressure, tube discharge pressures, pressure to the IU cells, and pressure to the RPF tanks are monitored. The pressure instrument output is provided to PICS.

The N2PS includes flow switches to provide indication of normal operation when the purge is actuated. The flow switch status is provided to PICS.

N2PS solenoid valves include valve position indication. The position status for each valve is provided to TRPS if it serves the IU cells or to ESFAS if it serves the RPF tanks.

Oxygen sensors are provided in locations near N2PS equipment. The oxygen instruments alert operators locally of an asphyxiation hazard in the event of a nitrogen leak.

TRPS actuates the N2PS purge of the affected IU on a loss of normal power to an IU cell after a delay or on a loss of flow in TOGS. A detailed discussion of the IU cell nitrogen purge is provided in SHINE FSAR section 7.4, “Target Solution Vessel Reactivity Protection System.”

ESFAS actuates the N2PS purge of the RPF tanks on a loss of normal power to the PVVS or on a loss of flow in PVVS. A detailed discussion of the RPF nitrogen purge is provided in SHINE FSAR section 7.5, “Engineered Safety Features Actuation System.”

The NRC staff evaluated SHINE's instrumentation and control system, including TRPS, ESFAS, and PICS, in Chapter 7 of this SER.

<u>Design Criteria</u>

As stated in SHINE FSAR section 3.1, the nuclear safety classification of safety-related SSCs at SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents. SHINE FSAR table 3.1-1 identifies the SSCs at SHINE that are classified as safety-related. The list includes the N2PS. SHINE FSAR table 3.1-3 provides the generically applicable design criteria to the SHINE facility. The NRC staff focused on the design criterion directly applicable to the N2PS, namely criterion 39.

For criterion 39, the NRC staff finds that the N2PS systems are designed to control the buildup of hydrogen that is released into the primary system boundary and tanks. The staff also finds that the N2PS is designed to control the buildup of hydrogen when the PVVS is not available.

Based on the above, the NRC staff finds that the applicant provided final analysis and evaluation of the design and performance of SSCs as it relates to the N2PS and, therefore, satisfies 10 CFR 50.34(b)(4).

<u>Conclusion</u>

Based on its review, the NRC staff finds that the level of detail provided on the N2PS demonstrates an adequate description of its performance and, therefore, concludes that SHINE's operating license application satisfies 10 CFR 50.34(b)(2).

The NRC staff evaluated the descriptions and discussions of SHINE's N2PS, including proposed TSs, as described in SHINE FSAR section 9b.6.2, and finds that the final design of the N2PS, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9b.4.7 Other Auxiliary Systems

The NRC staff evaluated the sufficiency of SHINE's other auxiliary systems in the RPF, as presented in SHINE FSAR section 9b.7, "Other Auxiliary Systems," by reviewing the following systems, using the guidance and acceptance criteria from section 9.7, "Other Auxiliary Systems," of NUREG-1537, Parts 1 and 2, and section 9b.7, "Other Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

9b.4.7.1 Molybdenum Isotope Product Packaging System

SHINE FSAR section 9a.7.1.2, "System Description," states, in part, that the molybdenum isotope product packaging system (MIPS) prepares the Mo-99, iodine, or xenon product bottles for shipment. The FSAR further describes the MIPS as providing a quarantine area for products undergoing quality control testing prior to shipment. The equipment within the MIPS includes product bottles, secondary containers, shipping casks, leak test equipment, and label printers. The Mo-99 product volume depends on the specific customer. The MIPS is a nonsafety-related system and is located in a shielded hot cell within the supercell. SHINE FSAR section 9b.7.1.3, "Operational Analysis and Safety Function," states that shielding on the packaging hot cells limits the radiation exposure of individuals to within the regulatory limits described in 10 CFR Part 20. The shielding of the packaging hot cell is evaluated in section 4b.4.2, “Radioisotope Production Facility Biological Shielding,” of this SER and the radiation protection program is evaluated in Chapter 11 of this SER. Based on the above, the NRC staff finds that the design of the MIPS will help reduce occupational doses by shielding workers from radiation produced by byproduct material. Further, the staff finds that the implementation of a radiation protection program will provide reasonable assurance that radiation dose from the MIPS to workers is minimized.

9b.4.7.2 Material Handling System

The material handling system (MHS) is defined in SHINE FSAR section 9b.7.2 and includes overhead cranes and hoists that are used to move or manipulate radioactive material within the RCA. The MHS design is evaluated for loads associated with two overhead bridge cranes, one servicing the IF area and one servicing the RPF area.

The IF overhead crane (40-ton capacity) removes IU cell plugs and TOGS cell plugs and provides neutron driver transport to and from IU cells and the NDAS service cell. The IF overhead crane is used for lifting, repositioning, and landing operations associated with major components of the subcritical assembly system (SCAS), PCLS, TOGS, and TPS as well as various planned maintenance activities throughout the IF.

The applicant stated that the IF overhead crane is designed and constructed such that it would remain in place and support the critical load during and after an aircraft impact, but that it would not necessarily be operational after this event. The applicant also stated that single failure-proof features are included in the IF crane such that any credible failure of a single component would not result in the loss of capability to stop and hold the critical load.

The RPF overhead crane (15-ton capacity) is utilized for lifts including the removal of tank vault, valve pit, and pipe trench plugs, removal of carbon delay bed vault plugs, supercell slave manipulator replacements, and the removal of column waste drums and post cooldown shielding and packaging. The RPF overhead crane is also used for various planned maintenance activities. In addition, the crane performs lifting of empty tanks in the RPF, immobilized waste drums and the associated shielding and packaging hardware, and other major components within the RPF.

The applicant stated that the RPF overhead crane would employ mechanical stops, electrical-interlocks, and predetermined safe load paths to minimize the movement of loads in proximity to redundant or dual safe shutdown equipment. The applicant also stated that the RPF overhead crane would be designed and constructed following the seismic requirements for an ASME NOG-1, “Rules for Construction of Overhead and Gantry Cranes,” Type II crane so that it will remain in place with or without a load during a design basis earthquake, but it would not necessarily be operational after this event.

The IF and RPF overhead cranes are nonsafety-related. As defined in SHINE FSAR table 3.4-1, “Seismic Classification of Structures, Systems, and Components,” the MHS cranes are designed to Seismic Category II. SHINE FSAR section 3.4.3.1, “Seismic Classification,” defines Seismic Category II SSCs as SSCs co-located with a Seismic Category I SSC and that must maintain structural integrity in the event of a safe shutdown earthquake to prevent unacceptable interactions with a Seismic Category I SSC but are not required to remain functional. SHINE FSAR section 9b.7.2 indicates the Seismic Category II cranes are designed to remain in place on the runway girder, with or without a load, during and after a seismic event. With respect to the SHINE facility, a heavy load is defined as a load that, if dropped, may cause radiological consequences that challenge 10 CFR Part 20 limits.

Material Handling System Operations

To reduce the probability and mitigate the consequences of an accidental load drop, the applicant describes a heavy load handling program consistent with the NRC general programmatic guidelines for design, operation, testing, maintenance, and inspection of heavy load material handling systems. With respect to the MHS, the applicant defined a heavy load as a load that, if dropped, may cause radiological consequences that challenge 10 CFR Part 20 limits. The applicant provided that guidance from section 5.1.1 of NUREG-0612, "Control of Heavy Loads at Nuclear Power Plants: Resolution of Generic Technical Activity A-36" (ML070250180), would be applied to heavy load handling as follows:

(1) Safe load paths will be defined for the movement of heavy loads; deviations from the defined load paths will require written procedures approved by site safety personnel.

(2) Procedures will be developed to cover load handling operations for heavy loads. Procedures will include the identification of required equipment, inspections, and acceptance criteria required before movement of loads; the steps and proper sequence to be followed in handling the load; the defined safe load path and other special precautions.

(3) Crane operators will be trained, qualified, and conduct themselves in accordance with Chapter 2-3 of ASME B30.2, "Overhead and Gantry Cranes."

(4) Special lifting devices used in the vicinity of safety-related SSCs will satisfy the guidelines of ANSI N14.6, "Radioactive Materials - Special Lifting Devices for Shipping Containers Weighing 10,000 Pounds (4500 kg) or More."

(5) Lifting devices that are not specially designed will be installed and used in accordance with the guidelines of ASME B30.9, "Slings."

(6) Tests and inspections will be performed prior to use where it is not practical to meet the frequencies of ASME B30.2 for periodic inspection and testing, or where frequency of crane use is less than the specified inspection and test frequency.

(7) The crane will be designed to meet applicable criteria and guidelines of ASME B30.2 and Crane Manufacturers Association of America (CMAA) 70.

SHINE FSAR section 9b.7.2.3, "Operational Analysis and Safety Function," provides a discussion on operational analysis and safety function. This section specifies that the IF and RPF overhead cranes are inspected, tested, and maintained in accordance with ASME B30.2. The inspection requirements reduce the probability of a load drop that could result in a release of radioactive materials or damage to essential safe shutdown equipment that could cause unacceptable radiation exposures. Inspection and testing of special lifting devices are performed in accordance with N14.6. Inspection and testing of lifting devices not specially designed are performed in accordance with ASME B30.9.

IF Overhead Crane:

SHINE FSAR section 9b.7.2.1, “Design Bases,” provides that the IF overhead crane is designed to the following criteria:

- Meet seismic requirements and prevent failures of the crane that could damage safety-related equipment such that the equipment would be prevented from performing its safety function. SHINE FSAR Table 3.4-1 defines MHS as Seismic Category II.
- Meet the single-failure-proof design criteria and construction of ASME NOG-1, Type I cranes and be designed to perform as a Service Level B – Light Service crane as described in CMAA 70.
- Secure its load in place upon a loss of power and any fault condition. The hoisting machinery and wire rope reeving system, in addition to other affected components, is designed to withstand the most severe potential overload, including two-blocking and load hang-up.
- Remain in place on the runway girder, with or without a load, during and after a seismic event.

RPF Overhead Crane:

SHINE FSAR section 9b.7.2.1 provides that the RPF overhead crane is designed to the following criteria:

- Meet seismic requirements and prevent failures of the crane that could damage safety-related equipment such that the equipment would be prevented from preforming its safety function.
- Meet the design criteria and construction of ASME NOG-1, Type II cranes and be designed to perform as a Service Level B – Light Service crane as described in CMAA 70.
- Remain in place on the runway girder, with or without a load, during and after a seismic event.

Conclusion

The NRC staff evaluated the descriptions and discussions of SHINE’s MHS, as described in SHINE FSAR Section 9b.7.2, and finds that the final design of SHINE’s MHS, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license. Specifically, the descriptions of the MHS satisfy the requirements of 10 CFR 50.34(b) related to descriptions of radioactive material handling system design, maintenance, operations, and testing. There are design basis accidents related to the MHS; the staff evaluated SHINE’s design basis accidents in Chapter 13 of this SER.

9b.4.7.3 Radioactive Liquid Waste Immobilization System

SHINE FSAR section 9b.7.3, "Radioactive Liquid Waste Immobilization System," states that the RLWI system solidifies blended liquid waste to a form suitable for shipping and disposal. The RLWI system removes selected isotopes, as needed, from the blended liquid waste and then immobilizes the wastes for ultimate disposal. The headspace cover gas in the immobilization feed tank is swept by the PVVS. Liquid wastes in the RLWS system may contain SNM. Solutions are transferred to the RLWI system by the VTS from the RLWS system. Liquids are solidified in drums pre-filled with immobilization agents.

SHINE FSAR section 4b.1.3.8, "Radioactive Liquid Waste Immobilization," provides a general process description. Wastes may be recirculated in the RLWI system through a set of adsorption columns to remove isotopes that impact dose. Solution in the RLWI system is pumped into a waste drum pre-filled with solidification agents, and the drum is mixed and allowed to cure. The solidified waste drum is transported from the RPF to the material staging building. The SNM within the RLWI system is from process wastes where target solution was present and from spent target solution. The maximum inventory of SNM in the system is 10 kilograms (kg) within the RLWI process vessels and piping. SHINE FSAR figure 9b.7-1 provides a flow diagram of the RLWI system.

The RLWI system is safety-related and Seismic Category I. As defined in SHINE FSAR section 3.1, safety-related SSCs at SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents. The safety function of the RLWI system is to prevent inadvertent criticality through design of equipment in accordance with the criticality safety controls. A description of provisions for criticality control in the RLWI system is provided in SHINE FSAR section 6b.3.2.9, "Radioactive Liquid Waste Immobilization System." The NRC staff evaluated SHINE's nuclear criticality safety in Chapter 6 of this SER.

The flow through the RLWI system consists of the receipt of liquid waste from the RLWS liquid waste blending tank to solidified waste loaded in waste solidification drums. Waste with a uranium concentration capable of meeting the waste acceptance and storage requirements enters the system from the RLWS liquid waste blending tanks to the immobilization feed tank. Upon receipt of liquid waste from the RLWS system, the RLWI system and process is performed within a shielded enclosure located in the RPF. When the waste is ready to be immobilized, it is pumped from the immobilization feed tank by the liquid waste drum fill pump and into a radioactive liquid waste drum pre-loaded with solidification agents. The empty waste drums are prefilled with measured amounts of dry, powdered solidification agent in accordance with the process control program (PCP). The waste drum is then transferred outside the RLWI system to a separate enclosure for contamination control.

The RLWI system is also capable of removing selected isotopes, as needed, from the blended liquid waste and immobilizing the wastes for ultimate disposal. Selective isotope removal and mixing are performed within the shielded enclosure. The RLWI shieled enclosure is ventilated by RVZ1e. The RVZ1e equipment processes air from the enclosure through a HEPA and carbon filter before discharging to the facility stack. Transfer of the waste drum inside the enclosure is by remote handling equipment and positioners. For combustion control, the immobilization feed tank cover gas and waste drum vent both discharge via a common header to the PVVS vent header.

Remote sampling for waste characterization is performed in the RLWS system prior to solidification activities within the RLWI system. Radiation measurements are performed on the solidified waste drum prior to shipment in the material staging building to verify that it meets shipping dose rate requirements. The RLWS system transfers blended liquid waste to the RLWI system, as described in SHINE FSAR section 9b.7.4, “Radioactive Liquid Waste Storage System.” The RLWI system immobilization feed tank level instrumentation provides for metering of liquid waste transfers from the RLWS system blended liquid waste tanks.

The RLWI system is contained within a shielded enclosure within the RPF. The RLWI shielded enclosure provides dose reduction and supports compliance with the ALARA objectives and dose limits required by 10 CFR Part 20. The liquid process wastes enter the RLWI shielded enclosure through the process piping trench, they are solidified in the cell, and the solidified waste drums exit through the RLWI drum access door. New drums enter the RLWI shielded enclosure through the same drum access door, and personnel can enter and leave the shielding via the personnel access door. Contaminated process equipment is removed via the drum access door or shield plugs. Selective isotope removal and waste drum filling and mixing are also performed within the shielded enclosure. Piping that contains radioactive and potentially radioactive materials is routed through shielded pipe chases to limit the exposure of individuals to radiation.

Design Criteria

SHINE FSAR table 3.1-1 identifies the SSCs at SHINE that are classified as safety-related. The list includes the RLWI system. SHINE FSAR table 3.1-3 provides the generically applicable design criteria to the SHINE facility. The NRC staff focused on the design criteria applicable to RLWI system, namely criteria 35, 36, and 37.

For criterion 35, the NRC staff finds that the RLWI system is equipped to control the release of radioactive materials in liquid effluents and to handle radioactive solid wastes produced during normal operation, including anticipated transients.

For criterion 36, the NRC staff finds that the facility handling of the liquid waste, solid waste, and other systems that contain radioactivity are designed with adequate safety under normal and postulated accident conditions. The staff also finds that the RLWI system is contained within suitable shielding with adequate controls for the safe handling of radioactive waste.

For criterion 37, the NRC staff finds that the facility description of provisions for criticality control in the RLWI system is provided in SHINE FSAR section 6b.3.2.9 and the staff evaluated SHINE’s nuclear criticality safety in Chapter 6 of this SER.

Based on the above, the NRC staff finds that the applicant provided final analysis and evaluation of the design and performance of SSCs as it relates to the RLWI system and, therefore, satisfies 10 CFR 50.34(b)(4).

Conclusion

The NRC staff evaluated the descriptions and discussions of SHINE’s RLWI system, as described in SHINE FSAR section 9b.7.3, and finds that the final design of SHINE’s RLWI system, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license. There are design basis accidents related to the RLWI system; the staff evaluated SHINE's DBAs in Chapter 13 of this SER.

9b.4.7.4 Radioactive Liquid Waste Storage System

SHINE FSAR section 9b.7.4 states that the RLWS system collects, stores, blends, conditions, and stages liquid wastes upstream of the RLWI system for solidification. The RLWS system is a set of below grade tanks used to provide storage for radioactive liquid wastes prior to immobilization. Liquid wastes from processes that may contain greater than trace amounts of uranium, including spent target solution, are placed in favorable geometry tanks until the solutions are verified to have a uranium concentration below the single-parameter administrative limit as described in SHINE FSAR section 6b.3. Liquid wastes from other processes are collected separately. Liquid wastes are blended prior to immobilization.

Liquid waste collected, blended, and stored by the RLWS system includes:

- Uranium liquid waste, with uranium concentrations potentially exceeding 25 grams of uranium per liter (gU/L). This waste is located in the uranium liquid waste tanks.

- Blended liquid waste, with low uranium concentrations (< 25 gU/L). Blended waste may originate from uranium liquid waste, radioactive liquid waste, or any combination of the two.

- Radioactive liquid waste, with negligible uranium concentration with respect to criticality safety (< 1 gU/L). This waste is stored in the liquid waste collection tanks.

The RLWS system is safety-related and Seismic Category I. As defined in SHINE FSAR section 3.1, safety-related SSCs at SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents. The safety function of the RLWS system is to prevent inadvertent criticality through design of equipment in accordance with the criticality safety evaluation. A description of provisions for criticality control in the RLWS system is provided in SHINE FSAR section 6b.3.2.2, "Radioactive Liquid Waste Storage System."

Following isotope extraction, the target solution is directed to one of the target solution hold tanks, the target solution storage tanks, or the RLWS system. The RLWS system contains a first and a second uranium liquid waste tank, four radioactive liquid waste tanks, and eight liquid waste blending tanks. The uranium liquid waste tanks are of geometrically favorable design and are contained in individual below grade vaults. The first and second uranium liquid waste tanks are connected in series to preclude inadvertent direct transfers to the non-favorable-geometry liquid waste blending tanks. The liquid waste blending tanks are large volume, non-favorable-geometry tanks that store low concentration wastes. These blending tanks receive low concentration wastes from the second uranium liquid waste tank and negligible concentration waste from the upstream radioactive liquid waste tank. The radioactive liquid waste tanks are large volume, non-favorable-geometry tanks that receive and store negligible concentration wastes from the PVVS, MEPS, and IXP.

The normal RLWS system process for receiving high concentration wastes proceeds as follows. First, the high concentration wastes are moved from an upstream system into the first uranium liquid waste tank. When the waste is desired to be transferred to the RLWI system, it is first down-blended if needed with PVVS condensate or water to less than 25 gU/L. The first uranium liquid tank is sampled prior to the authorization of any transfers to verify that the less than 25 gU/L limit is met. Then, the waste is transferred to the second uranium liquid waste tank and re-sampled. If the sampling conditions are met, the low concentration waste is then transferred by vacuum to the liquid waste blending tank. Blended waste may originate from uranium liquid waste, radioactive liquid waste, or any combination of the two. The liquid waste blending tank may be further down-blended with negligible concentration wastes from the radioactive liquid waste tanks to meet downstream waste disposal specifications in the RLWI system. Liquid waste is transferred between RLWS system tanks by use of the VTS.

Valve position indicators and temperature and level instrumentation provide remote indication of the operating state of the RLWS system tank to PICS.

The RLWS system tanks, valves, and piping are located in shielded tank vaults, valve pits, and pipe trenches within the RPF. The waste tanks of the RLWS system are located below ground. The below grade portions of the PFBS are the process tank vaults, pipe trench, valve pits, drum storage bore holes, and carbon delay bed vault. Each of the below grade PFBS volumes can be accessed through concrete shield plugs, which are either grouted or sealed by other means.

Design Criteria

SHINE FSAR table 3.1-1 identifies the SSCs at SHINE that are classified as safety-related. The list includes the RLWS system. SHINE FSAR table 3.1-3 provides the generically applicable design criteria to the SHINE facility. The NRC staff focused on the design criteria applicable to the RLWS system, namely criteria 29–37 and 39.

For criteria 29–34, the NRC staff finds that the confinement is adequately addressed, as the RLWS system and tanks are located entirely within the RPF confinement. The RLWS system does not contain any piping or tanks that penetrate the RPF confinement boundary.

For criterion 35, the NRC staff finds that the RLWS system is equipped to control the release of radioactive materials and to handle radioactive liquid wastes produced during normal operation, including anticipated transients.

For criterion 36, the NRC staff finds that the RLWS system has provided adequate shielding, sampling, and other protective measures to allow for the safe handling of liquid waste.

For criterion 37, the NRC staff finds that the facility description of provisions for criticality control in the RLWS system is provided in SHINE FSAR section 6b.3.2.2 and the staff evaluated SHINE's nuclear criticality safety in Chapter 6 of this SER.

For criterion 39, the NRC staff finds that the design of the RLWS system has provisions to control the buildup of hydrogen that is released into the primary system boundary and tanks or other volumes as the headspace in each RLWS system tank is swept with air by the PVVS or by the N2PS to remove the potential accumulation of radiolytically generated hydrogen gas.

Based on the above, the NRC staff finds that the applicant provided final analysis and evaluation of the design and performance of SSCs as it relates to the RLWS system and, therefore, satisfies 10 CFR 50.34(b)(4).

Conclusion

The NRC staff evaluated the descriptions and discussions of SHINE's RLWS system, as described in SHINE FSAR section 9b.7.4, and finds that the final design of SHINE's RLWS system, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9b.4.7.5 Solid Radioactive Waste Packaging System

SHINE FSAR section 9b.7.5, "Solid Radioactive Waste Packaging System," states that the design bases function of the solid radioactive waste packaging (SRWP) system is to collect, segregate, process (i.e., encapsulate), and stage for shipment solid radioactive wastes. The solid waste may include dry active waste, spent ion exchange resin, and filters and filtration media. The SRWP system also inventories materials entering and exiting the facility structure storage bore holes. The SRWP system is a nonsafety-related system.

Solid radioactive waste is collected in segregated containers and the containers may be sorted for non-contaminated waste. Contaminated waste is sealed, labeled, and transported to the material staging building. Solid wastes potentially having high levels of radioactivity are collected and transported to the material staging building in shielded casks. Used NDAS units are disassembled to transport to the material staging building or for storage in storage bore holes. Used separation columns are stored on storage racks for a minimum of 14 days following their use, and the columns are then transferred to column waste drums. The column waste drums are exported and transferred to the drum storage bore holes. The column waste drums are removed following extended decay. Prior to disposal, the column waste drums may require encapsulation to meet the designated licensed disposal facility's waste acceptance criteria. The encapsulation process will be performed in the material staging building in accordance with the radioactive waste management program. There are no TSs or instrumentation and controls identified for the SRWP system.

The NRC staff finds that waste is handled and shipped in accordance with SHINE's radioactive waste management program. The staff also finds that SRWP system operations are performed in accordance with the requirements of the radiation protection program. The staff finds that the implemented programs provide reasonable assurance that the SRWP system should not cause an uncontrolled release of radioactivity. The staff evaluated SHINE's radioactive waste management program and radiation protection program in Chapter 11 of this SER.

The NRC staff evaluated the descriptions and discussions of SHINE's SRWP system, as described in SHINE FSAR section 9b.7.5, and finds that the final design of SHINE's SRWP system, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license.

9b.4.7.6 Radioactive Drain System

SHINE FSAR section 9b.7.6, “Radioactive Drain System,” states that the Radioactive Drain System (RDS) is normally empty, prevents the accumulation of radioactive solution, and provides liquid detection sensor to detect fluid in-leakage to protect confinement boundary. The RDS is confined within the RCA without any penetration to a non-RCA system and consists of drip pans with drain lines, tank overflow lines, collection tanks, and instrumentation to alert operators of system status. The RDS includes drip pans located beneath the extraction and IXP hot cells, favorable geometry tanks, and piping for systems that normally contain high concentration fissile solution. The RDS contains two favorable geometry tanks that collect leakage from postulated sources. The leakage and overflow from system tanks are connected by piping that is substantially located within the basemat of the RPF as well as in the RPF pipe trench.

The RDS is safety-related and Seismic Category I. As defined in SHINE FSAR section 3.1, safety-related SSCs at SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents.

The RDS operates by gravity drain, where overflows and leakage flow through installed piping directly to the RDS hold tanks. The hold tank contents can be mixed, sampled, and withdrawn through the VTS to the TSSS or RLWS system, as appropriate. Gravity provides the motive force between the various drip pans and the RDS hold tanks. No valves are installed between the potential collection source and the hold tanks. SHINE FSAR figure 6b.3-7 provides a flow diagram of the RDS interfaces draining into the RDS hold tanks. The RDS collects solution from drip pans located in the supercell, valve pits, tank vaults, and trenches that have the potential to contain liquid that requires favorable geometry.

Each of the RDS sump tanks is sized to accept the largest volume of liquid containing SNM that is postulated to leak from a favorable geometry tank. SHINE defines this volume as liquid containing SNM postulated to leak into the RDS system, assuming that the tank is filled to the overflow line. In accordance with criterion 39, the design must have provisions to control the buildup of hydrogen that is released into the primary system boundary and tanks or other volumes. The NRC staff finds that the PVVS provides the RDS sump tanks with ventilation to mitigate hydrogen accumulation in the tank headspace. Additionally, the N2PS provides a source of sweep gas to mitigate hydrogen accumulation in RDS sump tanks in the event of a failure of the PVVS to provide the sweep gas.

The facility nitrogen handling system (FNHS) provides a nitrogen gas supply for liquid detectors for the RDS sump tanks. The FNHS provides compressed gas to the RDS sump tanks for solution agitation.

As indicated in the SHINE FSAR, the contents of the RDS tanks are sampled and transferred by the VTS to the appropriate location. Piping that contains potentially radiological material is routed through shielded pipe chases to limit the exposure of personnel to radiation. The RDS tanks are shielded by a tank vault, which is a part of the PFBS. The PFBS provides shielding from sources of radiation in the RDS to ensure that accumulated doses in occupied areas do not exceed defined limits. Fluids collected in the RDS can be returned to production or transferred to the RLWS system for disposal. In accordance with criterion 36, the NRC staff finds that the target solution storage and handling, radioactive waste, and other systems within the RDS containing radioactivity have the capability to permit appropriate periodic inspection, suitable shielding for radiation protection, and appropriate confinement and filtering systems.

The RDS does not contain fissile material under normal process conditions and leakage or overflow of target solution to the RDS is considered an abnormal condition. The RDS hold tanks and piping are favorable geometry for the most reactive concentration of target solution. In accordance with criterion 37, a detailed description of the criticality safety program is provided in SHINE FSAR section 6b.3. The NRC staff evaluated SHINE's nuclear criticality safety in Chapter 6 of this SER.

PICS directly monitors and provides alarms for RDS sump tank temperature and level. The RDS liquid detection switch signal is received by the ESFAS as a discrete input from a liquid detection switch. When one or more RDS liquid detection switch signal channels are active, then a VTS safety actuation is initiated. The NRC staff evaluated SHINE's instrumentation and control system, including ESFAS and PICS, in Chapter 7 of this SER.

The NRC staff evaluated the descriptions and discussions of SHINE's RDS, as described in SHINE FSAR section 9b.7.6, and finds that the final design of SHINE's RDS, including the principal design criteria, design bases, and information relative to the subject system, meets all applicable regulatory requirements and acceptance criteria for the issuance of an operating license. The staff also finds that target solution storage and handling within the RDS provides adequate radioactivity confinement, critically control, and hydrogen mitigation features and is, therefore, acceptable.

9b.4.7.7 Facility Potable Water System

SHINE FSAR section 9b.7.7, "Facility Potable Water System," states that the facility potable water system (FPWS) provides a potable water supply to the SHINE facility and is connected to the City of Janesville water supply. The boundaries of the FPWS include the components from the City of Janesville water main to the fixtures in each of the buildings on the SHINE facility. The fixtures themselves are part of the facility sanitary drain system (FSDS).

Potable water is distributed throughout the SHINE facility through a subgrade piping network. The FPWS site main connects to SHINE facility building mains, which include the main production facility (outside the RCA), the storage building, and the resource building. The FPWS protects the public water system from backflow of contaminants through the water service connection into the public water system through the installation of backflow prevention devices.

The FPWS supplies inventory to both the facility demineralized water system (FDWS) and FHWS with a backflow prevention device at system interfaces. The FPWS supplies water to the eye wash stations and chemical showers within the non-RCA working areas of the chemical storage and preparation room, and storage building where reagent preparation is performed, which are located outside the RCA.

The FPWS is not a safety-related system because it performs no function to prevent or mitigate postulated accidents, and potable water contains no radioactive material or SNM. Shielding and radiological protection is not required for the FPWS. For instrumentation, the FPWS hot water supply is equipped with automatic temperature controls capable of adjustments.

The NRC staff finds that the FPWS interfaces only with systems outside the RCA and contains backflow preventors to prevent inadvertent contamination with interfacing systems. Therefore, the staff finds that the applicant adequately described the design and function of the FPWS to comply with the requirements of 10 CFR 50.34 and that the system has reasonable protections against radioactive contamination such that the requirements of 10 CFR Part 20 are satisfied.

9b.4.7.8 Facility Nitrogen Handling System

SHINE FSAR section 9b.7.8, "Facility Nitrogen Handling System," states that the FNHS is designed to supply both liquid nitrogen and compressed gaseous nitrogen to interfacing systems inside and outside the RCA. Outside the main production facility, bulk liquid nitrogen is stored in tanks and is supplied to vaporizer units. The FNHS vaporizer units vaporize the liquid nitrogen to provide a clean gaseous nitrogen supply that is piped into the main production facility. A liquid nitrogen supply line upstream of the vaporizers supplies liquid nitrogen from the bulk storage tank into the main production facility via vacuum jacketed cryogenic piping.

Inside the RCA, a portion of the nitrogen supply gas is piped to a main receiver storage tank which feeds the FNHS ring header. The remainder of the nitrogen supply gas is piped to the TPS room serving the TPS.

Systems that use the FNHS nitrogen supply to support their functions are identified in SHINE FSAR table 9b.7-5. Although the FNHS interfaces with these systems, FNHS is nonsafety-related and not relied upon to prevent or mitigate accidents.

The FNHS bulk liquid nitrogen storage tank and vaporizers supply nitrogen gas to the main FNHS receiver tank, the facility nitrogen gas ring header, and the FNHS remote receiver tank located inside the RCA. The FNHS ring header inside the RCA supplies nitrogen gas to sampling equipment, tank sparging and mixing equipment, and level indication equipment. The FNHS ring header also supplies nitrogen gas to each FNHS cooling room receiver tank where it is used by TOGS. The FNHS provides liquid and gaseous nitrogen to the TPS as shown in SHINE FSAR figure 9b.7-6. Gaseous nitrogen is used by the TPS to operate pneumatic equipment.

Liquid nitrogen is supplied from an outside bulk liquid nitrogen storage tank to the filling station and the TPS within the RCA through a valved penetration. The FNHS supplies liquid nitrogen to an adjustable pressure phase separator inside the main production facility that has the capability to store and deliver high quality liquid nitrogen to the TPS. Liquid nitrogen is also supplied to a fill station inside the main production facility. The fill station is installed to fill portable dewars for the disbursement of liquid nitrogen in small quantities as needed by facility processes. A separate remote receiver tank is maintained on the FNHS ring header to supply abrupt demands and provide consistent nitrogen gas flow and pressure to all serviced areas in the RCA.

The FNHS bulk liquid nitrogen storage tanks outside the RCA are continuously pressurized by the naturally occurring liquid to gas phase change inside the tank with overpressure venting to the atmosphere. Liquid nitrogen is directed to either vaporizers or sent to phase separator for supply to the TPS. The supply nitrogen gas from the vaporizer is routed through a manifold with a pressure regulator to the primary receiver tank, facility nitrogen gas ring header, and remote receiver tank located inside the RCA. The nitrogen gas is regulated through a control manifold designed to control the pressure and prevent possible liquid carryover to the FNHS end users. The control manifold ensures that adequate pressure is maintained within the main production facility.

Overpressure protection is provided for the FNHS with venting both inside and outside the RCA. The components outside the RCA consist of a FNHS bulk liquid nitrogen storage tank, vaporizer, and manifold. A pressure relief system with a vent path to the atmosphere is maintained on each bulk liquid storage tank to prevent over-pressurization of the vessel. SHINE FSAR figure 9b.7-6 shows a pressure relief system and a control manifold downstream of vaporizers prior to entering the RCA for overpressure protection and to ensure that adequate pressure is maintained within the main production facility. Inside the RCA, nitrogen supply gas received from the manifold is piped to a primary receiver storage tank which feeds a remote receiver tank on the ring header inside the RCA. Primary and remote receiving tanks contain overpressure devices venting to the RVZ2e within the RCA. Through a second RCA penetration, the FNHS supplies liquid nitrogen to an adjustable pressure phase separator with the capability to store and deliver high quality liquid nitrogen to the filling station and the TPS. Off-gassing from this phase separator is vented through a connection to the RVZ2e.

The NRC staff finds that acceptable design provisions have been made to safely supply nitrogen to the supported systems and prevent over-pressurization of the FNHS by use of pressure relief components. Additionally, the FNHS contains pressure monitoring within PICS isolation provisions at RCA penetrations. Therefore, the staff finds that the applicant adequately described the design and function of the FNHS to comply with the requirements of 10-CFR 50.34 and that the system has reasonable protections against radioactive contamination such that the requirements of 10 CFR Part 20 are satisfied.

9b.4.7.9 Facility Sanitary Drain System

SHINE FSAR section 9b.7.9, “Facility Sanitary Drain System,” states that the FSDS removes domestic sanitary waste and wastewater from the areas of the main production facility (outside the RCA), the storage building, and the resource building; and discharges sanitary waste and wastewater to the City of Janesville public sewer main. The FSDS building sewer removes sanitary waste via a gravity drainage system. The subsystem includes distribution piping, pipe fittings, isolation valves, backwater valves, vents, traps, cleanouts, manholes, and fixtures.

The FSDS is not a safety-related system because it performs no function to prevent or mitigate postulated accidents, and sanitary waste sources contain no radioactive material or SNM. Shielding and radiological protection is not required for the FSDS. The FSDS has no instrumentation or control equipment.

Building drains that are subject to backflow are protected with a backwater valve or sump and pumping equipment to comply with applicable requirements of the Wisconsin Administrative Code.

The NRC staff finds that the FSDS service drains are outside the RCA and not connected to contaminated systems. As such, the risk of contamination is extremely low. Therefore, the staff finds that the applicant adequately described the design and function of the FSDS to comply with the requirements of 10 CFR 50.34 and that the system has reasonable protections against radioactive contamination such that the requirements of 10 CFR Part 20 are satisfied.

9b.4.7.10 Facility Chemical Reagent System

SHINE FSAR section 9b.7.10, "Facility Chemical Reagent System," states that the facility chemical reagent system (FCRS) provides storage and equipment for non-radioactive chemical reagents used in the SHINE processes and the design basis of the FCRS includes:

- Provide intermediate storage for chemical reagents and bulk chemicals used to prepare chemical reagents.
- Provide for preparation of chemical reagents from bulk chemicals.
- Transfer reagents from their intermediate storage locations to process at tie-in locations.
- Deliver reagents into the SHINE process.
- Provide compressed oxygen to the TOGS.

Systems that use the FCRS reagents to support their functions are identified in SHINE FSAR table 9b.7-6. Although the FCRS interfaces with systems identified as safety-related, the FCRS is nonsafety-related.

Bulk chemical storage is provided in the storage building outside the RCA. Chemical storage is also provided in the chemical storage and preparation room in the main production facility, which is also located outside the RCA. Chemical reagents are placed into volume-limited FCRS containers for transfer to process tie-in location tanks and into single-use laboratory scale containers (e.g., flasks, syringes, pipets) for import into hot cells inside the RCA.

SHINE FSAR section 9b.7.10.2, "System Description," and table 9b.7-6 provide a list of systems that use reagents transported in portable containers, transferred into the tanks, and pumped on demand directly into the respective process tie-in locations. These systems primarily use FCRS during the SHINE processes of extraction, purification, flushing, and pH adjustment.

Storage of compressed oxygen gas, used as a reagent, is provided by the FCRS. Compressed oxygen is supplied to the TOGS to facilitate the recombination of radiolytic hydrogen. Compressed oxygen cylinders are stored inside the IF to service the TOGS. The oxygen is routed through dry particulate filters, regulated, and distributed to the TOGS. The SHINE FSAR states that the storage and delivery of oxygen gas inside the RCA complies with the FHA, as described in SHINE FSAR section 9a2.3. The PICS provides monitoring and alarms for pressure in oxygen receivers for end users. Other chemical reagents are used for batch production, solution adjustment, and process flushing.

Reagents from FCRS process delivery tanks are pumped directly into the respective process tie-in points at controlled flow rates and temperatures in accordance with the process requirements. Administrative and engineered controls, including accurate identification of reagents inside process delivery tanks and containers, and color-coded and size specific connections, ensure that reagents are not inadvertently supplied at incorrect process tie-in points. The FCRS process delivery tanks are volume limited, thereby setting the maximum volume of reagents that can be supplied to respective production-related processes.

The FCRS provides pumped MEPS extraction and purification reagents. Reagents in laboratory containers are manually introduced into the MEPS purification hot cells through hot cell pass-throughs. Hot cell manipulators are used to add chemicals to the laboratory scale purification processes performed in the hot cells. As discussed in SHINE FSAR section 6b.3.2, “Criticality Safety Controls,” a three-way valve design prevents flow of target solution toward the FCRS reagent vessels. An isolation valve is installed between the FCRS and upper vacuum lift tanks, which is administratively closed during target solution processing, and a check-valve also exists to prevent inadvertent flow of target solution to the reagent vessels.

Prevention of target solution backflow into the FCRS provides protection against criticality accidents. A check valve is installed to prevent the flow of solution upstream to the FCRS. Additionally, an isolation valve located between the check valve and the FCRS is administratively closed during the processing of target solution. The FCRS contains no SNM; however, the addition of basic chemical reagents to interfacing systems may result in uranium precipitation. Chemical additions to process tanks in interfacing systems are evaluated under the nuclear criticality safety program, as described in SHINE FSAR section 6b.3. The NRC staff evaluated SHINE’s nuclear criticality safety in Chapter 6 of this SER.

The NRC staff finds that acceptable design provisions have been made to prevent the inadvertent contamination of the systems with radioactive material or SNM during the storage and handling of chemical reagents. Therefore, the staff finds that the FPWS is adequately described, including its design and function, to comply with the requirements of 10 CFR 50.34 and that the system has reasonable protections against radioactive contamination such that the requirements of 10 CFR Part 20 are satisfied.

9b.4.8 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant’s proposed TSs for the SHINE RPF auxiliary systems as described in SHINE FSAR Chapter 9.

The proposed TS 2.2, “Limiting Safety System Settings (LSSS),” Table 2.2, “Limiting Safety System Settings,” states, in part, the following:

LSSS 2.2.9	Low process vessel vent system (PVVS) flow	≥ 7.1 SCFM	RPF Nitrogen Purge not Operating when the Facility is not Secured

LSSS 2.2.9 provides a setpoint to ensure that the PVVS flow rate is at least 7.1 standard cubic feet per minute (SCFM) with the RPF nitrogen purge not operating when the facility is not secured. The NRC staff finds that this flow limit is bounded by the analytical limit for the PVVS flow limit. The staff finds that the analytical limit ensures that the concentration of hydrogen does not reach the lower flammability limit and prevents a deflagration. Therefore, the staff finds the LSSS acceptable.

The proposed TS 3.5, “Ventilation Systems,” LCO 3.5.1 and SR 3.5.1 state the following:

LCO 3.5.1	The PVVS shall be Operable. PVVS is considered Operable if:

	1. At least 2 PVVS blowers are Operating, with total flow ≥ 7.1 SCFM, 2. At least 1 PVVS inlet header flow path is open, 3. At least 7 carbon delay beds are Operating, and 4. PVVS flow from the individual tanks containing target solution or radioactive liquids listed in Table 3.5.1-a is above corresponding minimum flowrate. Note – PVVS flow from individual tanks is allowed to drop below the minimum required flowrate during tank sparging or fluid transfer operations.
Applicability	Facility not Secured
Action	According to Table 3.5.1
SR 3.5.1	7. Verify total flowrate at the exhaust of the PVVS is above the limit daily. 8. Verify flow from individual tanks listed in Table 3.5.1-a quarterly.

The proposed TS Table 3.5.1, "PVVS Actions," states the following:

	Condition and Action	**Completion Time**
1.	If fewer than 2 PVVS blowers are Operating, OR If PVVS total flow is < 7.1 SCFM, OR If no PVVS inlet header flow path is open, Verify actuation of the RPF Nitrogen Purge.	1 hour
2.	If fewer than 7 carbon delay beds are Operating, Restore at least 7 carbon delay beds to Operating.	60 days

3.	If fewer than 5 carbon delay beds are Operating, OR Action and completion time of Condition 2 not met, Suspend operations to transition any IU in Mode 0 to Mode 1 AND Place all Mode 1 IUs in Mode 3 AND Verify a flow path exists for PVVS flow through the carbon guard bed or its bypass, and through the Operating delay beds to the facility exhaust.	 1 hour 6 hours 1 hour
4.	If PVVS flow from the individual tanks listed in Table 3.5.1-a is ≤ the corresponding minimum flowrate, Remove target solution or radioactive liquids from affected tank(s).	 12 hours

The proposed TS Table 3.5.1-a, "PVVS Tank Flowrates," states the following:

	Component	**Number of Tanks**	**Minimum Flowrate Per Tank (SCFM)**
a.	Target solution hold tank	8	1.1E-01
b.	Target solution storage tank	2	1.1E-01
c.	Uranium waste tank	2	1.1E-01
d.	Radioactive liquid waste collection tank	4	2.8E-01
e.	Radioactive liquid waste blending tank	8	2.8E-01
f.	Radioactive drain sump tank	2	1.1E-01

LCO 3.5.1 requires the PVVS to be operable, provides the conditions for the PVVS to be considered operable, and provides the actions to be taken if it is not operable. The NRC staff finds that the requirements to be considered operable would ensure that the PVVS is able to perform its safety function. The staff finds that Action 1 and its completion time would ensure that hydrogen mitigation for the RPF is maintained. The staff finds that Action 2 would ensure that the limits in 10 CFR Part 20 are not exceeded, and that the completion time is acceptable due to the limited duration. The staff also finds that the completion time would allow for investigation and the repair of a carbon delay bed. The staff finds that Action 3 would prevent the increase of the facility's radionuclide inventory and ensure that the sweep gas flow path is sufficient. The staff finds that the completion times are acceptable due to the availability of the ESFAS automatic safety function to initiate an RPF nitrogen purge on low PVVS flow (e.g., a blocked flow path) and the availability of at least one carbon delay bed or carbon guard bed to continue to provide limited hold up of radionuclides prior to release. The staff finds that Action 4

would eliminate the need for sweep gas in the affected tank. The staff finds that this completion time provides adequate time to repair a minor problem or remove radioactive liquids from affected tanks. The staff finds that there is a low rate of hydrogen generation in these tanks during the completion time. Therefore, the staff finds the LCO acceptable.

SR 3.5.1 requires the daily verification of the total flowrate at the PVVS exhaust and the quarterly verification of flow from the tanks listed in Table 3.5.1-a. The NRC staff finds that the frequency of the verifications would ensure that the PVVS is operating within design limits. Therefore, the staff finds the SR acceptable.

The proposed TS 3.8, “Facility-Specific,” LCO 3.8.1 and SR 3.8.1 state the following:

LCO 3.8.1	The N2PS shall be Operable. The N2PS is considered Operable if: 1. At least 11 nitrogen storage tubes are filled with nitrogen at a minimum pressure of 2,100 psig per tube, and 2. The N2PS is capable of delivering ≥ 16 SCFM of sweep gas flow.
Applicability	Facility not Secured
Action	According to Table 3.8.1
SR 3.8.1	1. Nitrogen pressure in each tube shall be verified to be above the minimum pressure weekly. 2. A verification of the N2PS capability to deliver the required sweep gas flow shall be performed every five years.

The proposed TS Table 3.8.1, “Nitrogen Purge System Actions,” states the following:

	Condition and Action	Completion Time
1.	If fewer than 11 nitrogen storage tubes are pressurized to ≥ 2,100 psig, OR If N2PS is unable to deliver ≥ 16 SCFM of sweep gas flow, Place all IUs undergoing irradiation in Mode 3 AND Restore N2PS to Operable.	 12 hours 72 hours

LCO 3.8.1 requires the N2PS to be operable, provides the conditions for N2PS to be considered operable, and provides the actions to be taken if it is not operable. The NRC staff finds that 11 out of 12 N2PS storage tubes pressurized to a minimum pressure would ensure that there is sufficient nitrogen capacity to adequately control hydrogen concentrations in process tanks and IUs during accident scenarios for the required 72 hours. The staff finds that placing all IUs

undergoing irradiation in Mode 3 if the N2PS is not operable would limit the amount of hydrogen generated. The staff finds that the completion time of 12 hours would allow time to restore the N2PS to operable or to transition the operating IUs to Mode 3 in a controlled manner. There is also a low likelihood of an event requiring an N2PS activation during this time. The staff finds that restoring N2PS to operable within 72 hours would allow for more extensive maintenance of the N2PS to be performed. Therefore, the staff finds the LCO acceptable.

SR 3.8.1 requires the nitrogen pressure to be verified weekly and the N2PS sweep gas flow to be verified every five years. The NRC staff finds that verification of the nitrogen pressure weekly would ensure that the N2PS can perform its required function. The staff finds that the sweep gas flow verification every five years is acceptable based on the passive design of the N2PS. Therefore, the staff finds the SR acceptable.

The proposed LCO 3.8.10 and SR 3.8.10 state the following:

LCO 3.8.10	Each safety-related valve listed in Table 3.8.10-a shall be Operable. A valve is considered Operable if: 1. The valve is capable of opening or closing on demand from ESFAS. Note – A single Division of required component(s) may be inoperable for up to 2 hours during the performance of required surveillances.
Applicability	According to Table 3.8.10-a when the Facility is not Secured
Action	According to Table 3.8.10
SR 3.8.10	1. Safety-related valves listed in Table 3.8.10-a shall be verified to stroke on demand from ESFAS annually.

The proposed TS table 3.8.10, "Safety-Related Valves Actions," provides the actions to be taken and the completion time for each action if the LCO is not met.

The proposed TS table 3.8.10-a, "Automatically-Actuated Safety-Related Valves," provides a list of the safety-related valves that shall be operable according to LCO 3.8.10, the number of valves provided per flow path, the applicability for each valve, and the applicable actions for each valve.

LCO 3.8.10 requires the safety-related valves listed in TS table 3.8.10-a to be operable, provides the condition for the valves to be considered operable, and provides the actions to be taken if they are not operable. The NRC staff finds that the operability of the safety-related valves would ensure that the valves are able to provide the applicable isolation functions. The staff finds that the actions taken if a safety-related valve is not operable would ensure that any hazards caused by the inoperable valves are minimized. The staff finds that the completion times provide reasonable time to investigate and repair minor problems. The staff also finds that the likelihood of a release within the completion times is low. Therefore, the staff finds the LCO acceptable.

SR 3.8.10 requires the safety-related valves to be verified to stroke on demand from ESFAS annually. The NRC staff finds that the frequency is based on industry experience. Therefore, the staff finds the SR acceptable.

The proposed LCO 3.8.11 and SR 3.8.11 state the following:

LCO 3.8.11	The safety-related check valves listed in Table 3.8.11-a shall be Operable.
Applicability	According to Table 3.8.11-a when the Facility is not Secured
Action	According to Table 3.8.11
SR 3.8.11	1. The check valves listed in Table 3.8.11-a shall be inspected semi-annually.

The proposed TS table 3.8.11, “Safety-Related Check Valve Actions,” provides the actions to be taken and the completion time for each action if the LCO is not met.

The proposed TS table 3.8.11-a, “Safety-Related Check Valves,” provides a list of the safety-related check valves that shall be operable according to LCO 3.8.11, the applicability for each check valve, and the applicable action for each check valve.

LCO 3.8.11 requires the safety-related check valves listed in table 3.8.11-a to be operable and provides the actions to be taken if they are not operable. The NRC staff finds that the operability of the safety-related check valves would ensure that the valves are able to provide the applicable isolation functions. The staff finds that the actions taken if a safety-related check valve is not operable would ensure that any hazards caused by the inoperable check valves are minimized. The staff finds that the completion times provide reasonable time to investigate and repair minor problems and to isolate the affected flow path. The staff also finds that the likelihood of a release within the completion times is low. Therefore, the staff finds the LCO acceptable.

SR 3.8.11 requires the safety-related check valves to be inspected semi-annually. The NRC staff finds this frequency to be consistent with the expected reliability of the components. Therefore, the staff finds the SR acceptable.

The proposed TS 4.1, “Site and Facility Description,” Design Feature (DF) 4.1.5 states the following:

DF 4.1.5	The design of the N2PS contains the following characteristics to protect its equipment from the effects of external events: 1. Reinforced concrete structure for the compressed gas supply tanks and piping to protect against severe weather and tornado generated missiles. 2. Nitrogen gas purge exhaust height designed to be above the design snow accumulation depth of 4.95 feet. 3. N2PS and SSCs in interfacing systems that could significantly impact its operation are seismically designed to ensure N2PS operability during and after a seismic event.

DF 4.1.5 states the design characteristics of the N2PS to protect its equipment from the effects of external events. SHINE FSAR section 12a2.1.6.2 discusses external event scenarios that include the N2PS and the design of the system. The NRC staff finds that the reinforced concrete structure would protect against severe weather and tornado generated missiles. The staff finds that the nitrogen gas purge exhaust height is designed to be above the potential snow drift height to ensure operability. The staff also finds that the N2PS is Seismic Category 1 and is designed to perform its safety function after a safe shutdown earthquake. Therefore, the staff finds the DF acceptable.

The proposed TS 4.4, “Fissionable Material Storage,” DF 4.4.1 states the following:

DF 4.4.1	The margin of subcriticality for uranyl sulfate systems in the RPF shall be greater than or equal to 0.06.

DF 4.4.1 states that the margin of subcriticality for uranyl sulfate systems in the RPF shall be greater than or equal to 0.06. SHINE FSAR section 4a2.6.2.6.1 discusses the calculations and uncertainties of the effective neutron multiplication factor. The NRC staff finds that this margin would ensure that subcriticality is adequately maintained. Therefore, the staff finds the DF acceptable.

9b.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE RPF auxiliary systems, as described in SHINE FSAR section 9b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the RPF auxiliary systems and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE’s RPF auxiliary systems are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

10.0 EXPERIMENTAL FACILITIES

The SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR) chapter 10, “Experimental Facilities,” states that the SHINE facility does not contain experimental facilities as described in NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996 and the “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

The U.S. Nuclear Regulatory Commission staff evaluated the descriptions and discussions of the SHINE facility in the FSAR and finds that the final design of the SHINE facility does not contain experimental facilities. Therefore, the staff concluded that an evaluation of the guidelines of NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996 and the “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012, is not required.

11.0 RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

The principal purpose of the radiation protection program and waste management is to ensure the safety of the SHINE Medical Technologies, LLC (SHINE, the applicant) facility and the public. The radiation protection program and waste management, identified by the analyses in the SHINE final safety analysis report (FSAR), should be conducted using the appropriate methods and engineering design criteria.

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE radiation protection program and waste management, as presented in chapter 11, "Radiation Protection Program and Waste Management," of the SHINE FSAR and supplemented by the applicant's response to staff requests for additional information (RAIs).

11.1 Areas of Review

SHINE FSAR chapter 11 identifies the aspects of the radiation protection program and waste management considered to ensure facility safety and the protection of the public. SHINE FSAR chapter 11 is applicable to both the SHINE irradiation facility (IF) and radioisotope production facility (RPF). The NRC staff reviewed SHINE FSAR chapter 11 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design of the SHINE facility radiation protection program and waste management.

11.2 Summary of Application

Chapter 11 of the SHINE FSAR describes all of the relevant aspects of the applicant's radiation protection program and how the radiation protection program meets the NRC's requirements. The description of the radiation protection program identifies the sources of radiation and radioactive material that will be received, used, or generated in the SHINE facility; the sources and nature of the airborne, liquid, and solid radioactive materials; and the types of radiation that could be emitted by these radiation sources. With the consideration of the radiation sources identified by the applicant, the SHINE FSAR also describes the applicant's programs and processes for maintaining occupational and public doses as low as is reasonably achievable (ALARA); radiation monitoring and surveying; radiation exposure control and dosimetry; facility contamination control; and radiological environmental monitoring. In addition, chapter 11 of the SHINE FSAR describes the applicant's radioactive waste management program, controls, and disposal pathways that will be established to comply with all applicable federal regulations for radioactive wastes and ensure proper identification, classification, control, processing, and packaging for the applicable radioactive waste streams that will be generated by the SHINE facility.

11.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 11 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE radiation protection program and waste management for the issuance of an operating license.

11.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE radiation protection program and waste management are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Section 19.12, "Instruction to workers."
- 10 CFR 19.13, "Notifications and reports to individuals."
- 10 CFR Part 20, "Standards for Protection Against Radiation," Subpart L, "Records."
- 10 CFR 20.1101, "Radiation protection programs."
- 10 CFR 20.1201, "Occupational dose limits for adults."
- 10 CFR 20.1202, "Compliance with requirements for summation of external and internal doses."
- 10 CFR 20.1203, "Determination of external dose from airborne radioactive material."
- 10 CFR 20.1204, "Determination of internal exposure."
- 10 CFR 20.1206, "Planned special exposures."
- 10 CFR 20.1208, "Dose equivalent to an embryo/fetus."
- 10 CFR 20.1301, "Dose limits for individual members of the public."
- 10 CFR 20.1302, "Compliance with dose limits for individual members of the public."
- 10 CFR 20.1406, "Minimization of contamination."
- 10 CFR 20.1601, "Control of access to high radiation areas."
- 10 CFR 20.1602, "Control of access to very high radiation areas."
- 10 CFR 20.1901, "Caution signs."
- 10 CFR 20.1902, "Posting requirements."
- 10 CFR 20.1903, "Exceptions to posting requirements."
- 10 CFR 20.1904, "Labeling containers."
- 10 CFR 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."

- 10 CFR 50.36, “Technical specifications.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR 50.57, “Issuance of operating license.”
- 10 CFR Part 61, “Licensing Requirements for Land Disposal of Radioactive Waste.”
- 10 CFR Part 71, “Packaging and Transportation of Radioactive Material.”
- 40 CFR, Chapter I, Subchapter F, “Radiation Protection Programs.”
- 40 CFR, Chapter I, Subchapter I, “Solid Wastes.”
- 49 CFR, Chapter I, Subchapter C, “Hazardous Materials Regulations.”

11.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in Appendix B, "References," of this SER.

11.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR chapter 11, as supplemented, to assess the sufficiency of the radiation protection program and waste management for the issuance of an operating license. The sufficiency of the radiation protection program and waste management is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 11.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in section 11.5, "Review Findings," of this SER.

11.4.1 Radiation Protection

The SHINE facility is designed to produce molybdenum-99 (Mo-99) for use as a medical isotope. The SHINE facility produces Mo-99 along with other radioactive fission and activation products by irradiating a uranyl sulfate target solution inside a target solution vessel (TSV) with a low-energy, accelerator-based neutron source. After the completion of an irradiation cycle, the target solution is pumped through an extraction column, which separates the Mo-99 from the rest of the target solution. The rest of the target solution is then returned for re-use in the irradiation process. The separated Mo-99 is purified via a chemical process. As a result of this process, the radioactive materials produced during the cycle are transferred, by means of piping in shielded trenches, through various locations and systems throughout the facility.

The major radioactive sources that could become airborne during the production process are primarily tritium and other radioactive gases that are byproducts of the Mo-99 production process. The systems that would primarily handle the gaseous radioactive materials include the TSV off-gas system (TOGS) and tritium purification system (TPS), which are located in the IF area; and the process vessel vent system (PVVS) and vacuum transfer system (VTS), which are located in the RPF area. The primary liquid radioactive sources in the SHINE facility, which are contained in closed systems (piping and tanks), are primarily byproducts of the uranyl sulfate target solution and exist in the primary cooling water. As for major solid radioactive sources, they exist in several locations within the facility. The major solid radioactive sources include fresh low enriched uranium, spent Mo-99 extraction columns, spent filters, and solidified liquid waste. These solid radioactive sources are contained in irradiation unit (IU) cells, shielded cells, hot cells, and/or preparation areas within the radiologically controlled area (RCA) of the facility.

11.4.1.1 Radiation Sources

The NRC staff evaluated the sufficiency of the information provided on the radiation sources, as presented in SHINE FSAR section 11.1.1, "Radiation Sources," using the guidance and acceptance criteria from section 11.1.1, "Radiation Sources," of NUREG-1537, Parts 1 and 2, and Section 11.1, "Radiation Protection," of the ISG augmenting NUREG-1537, Parts 1 and 2.

This section contains the NRC staff's review of the sources of radiation that are monitored and controlled by the radiation protection and radioactive waste programs. In general, the sources of radioactivity are categorized as airborne, liquid, or solid.

The applicant provided two radionuclide inventory scenarios with the assumptions in SHINE FSAR table 11.1-1, "Parameters Applicable to Target Solution Radionuclide Inventories." The applicant described the two scenarios as nominal and safety basis values. The nominal parameter values are reflective of the applicant's best estimate of the SHINE facility's normal, full-power operating conditions. The safety basis parameter values define the bounding radionuclide inventories for the TSV, TSV dump tank, and supercell.

Operation of a TSV produces radioactive fission products and actinides through neutron capture in uranium. SHINE FSAR table 11.1-2, "Nominal Versus Safety Basis Radionuclide Inventories in Target Solution," summarizes the results for the total activities from actinides and fissions products contained within the TSV. SHINE FSAR table 11.1-3, "Irradiated Target Solution Activity for Select Radionuclides Pre-Extraction," provides the curie content by nuclide using NUREG/CR-4467, "Relative Importance of Individual Elements to Reactor Accident Consequences Assuming Equal Release Fractions," as a basis for providing a radionuclide listing.

The values contained in SHINE FSAR table 11.1-3 are stated to be the bounding values. The NRC staff's review of the applicant's listed activities as provided in SHINE FSAR table 11.1-3 determined that sufficient information is provided to detail the applicant's anticipated source terms for use in evaluating what source terms will be contained in downstream systems. The staff finds that the SHINE FSAR demonstrates compliance with 10 CFR 50.34(b)(3) by providing a list of radionuclides that reflects the anticipated source terms contained in each system.

Airborne Radioactive Sources

SHINE FSAR section 11.1.1.1, "Airborne Radioactive Sources," states that the primary forms of airborne radiation at the SHINE facility are tritium and radioactive gases produced by the Mo-99 production process. Argon (Ar)-41 is produced in an IU during irradiation. Nitrogen (N)-16 is produced within the primary cooling loop and the light water pool due to the neutron activation of oxygen. The systems that handle the airborne radioactivity are the TPS, the TOGS, the VTS, and the PVVS. The TPS and the TOGS are in the IF, and the VTS and the PVVS are in the RPF. SHINE FSAR table 11.1-5, "Airborne Radioactive Sources," provides information on the location of airborne radioactive sources in various plant areas. The information contained in this table allowed the NRC staff to review and understand the airborne sources when evaluating the dose impacts to workers.

Gaseous activity collected from a TSV and process operations is routed through the PVVS. The PVVS includes carbon delay beds, which are used to delay airborne radioactive sources, primarily krypton and xenon isotopes, to acceptable levels prior to release to the environment. Another pathway for gaseous activity is through the radiological ventilation zone 1 (RVZ1) hot cell ventilation and radiological ventilation zone 2 (RVZ2) general area ventilation. The RVZ1 and RVZ2 do not have carbon delay beds but do include HEPA filtration. These flow paths to the environment all exit to the SHINE facility stack, which has the stack release monitor to monitor the radiological releases to the environment. The flow path for these pathways is provided in SHINE FSAR figure 9a2.1-8, “Radiological Ventilation Zone 1 Exhaust Subsystem (RVZ1e) and Radiological Ventilation Zone 2 Exhaust Subsystem (RVZ2e) Mezzanine,” and figure 9b.6-1, “PVVS Process Flow Diagram.”

SHINE FSAR table 11.1-6, “Estimated Derived Air Concentrations,” provides estimated Derived Air Concentrations (DAC) for different areas in the SHINE facility. SHINE FSAR figure 11.1-2 provides a map of the DAC zone categorization for the facility. The NRC staff finds the zoning acceptable given the information provided about the airborne source terms and the potential for leakage from the facility systems in the FSAR tables.

SHINE FSAR table 11.1-8, “Estimated Annual Releases from Normal and Maintenance Operations (Nuclides with Greater than 1 Ci Annual Release),” provides the source term for use in the gaseous release dose calculations. This table is used in conjunction with metrological data to assess the doses to the nearest residents and the maximally exposed individual. The NRC staff’s assessment of the airborne effluent doses is contained in the Gaseous Waste Streams of section 11.4.2.3 of this SER.

The NRC staff’s review of the airborne radioactive sources determined that SHINE provided sufficient details about the airborne radioactive sources. These source terms allow the staff to perform confirmatory analyses for dose calculations to confirm that SHINE is meeting ALARA objectives and 10 CFR 20.1101(d).

Liquid Radioactive Sources

SHINE FSAR section 11.1.1.2 states that the liquid sources of radioactivity within the SHINE facility are generally derived from the irradiated uranyl sulfate target solution as it is processed by the facility. The primary coolant and the low activity fresh uranyl sulfate target solution are identified as additional liquid sources of radioactivity in the facility. The liquid sources of radioactivity in the facility are contained in closed systems. The summary of the sources of liquid radioactivity is provided in SHINE FSAR table 11.1-9, “Liquid Radioactive Sources.” Based on the FSAR, there are no piped direct radioactive liquid discharges from the SHINE facility. Liquid waste generated by the applicant is solidified and shipped to a disposal facility. Non-radioactive liquid waste is also generated during normal operations. This waste is collected and sampled prior to disposal into the sanitary sewers or disposed of as low-level waste if sampling determines that it cannot be released through the sanitary sewer. SHINE FSAR table 11.2-1, “Estimated Annual Waste Stream Summary,” provides information on the volumes of waste generated by the SHINE facility.

The NRC staff’s review of the liquid radioactive sources determined that there are no doses attributed to liquid effluent releases. In review of the information contained in SHINE FSAR table 11.1-9, the staff finds that SHINE provided sufficient details to allow the staff to perform dose calculations to understand the radiation environment in the facility and to ensure that doses for facility workers are ALARA and within regulatory limits.

Solid Radioactive Sources

SHINE FSAR section 11.1.1.3 states that the solid sources of radioactivity include the low enriched uranium, which undergoes processing to be converted into uranyl sulfate, spent extraction columns from the Mo-99 extraction process, spent filters, and solidified liquid waste. SHINE FSAR table 11.1-10, “Solid Radioactive Sources,” provides information on the locations, types, and sources of solid radioactivity. The radionuclide inventory is a function of TSV system operation. SHINE FSAR table 11.2-1 provides information on the quantities of waste generated by the SHINE facility.

The NRC staff's review of the solid radioactive sources determined that SHINE provided sufficient details about the solid radioactive sources to allow the staff to perform dose calculations to understand the radiation environment in the facility and to ensure that doses for facility workers are ALARA and within regulatory limits. The staff reviewed the description of potential radiation sources and associated doses including the inventories, chemical and physical forms, and locations of radioactive materials, as well as other facility radiation and operational parameters related to radiation safety presented in the FSAR. This review included a comparison of the bases for identifying potential radiation safety hazards with the process and facility descriptions to verify that such hazards were accurately and comprehensively identified. This review and evaluation confirmed that the FSAR identifies the potential radiation safety hazards associated with the SHINE facility and this provides an acceptable basis for the development and independent review of the radiation protection program.

11.4.1.2 Radiation Protection Program

The NRC staff evaluated the sufficiency of the SHINE radiation protection program, as presented in SHINE FSAR section 11.1.2, "Radiation Protection Program," using the guidance and acceptance criteria from section 11.1.2, "Radiation Protection Program," of NUREG-1537, Parts 1 and 2, and section 11.1, "Radiation Protection," of the ISG augmenting NUREG-1537, Parts 1 and 2.

The NRC staff reviewed the information provided in the SHINE FSAR regarding radiation protection program personnel in SHINE FSAR sections 11.1.2.1.1, "Responsibilities of Key Program Personnel," and 11.1.2.1.2, "Radiation Protection Program Staffing and Qualifications." The staff finds that the applicant's description of radiation protection personnel is consistent with the guidance contained in Regulatory Guide (RG) 8.2, "Administrative Practices in Radiation Surveys and Monitoring" (Agencywide Documents Access and Management System No. ML110460093), and Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable" (ML16105A136). The staff finds that the roles for facility personnel are adequately defined in SHINE FSAR section 11.1.2.1.1, and that the commitment to follow RG 8.2 and RG 8.10 is appropriate.

SHINE FSAR section 11.1.2.1.6, "Commitment to Radiation Protection Training," provides information related to the commitment to radiation protection training. The applicant stated that the program will comply with the requirements of 10 CFR 19.12. The applicant also stated that the radiation protection training program will be consistent with the guidance provided in RG 8.10, Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" (ML003739505), Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure" (ML003739438), and American Society for Testing and Materials (ASTM) E1168-95, "Radiological Protection Training for Nuclear Facility Workers." The NRC staff finds that the inclusion of these guidance documents is appropriate for a radiation protection program. The staff also finds that the FSAR demonstrates compliance with 10 CFR 19.12 and 10 CFR 19.13 by providing a description of the program implemented at the SHINE facility to keep workers informed about the storage, transfer, and use of radioactive material and the requirements for monitoring radiation exposures in the SHINE facility.

SHINE FSAR section 11.1.2.1.7, "Radiation Safety Audits," provides information related to the applicant's ability to review and determine the effectiveness of the radiation protection program. The applicant stated that audits will be conducted on an annual basis to meet the requirements of 10 CFR 20.1101(c). The NRC staff finds that this is consistent with 10 CFR 20.1101(c), which requires that audits are to be conducted at least annually.

SHINE FSAR section 11.1.2.1.8, "Record Keeping," addresses the applicant's management of records by stating that the radiation protection program will meet the requirements of 10 CFR Part 20, "Standards for Protection Against Radiation," Subpart L, "Records." The NRC staff finds that this is appropriate as Subpart L details the NRC requirements for what documentation needs to be retained.

SHINE provided the anticipated administrative exposure limits in SHINE FSAR table 11.1-11, "Administrative Radiation Exposure Limits." This table provides a comparison of the 10 CFR Part 20 limits to the specified SHINE administrative limits. The SHINE administrative limits are approximately a factor of 2.5 less than the limits in 10 CFR Part 20, which is acceptable.

The NRC staff reviewed the radiation protection program presented in the SHINE FSAR for the SHINE facility. This review included an evaluation of (1) the roles, responsibilities, authorities, organization, and staffing of the radiation protection organization; (2) the roles, responsibilities, authorities, staffing, and operation of committees responsible for the review and audit of the radiation protection program; (3) the effectiveness and comprehensiveness of the radiation protection training program; (4) radiation protection plans and information that form the bases of procedures and the management systems employed to establish and maintain them; (5) the effectiveness and comprehensiveness of the program for independent oversight reviews and audits of the radiation protection program; (6) the effectiveness and comprehensiveness of the process to evaluate the radiation protection program to improve the program and the process to examine problems and incidents at the facility; and (7) the management of records relating to the radiation protection program. The staff finds that the radiation protection program presented in the FSAR both complies with applicable requirements and provides reasonable assurance that management's commitment to radiation protection in all activities will protect the facility staff, the environment, and the public from unacceptable exposure to radiation.

11.4.1.3 As Low As Is Reasonably Achievable Program

The NRC staff evaluated the sufficiency of the provisions at the SHINE facility for maintaining worker and public doses and radiological releases ALARA, as presented in SHINE FSAR section 11.1.3, "ALARA Program," using the guidance and acceptance criteria from section 11.1.3, "ALARA Program," of NUREG-1537, Parts 1 and 2, and section 11.1, "Radiation Protection," of the ISG augmenting NUREG-1537, Parts 1 and 2.

The NRC staff's review focused on the description of the ALARA program, including how plant management is engaged with the ALARA program and how the ALARA program would be used to reduce radiation exposures. The applicant stated that its ALARA program will be compliant with RG 8.2, RG 8.13, and RG 8.29. The applicant also stated that the operation of the SHINE facility will be consistent with RG 8.10. SHINE FSAR section 11.1.3 also identifies the responsibilities of the Radiation Protection Manager in implementing the ALARA program and identifies ALARA program evaluation reports that are evaluated by the Radiation Safety Committee (RSC).

The NRC staff reviewed the ALARA design considerations in SHINE FSAR section 11.1.3.2, “ALARA Facility Design Considerations.” The staff determined that the design considerations as described by the applicant are consistent with Regulatory Guide 8.8, “Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable” (ML003739549). Examples of the applicant’s design considerations include the remote handling of material, where possible, in hot cells to greatly reduce radiation exposures. In addition, the applicant discussed the use of features to allow for draining, flushing, decontamination of equipment and piping, shielding for personnel during repair work, and separation of highly radioactive equipment from less radioactive equipment. The applicant provided additional features for maintaining exposures ALARA in SHINE FSAR section 11.1.3.2. The staff finds that the applicant follows the guidance in RG 8.8 to meet the ALARA guidelines in accordance with 10 CFR 20.1101(b).

The NRC staff reviewed the ALARA program at the SHINE facility. The policies and the bases for procedures give reasonable assurance that doses to occupational workers and the public will be maintained below regulatory limits and ALARA. The controls and procedures for limiting access and personnel exposure (including allowable doses, effluent releases, ALARA goals, and criteria used for the action levels in radiation alarm systems) meet the applicable radiation protection program requirements and provide reasonable assurance that radiation doses to the environment, the public, and facility personnel will be ALARA. The ALARA program is adequately supported at the highest levels of management for the facility.

11.4.1.4 Radiation Monitoring and Surveying

The NRC staff evaluated the sufficiency of the radiation monitoring equipment and the performance of radiation surveys, as presented in SHINE FSAR section 11.1.4, “Radiation Monitoring and Surveying,” using the guidance and acceptance criteria from section 11.1.4, “Radiation Monitoring and Surveying,” of NUREG-1537, Parts 1 and 2, and section 11.1, “Radiation Protection,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 11.1.4 provides information about the monitors and survey equipment that will be used within the SHINE facility. SHINE FSAR section 7.7 “Radiation Monitoring Systems,” contains the system descriptions for the various radiation monitors used in the facility.

The applicant stated that there will be monitoring for tritium within each IU, the TPS glovebox room, and at the facility stack. In addition, the applicant stated that there will be continuous monitoring of noble gases, aerosols, and iodine at the facility stack. The facility stack monitor is used to demonstrate that the gaseous releases from the facility are below the regulatory limits. For liquid effluents, there are no radioactive liquid effluent discharges from the facility and, therefore, the applicant stated that there will be no liquid effluent monitors. In the scenario where liquid waste is collected, SHINE stated that the effluent will be transported outside of the RCA, sampled to ensure that it meets the release limits, and then disposed of through the sanitary sewer. SHINE FSAR section 11.2.3, “Release of Radioactive Waste,” states that the effluent will be disposed of as low-level waste if sampling determines that it cannot be released through the sanitary sewer.

SHINE FSAR table 11.1-12, “Radiation Monitoring Equipment,” provides a summary of the radiation monitoring equipment used at the site, along with the anticipated locations and functions of the monitors being provided.

The applicant stated that its gaseous effluent monitoring will be capable of continuous monitoring for noble gas releases, generating real time data for control room display and recording. SHINE FSAR section 7.7.5, “Effluent Monitoring,” provides the anticipated ranges for the noble gas radiation monitor and tritium monitors. The NRC staff’s review of the information contained in SHINE FSAR sections 7.7.5 and 11.1.4 finds that the ranges listed are appropriate to monitor and track the releases from the facility and that the description and ranges of these effluent monitors are acceptable. Iodine and particulate monitoring at the SHINE facility is performed through collection onto filter cartridges, which are then analyzed. In addition, the facility’s environmental monitoring program also ensures that the releases are being adequately tracked.

Within the facility, there will be continuous air monitors (CAM) and radiation area monitors (RAM). SHINE FSAR section 11.1.4 provides general descriptions with more detailed descriptions provided in SHINE FSAR section 7.7.3, “Area Radiation Monitoring,” and section 7.7.4, “Continuous Air Monitoring.” SHINE FSAR tables 7.7-2, “Radiation Area Monitor Locations,” and 7.7-3, “Continuous Airborne Monitor Locations,” provide information describing where the CAMs and RAMs are located within the facility. The NRC staff’s review of the locations of the CAMs and RAMs determined that the applicant provided sufficient descriptions and placed monitoring equipment in areas that allow the applicant to understand the radiation environment of the facility.

The applicant stated that it will follow IEEE/ANSI N323AB-2013, “American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments,” for the calibration of portable radiological monitoring equipment used to document survey results. The applicant also stated that it will use ANSI/HPS N13.1-1999, “Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities,” for the effluent stack monitors to ensure representative sampling of the radioactive effluents. In addition, the applicant stated that it will develop procedures to specify the methods and frequency for which monitoring equipment will need to be calibrated. The NRC staff’s review of these sampling and calibration methods determined that the information provided by the applicant is acceptable to ensure appropriate calibrations and representative sampling necessary to monitor the radiological conditions of the facility and the releases to the environment.

As stated in the SHINE FSAR, radiation surveys are performed to understand the radiation levels, concentrations, and the radiological hazards that could be present in the facility, and to understand the potential releases from facility equipment. Furthermore, the surveys performed will be compliant with 10 CFR Part 20, Subparts C, “Occupational Dose Limits,” F, “Surveys and Monitoring,” L, and M, “Reports.” The applicant also referenced RG 8.2, Regulatory Guide 8.7, “Instructions for Recording and Reporting Occupational Radiation Dose Data” (ML17221A245), Regulatory Guide 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program” (ML003739554), Regulatory Guide 8.24, “Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication” (ML110400305), and Regulatory Guide 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses” (ML1433A641), for demonstrating compliance with NRC regulations. The NRC staff finds that the inclusion of these RGs is acceptable in demonstrating an adequate radiation survey program.

The NRC staff reviewed the design of radiation monitoring and sampling provisions at the SHINE facility. The fixed and portable equipment used for radiation monitoring and sampling inside the facility is selected, located, calibrated, tested, and maintained in accordance with guidance contained in recognized national standards and the manufacturers' instructions, and with applicable regulations. The methods and bases of procedures used to determine the placement of the equipment, the circumstances under which the equipment is used, and the selection of the equipment function and sensitivity are appropriate to the facility and give reasonable assurance that appropriate types of radiation in significant intensities will be detected, monitored, and sampled consistent with 10 CFR Part 20 requirements and the facility ALARA program.

11.4.1.5 Radiation Exposure Control and Dosimetry

The NRC staff evaluated the sufficiency of the provisions at the SHINE facility for radiation exposure control and dosimetry, as presented in SHINE FSAR section 11.1.5, "Radiation Exposure Control and Dosimetry," using the guidance and acceptance criteria from section 11.1.5, "Radiation Exposure Control and Dosimetry," of NUREG-1537, Parts 1 and 2, and section 11.1, "Radiation Protection," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 11.1.5 provides information related to the established controls at the SHINE facility. The applicant provided information on the radiological zoning, access controls, radiological postings, protective clothing and equipment, monitoring of external doses, and the evaluation of doses in general.

The NRC staff's review determined that the applicant provided adequate information related to the radiological boundaries that are defined for the SHINE facility. The applicant followed those definitions in 10 CFR Part 20 for establishing the unrestricted area, restricted area, and radiologically controlled areas. The applicant provided additional information related to the posting of radiological areas in SHINE FSAR table 11.1-13, "Radiological Postings."

As stated in the SHINE FSAR, the applicant will establish a program that ensures the appropriate use of signs and postings, will establish restricted areas that will prevent the spread of contamination, and will provide those controls necessary when working in contaminated areas. Furthermore, the postings will be done in accordance with 10 CFR 20.1902. The FSAR also provides information on how the applicant will limit access to high radiation areas and describes those controls and interlocks that will prevent access to the high radiation areas. Specifically, hot cells have interlocks that prevent the doors from being open during times with excessive radiation fields and during target solutions transfers. In addition, the neutron driver service cell and the hot cells are equipped with audible and visual warnings to inform individuals that they are entering a high radiation area or the area is controlled by locked entry. Lastly, the use of radiological shielding and engineered physical barriers are provided to limit access to high radiation areas. The NRC staff finds that the use of these features is in accordance with the requirements in 10 CFR 20.1601, and that the information provided in the FSAR to control access to high radiation areas is acceptable.

The NRC staff reviewed the engineered radiation exposure controls employed at the SHINE facility. The staff finds that the applicant provided sufficient information related to the design of the confinement, radiological shielding, ventilation, remote handling, decontamination equipment, and entry control devices to allow for an assessment of the design of these radiological protection features. The entry control devices employed are adequate to alert workers to, or prevent entry into, radiological areas, including high or very high radiation areas. The confinement system design provides reasonable assurance that uncontrolled radiological releases to the unrestricted environment, controlled area (if present), or the restricted work area will not occur during any anticipated normal operations.

Personnel monitoring at the SHINE facility is through personal dosimetry worn by those individuals that enter and work in the restricted areas of the facility. SHINE FSAR section 11.1.5.5, “Personnel Monitoring for External Exposures,” provides information related to the procedures for use of personal dosimetry at the facility. Provisions have been made for external and internal radiation monitoring of all individuals required to be monitored. The NRC staff determined that the proposed dosimetry program meets the requirements of the regulations in 10 CFR Part 20. In addition, the staff determined that the provisions incorporated for personal dosimetry, shielding, ventilation, remote handling, and decontamination equipment provide reasonable assurance that radiation doses are maintained ALARA and within applicable regulations.

The NRC staff reviewed the calculational files to understand the assumptions and models used for the dose calculations. The applicant provided various source term information for the SHINE facility in SHINE FSAR Tables 11.1-5, 11.1-9, and 11.1-10. Shielding details are also in SHINE FSAR chapter 4, “Irradiation Unit and Radioisotope Production Facility Description,” describing IU shielding, super cell shielding, shield plug shielding, and various other shielding in the facility that are assumed in the SHINE analysis. The applicant performed shielding calculations using the Monte Carlo N-Particle (MCNP) computer code. The staff’s review of the applicant’s calculations determined that the approach and models used in the analysis were reasonable and should accurately model the radiation areas within the SHINE facility. To verify the calculations, the staff performed independent verifications using the MicroShield computer code and found that the results detailed by SHINE’s estimated dose maps in SHINE FSAR figures 11.1-1 and 11.1-2 are acceptable.

The applicant discussed the procedures for use of personal dosimetry at the SHINE facility. Provisions have been made for external and internal radiation monitoring of all individuals required to be monitored. The proposed dosimetry program meets the requirements of the regulations in 10 CFR Part 20. The NRC staff finds that the provisions incorporated for personal dosimetry, shielding, ventilation, remote handling, and decontamination equipment provide reasonable assurance that radiation doses are maintained ALARA and within applicable regulations.

11.4.1.6 Contamination Control

The NRC staff evaluated the sufficiency of the provisions at the SHINE facility for contamination control, as presented in SHINE FSAR section 11.1.6, “Contamination Control Equipment and Facility Layout General Design Considerations for 10 CFR 20.1406,” using the guidance and acceptance criteria from section 11.1.6, “Contamination Control,” of NUREG-1537, Parts 1 and 2, and section 11.1, “Radiation Protection,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 11.1.6 provides information on the design features managing the levels of contamination at the SHINE facility to demonstrate compliance with 10 CFR 20.1406.

Shielded compartments and hot cells are provided in the SHINE facility to minimize the spread of contamination for components that do not require local operator actions and when handling material during processing activities. The SHINE FSAR details that piping is in shielded compartments or hot cells. The transfer areas for pipes are in pipe trench areas to contain the radioactive liquid and gases. The FSAR describes the use of inspection ports to allow for visual inspections of the pipes in these shielded areas. In addition, the FSAR describes how the design considered the spread of contamination by implementing means of controlling ventilation air flow patterns from areas of low radioactivity to areas of higher activity.

Furthermore, monitoring of personnel access to areas is employed as a means of reducing the levels of contamination in the SHINE facility and personal protective equipment is used to minimize the contamination of plant personnel. CAMs are also located within the facility to detect the spread of airborne contamination in restricted areas. The RAMs within the facility are used to identify increased background radiation levels within the facility.

The NRC staff reviewed the information provided in the SHINE FSAR related to contamination control features and finds the features consistent with the requirements in 10 CFR 20.1406 for the minimization of contamination. The staff's review determined that the applicant has controls and design features in place to limit the spread of contamination at the SHINE facility.

11.4.1.7 Environmental Monitoring

The NRC staff evaluated the sufficiency of the provisions at the SHINE facility for environmental monitoring, as presented in SHINE FSAR section 11.1.7, "Environmental Monitoring," using the guidance and acceptance criteria from section 11.1.7, "Environmental Monitoring," of NUREG-1537, Parts 1 and 2, and section 11.1, "Radiation Protection," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 11.1.7 provides information related to the environmental monitoring program and effluent monitoring program at the SHINE facility. The applicant stated that it followed Regulatory Guide 4.1, "Radiological Environmental Monitoring for Nuclear Power Plants" (ML091310141), and NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors" (ML091050061), in the development of the SHINE radiological environmental monitoring program (REMP).

The applicant identified that direct radiation exposure, inhalation, and ingestion pathways are monitored from the SHINE facility. These pathways are from direct radiation and gaseous effluent releases. As previously identified, there are no liquid effluent releases from the SHINE facility. However, as stated in SHINE FSAR section 11.1.7, any releases to the sanitary sewer will be made in accordance with 10 CFR 20.2003, "Disposal by release into sanitary sewerage," and 10 CFR 20.2007, "Compliance with environmental and health protection regulations," which require compliance with 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," Table 3, "Sewer Disposal," and other Federal, State, and local environmental regulations.

SHINE FSAR table 11.1-14, "Environmental Monitoring Locations," provides a list of the environmental monitors that will be set up by the applicant. The applicant also provided a map of the environmental dosimeter locations in SHINE FSAR figure 11.1-4, "Environmental Dosimeter Locations."

The SHINE facility will establish direct radiation monitoring and air sampling locations based on the guidance contained in NUREG-1301. This guidance describes the rationale for placing monitoring and establishing the necessary background data for the measurement. This air sampling program around the site allows the applicant to verify the effectiveness of the air effluent monitoring program.

As stated in SHINE FSAR sections 11.1.7.2.3, “Ingestion Pathway,” and 11.1.7.2.4, “Groundwater Monitoring,” surface water and biota monitoring are not anticipated at this time due to the environment in which the facility is located. Specifically, there are no nearby biota that require monitoring since surface waters are not expected to be contaminated given that there are no direct liquid releases to the environment. The NRC staff finds this acceptable given that the REMP is evaluated annually to verify the effectiveness of the program.

The NRC staff reviewed the applicant’s environmental monitoring program. The staff reviewed the monitoring locations and pathways for doses from effluent and direct sources. The staff concludes that the applicant appropriately included air sampling and dosimeters that would appropriately track effluent releases to demonstrate compliance with SHINE Design Criteria Criterion 38, as described in SHINE FSAR section 3.1, “Design Criteria.” In addition, the staff reviewed the locations for proposed offsite monitoring and concludes that the applicant provided enough information to conclude that the proposed offsite monitoring is sufficient to observe offsite dose impacts. The staff finds that the SHINE FSAR demonstrates compliance with 10 CFR 20.1301 by providing for the monitoring of the expected gaseous releases to the environment. The applicant showed that the releases will result in doses to members of the public below the limits contained in 10 CFR 20.1301.

11.4.2 Radioactive Waste Management

SHINE FSAR section 11.2, “Radioactive Waste Management,” states that the production of medical isotopes creates liquid, gaseous, and solid radioactive wastes. The applicant described the management program, controls, and disposal pathways established to ensure proper identification, classification, control, processing, and packaging for each generated waste stream. All radioactive wastes generated at the SHINE facility are prepared for shipment in approved shipping containers and shipped offsite using carriers in compliance with applicable regulations. The state of Wisconsin is a part of the Midwest Interstate Low-Level Radioactive Waste Compact. The waste disposal sites available for SHINE’s use are Energy*Solutions* in Clive, UT and Waste Control Specialists in Andrews, TX.

11.4.2.1 Radioactive Waste Management Program

The NRC staff evaluated the sufficiency of the SHINE radioactive waste management program, as presented in SHINE FSAR section 11.2.1, “Radioactive Waste Management Program,” using the guidance and acceptance criteria from section 11.2.1, “Radioactive Waste Management Program,” of NUREG-1537, Parts 1 and 2, and section 11.2, “Radioactive Waste Management,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 11.2.1 describes the overall structure of the radioactive waste management program including, in detail, the authority, duties, and responsibilities of the Director of Corporate Support, Radiation Protection Manager, Training Manager, Quality Manager, and shipping personnel, and how this allows the program to comply with federal and state regulations. SHINE FSAR section 11.2.1 states that the SHINE facility Radioactive Waste Management Program is coordinated with the Radiation Protection Program, under the Director of Corporate Support, and designates disposal pathways and controls necessary to ensure proper identification, classification, control, processing, and packaging for the anticipated radioactive waste streams generated by the facility. The goal of this program is to minimize waste generation, minimize radiation exposure to personnel, and protect the public and environment. The program is committed to complying with all applicable local (State of Wisconsin) and federal regulations for managing radioactive wastes.

The NRC staff reviewed the radioactive waste management program as presented in SHINE FSAR section 11.2.1. This review included an evaluation of: (1) the authority, duties, and responsibilities of the Director of Corporate Support and Radiation Protection Manager; (2) the roles and responsibilities of the Training Manager and Quality Manager; (3) implementing procedures applicable to waste management; (4) the management of records pertaining to the radioactive waste management program; and (5) the program's provisions for reviews, audits, and assessments.

The NRC staff finds that the applicant's description of the Radioactive Waste Management Program presented in SHINE FSAR section 11.2.1 provides reasonable assurance that radioactive wastes will be adequately controlled by the applicant and will not pose any risk of undue radiation exposure to the facility staff, the environment, or the public. The staff also finds that the program provides reasonable assurance that radioactive waste released from the facility will not exceed the limits in 10 CFR Part 20 or endanger the public or the environment.

11.4.2.2 Radioactive Waste Controls

The NRC staff evaluated the sufficiency of the provisions at the SHINE facility for radioactive waste controls, as presented in SHINE FSAR section 11.2.2, "Radioactive Waste Controls," using the guidance and acceptance criteria from section 11.2.2, "Radioactive Waste Control," of NUREG-1537, Parts 1 and 2, and Section 11.2, "Radioactive Waste Management," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 11.2.2 states that the SHINE Radiation Protection Program and ALARA Program apply to radioactive waste management, including, but not limited to, control of materials, monitoring and surveys, RCA access control, contamination control, and personnel monitoring. In addition, the radioactive waste management operating procedures will ensure proper identification, characterization, and separate treatment of radioactive wastes. For the purposes of meeting the ALARA principle, radioactive waste at the SHINE facility may be categorized as either contact handled or handled remotely. The primary forms of radioactive waste generated at the SHINE facility are all classified as low-level waste and do not include spent nuclear fuel, high-level waste, or the paragraphs (2), (3), and (4) definitions of byproduct material in 10 CFR 20.1003. The neutron multipliers are designed for the life of the facility and will be disposed of as greater-than Class C waste during decommissioning. When transporting radioactive waste, the waste may be categorized as low specific activity requiring Type A packaging or requiring Type B packaging. The material staging building is used for the interim storage of radioactive waste for decay and preparation for transportation. The building is designed to ensure that the dose limits in 10 CFR Part 20 are not exceeded while maintaining doses ALARA. Radioactive waste stored in the staging building is not stored for more than 5 years.

<u>Radioactive Waste Minimization</u>

SHINE FSAR section 11.2.2.1, "Radioactive Waste Minimization," states that waste minimization and pollution prevention are key elements of the SHINE Radiological Waste Management Program. The implementing procedures for waste minimization and pollution address: (1) employee training and education on environmental activities and hazards regarding the SHINE facility, operations, pollution prevention, and waste minimization goals and accomplishments; (2) goals for reducing the volume of radioactivity in each waste stream; (3) sorting and compacting waste to reduce overall volume; (4) segregation of non-radiological and radiological wastes to reduce the volume of contaminated waste; (5) process controls that minimize generation of wastes; and (6) periodic program assessments. The NRC staff finds that the FSAR describes adequate efforts to reduce and minimize the amount of waste produced when feasible.

Waste Stream Sources

SHINE FSAR section 11.2.2.2, "Waste Stream Sources," states that waste management operations occur in the RPF and the material staging building. SHINE will use approximately 5,600 square feet of the material staging building for temporary storage of radioactive waste to allow time for decay. Drums that are being stored in the material staging building may be stored in multiple layers if the waste drum design, building design, and programmatic controls allow for the drums to be stored safely. The equipment and design features used for the containment and/or packaging, storage, and disposal of solid, liquid, and gaseous radioactive waste include the radioactive liquid waste immobilization system, the radioactive liquid waste storage system, and the solid radioactive waste packaging system. Detailed descriptions of these systems are contained in SHINE FSAR chapter 9.

The anticipated waste streams, characteristics, generation rates, and shipment categories for the SHINE facility are detailed in SHINE FSAR table 11.2-1 and sections 11.2.2.2.1 through 11.2.2.2.12.

Based on its review of SHINE FSAR section 11.2.2, the NRC staff concludes that the radioactive waste controls are acceptable. The FSAR provides sufficient details by discussing the high-level function of the waste systems and the anticipated waste streams generated. Included in these discussions, the applicant described details such as the anticipated radionuclides, cleanup systems involved with the waste streams, and the expected waste output classification for each waste stream. As described in the FSAR, the applicant provides methods by which waste products will be monitored and assessed for radioactive material contents, has controls established for waste streams and products to prevent uncontrolled exposures or release of radioactive waste, has descriptions of the plans and procedures for controlled radioactive wastes to protect the environment and the health and safety of the facility staff and public, and has described efforts to reduce and minimize the amount of waste produced when feasible.

11.4.2.3 Release of Radioactive Waste

The NRC staff evaluated the sufficiency of the provisions at the SHINE facility for release of radioactive waste, as presented in SHINE FSAR section 11.2.3, "Release of Radioactive Waste," using the guidance and acceptance criteria from section 11.2.3, "Release of Radioactive Waste," of NUREG-1537, Parts 1 and 2, and section 11.2, "Radioactive Waste Management," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 11.2.3 states that prior to the release of radioactive waste, the applicant ensures that the wastes are adequately processed and packaged as required to meet the waste acceptance criteria for the disposal facility that the waste is being transported to. Processing at the SHINE facility can be comprised of one or more operations. These operations can include compaction, solidification, adsorption onto a solid medium (elemental iodine onto activated carbon filters), interim storage for decay of radionuclides, consolidated handling and processing, extraction and consolidation of radionuclides by segregation, and mixing waste streams so that the bulk volume of waste is readily disposable. The final determinations of waste classification and management will be made in accordance with the SHINE Radioactive Waste Management Program.

Gaseous effluent waste streams at the SHINE facility are monitored by the main facility stack release monitor (SRM) and the carbon delay bed effluent monitors (CDBEM) located at the exhaust of the PVVS carbon delay beds. The SRM is used to monitor gaseous effluent releases from the facility to demonstrate that the releases are within the limits of 10 CFR Part 20. The CDBEM monitors provide the ability to monitor the safety-related effluent release pathway when it is in use to demonstrate that gaseous effluent releases from the facility are within regulatory limits.

At the SHINE facility, there are no piped liquid effluent pathways from the RCA to the sanitary sewer. During operations at the SHINE facility, liquid effluents are not expected to be routinely discharged from the RCA. Prior to liquid discharges to the sanitary sewer, sampling will be performed to determine suitability for release and compliance with 10 CFR Part 20.

Solid Wastes

SHINE FSAR section 11.2.3.1, “Solid Wastes,” describes the methodology that the applicant will use for the eventual release of major solid wastes that may be generated at the SHINE facility. For all shipments of solid waste for disposal, SHINE’s processing requirements will be in accordance with the receiving facility’s waste acceptance criteria. If the receiving facility’s acceptance criteria change, SHINE will modify its practices to account for any changes. SHINE FSAR table 11.2-1, “Estimated Annual Waste Stream Summary,” provides the details for the wastes generated, the class of the waste generated, the amount of the waste generated, and the destination for disposal.

SHINE FSAR sections 11.2.3.1.1 through 11.2.3.1.6 provide the sources of expected solid waste generation at the SHINE facility. The applicant detailed the waste forms and expected handling for the various solid waste types.

The NRC staff reviewed the description of solid wastes generated at the SHINE facility and finds that the applicant adequately described the expected forms and quantities of solid waste generated at the facility. In addition, the applicant provided details regarding wastes that will be shipped to and disposed of at either Waste Control Specialists or Energy*Solutions*.

Liquid Waste Streams

As discussed in section 11.2.2.2 of this SER, the consolidated liquid waste stream once solidified is expected to be Class A waste at Energy*Solutions*. Liquid waste that remains is disposed of through the sanitary sewer outside of the RCA, consistent with applicable limits.

The estimated generated volumes of radioactive liquid waste are provided in SHINE FSAR table 11.2-1. The radioactive liquid wastes presented in the table are collected and processed separately, then blended prior to solidification. Blending of the wastes will be performed without exceeding the maximum uranium concentrations allowed by the disposal site that will be receiving the waste. For the purposes of the transportation of the material to a disposal site, certain fissile material may be exempted in accordance with 10 CFR 71.15, “Exemption from classification as fissile material.” Additional staff review is discussed in Material Staging Building of chapter 6, “Engineered Safety Features,” of this SER.

SHINE FSAR section 11.1.1.2 states that while liquid wastes generated at the SHINE facility will generally be solidified and then shipped, the applicant does have the ability to dispose of liquid waste through the sanitary sewer. SHINE FSAR section 11.2.3 states that there are no piped pathways from the RCA to the sanitary sewer, therefore, liquid discharge has no pathway from the RCA to the sanitary sewer. SHINE estimates that around 40 gallons per week of liquid waste are planned to be disposed of through the sanitary sewer. This liquid waste is expected to have no sources of radioactivity and is produced from the facility's cooling and air handling system operations. Liquid waste generated in this manner will be sampled for radioactivity prior to disposal through the sanitary sewer.

The NRC staff reviewed the description of liquid wastes generated at the SHINE facility and finds that the applicant will adequately control the liquid radioactive waste generated and that radioactive liquid waste disposal is not anticipated at the site.

<u>Gaseous Waste Streams</u>

The estimated generated release of airborne radioactive materials is provided in SHINE FSAR section 11.2.3.3, "Gaseous Waste Streams," and the airborne sources are discussed in SHINE FSAR section 11.1.1.1. SHINE FSAR table 11.1-5 provides information on the airborne radioactive sources. The gaseous release path for the SHINE facility is from the facility exhaust stack. The facility exhaust stack is continuously monitored for noble gases, particulates, iodine, and tritium to ensure compliance with effluent release limits.

The NRC staff reviewed the information contained in SHINE FSAR table 11.1-8 and the annual average relative atmospheric concentration (χ/Q) information provided in SHINE FSAR section 11.1.1.1, and performed a confirmatory calculation using the GENII computer code. The applicant's dose calculation determined that the estimated annual doses were 4.6 millirem (mrem) to the maximally exposed individual and 0.3 mrem to the nearest resident. The staff's confirmatory calculation determined that the airborne releases from SHINE would be less than 10 mrem per year. Paragraph 20.1101(d) of 10 CFR requires that air emissions shall have a dose limit of 10 mrem per year. The applicant provided the estimated gaseous activity production rates for a single TSV in SHINE FSAR table 11.1-8 to support the dose analysis for demonstrating compliance with 10 CFR 20.1101(d). Based on the information provided, the staff finds that the facility's gaseous releases will be compliant with the dose limits contained in 10 CFR 20.1101(d).

11.4.3 Respiratory Protection Program

The NRC staff evaluated the sufficiency of the SHINE respiratory protection program, as presented in SHINE FSAR section 11.3, "Respiratory Protection Program," using the guidance and acceptance criteria from section 11.3, "Respiratory Protection Program," of the ISG augmenting NUREG-1537, Parts 1 and 2.

The NRC staff examined whether the SHINE respiratory protection program provides adequate protection of personnel from airborne concentrations exceeding the limits in 10 CFR Part 20, Appendix B. Given that the SHINE facility will conform to the NRC guidance contained in Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection" (ML993420049), the staff determined that the facility will have a program that supports a respiratory protection program capable of protecting its personnel from airborne concentrations exceeding the limits of 10 CFR Part 20, Appendix B.

The NRC staff finds that SHINE has committed to an acceptable radiation protection program that includes a program to control airborne concentrations of radioactive material with engineering controls and a respiratory protection program.

11.4.4 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed technical specifications (TSs) for the SHINE radiation protection program and waste management as described in SHINE FSAR chapter 11.

The proposed TS 3.7, "Radiation Monitoring Systems and Effluents," Limiting Condition for Operation (LCO) 3.7.1 and Surveillance Requirement (SR) 3.7.1 state the following:

LCO 3.7.1	Radiation monitoring instruments listed in Table 3.7.1-a shall be Operable. Note – Any single SFM may be bypassed for up to 2 hours while in the condition of applicability for the purpose of performing a Channel Calibration.
Applicability	According to Table 3.7.1-a when the Facility is not Secured
Action	According to Table 3.7.1
SR 3.7.1	1. A Channel Check shall be performed for radiation monitors monthly. 2. A Channel Calibration shall be performed for radiation monitors annually.

The proposed TS table 3.7.1-a, "Safety-Related Radiation Monitoring Instruments," states the following:

	Monitored Location	Setpoint and Monitored Material	Required Channels	Applicability (per IU, TPS train, or monitored location)	Action
a.	RVZ1 supercell exhaust ventilation (PVVS hot cell)	≤ 7.6E-05 µCi/cc Fission products	3	RPF Nitrogen Purge not Operating when the Facility is not Secured	1, 2, 3
b.	RVZ1 supercell exhaust ventilation (Extraction and IXP hot cells)	≤ 7.6E-05 µCi/cc Fission products	2 (per hot cell)	Target solution or radioactive process fluids present in the associated hot cell	4, 5
c.	RVZ1 supercell exhaust ventilation (Purification and Packaging hot cells)	≤ 7.6E-05 µCi/cc Fission products	2 (per hot cell)	Radioisotope products or radioactive process fluids present in the associated hot cell	4, 5

d.	RVZ1 RCA exhaust	≤ 1.3E-05 µCi/cc Fission products	3	Facility not Secured	1, 6, 7
e.	RVZ2 RCA exhaust	≤ 9.1E-07 µCi/cc Fission products	3	Facility not Secured	1, 6, 7
f.	RVZ1e IU cell exhaust	≤ 9.6E-03 µCi/cc Fission products	3 (per IU)	Associated IU in Mode 1, 2, 3, or 4	1, 8
g.	TPS confinement A/B/C	≤ 927 Ci/m^3 Tritium	2 (per TPS train)	Tritium present in associated TPS process equipment and not in storage	9
h.	TPS exhaust to facility stack	≤ 0.96 Ci/m^3 Tritium	3	Tritium present in any TPS process equipment and not in storage	1, 10
i.	MEPS heating loop extraction area A/B/C	≤ 1110 mR/hr Fission products	2 (per hot cell)	Target solution or radioactive process fluids present in the associated hot cell	11, 12

LCO 3.7.1 requires the radiation monitoring instruments listed in Table 3.7.1-a to be operable. The NRC staff finds that this LCO limits the spread of contamination and effluent releases by ensuring that appropriate setpoints are in place to monitor the radionuclides of concern for each area in which the monitors are located. The staff finds that the LCO will ensure that elevated levels of radiation that may result in radiation exposure to workers or individual members of the public are detected. The staff also finds that LCO 3.7.1 is consistent with the information contained in SHINE FSAR sections 7.7.1, “Safety-Related Process Radiation Monitoring,” and 7.7.5, “Effluent Monitoring,” in establishing setpoints and channel requirements. Therefore, the staff finds the LCO acceptable. Additional staff review of LCO 3.7.1, table 3.7.1, and table 3.7.1-a is discussed in chapter 7, “Instrumentation and Control Systems,” of this SER.

SR 3.7.1 requires monthly channel checks and annual channel calibrations for radiation monitors. The NRC staff finds that the SR will ensure that radiation monitoring instruments are operable to detect elevated levels of radiation that may result in radiation exposure to workers or individual members of the public. The NRC staff also finds that the monthly periodicity of channel checks and the annual periodicity of channel calibrations are consistent with applicable guidance. Therefore, the NRC staff finds the SR acceptable.

The proposed TS 3.7, LCO 3.7.2 and SR 3.7.2 state the following:

LCO 3.7.2	The annually averaged concentration of radioactive material released in gaseous effluents to unrestricted areas shall meet the requirements of 10 CFR 20.
Applicability	Facility not Secured
Action	According to Table 3.7.2

SR 3.7.2	1. Total curies released shall be assessed monthly.

The proposed TS table 3.7.2, “Gaseous Effluents Actions,” states the following:

	Action	Completion Time
1.	If the curie assessment exceeds the established limit, Submit a Special Report as described in Section 5.8.2.	 As described in Section 5.8.2

LCO 3.7.2 requires gaseous effluents released to the environment to meet the requirements of 10 CFR Part 20. The NRC staff finds that this LCO will limit the releases of gaseous effluents to concentrations within the effluent concentration limits found in 10 CFR Part 20. The staff also finds that if the curie assessment exceeds the established limit, submitting a special report not later than the following working day by telephone to be followed by a written report within 14 days, as described in TS 5.8.2, “Special Reports,” is consistent with applicable guidance. Therefore, the staff finds the LCO acceptable.

SR 3.7.2 requires the total curies released to be assessed monthly. The NRC staff finds that this SR will ensure that gaseous effluents released to the environment are within the allowable limits. The staff also finds that assessing the total curies released monthly will ensure that monthly and annual releases are appropriately monitored and evaluated. Therefore, the NRC staff finds the SR acceptable.

The proposed TS 4.1, “Site and Facility Description,” Design Feature (DF) 4.1.2, part 4 states the following:

DF 4.1.2	4. The normal effluent release height is 67 feet above grade.

DF 4.1.2, part 4 states the normal effluent release height. SHINE FSAR Section 2.1.1.2 states that the free-standing exhaust stack is at 67 feet above grade. The NRC staff finds that the stack and release height information is sufficiently described in the SHINE FSAR. The staff also finds that the SHINE facility’s normal effluent releases will be compliant with the dose limits contained in 10 CFR Part 20. Therefore, the staff finds the DF acceptable.

The proposed TS 5.3, “Radiation Safety,” states the following:

> The Radiation Protection Manager (RPM) shall be responsible for the implementation of the radiation protection program. The requirements of the radiation protection program are described in Section 5.5.3.
>
> The individuals who implement the radiation protection program shall have sufficient organizational freedom to ensure their independence from operating pressures. This independence ensures that the radiation protection organization maintains its objectivity and is focused only on implementing sound radiation protection principles

> necessary to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA).
>
> Radiation protection personnel maintain the ability to communicate directly with the review and audit committee or executive management.

The proposed TS 5.5.3, “Radiation Protection,” states the following:

> The SHINE radiation protection program is provided to protect the radiological health and safety of workers and the public. The program meets the requirements of 10 CFR 20, Subpart B, and is consistent with the guidance provided in ANSI/ANS 15.11-2016, Radiation Protection at Research Reactor Facilities, and Regulatory Guide 8.2, Revision 1, Administrative Practices in Radiation Surveys and Monitoring. The program is implemented by the radiation protection organization as described in Section 5.3. In addition, SHINE has established this program to maintain occupational radiation exposures and releases to the environment ALARA.

TS 5.3 requires the RPM to be responsible for the implementation of the SHINE radiation protection program. The TS also states that the requirements of the SHINE radiation protection program are described in TS 5.5.3. TS 5.5.3, in turn, requires that the SHINE radiation protection program meet the requirements in 10 CFR Part 20 and the guidelines of ANSI/ANS-15.11-2016 and RG 8.2. The NRC staff finds that TS 5.3, TS 5.5.3, and the referenced requirements and guidance are appropriate for the establishment of the SHINE radiation protection program and are consistent with NUREG-1537. Therefore, the staff finds TS 5.3 and TS 5.5.3 acceptable.

11.5 <u>Review Findings</u>

The NRC staff reviewed the descriptions and discussions of the SHINE facility radiation protection program and waste management, as described in SHINE FSAR chapter 11, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the facility radiation protection program and waste management and the respiratory protection program and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 19, 10 CFR Part 20, 10 CFR Part 50, 10 CFR Part 61, 10 CFR Part 71, 40 CFR, chapter I, and 49 CFR, chapter I, and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's radiation protection program and waste management are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

12.0 CONDUCT OF OPERATIONS

The conduct of operations involves the administrative aspects of facility operation, the facility emergency plan, the quality assurance (QA) plan, the security plan, the licensed operator initial training and requalification training programs, and the startup plan. The administrative aspects of facility operation are the facility organization, review and audit activities, organizational aspects of radiation safety, facility procedures, required actions in case of license or technical specifications (TSs) violations, reporting requirements, and recordkeeping.

This chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) describes the review and evaluation by the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the SHINE conduct of operations, as presented in chapter 12, "Conduct of Operations," of the SHINE final safety analysis report (FSAR) and supplemented by the applicant's response to staff requests for additional information (RAIs).

12.1 Areas of Review

SHINE FSAR chapter 12 is applicable to both the SHINE irradiation facility (IF) and radioisotope production facility (RPF) (together, the SHINE facility). SHINE FSAR chapter 12 describes the conduct of operations for the SHINE facility. The NRC staff reviewed SHINE FSAR chapter 12 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the SHINE conduct of operations.

12.2 Summary of Application

SHINE FSAR chapter 12 describes the SHINE organizational structure, the functional responsibilities, levels of authority, and interface for establishing, executing, and verifying the organizational structure, staffing, and selection and training of personnel. The organizational aspects of the radiation protection program and the production facility safety program, staffing, and selection and training of personnel are also included in the conduct of operations. This discussion is included in SHINE FSAR section 12.1, "Organization," section 12.2, "Review and Audit Activities," section 12.3, "Procedures," section 12.4, "Required Actions," section 12.5, "Reports," section 12.6, "Records," section 12.7, "Emergency Planning," section 12.8, "Security Planning," section 12.9, "Quality Assurance," section 12.10, "Operator Training and Requalification," section 12.11, "Startup Plan," and section 12.13, "Material Control and Accountability Plan."

SHINE FSAR section 12.12, "Environmental Reports," is vacated. By letter dated November 16, 2021, SHINE submitted Revision 7 of its operating license stage supplement to its construction permit stage environmental report for the SHINE facility (Agencywide Documents Access and Management System Accession No. ML21320A066). The NRC staff's evaluation of the environmental, economic, technical, and other benefits against the environmental and other costs of the proposed action of deciding whether to issue an operating license for the SHINE facility, based, in part, on SHINE's supplemental environmental report, is documented in NUREG-2183, Supplement 1, "Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility" (ML22179A346).

12.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 12 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the information regarding SHINE's conduct of operations for the issuance of an operating license.

12.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's conduct of operations are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) section 50.34, "Contents of applications; technical information," paragraph (b)(6).
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.57, "Issuance of operating license."
- 10 CFR Part 20, "Standards for Protection Against Radiation."
- 10 CFR 70.22, "Contents of applications."
- 10 CFR 73.57, "Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information."
- 10 CFR 73.67, "Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance."
- 10 CFR 73.71, "Reporting of safeguards events."
- 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

As discussed below, the NRC staff determined that the licensed operator requirements of 10 CFR Part 55, "Operators' Licenses," applicable to test and research reactor licensees, with the exception of 10 CFR 55.40, "Implementation," must apply at the SHINE facility to provide, in part, reasonable assurance that the activities authorized by the operating license can be conducted without endangering the health and safety of the public. Accordingly, the conditions in every nuclear power reactor operating license issued under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," that are generally related to licensed operators at facilities with 10 CFR Part 50 operating licenses, 10 CFR 50.54, "Conditions of licenses," paragraphs (i), (i-1), (k), and (l) must also be conditions in the SHINE operating license. Therefore, the NRC conditions the SHINE operating license as follows:

> SHINE must comply with the requirements of 10 CFR Part 55, "Operators' Licenses," to the same extent as would a test and research/non-power reactor licensee, with the

exception of 10 CFR 55.40, “Implementation.” In lieu of 10 CFR 55.40, SHINE will prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and will prepare the operating tests required by 10 CFR 55.45, subject to the following conditions:

a. SHINE shall prepare the required examinations and tests in accordance with the content requirements of 10 CFR 55.41(b), 55.43(b), and 55.45(a);

b. Pursuant to 10 CFR 55.49, SHINE shall establish, implement, and maintain procedures to control examination security and integrity;

c. An authorized representative of SHINE shall approve the required examinations and tests before they are submitted to the Commission for review and approval;

d. SHINE shall establish acceptance criteria for preparation and approval of written examinations and operating tests, and submit the acceptance criteria to the NRC in writing no later than 120 days before the first scheduled examination date;

e. SHINE shall submit any subsequent changes to the acceptance criteria to the NRC in writing no later than 120 days before any scheduled examination dates;

f. SHINE must receive Commission approval of its proposed written examinations and operating tests; and

g. In lieu of conditions (a) through (f) and upon written request from an authorized representative of SHINE pursuant to 10 CFR 55.31(a)(3), the Commission shall, for SHINE, prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and the operating tests required by 10 CFR 55.45. In addition, the Commission may exercise its discretion to itself prepare, proctor, and grade the required written examinations and operating tests for SHINE.

This license shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(i), (i-1), (k), and (l).

12.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.

- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

- Regulatory Guide 5.59, Revision 1, “Standard Format and Content for Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance,” dated February 1983.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides (RG), Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

12.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR chapter 12, as supplemented, to assess the sufficiency of SHINE’s conduct of operations for the issuance of an operating license. The sufficiency of SHINE’s conduct of operations is determined by ensuring that it meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 12.3, “Regulatory Requirements and Guidance and Acceptance Criteria,” of this SER. The findings of the staff review are described in section 12.5, “Review Findings,” of this SER.

12.4.1 Organization

The NRC staff evaluated the sufficiency of SHINE’s organization, as presented in SHINE FSAR section 12.1, using the applicable guidance and acceptance criteria from section 12.1, “Organization,” of NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14, “Technical Specifications,” of NUREG-1537, ANSI/ANS-15.1-2007, “The Development of Technical Specifications for Research Reactors,” and ANSI/ANS-15.4-2016, “Selection and Training of Personnel for Research Reactors,” to evaluate the description of the SHINE organization to ensure that the SHINE FSAR provides a basis for the TS requirements for the organization.

SHINE FSAR section 12.1.1, “Structure,” including SHINE FSAR figure 12.1-1, “SHINE Operational Organization Chart,” provides a multi-level functional organization description, consistent with ANSI/ANS-15.1-2007. The organization chart shows the various levels of the organization, including reporting and communication lines between operations staff, supervisors, managers, and committees.

Based on its review, the NRC staff determined that SHINE presented an organizational structure that reflects the complete SHINE facility organization from the license holder to the operations staff. All organizational relationships important to safety are shown, including the review and audit function and the radiation safety function. The organization meets the standards in ANSI/ANS-15.1-2007 and ANSI/ANS-15.4-2016 and is, therefore, acceptable.

SHINE FSAR section 12.1.2, “Responsibility,” describes the responsibilities of the persons in the organizational structure described in SHINE FSAR section 12.1.1 and SHINE FSAR figure 12.1-1 consistent with ANSI/ANS-15.4-2016. Therefore, the NRC staff finds that the responsibility for the safe operation of the SHINE facility and for the protection of the health and safety of the workers and the public has been shown.

SHINE FSAR section 12.1.3, “Staffing,” describes the SHINE facility staffing requirements that demonstrate the ability to safely operate the facility and protect the health and safety of the workers and the public consistent with ANSI/ANS-15.4-2016. SHINE’s minimum staffing ensures that the manipulation of the controls of the facility will be performed by licensed operators or senior operators as provided in 10 CFR Part 55; an operator or senior operator licensed pursuant to 10 CFR Part 55 will be present at the controls at all times during operation; licensed senior operators will be designated to be responsible for directing licensed activities of license operators; and a senior operator will be present at the facility or readily available on call at all times during operation and as prescribed in the facility license.

Therefore, the NRC staff finds that the SHINE staffing meets the applicable acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, for the issuance of an operating license.

SHINE FSAR section 12.1.4, “Selection and Training of Personnel,” describes the minimum qualification for each level of personnel. Consistent with ANSI/ANS-15.4-2016, SHINE describes the necessary experience, education, and training for each of the four qualifications levels and for other technical personnel. SHINE also provides for radiation training consistent with the requirements in 10 CFR 19.12, “Instruction to workers.”

Therefore, the NRC staff finds that SHINE will select staff that meet acceptable minimum qualifications. Also, radiation protection training and specialized training will be conducted at an acceptable level. SHINE describes its initial training and requalification programs for licensed operators in SHINE FSAR section 12.10, which are evaluated by the staff in section 12.4.10 of this SER.

SHINE FSAR section 12.1.5, “Radiation Safety,” refers to the information in SHINE FSAR sections 12.1.1 and 12.1.2 for the organizational structure and responsibilities for radiation safety. As depicted in SHINE FSAR figure 12.1-1, the Radiation Safety Function has communication lines established with the Chief Executive Officer, Review and Audit Committee, and Shift Supervisor, which are separate from its reporting line to the Diagnostics General Manager. Consistent with the acceptance criteria in section 12.1 of NUREG-1537, Part 2, SHINE stated the following:

> RP [Radiation Protection] staff maintain the ability to raise safety issues with the review and audit committee or executive management. The RP staff encompasses the clear responsibility and ability to interdict or terminate licensed activities that it believes are unsafe. This does not mean that the RP staff possesses absolute authority. If facility managers, the review and audit committee, and executive management agree, the decision of the RP staff could be overruled. However, this would be a rare occurrence that would be carefully analyzed and considered.

Therefore, the NRC staff finds that SHINE has described a radiation safety organization that is acceptable. This organization has direct access to upper management and the review and audit committee to express concerns, if necessary. The radiation safety staff has the authority to interdict or terminate activities to ensure safety.

12.4.2 Review and Audit Activities

The NRC staff evaluated the sufficiency of SHINE’s review and audit activities, as presented in SHINE FSAR section 12.2, using the applicable guidance and acceptance criteria from section 12.2, “Review and Audit Activities,” of NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE review and audit activities to ensure that the SHINE FSAR provides a basis for the TS requirements for the review and audit function.

SHINE FSAR section 12.2.1, “Composition and Qualifications,” describes a review and audit function for the facility. Consistent with ANSI/ANS-15.1-2007, the review and audit committee members appear to be well qualified, with a wide spectrum of expertise. The committee membership includes provisions for including persons from outside the company. Therefore, the NRC staff finds that the committee membership is acceptable.

SHINE FSAR section 12.2.2, “Charter and Rules,” describes the charter for the review and audit committee. Consistent with ANSI/ANS-15.1-2007, SHINE proposed a charter and rules that describe the number of times the committee meets, the way the committee conducts business, the requirements for a quorum when voting, and the way the committee distributes its reports and reviews. Therefore, the NRC staff finds that the charter and rules for the committee are acceptable.

SHINE FSAR sections 12.2.3, “Review Function,” and 12.2.4, “Audit Function,” provide lists of the minimum items to be reviewed and audited, respectively. Except as described below, SHINE followed the guidance in ANSI/ANS-15.1-2007 for establishing its lists of items to be reviewed and audited.

With respect to reviews, the NRC staff finds it acceptable that SHINE excluded experiments from its list of items to be reviewed since SHINE will not be conducting experiments at its facility. With respect to audits, the staff finds it acceptable that SHINE included its QA program description, physical security plan, and nuclear criticality safety program within the scope of items to be audited as this goes beyond the minimum items in ANSI/ANS-15.1-2007.

Therefore, the NRC staff finds that SHINE proposed a comprehensive and acceptable list of items that the committee will review and audit.

12.4.3 Procedures

The NRC staff evaluated the sufficiency of SHINE's procedures, as presented in SHINE FSAR section 12.3, using the applicable guidance and acceptance criteria from section 12.3, "Procedures," of NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE procedures to ensure that the SHINE FSAR provides a basis for the TS requirements for procedures.

SHINE FSAR section 12.3 describes the review and approval process for procedures and also describes the method for making minor and substantive changes to existing procedures and for the temporary deviation from procedures during operation. Except as described below, SHINE followed the guidance in ANSI/ANS-15.1-2007 for describing its review and approval process for procedures; methodology for making changes to or deviations from procedures; and the topics for which written procedures will be prepared, reviewed, and approved.

Because the SHINE facility is not a reactor, the NRC staff finds it acceptable that the topics for which written procedures will be prepared, reviewed, and approved include topics related to SHINE's irradiation units (IUs) and target solution. The staff also finds it acceptable that SHINE excludes topics related to experiments since SHINE will not be conducting experiments at its facility.

Therefore, the NRC staff finds that SHINE proposed a set of required procedures that is appropriate to the operation of the SHINE facility, and that the process and method described by SHINE will ensure proper management control and proper review of the procedures.

12.4.4 Required Actions

The NRC staff evaluated the sufficiency of SHINE's required actions, as presented in SHINE FSAR section 12.4, using the applicable guidance and acceptance criteria from section 12.4, "Required Actions," in NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE required actions to ensure that the SHINE FSAR provides a basis for the TS requirements for required actions.

SHINE FSAR section 12.4 describes the required actions, as provided in the TSs, to be taken in the event of either a safety limit violation or an occurrence requiring a special report other than a safety limit violation. Except as described below, SHINE followed the guidance in ANSI/ANS-15.1-2007 for defining reportable events and the actions to be taken should a reportable event occur.

Because the SHINE facility is not a reactor, the NRC staff finds it acceptable for SHINE to use language encompassing operations and processes within both the IF and RPF as being within the scope of reportable events and the actions to be taken should a reportable event occur.

Therefore, the NRC staff finds that SHINE defined specific incidents as reportable events and described the required actions to be taken if a reportable event occurs. The definition of reportable events provides reasonable assurance that safety-significant events will be reported by the applicant. The staff also finds that SHINE proposed actions to be taken if a safety limit is violated or a reportable event occurs. Based on the above, the staff concludes that SHINE will take the actions necessary to protect the health and safety of the public.

12.4.5 Reports

The NRC staff evaluated the sufficiency of SHINE's reports, as presented in SHINE FSAR section 12.5, using the applicable guidance and acceptance criteria from section 12.5, "Reports," in NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE reports to ensure that the SHINE FSAR provides a basis for the TS requirements for reports.

SHINE FSAR section 12.5 provides listings of both the content and timing of submission to the NRC of annual operating reports and special reports for unplanned events or planned major facility and administrative changes. Except as described below, SHINE followed the guidance in ANSI/ANS-15.1-2007 for the content, timing of submittals, and distribution of its operating and special reports.

For annual operating reports, the NRC staff finds the following deviations from ANSI/ANS-15.1-2007 acceptable:

- Exclusion of the tabulation of new tests or experiments because SHINE will not be performing tests or experiments at its facility.
- Provision of results of individual monitoring carried out by SHINE for each individual for whom monitoring is required by 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," because this is more conservative than the criterion provided in ANSI/ANS-15.1-2007.

Therefore, the NRC staff finds that SHINE adequately described the content, the timing of the submittal, and the distribution of the reports to ensure that important information will be provided to the NRC in a timely manner.

12.4.6 Records

The NRC staff evaluated the sufficiency of SHINE's records, as presented in SHINE FSAR section 12.6, using the applicable guidance and acceptance criteria from section 12.6, "Records," in NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE records to ensure that the SHINE FSAR provides a basis for the TS requirements for records.

SHINE FSAR section 12.6 describes the scope of the SHINE record management program from identification to disposition, as well as the storage method of keeping records in the SHINE electronic data management system. Except as described below, SHINE provided a list of records to be maintained for one of the following time periods consistent with ANSI/ANS-15.1-2007: (1) the lifetime of the SHINE facility; (2) five years or for the life of the component involved if less than five years; or (3) at least one operator certification cycle.

For the records to be maintained for five years or for the life of the component involved if less than five years, the NRC staff finds the following deviations from ANSI/ANS-15.1-2007 acceptable:

- Exclusion of records for experiments because SHINE will not be performing experiments at its facility.

- Maintaining of records for radioactive material inventories rather than for fuel inventories because SHINE will have special nuclear material in the form of an aqueous target solution rather than in the form of heterogeneous fuel.

Therefore, the NRC staff finds that SHINE adequately described the types of records that will be retained by the facility and their period of retention to ensure that important records will be retained for an appropriate time.

12.4.7 Emergency Planning

The NRC staff evaluated the SHINE Emergency Plan, presented in document EMG-01-01, Revision 2, "Emergency Plan" (ML22202A448), Enclosure 2 (ML22202A451) (the SHINE Emergency Plan), against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess its sufficiency. Previously, the staff reviewed the SHINE Preliminary Emergency Plan (ML13269A378), submitted as part of SHINE's construction permit application. In its SER associated with the construction permit application (ML16229A140), the staff identified several regulatory commitments concerning the emergency plan that the applicant was to address in the SHINE Emergency Plan and in the SHINE FSAR supporting the operating license application. The staff confirmed that all of the regulatory commitments previously identified have been satisfactorily addressed. The specific regulatory commitments are not individually documented in this SER, as the review effort was conducted to ensure that the SHINE Emergency Plan satisfies the appropriate regulatory guidance and acceptance criteria and, therefore, meets the applicable regulatory requirements.

Section 50.34(b)(6)(v) of 10 CFR requires that each application for an operating license include an FSAR that contains, among other things, the applicant's plans for coping with emergencies, including the items specified in appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," to 10 CFR Part 50.

Footnote 2 to section I.3 of appendix E to 10 CFR Part 50 specifies that Regulatory Guide 2.6, Revision 2, "Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities" (ML17263A472) will be used as guidance for the acceptability of research and test reactor emergency response plans. RG 2.6, Revision 2, in turn endorses ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors." This standard identifies the elements of an emergency plan for minimizing the accident consequences at non-power reactors.

The NRC staff evaluated the sufficiency of the SHINE Emergency Plan using the applicable guidance and acceptance criteria from section 12.7, "Emergency Planning," of NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used ANSI/ANS-15.16-2015, NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors" (ML062190191), and NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications" (ML15176A258), as appropriate, to evaluate the SHINE Emergency Plan.

12.4.7.1 Introduction

The guidance in section 1.0, "Introduction," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.1, "Introduction," of ANSI/ANS-15.16-2015 provides that the emergency plan should contain a description of the facility including the authorized power level of the facility, the location of the facility, and the access routes to the facility. The owner and operator of the facility should be identified, and the objectives of the emergency plan explained.

The NRC staff reviewed section 1, "Introduction," of the SHINE Emergency Plan, including associated figures, site layout, and maps provided in the plan. The SHINE Emergency Plan provides that the SHINE facility is owned and operated by SHINE Medical Technologies, LLC and is located at 4021 South US Highway 51, Janesville WI, 53546.

The SHINE facility includes the following structures:

- Main production facility,
- Resource building,
- Material staging building,
- Storage building, and
- Nitrogen purge system structure.

The SHINE facility involves the use of a non-reactor based, subcritical fission process for the purpose of manufacturing medical isotopes. The SHINE facility contains eight IUs, each with a target solution vessel (TSV) with a licensed fission power of 125 kilowatts-thermal, located in the IF area of the main production facility. Also located in the IF are rooms and cells housing off-gas handling equipment, cooling equipment, tritium purification equipment, and an area for servicing neutron drivers.

The RPF area of the main production facility contains a hot cell bank; below-grade vaults containing tanks, other process components, and storage space; two laboratories; and areas for waste handling, cooling, and other equipment. The remaining areas of the facility (the control room area and the administrative annex area) contain the control room, electrical equipment, additional auxiliary equipment, and other miscellaneous areas.

The SHINE site consists of an approximately 91-acre parcel in the City of Janesville, Rock County, Wisconsin and is accessed from U.S. Highway 51. Figure 1, "SHINE Facility Site Layout," of Appendix 1, "Figures," to the SHINE Emergency Plan depicts the site boundary, fences, gates, roads and parking lots on site, onsite structures and tanks, and U.S. Highway 51. Figure 2, “SHINE Main Production Facility General Arrangement,” depicts the general arrangement layout of the main production facility, which includes the IF, RPF, control room area, and administrative annex area. Figure 3, “SHINE Site Buildings and Surrounding Area,” provides an aerial view of the area surrounding the SHINE site, including the location of onsite structures and sensitive facilities near the SHINE site (0-1 mile), including churches, parks, residences, airstrips, and educational facilities. Farms are distributed throughout the one-mile radius of the SHINE site. There are no medical facilities within one mile of the SHINE site. Figure 4, “SHINE Site General Area Map,” contains a general area map constructed from U.S. Geological Survey topographical quadrangles and includes the SHINE facility site boundary.

The major activities conducted at the SHINE facility are: (1) preparation and irradiation of uranyl sulfate target solution and (2) extraction, purification, and packaging of medical isotopes from irradiated target solution inside hot cells. The SHINE facility contains radioactive and hazardous materials that are part of the overall medical isotope production process. Appendix 2, “Radioactive and Hazardous Materials,” to the SHINE Emergency Plan provides the types, quantities, and locations of radioactive and hazardous materials normally on the SHINE site.

The SHINE main production facility contains a facility vent stack for facility emissions. The stack uses high efficiency particulate air filters and single stage high efficiency gas adsorption filter equipment for emission control. There is a stack release monitor that provides information on radiation released from the facility stack.

Section 1.9, “Accident Summary,” of the SHINE Emergency Plan describes the general types of accidents that may require the implementation of protection actions. Additional information on potential facility accidents is contained in chapter 13, “Accident Analysis,” of the SHINE FSAR. Measures and equipment used to respond to and detect accidents and releases are described in section 9, “Emergency Facilities and Equipment,” of the SHINE Emergency Plan.

The NRC staff finds that the information in the SHINE Emergency Plan concerning the site layout and location, consideration of access routes, surrounding population distribution, land use and jurisdictional boundaries, authorized power level, identification of the owner and operator of the facility, and an explanation of the objectives of the emergency plan are acceptable and meet the relevant standards set forth in NUREG-0849 and the ISG augmenting NUREG-1537. The staff concludes that this information meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.2 Definitions

The guidance in section 2.0, “Definitions,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.2, “Definitions,” of ANSI/ANS-15.16-2015 provides that the emergency plan should identify definitions for terms that are unique to the facility and should include phrases with meanings specific to the facility.

The NRC staff reviewed section 2, “Definitions” of the SHINE Emergency Plan, which describes the terms defined as having special meaning unique to the facility, as well as acronyms and abbreviations used throughout the document. The staff finds the defined terms, acronyms, and abbreviations to be complete and to be used consistently throughout the document. The staff finds the information acceptable and determined that the definitions, acronyms, and abbreviations are consistent with the guidance in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.3 Organization and Responsibilities

The guidance in section 3.0, "Organization and Responsibilities," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.3, "Organization and responsibilities," of ANSI/ANS-15.16-2015 provides that the emergency plan should identify the emergency organization, including the onsite emergency organization, any augmentation from offsite groups, and the identification, by normal everyday title, of all persons or groups that will fill positions in the emergency organization. These criteria include:

- A description of the emergency planning functions of Federal, State, and local government agencies, and identification of the assistance they would provide and of the applicant's emergency organization, including augmentation of the operations staff to provide assistance during an emergency, recovery from the emergency, and maintaining emergency preparedness.

- The arrangements and written agreements with local support organizations that would augment and extend the capability of the facility's emergency organization.

- A block diagram illustrating the interrelationship of the facility emergency organization to the total emergency response effort, including specification of the interface between the onsite emergency organization and offsite local support organizations and agencies.

- The identification by title of the individuals in charge of directing emergency operations; of coordinating emergency preparedness planning, updating emergency plans and procedures, and coordinating plans with other supporting organizations; of relating information about the emergency to the news media and the public, and of both onsite and offsite radiological assessments including a line of succession, and responsibilities and authorities and those responsibilities which may not be delegated (such as notification and protective action decisions).

- The identification by title of the individuals providing onsite and offsite dose assessments and recommended protective actions; authorizing reentry into radiological controlled areas or portions of the facility that may have been evacuated during the emergency; terminating an emergency and initiating recovery actions and informing the emergency organization of planned organizational actions or changes; and authorizing volunteer emergency workers to incur radiation exposures in excess of normal occupational limits.

- The identification by title of the individuals who will declare an alert or site area emergency classification, activate the onsite emergency response organization (ERO) during all shifts, promptly notify offsite response authorities that an alert or site area emergency classification has been declared, notify the NRC Operations Center, initiate onsite and offsite protective actions, request support from offsite organizations, and either terminate the emergency or enter recovery mode.

Section 3.1, "Emergency Response Organization," of the SHINE Emergency Plan states that the ERO is responsible for taking actions in an emergency to avoid an accident or to mitigate the consequences of one. At the SHINE facility, the ERO would be staffed with trained and qualified personnel that would be required to attend formal initial and continuing training, as well as participate in drills and exercises. In addition, the applicant explained that the ERO at the SHINE facility would consist of two groups of personnel: (1) the normal facility operating organization and (2) the facility emergency organization.

As summarized below, the on-shift personnel present at the site will initially staff the facility emergency organization. Upon activation of the ERO, designated off-shift personnel will be notified to report to the Emergency Support Center (ESC), once it has been activated, or to the control room if the ESC has not yet been activated. Section 7, "Activation of the ERO and Notification," of the SHINE Emergency Plan further describes this response effort.

The NRC staff reviewed section 3, "Organization and Responsibilities," of the SHINE Emergency Plan. The organization for managing and operating the SHINE facility is provided in figure 10, "SHINE Normal Facility Operation Organization Chart," of appendix 1 to the SHINE Emergency Plan and is summarized below.

Chief Executive Officer (CEO): The CEO is responsible for the overall management and leadership of the company.

Diagnostics General Manager: The Diagnostics General Manager is responsible for operational aspects of the diagnostics division.

Director of Plant Operations: The Director of Plant Operations is responsible for the overall operation of the facility.

Director of Corporate Support: The Director of Corporate Support is responsible for facility radiation protection, security, and training.

Operations: The facility operations personnel are responsible for the operation of the facility and safe, reliable, and efficient plant operations.

Security: The facility security personnel are responsible for the physical security of the facility.

Engineering: The facility engineering personnel are responsible for providing technical expertise and support of facility operation and maintenance, and for controlling the physical facility configuration to ensure that facility operation, maintenance, and configuration are maintained in accordance with the design basis.

Radiation Protection: The facility radiation protection personnel, which are part of the facility technical staff, are responsible for the handling and monitoring of radioactive materials.

Maintenance: The facility maintenance personnel are responsible for performing maintenance on facility equipment in accordance with facility procedures, instructions, and technical requirements.

Chemistry: The facility chemistry personnel, which are part of the facility technical staff, are responsible for sampling, analysis, and product quality control activities.

Executive, support, administrative, and other personnel (“support personnel”): These individuals have various responsibilities involving procurement, licensing, quality, finance, etc., and may include personnel normally stationed offsite.

On-shift personnel

Shift supervisor: A senior licensed operator responsible for the safe operation of the facility.

Licensed operators (including any additional on-shift senior licensed operators, if present): Responsible for ensuring that licensed activities are conducted safely and in accordance with the facility license and procedures.

Non-licensed operating staff: Responsible for conducting operations in the facility in accordance with procedures and under the direction of licensed operators.

Security personnel: Responsible for the physical security of the facility.

Radiation protection individual: At least one individual capable of monitoring radiation dose rates and contamination levels is present on each shift.

During an emergency, personnel may deviate from actions described in the SHINE Emergency Plan for unusual or unanticipated conditions. The ERO at the SHINE facility is comprised of the following individuals, as illustrated by figure 11, “SHINE Facility Emergency Organization,” of appendix 1 to the SHINE Emergency Plan:

- Emergency Director: The Emergency Director is authorized to and responsible for directing and coordinating the overall emergency response. The Emergency Director has the following non-delegable responsibilities:

  - Emergency event classification and decision to declare an emergency;
  - Decision to activate the ERO;
  - Decision to initiate onsite protective actions;
  - Decision to notify offsite response authorities;
  - Decision to request support from offsite organizations;
  - Authorization of reentry into portions of the facility or site that may have been evacuated during the emergency;
  - Authorization of volunteer emergency workers to incur radiation exposures in excess of normal 10 CFR Part 20 occupational limits; and
  - Decision to terminate the emergency and initiate recovery actions.

- The Emergency Director may delegate the following responsibilities, based on his/her decision (as stated above):

  - Notifying the appropriate personnel to activate the ERO;
  - Performing the notification of offsite response authorities within 15 minutes

of a Notification of Unusual Event, Alert, or Site Area Emergency classification;
  - Notification of the NRC Operations Center within one hour of declaring the emergency;
  - Assessment of damage to and status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with licensed activities;
  - Prioritizing responses to concurrent emergencies; and
  - Informing the ERO of planned emergency organization actions or changes.

- Shift Supervisor: The Shift Supervisor acts as the initial Emergency Director upon declaration of an emergency. Additionally, the Shift Supervisor has the following responsibilities:

  - Implementing immediate actions to respond to the emergency in accordance with facility emergency procedures;
  - Directing and supervising the activities of the control room staff; and
  - Safe operation of the plant in compliance with the facility NRC operating license, TSs, facility operating procedures, and the requirements for their use.

- Emergency Communicator: The Emergency Communicator assists in the execution of the Emergency Director's duties. The Emergency Communicator is responsible for:

  - Exchanging information with offsite authorities responsible for coordinating and implementing offsite emergency measures, including transmitting dose projections, and monitoring and surveying information;
  - Relating information about the emergency situation to the news media and the public; and
  - Ensuring a record of the events during and following the emergency is maintained.

- Radiation Safety Coordinator: The Radiation Safety Coordinator is responsible for making radiological assessments and advising the Emergency Director, including responsibility for the following tasks:

  - Making onsite and offsite dose assessments and projections;
  - Recommending protective actions; and
  - Identifying exposed personnel and determining their radiation dose.

- Technical Support Coordinator: The Technical Support Coordinator is responsible for coordinating the technical response to the event, including:

  - Performing technical assessments of facility emergencies;
  - Assisting the Emergency Director and Radiation Safety Coordinator in technical matters; and
  - Coordinating the technical staff to augment the ERO on an as-needed basis to support accident assessment and mitigation activities.

- Criticality Safety Engineer: A criticality safety engineer is called-in upon activation of the ERO, at the discretion of the Emergency Director or Technical Support Coordinator, if a criticality event is suspected or confirmed. The Criticality Safety Engineer is responsible for the following tasks:

  – Advising and assisting the Emergency Director in responding to the criticality accident; and
  – Assisting the Radiation Safety Coordinator in conducting a radiological dose assessment appropriate for a criticality accident.

- Security personnel: Security personnel that are present at the facility when an emergency is declared will implement emergency plan implementing procedures (EPIPs) appropriate to the event classification. Security personnel are responsible for the following tasks:

  – Performing personnel Accountability, if required; and
  – Implementing access control of facility areas at the direction of the Emergency Director, if required.

- Operations personnel: Operations personnel that are present at the facility when an emergency is declared will implement EPIPs appropriate to the event classification. Operations personnel are responsible for performing the following tasks:

  – Monitoring facility instrumentation and reporting results to the Emergency Director; and
  – Implementing corrective actions at the direction of the Emergency Director.

- Assessment Teams: Assessment Teams are comprised of facility operations, technical staff, or support personnel that may be called upon by the Emergency Director following activation of the ERO. Assessment Teams are responsible for the following tasks:

  – Collecting onsite and offsite field monitoring data;
  – Monitoring radiation dose rates and contamination levels; and
  – Assessing collateral damage to the facility.

- Reentry and Damage Control Teams: Reentry and Damage Control Teams are comprised of facility operations, technical staff, or support personnel who may be called in by the Emergency Director upon activation of the ERO. Reentry and Damage Control Teams are responsible for the following tasks:

  – Reentering an immediate evacuation zone during the emergency on a voluntary basis after being informed of the potential hazards and risks; and
  – Performing actions at the direction of the Emergency Director associated with controlling and stabilizing emergency events in-progress.

Section 3.4, "Emergency Support Organizations," of the SHINE Emergency Plan states that in the event that the Emergency Director makes the decision to request support from offsite organizations, the following offsite support agencies and organizations would aid:

- Janesville Fire Department: Fire support, first aid support, ambulance services, and hazardous materials response;

- Janesville Police Department: Law enforcement support;

- SSM [Sisters of St. Mary] Health St. Mary's Hospital: Support services for any radiation exposed or contaminated injured individuals transported from the site;

- Rock County Emergency Management: Responsible for coordinating major emergencies, disaster response, and recovery efforts in support of county and local governments; and

- The State of Wisconsin: Has the general authority and responsibility to assist local units of government and local law enforcement agencies in responding to a disaster or the imminent threat of a disaster. The State of Wisconsin coordinates its response with Rock County Emergency Management as needed.

SHINE stated that local government agencies and organizations, as described above, will be initially notified as described in section 7 of the SHINE Emergency Plan by contacting the Rock County 911 Communications Center. The applicant further explained that the SHINE facility does not anticipate the need for State or Federal assistance. The NRC staff confirmed that appendix 3, "Agreement Letters," to the SHINE Emergency Plan provides arrangements and agreements with the support organizations described above that would augment and extend the capability of the facility's emergency organization as specified in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537.

Section 3.3, paragraph (2) of ANSI/ANS-15.16-2015 states, in part, that the organizational description shall include, as applicable, the authority and responsibility of each support agency or organization (local, county, state, or all three) having radiological emergency responsibilities for emergency preparedness planning and emergency response assistance. Section 3.4 of the SHINE Emergency Plan states, in part, that in the event that the decision is made by the Emergency Director to request support from those offsite agencies and organizations, assistance as outlined above would be provided. The applicant further stated that the State of Wisconsin has the general authority and responsibility to assist local units of government and local law enforcement in responding to a disaster or the imminent threat of a disaster and will coordinate its response with Rock County Emergency Management, as needed.

Section 3.7.1, "Activation of emergency organization," of ANSI/ANS-15.16-2015 states the specific actions to take to notify and mobilize the emergency organization and the applicable offsite support organizations for each emergency class. Section 7.3, "Notification of Off-site Organizations," of the SHINE Emergency Plan states that the Emergency Director ensures that emergency notifications are promptly made to offsite EROs and that a notification will be made to the State of Wisconsin promptly after notification to the NRC.

Section 3.5, "Maintaining Emergency Preparedness," of the SHINE Emergency Plan describes the roles and responsibilities of individuals that have roles related to maintaining emergency preparedness. The SHINE Emergency Plan provides a description of how the effectiveness of the emergency plan will be maintained, including training, review, and update of the emergency plan and associated implementing procedures along with maintenance and inventory of equipment and supplies that would be used in an emergency.

Section 3.10.1, “Training and drills,” of ANSI/ANS-15.16-2015 identifies and describes training and drill criteria to demonstrate emergency preparedness. Section 3.10.1 states that at least every two years, exercise drills shall contain provisions for coordination with offsite emergency personnel. Section 11.4.2, “Planning and Controlling Drills and Exercises,” of the SHINE Emergency Plan states that offsite organizations or governments, including city, county, and State agencies, shall be invited and allowed to participate in drills or exercises at their request.

Based on the above, the NRC staff finds that section 3 of the SHINE Emergency Plan provides an adequate description of the emergency organization that would be activated to cope with radiological emergencies as it pertains to the onsite emergency organization and any augmentation necessary from offsite groups. Personnel or groups that will fill positions in the emergency organization are adequately identified by title and described within the SHINE Emergency Plan as specified in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.4 Emergency Classification System

The guidance in section 4.0, “Emergency Classification System,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.4, “Emergency classification system,” of ANSI/ANS-15.16-2015 provides the following standard emergency classifications; however, it states that each emergency plan shall include only those standard classifications appropriate for dealing with accident consequences determined to be credible for the specific facility:

- Notification of Unusual Event;
- Alert;
- Site Area Emergency; and
- General Emergency.

The NRC staff reviewed section 4, “Emergency Classification System,” of the SHINE Emergency Plan. The SHINE Emergency Plan provides for the classification of emergencies according to the severity of offsite radiological consequences. The standard classifications for the SHINE facility are: Notification of Unusual Event; Alert; and Site Area Emergency, which is consistent with the guidance in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015. SHINE identified no credible accidents for the SHINE facility that would result in radiological levels exceeding the action levels for a General Emergency classification level at the site boundary. As a result, the SHINE Emergency Plan does not include provisions for a General Emergency classification.

Section 4.2, “Emergencies Less Severe Than Notification of Unusual Events,” of the SHINE Emergency Plan also recognizes emergencies of lesser consequences than the Notification of

Unusual Event classification level. SHINE explained that these include physical occurrences within the facility requiring facility emergency organization response. Responses to these emergencies of lesser consequence than a Notification of Unusual Event are based on the recognition of immediate need for onsite staff to implement emergency measures to provide aid to affected persons or to mitigate the consequences of damage to equipment, coupled with assessing radiological monitors to determine if the possibility of a more serious emergency is present. Situations of lesser consequence than Notification of Unusual Events that may warrant implementation of portions of the SHINE Emergency Plan or select EPIPs are identified within section 4.2 of the plan.

Section 4.3, “Notification of Unusual Event,” of the SHINE Emergency Plan defines a Notification of Unusual Event, also referred to as an Unusual Event, as man-made events and natural phenomena creating a significant hazard potential that was previously non-existent. At the Unusual Event classification level, time is expected to be available to take precautionary and corrective steps to prevent the escalation of the accident or to mitigate the consequences should it occur. As a result, no releases of radioactive or hazardous materials requiring offsite responses are anticipated.

Section 4.4, “Alert,” of the SHINE Emergency Plan defines an Alert classification level as an event that may occur, is in progress, or has occurred, that could lead to a release of radioactive material or hazardous chemicals incident to the processing of licensed material. However, a release is not expected to require a response by an offsite response organization (ORO) to protect persons offsite. The applicant explained that substantial modification of facility operating status at the Alert classification level is a highly probable corrective action.

Section 4.5, “Site Area Emergency,” of the SHINE Emergency Plan defines this emergency classification level as an event that may occur, is in progress, or has occurred that could lead to a significant release of radioactive material or hazardous chemicals incident to the processing of licensed material and that could require a response by offsite EROs to protect persons offsite. The applicant stated that a Site Area Emergency may be initiated when events such as major damage of primary boundaries containing radioactive or hazardous materials incident to the processing of licensed material have occurred and actual or imminent failure of other physical barriers preventing releases have occurred and the projected offsite radiological consequences exceed the action levels for a Site Area Emergency classification level at the site boundary. The offsite radiological doses are listed in appendix 4, “Emergency Action Levels,” of the SHINE Emergency Plan. The applicant explained that monitoring at the site boundary will be conducted to assess the need for offsite protective actions and protective measures onsite will be implemented, as necessary.

Section 4.0 of NUREG-0849 states that the submitted emergency plan should include an appendix that contains titles and descriptions of implementing procedures for each emergency class described above. Appendix 5, “Emergency Plan Implementing Procedure (EPIP) List,” to the SHINE Emergency Plan provides a listing by title of implementing procedures for each class of emergency at the SHINE facility. The NRC staff confirmed that the EPIPs as described would adequately provide the facility personnel with the guidance on actions to provide a graded response in order of increasing severity based on the standard of emergency classifications at the site in the event of an emergency.

The NRC staff confirmed that the emergency classifications identified in the SHINE Emergency Plan are consistent with the guidance in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015 and are in conformance with appendix I, "Emergency Classes," of NUREG-0849. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.5 Emergency Action Levels

The guidance in section 5.0, "Emergency Action Levels," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.5, "Emergency action levels (EAL)," of ANSI/ANS-15.16-2015 provides that the emergency plan should include methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations within and outside the site boundary and assessing recommended protective actions. The guidance states, in part, that:

- The emergency action levels (EALs) should be appropriate to the specific facility and consistent with the emergency classes;
- To the extent possible, the EALs should specify the effluent monitors used to project dose rates and radiological effluent releases at the site boundary;
- The emergency plan should include EALs to initiate protective actions for facility staff and members of the general public onsite; and
- The protective action guides shall be 10 milliSievert (mSv) deep dose (1 rem whole body) or 50 mSv (5 rem) thyroid.

The NRC staff reviewed section 5, "Emergency Action Levels," of the SHINE Emergency Plan. The SHINE Emergency Plan does not identify any events that could lead to a release of hazardous chemicals incident to the processing of licensed material that would require activation of the SHINE ERO to protect persons onsite, or that would require a response by an ORO to protect persons offsite. For this reason, the applicant did not identify any EALs related to releases of hazardous chemicals incident to the processing of licensed material.

Appendix 4, "Emergency Action Levels," to the SHINE Emergency Plan provides a full list of events under the three standard classifications of emergencies at the SHINE facility: Notification of Unusual Event; Alert; and Site Area Emergency. Included in appendix 4 are specific dose values/set points used for emergency classification. The NRC staff confirmed that the information contained in appendix 4 is consistent with the emergency classifications identified in section 4 of the SHINE Emergency Plan. The staff also determined that the EALs have been established in terms of effluent monitors and other facility parameters from which the dose rates and radiological effluent releases at the site boundary can be projected. The staff finds that the SHINE Emergency Plan adequately includes appropriate EALs that contain specific values and setpoints used for determining when and what type of protective actions are necessary to protect the health and safety of the facility staff onsite. The protective actions identified by the applicant are defined by the protective action guides (PAGs) identified in U.S. Environmental Protection Agency (EPA) document EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents."

Section 7, "Activation of the ERO and Notification," of the SHINE Emergency Plan provides that elements of the ERO will be activated or notified to increase the state of readiness as warranted by the circumstances. Although the situation may not have resulted in damage to the facility, it may warrant preventative or mitigative actions or interruption of nonessential routine functions.

As a result, SHINE explained that protective evacuations or isolation of certain areas of the facility may be necessary.

The NRC staff verified that appendix 4 to the SHINE Emergency Plan describes the classes of emergency situations covering the spectrum of emergency conditions that involve the alerting or activating of progressively larger segments of the emergency organization. The staff also verified that for each class of emergency associated with an EAL there was a particular immediate action to provide an appropriate graded response. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.6 Emergency Planning Zones

The guidance in section 6.0, "Emergency Planning Zones," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.6, "Emergency planning zones," of ANSI/ANS-15.16-2015 provides, in part, that:

- The emergency plan should identify the emergency planning zone (EPZ);
- The emergency plan should provide an acceptable basis for the EPZ; and
- The size of the EPZ should be established so that the dose to individuals beyond the EPZ is not projected to exceed the EPA PAGs.

The potential radiological hazards to the public associated with the operation of research and test reactors and fuel cycle facilities licensed under 10 CFR Part 50 involve considerations different than those associated with nuclear power reactors. As endorsed by RG 2.6 and referenced to by the ISG augmenting NUREG-1537, ANSI/ANS-15.16-2015 describes an acceptable approach for emergency planning commensurate with the potential risk involved for facilities of various authorized power levels. This approach to an acceptable EPZ size is also described in NUREG-0849, appendix II, and was adopted by the applicant.

The NRC staff reviewed section 6, "Emergency Planning Zones," of the SHINE Emergency Plan, which states that there are no identified radiological emergencies at the SHINE facility that would result in offsite plume exposure exceeding 1 rem whole body or 5 rem thyroid. Therefore, the EPZ for the SHINE facility is identified as the operational boundary. Consistent with the guidance in NUREG-0849 and ANSI/ANS-15.16-2015, for a facility with the authorized power level of the SHINE facility, the NRC finds that an acceptable EPZ size is the SHINE operational boundary.

Based on the above, the NRC staff finds that the information provided adequately addresses the establishment of an appropriate EPZ for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.7 Emergency Response

The guidance in section 7.0, “Emergency Response,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.7, “Emergency response,” of ANSI/ANS-15.16-2015 provides criteria for emergency response measures that should be identified for each emergency. The criteria include the review and evaluation of the following:

- The notification information for emergency response, including the actions to notify and mobilize the emergency organization and the applicable offsite support organizations for each emergency class and the location of current notification lists. Initial and follow-up emergency messages to the NRC and to offsite authorities, as applicable, should include: caller information such as name, title, and telephone number; a description of the emergency event; date and time of incident initiation; the location of the incident and the emergency class; the quantity and type of radionuclides released or expected to be released; and the impact of releases and recommended offsite emergency actions. A method to ensure that offsite authorities have received the initial message and that it is authentic and that appropriate follow-up messages to offsite authorities are issued promptly.

- The methods for gathering and processing information for assessment actions should be described in the emergency plan, and PAGs are available and used by the appropriate personnel in a timely manner.

- The actions that could be taken to mitigate or correct the problem for each emergency class should be summarized in the emergency plan.

- The emergency plan should describe protective actions appropriate for the emergency class and should include: conditions for either partial or complete onsite evacuation, evacuation routes, and primary and alternate assembly areas; methods to ensure personnel accountability and the segregation of potentially contaminated personnel; protective measures and exposure guidelines for emergency personnel; provisions for isolating and access control of facility areas to minimize exposures to radiation and the spread of radioactive contamination; and the methods for monitoring radiation dose rates and contamination levels, both onsite and offsite, including provisions for transmitting collected information and data to those responsible for accident assessment.

- The emergency plan should describe the ability to promptly and effectively assess a release of radioactive material or hazardous chemicals, including: a description of procedures for estimating or measuring the release rate or source term; a description of the computer codes used to project doses, along with adequate justifications to show the validity of the assumptions; and a description of the method for assessing collateral damage to the facility.

SHINE addressed these criteria in section 7, “Activation of the ERO and Notification,” and section 8, “Emergency Response,” of the SHINE Emergency Plan.

The NRC staff reviewed section 7 of the SHINE Emergency Plan to evaluate the applicant's planned emergency response measures related to activation and notification of the ERO. Section 7 identifies that the Shift Supervisor will become the Emergency Director when conditions exist that exceed EALs, or other conditions exist that warrant activation of the facility emergency organization. Notification of the emergency declaration will be made in accordance with established EPIPs. Rosters for emergency notifications are maintained in the control room and the ESC, and in controlled copies of the EPIPs. Progressive notifications to ERO members are planned dependent on classification of the emergency with full activation at the Site Area Emergency classification. The ESC is to be activated at an Alert or higher classification level. The OROs are activated by calling the Rock County 911 Communications Center, using established EPIPs, which contain message authentication instructions. Notifications to OROs are to be made within 15 minutes of an emergency declaration. Notifications to the NRC Operations Center are to be made within one hour after event declaration. Preformatted messages and reporting checklists are used and include information consistent with that called for in guidance documents. After notification of the Rock County 911 Communication Center and the NRC, the State of Wisconsin will be promptly notified following the declaration of an emergency.

The NRC staff reviewed section 8 of the SHINE Emergency Plan to evaluate the applicant's planned emergency response measures. This section sets forth voluntary emergency work exposure guidelines that the Emergency Director can authorize when called for. The use of respiratory protection and protective clothing is outlined.

Actions that the applicant will take in response to events to assess the event and activate appropriate facilities and notify personnel, and corrective actions that could be taken for events and personnel protective actions, are discussed for each emergency classification level. Consideration of evacuation of personnel from impacted areas of the facility, along with assembly and accountability processes are described. The control room, main production facility break room, and main production facility conference room are identified as primary assembly areas for ERO personnel onsite and non-essential personnel. The main production facility conference room is designated as the alternate onsite assembly area for non-essential personnel. Back-up assembly locations in the storage building office area and the SHINE Headquarters breakroom are also identified.

The SHINE Emergency Plan identifies provisions for isolation and access control of facility areas to minimize exposures to radiation and the spread of contamination. It describes methods for monitoring radiation dose rates and contamination levels both onsite and offsite using installed monitoring equipment and portable survey equipment.

Section 8.7.3, "On-site and Off-site Surveying," of the SHINE Emergency Plan states, in part, that "Monitoring outside the facility and at the site boundary shall be implemented within two hours of declaring a Site Area Emergency involving a potential or actual release." Per section 3.3.4, "Radiation Safety Coordinator," of the SHINE Emergency Plan, the Radiation Safety Coordinator has the responsibility of making onsite and offsite dose assessments and projections. The role of the Radiation Safety Coordinator is initially filled by an onsite individual with radiation protection experience. A relief Radiation Safety Coordinator may be called in as part of the activation of the ERO, if required. Additionally, section 3.3.9, "Assessment Teams," of the SHINE Emergency Plan identifies collecting onsite and offsite field monitoring data as one of the responsibilities of an Assessment Team, which will assist the Radiation Safety Coordinator in making radiological assessments by monitoring or collecting radiation dose rates and contamination levels.

In addition, section 8.7, “Assessment Action Information,” and section 9.4, “Assessment Facilities and Equipment,” of the SHINE Emergency Plan provide protective actions in conformance with section 8.4.3.1.7, “Assessment of Releases,” of NUREG-1520.

Based on the above, the NRC staff finds that the information provided in sections 7 and 8 of the SHINE Emergency Plan adequately addresses the emergency response measures for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.8 Emergency Facilities and Equipment

The guidance in section 8.0, “Emergency Facilities and Equipment,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.8, “Emergency facilities and equipment,” of ANSI/ANS-15.16-2015 provides criteria for emergency facilities, and the type of equipment and their location that should be addressed in the emergency plan. The acceptance criteria for information on emergency facilities and equipment are:

- The emergency plan describes an ESC.

- Representative types of monitoring and sampling equipment that would be used for accident assessment and their location are described. For each type of accident identified, the emergency plan should describe the means of detecting the accident, the means of detecting any release of radioactive material or hazardous chemicals incident to the processing of licensed material, and the means of alerting operating staff.

- The sampling and monitoring equipment types should include portable and fixed radiation monitors, sampling equipment, equipment for personnel monitoring, equipment for specific radionuclide identification and analysis, and to assess the release to the environment of radioactive or hazardous chemicals incident to the processing of licensed material. The plan should also describe non-radiological monitors or indicators such as fire detectors, earthquake sensors, etc.

- The emergency plan should identify those measures that would be used to aid injured persons or those exposed to radiation. The capability to decontaminate, administer first aid, transport injured personnel, and arrange for treatment should be described including a description of both onsite and offsite services that support emergency response such as first aid personnel, firefighters, law enforcement assistance, and ambulance service. A list and description of both onsite and offsite emergency facilities, by location and purpose, should be provided.

- The emergency plan should identify the emergency communications systems that would be available to communicate instructions and information both onsite and offsite throughout the course of an emergency.

The NRC staff reviewed section 9, “Emergency Facilities and Equipment,” of the SHINE Emergency Plan to evaluate the emergency facilities and equipment that are available at the

SHINE facility. The SHINE Emergency Plan identifies the control room as the centralized onsite location from which effective control can be provided during an emergency. The plan also describes an ESC, both a primary and back-up location, to oversee operations in the control room and the rest of the facility in emergency conditions. The ESC is sized for at least six people.

The assessment of conditions of the facility and identification of emergency events is aided by the use of installed radiological instrumentation, a criticality accident alarm system, area radiation monitors, process radiation monitors, process tritium monitoring, a continuous air monitoring system, criticality accident dosimeters, and the ability to collect environmental monitoring information. Portable radiological monitoring equipment is available, as well as sampling kits and hand-held lights.

Two onsite laboratory facilities are available with instrumentation for specific radionuclide identification and analysis.

Non-radiological monitors and instrumentation for fire detection and seismic monitoring are available. Weather band radio receiver in the control room allows for the assessment of potential meteorological threats to the facility.

Section 9.5, “Decontamination Facilities, Supplies, and Controls,” of the SHINE Emergency Plan states that personnel are considered contaminated if they are found by direct frisk or use of a portal monitor to have contamination above background levels, as defined in the EPIP addressing emergency radiation exposure control. Equipment is considered contaminated if a survey of accessible surfaces results in contamination above background levels, as defined in the EPIP addressing emergency radiation exposure control.

A decontamination room is provided at the main exit from the radiologically controlled area of the facility. Supplies for temporary decontamination areas are available if needed. The normal personnel monitoring equipment used by the SHINE facility staff is also used in emergency conditions, supplemented with any additional specialized dosimetry deemed necessary. Emergency support organization personnel are provided dosimetry prior to entering affected areas.

First aid supplies are maintained in the control room, ESC, the storage building office, and the main production facility shipping and receiving dock area. Offsite medical arrangements with the City of Janesville Fire Department and SSM Health St. Mary’s Hospital are described in the SHINE Emergency Plan.

Communications systems using the normal facility phone system, which has a battery backup power supply, are relied upon for most communications in the event of an emergency. A public address system is also available throughout the facility. Sound powered phones are available in four strategic locations if needed. Handheld radios and base stations are also available and serve as a backup communications system. Radios are also capable of communication with the police and fire departments in Janesville, Wisconsin. The facility maintains an emergency mobile phone in the control room, and personal mobile phones are expected to be available if needed.

Based on the above, the NRC staff finds that the information provided in section 9 of the SHINE Emergency Plan adequately addresses the emergency facilities and equipment for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.9 Recovery

The guidance in section 9.0, "Recovery," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.9, "Recovery," of ANSI/ANS-15.16-2015 provides the criteria for recovery and reentry planning that should be addressed in the emergency plan, which are:

- The emergency plan specifies that recovery procedures will be written and approved as needed.
- The emergency plan describes the procedures for promptly determining the actions necessary to reduce any ongoing releases of radioactive material or hazardous chemicals incident to the processing of licensed material and to prevent further incidents.
- The emergency plan describes the provisions for promptly and effectively accomplishing required restoration plans.

The NRC staff reviewed section 10, "Recovery," of the SHINE Emergency Plan to ensure that the applicant appropriately considered the recovery phase of an accident. Section 10 states that the Emergency Director will determine, using criteria provided in the SHINE Emergency Plan, when emergency conditions no longer exist and recovery can begin. Assessment Teams, using established procedures, will conduct recovery assessments. Recovery plans and procedures will be prepared by facility technical staff based on current conditions and approved by an individual qualified as an Emergency Director at the facility. Personnel will be trained in specific recovery actions.

Based on the above, the NRC staff finds that the information provided in section 10 of the SHINE Emergency Plan adequately addresses recovery actions for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.10 Maintaining Emergency Preparedness

The guidance in section 10.0, "Maintaining Emergency Preparedness," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.10, "Maintaining emergency preparedness," of ANSI/ANS-15.16-2015 provides the criteria for maintaining an acceptable state of emergency preparedness, which are:

- The emergency plan should describe initial and periodic training for emergency response employees assigned functions for decision making and transmitting instructions and accident assessment, radiological monitoring and analysis teams, for personnel involved in first aid and rescue and medical support, and police, security, and ambulance and firefighting personnel.

- The emergency plan should describe the conduct of annual onsite emergency drills, include provisions for drill critiques, including timely evaluation of observer comments and correction of identified deficiencies, and discuss the development of written scenarios for the conduct of annual action drills.

- The emergency plan should provide for a biennial review and update of the emergency plan and implementing procedures and agreements with OROs and agencies that includes review and approval by those responsible for emergency planning, incorporating modifications resulting from drill results or changes to the facility, and timely forwarding of changes to the plan and implementing procedures and agreements to the appropriate individuals, agencies, and supporting organizations.

- The emergency plan should describe the provisions to ensure the operational readiness of emergency communications and emergency health physics equipment including the required maintenance and minimum calibration frequency, functional testing, and inventory of equipment and supplies.

- The emergency plan should describe the frequency, performance objectives, and plan for the emergency response training that the applicant will provide to the workers.

- The emergency plan should state the applicant’s commitment to conduct exercises and drills in a manner that demonstrates the capability of the organization to plan and perform an effective response to an emergency.

The NRC staff reviewed section 11, “Maintaining Emergency Preparedness,” of the SHINE Emergency Plan to evaluate the applicant’s maintenance of emergency preparedness and training of facility staff. The plan calls for initial (eight hours) and annual refresher (four hours) training on topics such as an overview of the emergency plan, emergency procedure usage, facility layout, characteristics of a criticality event, radiation safety, first aid, and the use of protective equipment and monitoring devices. Position-specific training is also provided for members of the ERO.

Training is offered annually to offsite emergency support organization personnel. This training may include facility tours for familiarization, reentry procedures, facility hazards, access control, permitted fire suppression techniques, potential accident scenarios, emergency action levels, notification procedures, exposure guidelines, personnel monitoring devices, communications, contamination control, and the responding organizations’ roles in emergency conditions.

Radiological and SHINE facility orientation opportunities are offered biannually to local service personnel, such as news media and local government officials.

The SHINE Emergency Plan states that drills are primarily onsite tests of one or more portions of the integrated capability of emergency response plans, equipment, and organizations, with offsite support functions being simulated. An exercise is a type of drill that is a full-scale test of the ERO, in which offsite organizations are invited to participate. Drills of the onsite ERO are to be conducted annually and exercises where the OROs will be invited to participate are to be conducted every 2 years. Critiques of drills and exercises are to be conducted to identify items that need correction. An annual review of the emergency plan, EPIPs, and EALs will be conducted. A review of agreement letters, the emergency plan, and EPIPs will also be conducted every 2 years with responsible OROs.

Based on the above, the NRC staff finds that the information provided in section 11 of the SHINE Emergency Plan adequately addresses the elements necessary for maintaining an acceptable state of emergency preparedness for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.11 Conclusion

Based on the above, the NRC staff finds that the SHINE Emergency Plan meets the guidance in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015. Therefore, the staff concludes that SHINE has satisfied the applicable requirement of 10 CFR 50.34(b)(6)(v) that each application for an operating license include an FSAR that contains, among other things, the applicant’s plans for coping with emergencies, including the items specified in appendix E to 10 CFR Part 50.

12.4.8 Security Planning

The SHINE physical security plan (PSP) contains safeguards information and is protected from public disclosure.

The SHINE facility is located on a previously undeveloped property in the city of Janesville, Rock County, Wisconsin. The site boundary encompasses approximately 91 acres (36.8 hectares) of land. All security-related structures are located within a square area near the center of the property (42° 37’ 26.8” latitude and -89° 01’ 29.7” longitude).

The SHINE facility utilizes a non-reactor based subcritical fission process to produce medical isotopes. The process includes the combination of high-output deuterium tritium gas-target neutron sources with a low-enriched uranyl sulfate target solution containing special nuclear material (SNM) of moderate strategic significance enriched in the isotope uranium-235 (U-235) to just under 20 percent enrichment. Neutrons created by an accelerator-driven neutron source induce fission in the target solution creating molybdenum-99 (Mo-99) as a byproduct. Additional fission products are created because of the fission of U-235 and are regulated under 10 CFR Part 37. Eventually, the quantity of the fission products will reach the threshold values specified in 10 CFR Part 37, Appendix A. Therefore, SHINE will be subject to the physical protection regulations contained in 10 CFR 73.67 and 10 CFR Part 37.

The SHINE facility consists of several structures including the main production facility, resource building, storage building, material staging building, and the nitrogen purge structure. The main production facility is where the irradiated material is processed to separate medical isotopes and includes packaging the resulting materials for shipment to customers.

The NRC staff evaluated the SHINE PSP to determine whether it meets the requirements for the physical protection of SNM at fixed sites. Specifically, the staff reviewed the SHINE PSP to determine whether the applicable requirements of 10 CFR 73.67, paragraphs (a), (c), (d), and (e); 10 CFR 73.57; and 10 CFR 73.71 are met. The SHINE PSP would also include items specific to 10 CFR Part 37, which the staff will review as part of its inspection of SHINE’s implementation of the PSP. In conducting its review, the staff used the applicable guidance in RG 5.59, Revision 1, which contains acceptable criteria that licensees may use to develop

PSPs. For example, these criteria consider the establishment of elements in the PSP to address a site (1) security organization; (2) physical barriers; (3) access controls; and (4) detection, surveillance, and alarms. Additionally, as discussed below, the staff is conditioning the SHINE operating license to apply site-specific Supplemental Security Measures (SSMs) based on those contained in the enclosure to COMSECY-17-0008, “Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99,” dated February 22, 2017.

In COMSECY-17-0008, the NRC staff requested Commission approval of the staff’s approach to address physical protection and security at non-power production and utilization facilities intending to possess or use a Category II quantity of SNM for the production of Mo-99 for medical isotope production. The Commission responded in SRM-COMSECY-17-0008, “Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99,” dated August 1, 2017, approving the staff’s recommendation to use license conditions to address physical protection and security for such facilities. The Commission further stated that the staff should provide the Commission with a voting paper that comprehensively describes the security considerations or requirements and staff’s rationale for each consideration or requirement. Subsequent to the receipt by the NRC of SHINE’s construction permit application, the staff provided to the Commission SECY-18-0063, “Response to Staff Requirements Memorandum (SRM)-COMSECY-17-0008 on Physical Protection for Non-Power Production and Utilization Facilities Intending to produce Molybdenum-99,” dated June 4, 2018. In response, in SRM-SECY-18-0063, “Response to Staff Requirements Memorandum (SRM)-COMSECY-17-0008 on Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99,” dated September 26, 2019, the Commission approved the staff’s proposed SSMs, with the understanding that the staff would tailor the SSMs into risk-informed site-specific license conditions that allow for flexible implementation approaches and would provide a rationale for each implementation.

Consistent with the above, the NRC staff determined with respect to the SHINE operating license application that to ensure adequate protection, additional SSMs were required beyond the otherwise applicable physical protection requirements. The additional SSMs were developed in coordination with SHINE using the generic SSMs from COMSECY-17-0008. To incorporate these SSMs into the SHINE operating license, the staff conditions the license as follows:

> The licensee shall fully implement and maintain in effect all provisions of the Commission-approved physical security plan (PSP), entitled “SHINE Physical Security Plan,” designated Revision 2, and dated October 12, 2021, and all changes made thereto pursuant to the authority of 10 CFR 50.90 and 50.54(p). The site-specific supplemental security measures (SSMs) in Appendix [ ] are hereby incorporated into this license. The licensee shall fully implement and maintain in effect all of the SSMs in Appendix [ ]. The PSP must describe how the SSMs will be implemented. The PSP and Appendix [ ] contain Safeguards Information protected under 10 CFR 73.21.

The NRC staff’s review of the SHINE PSP is documented separately because it contains safeguards information and is protected from public disclosure. Based on this review, the staff determined that the proposed physical protection activities at the SHINE facility meet the applicable regulatory requirements and applicable portions of the SSMs. Specifically, the method and procedures outlined in the SHINE PSP satisfy the performance objectives, systems capabilities, and reporting requirements specified in the applicable regulatory requirements and applicable portions of the SSMs. Therefore, the staff concludes that the SHINE PSP is acceptable and provides reasonable assurance that SHINE's physical protection of SNM is not inimical to the common defense and security and does not constitute an unreasonable risk to public health and safety.

12.4.9 Quality Assurance

The NRC staff evaluated the sufficiency of the SHINE Quality Assurance Program Description (QAPD), Revision 19 (ML22164A053), by reviewing whether the relevant requirements of 10 CFR 50.34(b)(6)(ii) are satisfied by using the applicable guidance and acceptance criteria from section 12.9, "Quality Assurance," of NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," as endorsed in Regulatory Guide 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors" (ML093520099).

As part of its review of the SHINE construction permit application, the NRC staff approved the SHINE QAPD, Revision 7, as documented in NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility" (ML16229A140). For the SHINE operating license application, the staff reviewed Revision 19 of the QAPD. The substantive changes to the SHINE QAPD since the revision previously approved by the staff are the following:

- QAPD revision log was added that provides the history of changes;
- Section 1.3, "Definitions," was revised to add definitions derived from 10 CFR 21.3, "Definitions," related to commercial grade dedication of equipment and to delete the definition of safety-related structure, system, or component (SSC) and replace it with the definition of safety-related items.
- Section 2.1, "Organization," was revised with roles and responsibilities changes that were administrative improvements.
- Section 3, "Facility Operations," was added to include a description of the operational QA program.
- Enclosure 1, "SHINE Functional Organizational Chart," was revised to make it consistent with the information provided in Section 2.1 of the QAPD.
- Enclosure 2, "Graded Approach to Quality," was revised by deleting the definition of Quality Level-3.
- Enclosure 3, "Procedure that Implement the QAPD," was revised to include additional procedures and implementing procedure numbers with titles for SHINE and its contractor.

The NRC staff reviewed the revision log added to the SHINE QAPD and finds that it accurately describes the history of the changes to the QAPD and, therefore, is acceptable.

The NRC staff reviewed the definitions derived from 10 CFR 21.3 related to the commercial grade dedication of equipment that were added to section 1.3 of the SHINE QAPD, which are basic component, commercial grade item, critical characteristics, dedication, and dedicating entity. The staff previously reviewed and approved these SHINE-specific definitions (as an exemption from the requirements of 10 CFR 21.3), as documented in an NRC Safety Assessment, dated April 30, 2021 (ML21076A519). In that review, the staff concluded that the use of the SHINE-specific definitions and, consequently, the use of commercial grade items by SHINE dedicated consistent with the definitions, did not adversely affect the public health and safety. Further, the staff considered the requirements of 10 CFR 21.7, “Exemptions,” and concluded that granting the exemption was authorized by law and would not endanger life or property or the common defense and security and was otherwise in the public’s interest. The staff finds that the definitions added to Revision 19 of the SHINE QAPD are the same as those definitions that were previously approved. Therefore, the staff concludes that their addition is acceptable, and that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

The NRC staff reviewed the replacement in section 1.3 of the SHINE QAPD of the previously approved definition of safety-related SSC with the definition of safety-related items. The definition of safety-related items explicitly addresses items whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public. While the safety-related items definition no longer contains explicit thresholds in determining the acceptability of the consequences of a postulated event, SHINE has retained similar safety criteria for the classification of physical SSCs in the licensing basis, specifically, as described in section 3.1, “Design Criteria,” of the SHINE FSAR. The staff determined that the replacement of the definition of safety-related SSC with the definition of safety-related items is acceptable because this definition is appropriate for the SHINE facility and is consistent with ANSI/ANS-15.8-1995. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license

The NRC staff reviewed section 2.1 of the SHINE QAPD in which SHINE made the following administrative changes since the staff’s previous approval to reflect SHINE organizational changes: removing the role of the Chief Financial Officer; removing the role of the Director of Engineering Support and Auxiliary Systems and replacing it with the Engineering Support Manager; deleting Chief Operating Officer; adding Diagnostics General Manager; deleting Plant Manager; adding Director of Plant Operations; and adding Director of Corporate Support. SHINE also replaced the role of Director of Process Engineering with the role of Vice President of Engineering (VPE) and changed the VPE role reporting to the Chief Executive Officer; replaced the role of Procurement Manager with Supply Chain Director; replaced the role of Information Technology Manager with Vice President of Cybersecurity and Information Technology; changed the Director of Engineering Support and Auxiliary Systems reporting to the VPE; and modified the programmatic responsibility for Document Control and Records Management from the Director of Engineering Support to the Chief Operating Officer. Enclosure 1 of the QAPD was updated to reflect the administrative title changes. In addition, Enclosure 3 was revised to identify additional procedures and to update procedure numbers and titles of SHINE implementing procedures.

The NRC staff determined that SHINE’s changes to the QAPD to reflect organizational changes represent administrative improvements with organizational revisions that continue to maintain persons and organizations performing QA functions having the requisite authority and organizational freedom. The changes to Enclosure 3 are consistent with commitments made in previous revisions of the QAPD. The staff noted that implementing procedures were added to all activities included in section 2, “Design, Construction, and Modifications,” of the QAPD except for section 2.9, “Control of Special Processes.” The implementing procedures will be reviewed as part of the staff's inspection of SHINE's implementation of the QAPD. Based on the above, the staff concludes that these changes are acceptable and that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

The NRC staff previously determined in NUREG-2189 that sections 2.2 through 2.18 of the SHINE QAPD are acceptable. The staff notes that SHINE did not make any changes to these sections of the QAPD. Therefore, the staff concludes that the information provided by these sections meets the applicable acceptance criteria and is sufficient for the issuance of an operating license.

Section 3 of the SHINE QAPD describes the elements of a QA program for the conduct of operations at the SHINE facility. The SHINE QAPD also establishes that some requirements of the QA program for operations may be found in documents other than the QAPD, such as the SHINE Training Program, Emergency Plan, PSP, TSs, and Radiation Protection Program, and are, therefore, not duplicated in the QA program. The NRC staff notes that there is no specific requirement to place these programs, plans, or TSs in the QA program. SHINE established its facility operations QA program based on ANSI/ANSI-15.8-1995.

The NRC staff evaluated the sufficiency of the SHINE QA program controls for the conduct of operations at the SHINE facility against applicable regulatory requirements using appropriate regulatory guidance and acceptance criteria. On the basis of its review, the staff determined that the level of SHINE's commitment to establish a QA program for the conduct of facility operations is adequate and supports applicable acceptance criteria in section 12.9 of NUREG-1537, Part 2, as supplemented by section 12.9 of the ISG augmenting NUREG-1537, Part 2, and ANSI/ANSI-15.8-1995. Accordingly, the staff concludes that the information provided satisfies the relevant requirements of 10 CFR 50.34(b)(6)(ii) and is, therefore, sufficient for the issuance of an operating license.

Section 4, "Applicability to Existing Facilities," of the SHINE QAPD states that "The SHINE facility will be a newly constructed facility and this section does not apply." The NRC staff determined that the SHINE facility will only include structures that are newly constructed. Therefore, the staff concludes that a discussion of the applicability of the QA program to existing facilities is not necessary to include in the SHINE QAPD.

Section 5, "Decommissioning," of the SHINE QAPD states that this section will be updated at a later date. The NRC staff defers the review of this section until the receipt of a decommissioning plan under 10 CFR 50.82(b). Following receipt of the decommissioning plan, the staff will confirm that this issue has been resolved.

Based on its review, the NRC staff finds that SHINE's organizational changes in Enclosure 1 are changes that represent administrative improvements with organizational revisions that continue to maintain that persons and organizations performing quality assurance functions have the requisite authority and organizational freedom. Therefore, the staff finds these changes acceptable. The staff also finds that SHINE's modifications and additions to Enclosure 3 are consistent with commitments made in previous revisions of the QAPD to include procedure numbers and titles of implementing procedures. Therefore, the staff finds these changes acceptable. The staff notes that implementing procedures are added to all activities included in Section 2 of the QAPD except for "Control of Special Processes." SHINE committed to develop an implementing procedure for this activity prior to the issuance of the operating license. The adequacy of the implementing procedures will be reviewed as part of the staff's inspection of

SHINE's implementation of the QAPD. Finally, the staff finds that removing Quality Level-3 from Enclosure 2 is acceptable because SHINE continues to maintain a graded approach to quality by applying Quality Level-1 and Quality Level-2 consistent with the importance to safety and reliability of SSCs.

Based on its evaluation of the SHINE QAPD, Revision 19, described in section 12.9 of the SHINE FSAR, and its previous evaluation in NUREG-2189, the NRC staff finds that the SHINE QA program meets the guidance in section 12.9 of NUREG-1537, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.8-1995, endorsed by the NRC in RG 2.5, Revision 1. Therefore, the staff concludes that the SHINE QA program satisfies the relevant requirements of 10 CFR 50.34(b)(6)(ii) for the design, fabrication, construction, and operation of the SHINE facility.

12.4.10 Operator Training and Requalification

The NRC staff evaluated the sufficiency of the SHINE licensed operator requalification training program, as described in section 12.10 of the SHINE FSAR and in Enclosure 12, "Licensed Operator Continuing Training Program," to the SHINE operating license application (ML19211C141), using the applicable guidance and acceptance criteria from section 12.10, "Operator Training and Requalification," of NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2. During the staff review, SHINE provided responses to staff RAIs (ML21307A306) and (ML21350A191), which were incorporated into revisions to the licensed operator requalification training program, where appropriate. Therefore, the below review concerns Revision 2 of the SHINE licensed operator continuing training program (ML21350A191).

The NRC staff also evaluated the sufficiency of the SHINE licensed operator initial training program, as described in section 12.10 of the SHINE FSAR and in Enclosure 13, "Licensed Operator Initial Training Program," to the SHINE operating license application (ML19211C144). During the staff review, SHINE provided a revision to the licensed operator initial training program along with the aforementioned responses to staff RAIs. Therefore, the below review concerns Revision 1 of the SHINE licensed operator initial training program (ML21307A306).

12.4.10.1 Licensed Operator Requalification Training Program

Under 10 CFR 50.34(b)(8), each application for a facility operating license must include a description and plans for implementation of a licensed operator requalification program that must as a minimum meet the requirements contained in 10 CFR 55.59, "Requalification." Section 1.1, "Purpose," of the SHINE licensed operator continuing training program states that this program ensures that suitable proficiency is achieved and maintained, satisfying the requirements of 10 CFR 55.59 and in accordance with ANSI/ANS-15.4-2016 and SHINE proposed TS 5.1.4, "Selection and Training of Personnel," states that ANSI/ANS-15.4-2016 is used in the selection and training of personnel. Accordingly, the NRC staff evaluated the sufficiency of this program using the applicable regulations and using the applicable guidance and acceptance criteria from section 12.10 of NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2, for consistency with the applicable guidance in ANSI/ANS-15.4-2016, and for appropriateness for the SHINE facility.

Chapter 1 – Introduction

Chapter 1, "Introduction," of the SHINE licensed operator continuing training program discusses purpose and scope, overview, applicability and effectiveness, evaluations and revisions, and document reviews. The information in this chapter is administrative in nature, with the exception of one more substantive issue, which is discussed next.

Section 1.3, "Overview," of the SHINE licensed operator continuing training program states that licensed operators will be enrolled into the licensed operator continuing training program within three months after their operating license is issued. The NRC staff notes that there are no specific requirements in 10 CFR Part 55 and no specific guidance in ANSI/ANS-15.4-2016 related to the timing of a newly licensed operator's enrollment in a requalification program. Paragraph (h) of 10 CFR 55.53, "Conditions of licenses," requires, as a condition of their licenses, that licensed operators complete a requalification program as described by 10 CFR 55.59, which, in turn, states that licensed operators must successfully complete a requalification program developed by the facility licensee that has been approved by the NRC. NUREG-1262, "Answers to Questions at Public Meetings Regarding Implementation of Title 10, Code of Federal Regulations, Part 55 on Operators' Licenses" (ML15198A217), provides that facilities have flexibility with respect to the implementation of requalification programs as long as the program meets its objectives. Therefore, the staff determined that this enrollment timeframe is adequate and acceptable.

Based on its review, the NRC staff finds that the information in chapter 1 of the SHINE licensed operator continuing training program is acceptable because it is largely administrative in nature, not contrary to the NRC's regulations or the guidance in ANSI/ANS-15.4-2016, and adequately describes the elements and objectives of the program in sufficient detail for the staff to review the rest of the program. The enrollment of licensed operators into the licensed operator continuing training program within three months after operator license issuance is also acceptable and not contrary to regulations or guidance. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 2 – Definitions

Chapter 2, "Definitions," of the SHINE licensed operator continuing training program describes terms having special meaning unique to the SHINE facility or that are necessary to understand aspects of the program. Specifically, the following definitions are included: annual requalification cycle, biennial requalification cycle, controls, graded approach to training, on-the-job training, quarterly, and simulation-based learning. The NRC staff reviewed these definitions for conformance with regulatory requirements and consistency with guidance, as applicable.

The proposed definition for "annual requalification cycle" is "[t]ime period corresponding to a 12-month interval comprising half of a biennial requalification cycle per ANSI/ANS-15.4-2016 Section 6.2." The NRC staff determined that this definition conforms with requirements in 10 CFR Part 55 and is consistent with the guidance in section 6.2 of ANSI/ANS-15.4-2016; therefore, it is adequate and acceptable.

The proposed definition for "biennial requalification cycle" is "[t]ime period corresponding to a 24-month interval that the requalification program is conducted in per ANSI/ANS-15.4-2016 Section 6.2. Each biennial requalification cycle is immediately followed by another 24-month cycle." The NRC staff determined that this definition conforms with 10 CFR 55.59(c)(1), "Schedule," meets the acceptance criteria for program duration in section 12.10 of

NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, and is consistent with the guidance in section 6.2 of ANSI/ANS-15.4-2016; therefore, it is adequate and acceptable.

The proposed definition for “controls” is “1) Apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of an Irradiation Unit (IU). 2) Apparatus and mechanisms, the manipulation of which could affect the chemical, physical, metallurgical, or nuclear process of the facility in such a manner as to affect the protection of health and safety against radiation.” The NRC staff determined that the first definition of controls conforms with 10 CFR 50.2, “Definitions,” and 10 CFR 55.4, “Definitions,” as applicable to the SHINE facility, because it is consistent with those definitions except for omitting the phrase “when used with respect to a nuclear reactor” and changing “of the reactor” to “of an Irradiation Unit (IU).” This definition is appropriate for the SHINE facility because, although their reactivity and power level may be affected, the SHINE facility IUs are not nuclear reactors or reactors as those terms are used in 10 CFR 50.2 and 10 CFR 55.4. The staff also determined that the second definition of controls conforms with 10 CFR 50.2 because it uses the same language as the second definition of controls in 10 CFR 50.2 and this definition is appropriate for the SHINE facility. Therefore, the definition is adequate and acceptable.

The proposed definition for “graded approach to training” is “[a] method of streamlining parts of the systematic approach to training (SAT) process, tying each of the five phases of SAT together in more efficient information management.” SAT is defined in 10 CFR 55.4 as a training program that includes five specific elements. Because SHINE’s proposed definition includes the use of each of the five elements of SAT, although in a streamlined manner, the NRC staff finds that the definition is adequate and acceptable.

The proposed definition for “on-the-job training” is “[p]erformance-based training (conducted in environment that replicates as much as possible the actual task conditions) through which trainees learn how to perform a task, and the task related knowledge and skills.” 10 CFR 55.4 does not contain a definition for “on-the-job training.” 10 CFR 55.59(c)(3), “On-the-job training,” requires that the requalification program include on-the-job training and 10 CFR 55.59(c)(3)(i)-(v) provides specific types of on-the-job training that must be completed by licensed operators, as applicable. ANSI/ANS-15.4-2016 defines “on-the-job training” as “[a] systematic, structured method using a qualified person to provide the required job-related knowledge and skills to a trainee, usually in the actual workplace, with proficiency documented.” Section 2.2, “Definitions,” of ANSI/ANS-15.4-2016 provides definitions that “will be useful in understanding this [standard] and companion or reference standards,” but these definitions do not necessarily constitute a requirement or recommendation. Although the SHINE definition of “on-the-job training” is different than that in ANSI/ANS-15.4-2016, it is not contrary to the discussion of on-the-job training in the NRC’s regulations. Therefore, the NRC staff finds that the definition is adequate and acceptable.

The proposed definition for “quarterly” is “[t]ime period corresponding to a calendar quarter.” The NRC staff determined that this definition conforms with requirements in 10 CFR Part 55 and is consistent with the guidance in section 6.5 of ANSI/ANS-15.4-2016; therefore, it is adequate and acceptable.

The proposed definition for “simulation-based learning” is “[a] technique to replace and amplify real experiences with guided ones, often ‘immersive’ in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion. Simulation-based learning may or may not include an actual simulation device.” 10 CFR 55.4 does not contain a definition for “simulation-based learning.” 10 CFR 55.59(c)(3)(v) states, in part, that “[i]f the simulator or simulation device is used to administer operating tests for a facility, as provided in [10 CFR] 55.45(b)(1), the device approved to meet the requirements of [10 CFR] 55.45(b)(1) must be used for credit to be given for meeting the requirements of [10 CFR 55.59(c)(3)(i)(G)-(AA)].” 10 CFR 55.59(c)(4)(iv) states, in part, that “[i]f a simulator is used in meeting the requirements of [10 CFR 55.59(c)(4)(iii)], it must accurately reproduce the operating characteristics of the facility involved and the arrangement of the instrumentation and controls of the simulator must closely parallel that of the facility involved.” Although SHINE has not submitted a request for approval of a simulator or simulation device, the definition provides SHINE with the future flexibility of incorporating a simulation device. Based on the above, the NRC staff did not identify this definition as contrary to the NRC’s regulations. Therefore, the staff finds that the definition is adequate and acceptable.

Based on its review, the NRC staff finds that the definitions in chapter 2 of the SHINE licensed operator continuing training program are not contrary to the NRC’s regulations, are consistent with the guidance in ANSI/ANS-15.4-2016, and are appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

<u>Chapter 3 – Responsibilities</u>

Chapter 3, “Responsibilities,” of the SHINE licensed operator continuing training program contains program-applicable positions and position responsibilities. The information in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information in chapter 3 is acceptable because it is administrative in nature, not contrary to the NRC’s regulations, consistent with the guidance in ANSI/ANS-15.4-2016, and adequately describes the responsibilities of those individuals involved in the continuing training program in sufficient detail for the staff to review the rest of the program. Therefore, this information is sufficient for the issuance of an operating license.

<u>Chapter 4 – Program Requirements</u>

Chapter 4, “Program Requirements,” of the SHINE licensed operator continuing training program contains several different categories of requalification requirements. The NRC staff reviewed the program requirements for conformance with regulatory requirements, consistency with guidance, and appropriateness for the SHINE facility, as applicable.

Under 10 CFR 55.59(c)(2), “Lectures,” the requalification program must include preplanned lectures on a regular and continuing basis throughout the license period in those areas where operator and senior operator written examinations and facility experience indicate that emphasis in scope and depth of coverage is needed for the subjects listed in 10 CFR 55.59(c)(2)(i)-(ix). Table 4-1, “Continuing Training Program Requirements,” of the SHINE licensed operator continuing training program provides that training lectures will be performed on a quarterly periodicity. Section 4.3, “Training Scope,” of the SHINE licensed operator continuing training program states that licensed operator continuing training includes knowledge of topics listed in Attachment A to the program, which are modified for applicability to the SHINE facility. SHINE stated that the specific content of the training sessions will be based on a number of items that can be considered as facility operating experience. The NRC staff determined that this conforms with 10 CFR 55.59(c)(2), meets the acceptance criteria for preplanned lectures contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, and is appropriate for the SHINE facility. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(i), the requalification program must include on-the-job training so that each licensed operator manipulates the plant controls and each licensed senior operator either manipulates the controls or directs the activities of individuals during plant control manipulations during the term of the licensed operator's or senior operator's license that are applicable to the plant design and involve reactivity control manipulations. Chapter 4 of the SHINE licensed operator continuing training program provides that the program will be administered, in part, through on-the-job training. Table 4-1 of the SHINE licensed operator continuing training program provides that ten reactivity manipulations will be performed once per annual requalification cycle. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(i), meets the acceptance criteria for on-the-job training contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, and is appropriate for the SHINE facility. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(ii), the requalification program must include on-the-job training so that each licensed operator and senior operator has demonstrated satisfactory understanding of the operation of the apparatus and mechanisms associated with the control manipulations in 10 CFR 55.59(c)(3)(i) applicable to the facility and knows the operating procedures in each area for which the operator or senior operator is licensed. Section 4.3 of the SHINE licensed operator continuing training program states that the scope of the training includes knowledge of topics listed in Attachment A to the program, which include facility design and operating procedures. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(ii), meets the acceptance criteria for on-the-job training contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, and is appropriate for the SHINE facility. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(iii), the requalification program must include on-the-job training so that each licensed operator and senior operator is cognizant of facility design changes, procedure changes, and facility license changes. Section 1.3 of the SHINE licensed operator continuing training program states that document reviews will be conducted to ensure that licensed individuals are cognizant of all design, procedure, and license changes, as appropriate. Table 4-1 of the SHINE licensed operator continuing training program provides that continuing training on facility design, procedure, and license changes will be performed on an as applicable periodicity. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(iii) and meets the acceptance criteria for on-the-job training contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(iv), the requalification program must include on-the-job training so that each licensed operator and senior operator reviews the contents of all abnormal and emergency procedures on a regularly scheduled basis. Table 4-1 of the SHINE licensed operator continuing training program provides that abnormal and emergency procedure reviews are performed once per annual requalification cycle. Additionally, as discussed previously, document reviews related to any procedure changes are performed on an as applicable periodicity. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(iv) and meets the acceptance criteria for on-the-job training contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(v), a simulator may be used in meeting the requirements of 10 CFR 55.59(c)(3)(i) and (ii). SHINE has not provided any additional information on the use of a simulator or simulation device. Additionally, as discussed previously, the NRC staff noted that SHINE has not submitted a request for approval of a simulator or simulation device.

Under 10 CFR 55.59(c)(4)(i), the requalification program must include comprehensive requalification written examinations and annual operating tests which determine areas in which retraining is needed for licensed operator and senior operator knowledge. Sections 5.1 and 5.2 of the SHINE licensed operator continuing training program provide that an annual operating evaluation and biennial written examination will be used to verify operator knowledge. For the operating test, this evaluation requires that operators demonstrate an understanding of and an ability to perform the actions necessary to accomplish a broad sample of topics listed in 10 CFR 55.45, “Operating tests,” paragraphs (a)(1) through (13), as applicable. The biennial written examinations will be used to verify operator knowledge, and preplanned training sessions will be used to address any deficiencies identified through the written examination. Sections 5.4 and 5.5 of the SHINE licensed operator continuing training program provides that a score of 70 percent on the written examination requires no additional retraining. A score of 65 percent to 69 percent will require retraining in areas or topics where weaknesses or deficiencies were identified. A score of lower than 65 percent will require an evaluation by the Operations Manager or designee within 30 days to identify the deficiencies requiring remediation, with the removal of the operator from licensed duties pending completion of any retraining and retesting. The NRC staff determined that the program implementation of annual operating tests and biennial written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(i) and meets the acceptance criteria contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(ii), the requalification program must include written examinations which determine licensed operators’ and senior operators’ knowledge of subjects covered in the requalification program and provide a basis for evaluating their knowledge of abnormal and emergency procedures. Section 4.3 of the SHINE licensed operator continuing training program provides that the scope of training includes knowledge of topics listed in Attachment A, including abnormal and emergency procedures. Additionally, table 4-1 of the SHINE licensed operator continuing training program provides that abnormal and emergency procedure reviews will be completed once per annual requalification cycle and that comprehensive written examinations will be completed once per biennial requalification cycle. The NRC staff determined that the program implementation of biennial written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(ii) and meets the acceptance criteria contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537 Part 2. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(iii), the requalification program must include systematic observation and evaluation of the performance and competency of licensed operators and senior operators by supervisors and/or training staff members, including evaluation of actions taken or to be taken during actual or simulated abnormal and emergency procedures. Section 4.3 of the SHINE licensed operator continuing training program provides that observations of operator performance will be made and that weaknesses in the training program or operator knowledge as determined by operating events, examination results, and crew or individual performance gaps will be identified. Section 4.3 further provides that the scope of training includes knowledge of topics listed in Attachment A and that the sequence and methodology of training will be based upon the training approach (e.g., simulation). Attachment A includes emergency and abnormal operating procedures, conditions of license (e.g., job observations), and the emergency plan. Additionally, chapter 6, “Program Review and Evaluation,” of the SHINE licensed operator continuing training program states that training effectiveness will be determined throughout the continuing training cycle based primarily on operator performance and oversight of the Operations Department by management, training, and supervisory personnel. The NRC staff determined that the program implementation of systematic observations and evaluations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(iii) and meets the acceptance criteria contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(iv), the requalification program must include simulation of emergency or abnormal conditions that may be accomplished by using the control panel of the facility involved or by using a simulator. Section 4.3 of the SHINE licensed operator continuing training program states that the scope of training includes knowledge of topics listed in Attachment A and that the sequence and methodology of the training will be based upon the training approach (e.g., simulation). Attachment A includes emergency and abnormal operating procedures, conditions of license (e.g., job observations), and the emergency plan. As the NRC staff evaluated above, SHINE proposed a definition for “simulation-based learning” that may or may not include an actual simulation device and SHINE has not submitted a request for approval of a simulator or a simulation device. The staff determined that the program implementation of simulation of emergency or abnormal conditions conforms with the applicable requirements of 10 CFR 55.59(c)(4)(iv) and meets the acceptance criteria contained in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.53(e), to maintain their license in active status, a licensed operator or a licensed senior operator is required to actively perform licensed functions for a specified amount of time per calendar quarter. Under 10 CFR 55.53(f), to restore a license to active status, a licensed operator or a licensed senior operator is required to perform a minimum amount of time of licensed functions under the direction of another operator or senior operator as appropriate. Table 4-1 of the SHINE licensed operator continuing training program provides that operators are to perform four hours of licensed duties on a quarterly basis, which is consistent with the timing requirements specific to research and test reactors in 10 CFR 55.53(e). Additionally, chapter 4 of the SHINE licensed operator continuing training program states that “[l]icensed operators and senior licensed operators who have not met the periodicity requirements for proficiency in Table 4-1 will perform a minimum of six hours of licensed duty under the direction of a qualified individual holding the same or higher-level license prior to being reinstated,” which is consistent with the timing requirements specific to research and test reactors in 10 CFR 55.53(f)(2). Since the SHINE facility is not a research and test reactor, SHINE submitted a request for exemption, under 10 CFR 55.11, “Specific exemptions,” from the requirements of 10 CFR 55.53(e) and 10 CFR 55.53(f) in order to allow it to use the timing requirements specific to research and test reactors as opposed to the timing requirements applicable to all other facilities (ML21350A190). The NRC staff review of that exemption follows.

Under 10 CFR 55.11, the NRC may, upon application by an interested person, or upon its own initiative, grant such exemptions from the requirements of the regulations in 10 CFR Part 55 as it determines are authorized by law and will not endanger life or property and are otherwise in the public interest.

The NRC has acknowledged the similarities of the SHINE facility and research and test reactors, including similarities of size, scope, and safety considerations. While the IUs at the SHINE facility represent new technology, the accelerator and neutron multiplier add sufficient external neutrons to the TSV to achieve a fission rate with a thermal power level comparable to that of research reactors typically licensed under 10 CFR Part 50 as utilization facilities (i.e., 5 watts to 20 megawatts). Specifically, the thermal power level of each of the eight of the SHINE facility IUs is 125 kilowatts, for a total of 1 megawatt, which is comparable to the thermal power level of research reactors and of a significantly smaller size and scope than that of power reactors. This smaller scope is also demonstrated by the fact that there are no postulated accident sequences that credit operator actions to mitigate the consequences of an event at the SHINE facility. Additionally, the SHINE facility IUs have many safety considerations that are similar to those of research reactors, including:

- Provisions for fission heat removal during operation.
- Considerations of decay heat generation after shutdown.
- Similarity of reactivity feedback mechanisms to research reactors.
- Control of fission gas release during operation and subsequent gas management engineering safety features.
- Control of fission product inventory buildup.
- Accident scenarios similar to research reactors, such as loss of coolant, reactivity additions, and release of fission products.

Application of the research and test reactor periodicity requirements in 10 CFR 55.53(e) and 10 CFR 55.53(f) to the SHINE facility would also be consistent with the applicable guidance. Specifically, with respect to the licensing of radioisotope production facilities and aqueous homogeneous reactors, the ISG augmenting NUREG-1537 provides that NUREG-1537 is applicable and NUREG-1537, in turn, provides that the research and test reactor periodicity requirements in 10 CFR 55.53(e) and 10 CFR 55.53(f) are applicable.

Based on the similarity of size, scope, and safety considerations of the SHINE facility as compared to research and test reactors and based on the applicable guidance, the NRC staff determined that the application of the research and test reactor periodicity requirements in 10 CFR 55.53(e) and 10 CFR 55.53(f) to the SHINE facility will ensure that licensed operators and senior operators will reasonably maintain or restore active status. Therefore, the staff finds that the requested exemption will not endanger life or property.

The NRC staff also determined that the requested exemption will be otherwise in the public interest because its approval will allow SHINE to maintain licensed operator and senior operator active status requirements in a cost-efficient manner to support the domestic commercial production of Mo-99 with no loss of safety.

Finally, the NRC staff has the ability to grant exemptions under 10 CFR 55.11. The staff determined that the requested exemption is permissible under the Atomic Energy Act of 1954, as amended, and that no other prohibition of law exists to preclude the activities that would be authorized by the exemption. Accordingly, the staff finds that granting the requested exemption is in accordance with law.

The requirements from which the exemption is sought involve education, training, experience, qualification, requalification or other employment suitability requirements and the NRC staff approval of the requested exemption is categorically excluded under 10 CFR 51.22(c)(25), and there are no extraordinary circumstances present that would preclude reliance on this exclusion. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the approval of the requested exemption.

Based on the above, and in conjunction with the license condition discussed below, the NRC staff grants the requested exemption such that SHINE may use the 10 CFR 55.53(e) and 10 CFR 55.53(f) timing requirements specific to research and test reactors as opposed to the timing requirements applicable to all other facilities. Accordingly, the staff finds that the discussion in the SHINE licensed operator continuing training program with respect to proficiency is consistent with 10 CFR 55.53(e) and 10 CFR 55.53(f), as exempted, and the SHINE operating license, as conditioned, and, therefore, is adequate and acceptable.

Under 10 CFR 55.21, "Medical examination," and 10 CFR 55.53(i), a licensed operator or licensed senior operator is required to have a medical examination by a physician every 2 years. Section 4.1 of the SHINE licensed operator continuing training program states that a medical evaluation is required for licensed operators and licensed senior operators once every 2 years with the periodic examination being completed no later than the last day of the 12^{th} month of the second year in accordance with section 7.1.2 of ANSI/ANS-15.4-2016. The NRC staff notes that this reflects that the medical examination must be completed within a 2-year period from the date of the initial or previous medical examination and that the periodicity is not extendable by an additional grace period. The staff determined that the program implementation of medical examinations for licensed operators and licensed senior operators conforms with the applicable requirements of 10 CFR 55.21 and 10 CFR 55.53(i) and, therefore, is adequate and acceptable.

Section 8, "Fitness for duty," of ANSI/ANS-15.4-2016 describes elements of a program or policy to ensure that licensed individuals are fit to perform licensed duties. Additionally, ANSI/ANS-15.4-2016 states that all licensed personnel shall adhere to the established policy or program, including drug testing if required. Under 10 CFR 55.53(j), licensed operators and licensed senior operators shall not use, possess, or sell any illegal drugs and shall not perform activities authorized by their license while under the influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect their ability to safely and competently perform licensed duties. Section 4.2 of the SHINE licensed operator continuing training program states that licensed operators are required to adhere to fitness for duty requirements as described in the SHINE employee handbook. The NRC staff determined that this conforms with the applicable requirements of 10 CFR 55.53(j) and is consistent with ANSI/ANS-15.4-2016. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 50.74, "Notification of change in operator or senior operator status," facility licensees are required to notify the NRC within 30 days of a change in licensed operator or licensed senior operator status. Section 4.4 of the SHINE licensed operator continuing training program states that the changes in operator status, as outlined in 10 CFR 50.74, will be communicated to the NRC within 30 days. The NRC staff determined that this conforms with 10 CFR 50.74 and, therefore, is adequate and acceptable.

Based on its review, the NRC staff finds that the program requirements in chapter 4 of the SHINE licensed operator continuing training program meet the applicable regulatory requirements and acceptance criteria and are appropriate for the SHINE facility. Therefore, the program requirements are sufficient for the issuance of an operating license.

Chapter 5 – Examinations

Chapter 5, "Examinations," of the SHINE licensed operator continuing training program contains requalification requirements related to evaluations. The NRC staff reviewed these requirements for conformance with regulatory requirements, consistency with guidance, and appropriateness for the SHINE facility, as applicable.

Under 10 CFR 55.59(c)(4)(i), the requalification program must include, in part, comprehensive requalification written examinations that determine areas in which retraining is needed to upgrade licensed operator and licensed senior operator knowledge. Under 10 CFR 55.59(c)(4)(ii), the requalification program must include written examinations that determine licensed operators' and licensed senior operators' knowledge of subjects covered in the program and provide a basis for evaluating their knowledge of abnormal and emergency procedures. Under 10 CFR 55.59(a)(2)(i), the written examination must sample the items specified in 10 CFR 55.41, "Written examination: Operators," and 10 CFR 55.43, "Written examination: Senior operators," to the extent applicable to the facility, the licensee, and any limitation of the license under 10 CFR 55.53(c). Section 5.2 of the SHINE licensed operator continuing training program states that biennial written examinations will be used to verify the operator's knowledge and that preplanned training sessions will be used to retrain those operators who demonstrate deficiencies in any part of the examination. Section 4.3 of the SHINE licensed operator continuing training program states that the scope of training includes the topics listed in Attachment A of the program, which are based, in relevant part, on the requirements of 10 CFR 55.41, modified for applicability to the SHINE facility. The NRC staff determined that Attachment A provides a list of licensed operator training material topics applicable to both licensed operators and licensed senior operators that is consistent with the topics in 10 CFR 55.41, to the extent applicable to SHINE, and a list of senior licensed operator training material topics applicable to licensed senior operators that is consistent with the topics in 10 CFR 55.43, to the extent applicable to SHINE. The staff determined that the program implementation of written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(i), 10 CFR 55.59(c)(4)(ii), and 10 CFR 55.59(a)(2)(i) and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(i), the requalification program must include, in part, annual operating tests that determine areas in which retraining is needed to upgrade licensed operator and licensed senior operator knowledge. Under 10 CFR 55.59(a)(2)(ii) the operating test must require the operator or senior operator to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a comprehensive sample of items specified in 10 CFR 55.45(a)(2)-(13) inclusive to the extent applicable to the facility. Section 5.1 of the SHINE licensed operator continuing training program states that an annual operating evaluation is administered to each licensed operator and licensed senior operator consisting of a broad sample of applicable items specified in 10 CFR 55.45(a)(1)-(13) inclusive to the extent applicable. Section 4.3 of the SHINE licensed operator continuing training program states that the scope of training includes the topics listed in Attachment A of the program, which are based, in relevant part, on the requirements of 10 CFR 55.45, modified for applicability to the SHINE facility. The NRC staff determined that Attachment A provides a list of licensed operator and senior licensed operator training material topics applicable to licensed operators and licensed senior operators that is consistent with the topics in 10 CFR 55.45, to the extent applicable to SHINE. The staff determined that the program implementation of annual operating tests conforms with the applicable requirements of 10 CFR 55.59(c)(4)(i) and 10 CFR 55.59(a)(2)(ii) and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(v), the requalification program must include provisions for each licensed operator and licensed senior operator to participate in an accelerated requalification program where performance evaluations conducted pursuant to 10 CFR 55.59(c)(4)(i)-(iv) clearly indicate the need. Section 6.3, "Evaluation and retraining," of ANSI/ANS-15.4-2016 describes the scoring criteria for requalification. Section 5.5 of the SHINE licensed operator continuing training program outlines provisions for accelerated requalification if performance evaluations indicated the need. Specifically, sections 5.4 and 5.5 of the SHINE licensed operator continuing training program discuss acceptance criteria for all graded examinations, operator status during retraining, performance evaluation and retraining time frames, determination of retraining content, and acceptance criteria to complete retraining. The NRC staff determined that the program implementation of accelerated requalification conforms with the applicable requirements of 10 CFR 55.59(c)(4)(v), is consistent with ANSI/ANS-15.4-2016, and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Based on its review, the NRC staff finds that the implementation of examinations in chapter 5 of the SHINE licensed operator continuing training program meets the applicable regulatory requirements and acceptance criteria and is appropriate for the SHINE facility. Therefore, the implementation of examinations is sufficient for the issuance of an operating license.

Chapter 6 – Program Review and Evaluation

Chapter 6, "Program Review and Evaluation," of the SHINE licensed operator continuing training program contains information on programmatic evaluation. The NRC staff reviewed this information for conformance with regulatory requirements, consistency with guidance, and appropriateness for the SHINE facility, as applicable.

Under 10 CFR 50.36(c)(5), TSs must include items in the category of administrative controls, which includes provisions relating to review and audit, necessary to assure operation of the facility in a safe manner. The foreword of ANSI/ANS-15.4-2016 provides that administrative and organizational requirements and structures, including reviews and audits, are found in companion standard ANSI/ANS-15.1-2007. Section 6.2.4, "Audit function," of ANSI/ANS-15.1-2007 describes the review and audit functions that are to be established, which include, in relevant part, audits for the retraining and requalification program for the operating staff to be conducted at least once every other calendar year with the interval between audits not to exceed 30 months. SHINE proposed TS 5.2.4.1.b incorporates this audit function into the SHINE licensing basis. Separately, chapter 6 of the SHINE licensed operator continuing training program states that the program is assessed at least once every biennium, with an interval between assessments not to exceed 24 months. The NRC staff notes that although it is inconsistent with the SHINE proposed TSs and ANSI/ANS-15.1-2007, the periodicity of the programmatic evaluation in the SHINE licensed operator continuing training program is more conservative than the TSs and ANSI/ANS-15.1-2007. The staff determined that the program implementation of programmatic evaluation conforms with the applicable requirements of 10 CFR 50.36(c)(5) and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable and sufficient for the issuance of an operating license.

Chapter 7 – Records

Chapter 7, “Records,” of the SHINE licensed operator continuing training program contains requirements related to recordkeeping. The NRC staff reviewed these requirements for conformance with regulatory requirements, consistency with guidance, and appropriateness for the SHINE facility, as applicable.

Under 10 CFR 55.59(c)(5), “Records,” the types and retention period of requalification program documentation are specified. Sections 7.1, 7.2, and 7.3 of the SHINE licensed operator continuing training program provide information on the record storage system, record formats, and an illustrative list of the programmatic and individual records that will be retained. Section 7.4 of the SHINE licensed operator continuing training program states that “[r]ecords of training and qualification of Operations Department personnel shall be maintained for the duration of the currently valid license.” SHINE proposed TS 5.9.2 states, in part, that records of meeting and audit reports of the review and audit committee will be maintained for a period of at least five years. SHINE proposed TS 5.9.3 states that records of retraining and requalification of operations personnel who are licensed pursuant to 10 CFR Part 55 shall be maintained at all times while the individual is employed as a licensed operator or until the license is renewed. The NRC staff determined that the program implementation of recordkeeping conforms with the applicable requirements of 10 CFR 55.59(c)(5) and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds that this is adequate and acceptable.

Based on its review, the NRC staff finds the implementation of recordkeeping in chapter 6 of the SHINE licensed operator continuing training program meets the applicable regulatory requirements and acceptance criteria and is appropriate for the SHINE facility. Therefore, the implementation of recordkeeping is sufficient for the issuance of an operating license.

Conclusion

The NRC staff reviewed the SHINE licensed operator continuing training program. The staff determined that the program conforms with the applicable regulations, meets the acceptance criteria in NUREG-1537 and the ISG augmenting NUREG-1537, is consistent with the applicable guidance, and is appropriate for the SHINE facility. Therefore, the staff concludes that in accordance with 10 CFR 50.34(b)(8), SHINE has included a description and plans for implementation of a licensed operator requalification program that meets the applicable requirements contained in 10 CFR 55.59.

12.4.10.2 Licensed Operator Initial Training Program

Under 10 CFR 50.34(b)(6)(i), each application for a facility operating license must include information concerning facility operation, including personnel qualifications requirements. Under 10 CFR Part 55, the NRC establishes the procedures and criteria for the issuance of licenses to operators and senior operators of utilization facilities, including the requirement that applicants for an operator or senior operator license successfully complete the facility licensee’s requirements to be licensed as an operator or senior operator and that evidence of this may be in the form of a certification that the applicant has successfully completed a Commission-approved training program that is based on a systems approach to training. The SHINE licensed operator initial training program describes how applicants for operator and senior operator licenses at the SHINE facility will be prepared for licensure under 10 CFR Part 55. Section 1.2, “Scope,” of the SHINE licensed operator initial training program states that this program complies with the applicable portions of 10 CFR Part 55 and follows the guidance of ANSI/ANS-15.4-2016 and SHINE proposed TS 5.1.4 states that ANSI/ANS-15.4-2016 is used in selection and training of personnel and compliance is maintained with 10 CFR Part 55, as it pertains to non-power facilities. Accordingly, the NRC staff evaluated the sufficiency of this program using the applicable regulations and using the applicable guidance and acceptance criteria from section 12.10 of NUREG-1537, Parts 1 and 2, and from the ISG augmenting NUREG-1537, Parts 1 and 2, for consistency with the applicable guidance in ANSI/ANS-15.4-2016, and for appropriateness for the SHINE facility.

Chapter 1 – Introduction

Chapter 1, "Introduction," of the SHINE licensed operator initial training program discusses the purpose, scope, and an overview of the program. The information in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information in chapter 1 is acceptable because it is administrative in nature, not contrary to the NRC's regulations, consistent with the guidance in ANSI/ANS-15.4-2016, and adequately describes the objectives of the program in sufficient detail for the staff to review the rest of the program. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 2 – Definitions

Chapter 2, "Definitions," of the SHINE licensed operator initial training program describes terms having special meaning unique to the SHINE facility or that are necessary to understand aspects of the program. Specifically, the following definitions are included: controls, graded approach to training, on-the-job training, and simulation-based training. The NRC staff reviewed these definitions for conformance with regulatory requirements and consistency with guidance, as applicable.

The proposed definition for "controls" is "1) Apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of an Irradiation Unit (IU). 2) Apparatus and mechanisms, the manipulation of which could affect the chemical, physical, metallurgical, or nuclear process of the facility in such a manner as to affect the protection of health and safety against radiation." The NRC staff determined that the first definition of controls conforms with 10 CFR 50.2 and 10 CFR 55.4, as applicable to the SHINE facility, because it is consistent with those definitions except for omitting the phrase "when used with respect to a nuclear reactor" and changing "of the reactor" to "of an Irradiation Unit (IU)." This definition is appropriate for the SHINE facility because, although their reactivity and power level may be affected, the SHINE facility IUs are not nuclear reactors or reactors as those terms are used in 10 CFR 50.2 and 10 CFR 55.4. The staff also determined that the second definition of controls conforms with 10 CFR 50.2 because it uses the same language as the second definition of controls in 10 CFR 50.2 and this definition is appropriate for the SHINE facility. Therefore, the definition is adequate and acceptable.

The proposed definition for "graded approach to training" is "[a] method of streamlining parts of the systematic approach to training (SAT) process, tying each of the five phases of SAT together in more efficient information management." SAT is defined in 10 CFR 55.4 as a training program that includes five specific elements. Because SHINE's proposed definition includes the use of each of the five elements of SAT, although in a streamlined manner, the NRC staff finds that the definition is adequate and acceptable.

The proposed definition for “on-the-job training” is “[p]erformance-based training (conducted in environment that replicates as much as possible the actual task conditions) through which trainees learn how to perform a task, and the task related knowledge and skills.” 10 CFR 55.4 does not contain a definition for “on-the-job training.” 10 CFR 55.59(c)(3) requires that a requalification program include on-the-job training and 10 CFR 55.59(c)(3)(i)-(v) provides specific types of on-the-job training that must be completed by licensed operators, as applicable. ANSI/ANS-15.4-2016 defines “on-the-job training” as “[a] systematic, structured method using a qualified person to provide the required job-related knowledge and skills to a trainee, usually in the actual workplace, with proficiency documented.” Section 2.2, “Definitions,” of ANSI/ANS-15.4-2016 provides definitions that “will be useful in understanding this [standard] and companion or reference standards,” but these definitions do not necessarily constitute a requirement or recommendation. Although the SHINE definition of “on-the-job training” is different than that in ANSI/ANS-15.4-2016, it is not contrary to the discussion of on-the-job training in the NRC’s regulations. Therefore, the NRC staff finds that the definition is adequate and acceptable.

The proposed definition for “simulation-based learning” is “[a] technique to replace and amplify real experiences with guided ones, often ‘immersive’ in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion. Simulation-based learning may or may not include an actual simulation device.” 10 CFR 55.4 does not contain a definition for “simulation-based learning.” 10 CFR 55.4 does, though, contain a definition for “simulation facility” and 10 CFR 55.46, “Simulation facilities,” contains requirements for Commission acceptance of the use of simulation facilities. Although SHINE has not submitted a request for approval of a simulator or simulation device, the definition provides SHINE with the future flexibility of incorporating a simulation device. Based on the above, the NRC staff did not identify this definition as contrary to the NRC’s regulations. Therefore, the staff finds that the definition is adequate and acceptable.

Based on its review, the NRC staff finds that the definitions in chapter 2 of the SHINE licensed operator initial training program are either consistent with or not contrary to the NRC’s regulations, are consistent with the guidance in ANSI/ANS-15.4-2016, and are appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 3 – Responsibilities

Chapter 3, “Responsibilities,” of the SHINE licensed operator initial training program contains program-applicable positions and position responsibilities. The information in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information in chapter 3 is acceptable because it is administrative in nature, not contrary to the NRC’s regulations, consistent with the guidance in ANSI/ANS-15.4-2016, and adequately describes the responsibilities of those individuals involved in the initial training program in sufficient detail for the staff to review the rest of the program. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 4 – Training

Chapter 4, “Training,” of the SHINE licensed operator initial training program contains information related to program implementation, which SHINE stated, in section 4.1, “Program Requirements,” meets the requirements of 10 CFR Part 55 and follows the guidance of ANSI/ANS-15.4-2016. The NRC staff reviewed this information for conformance with regulatory requirements, consistency with guidance, and appropriateness for the SHINE facility, as applicable.

Section 4.2, “Analysis,” of the SHINE licensed operator initial training program states that the actual manipulation of facility equipment by licensed operator candidates is conducted under the cognizance of a licensed operator. The NRC staff determined that this conforms with 10 CFR 55.13, “General exemptions,” and is consistent with ANSI/ANS-15.4-2016. Therefore, the staff finds that this is adequate and acceptable.

Section 4.3, “Reactivity Manipulations,” of the SHINE licensed operator initial training program states that each licensed operator candidate will perform a minimum of five reactivity control manipulations with at least one startup and one shutdown of an IU. The NRC staff determined that this conforms with the regulatory requirements in paragraph (a)(5) of 10 CFR 55.31, “How to apply,” as appropriate for the SHINE facility. Section 4.3 also states that each senior licensed operator candidate may receive credit for supervising and directing the performance of these activities, which will be considered as actual performance. The NRC staff will determine whether this conforms with the requirement of 10 CFR 55.31(a)(5) that “the applicant, as a trainee, … successfully manipulated the controls of … the facility” upon its review of any application for a senior operator license that takes credit for supervising and directing the performance of control manipulations or whether this would require an exemption in conformance with 10 CFR 55.11. Since exemptions from the requirements of the regulations in 10 CFR Part 55 are provided for by 10 CFR 55.11, the staff finds that this information is adequate and acceptable.

Section 4.4, “Exemptions,” of the SHINE licensed operator initial training program provides a process to account for a candidate’s previous experience and training and whether the candidate may receive credit based on this previous experience and training against a portion of the initial training program. The NRC staff notes that the use of the term “exemption” in this section is specific to whether a candidate may be exempted from the knowledge and skills portion of the initial training program and does not appear to be synonymous with a request for a specific exemption from the requirements of the regulations in 10 CFR Part 55 in accordance with 10 CFR 55.11 or a waiver of the initial written examination or operating test requirements in accordance with 10 CFR 55.47. The staff determined that this process is not contrary to the NRC’s regulations and is consistent with ANSI/ANS-15.4-2016 and, therefore, is adequate and acceptable.

Section 4.5, “Observation and Evaluation of Candidates,” of the SHINE licensed operator initial training program provides that candidates will be evaluated through periodic observations, oral boards, examinations, and an “NRC Exam Eligibility Review meeting.” The NRC staff determined that this candidate evaluation process is not contrary to the NRC’s regulations and is consistent with ANSI/ANS-15.4-2016 and, therefore, is adequate and acceptable.

Section 4.6, “Training Scope,” of the SHINE licensed operator initial training program provides training topics and a training schedule overview and states that the depth of the training is based on the trainee’s performance and experience. The NRC staff determined that the training topics listed in Attachment A of the SHINE licensed operator initial training program are consistent with the areas covered in 10 CFR 55.41, 10 CFR 55.43, and 10 CFR 55.45, to the extent applicable to the SHINE facility. The staff also determined that the training scope is consistent with ANSI/ANS-15.4-2016. Therefore, it is adequate and acceptable.

Section 4.7, “Senior Licensed Operator Specific Training,” of the SHINE licensed operator initial training program provides information on the additional training consistent with the appropriate knowledge, skills, and abilities for the licensed senior operator position, to the extent applicable to the SHINE facility. The NRC staff determined that the senior licensed operator specific training topics listed in Attachment A of the SHINE licensed operator initial training program are consistent with the areas covered in 10 CFR 55.43 and 10 CFR 55.45. The staff also determined that the development of position-specific training is consistent with ANSI/ANS-15.4-2016. Therefore, it is adequate and acceptable.

Based on its review, the NRC staff finds that the information in chapter 4 of the SHINE licensed operator initial training program is either consistent with or not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 5 – Medical Certification and Fitness for Duty

Chapter 5, "Medical Certification and Fitness for Duty," of the SHINE licensed operator initial training program states that licensed operator candidates will successfully complete a medical examination and evaluation prior to initial licensing, that licensed operator medical requirements follow the standards established in ANSI/ANS-15.4-2016, and that licensed operators are required to adhere to fitness for duty requirements per ANSI/ANS-15.4-2016 and that SHINE's fitness for duty policy is described in the employee handbook. The NRC staff reviewed this information for conformance with regulatory requirements and consistency with guidance, as applicable, and for appropriateness for the SHINE facility. Based on its review, the staff finds that this information is either consistent with or not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 6 – Candidate Selection

Chapter 6, "Candidate Selection," of the SHINE licensed operator initial training program contains information related to personnel selection criteria and qualifications. The NRC staff reviewed this chapter for conformance with regulatory requirements and consistency with guidance, as applicable, and for appropriateness for the SHINE facility.

Section 6.1, "Licensed Operator," section 6.2, "Senior Licensed Operator (Instant)," and section 6.3, "Senior Licensed Operator (Upgrade)," of the SHINE licensed operator initial training program provide position-specific qualification criteria. The NRC staff determined that these criteria are consistent with ANSI/ANS-5.4-2016 and, therefore, are adequate and acceptable.

Based on its review, the NRC staff finds that the information in chapter 6 is either consistent with or not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 7 - Examinations

Chapter 7, "Examinations," of the SHINE licensed operator initial training program contains information on methods, acceptance criteria, and review of written, oral, and on-the-job evaluations performed with trainees as part of the initial training program. Based on its review, the NRC staff finds that the information in chapter 7 is either consistent with or not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS15.4-2016, and is appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

With respect to the implementation of the written examinations required by 10 CFR 55.41 and 10 CFR 55.43 and the operating tests required by 10 CFR 55.45 for a candidate for an operator or a senior operator license at the SHINE facility, 10 CFR 55.40 provides that the NRC shall prepare these examinations and tests. For power reactor facility licensees, 10 CFR 55.40 provides that they may prepare, proctor, and grade the written examinations and may prepare the operating tests or, upon written request from the power reactor facility licensee, the NRC shall, for that facility licensee, prepare, proctor, and grade the written examinations and operating tests. For test and research reactor facility licensees, 10 CFR 55.40 provides that the NRC shall prepare, proctor, and grade the written examinations and operating tests. The SHINE facility, however, is neither a power reactor nor a test or research reactor as those terms are used in the NRC's regulations. Therefore, 10 CFR 55.40 does not fully address how the written examinations required by 10 CFR 55.41 and 10 CFR 55.43 and the operating tests required by 10 CFR 55.45 are to be implemented at the SHINE facility. To address this regulatory gap and ensure that the activities authorized by the SHINE operating license can be conducted without endangering the health and safety of the public, the NRC conditions the SHINE operating license, in part, as follows:

> In lieu of 10 CFR 55.40, SHINE will prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and will prepare the operating tests required by 10 CFR 55.45, subject to the following conditions:
>
> a. SHINE shall prepare the required examinations and tests in accordance with the content requirements of 10 CFR 55.41(b), 55.43(b), and 55.45(a);
>
> b. Pursuant to 10 CFR 55.49, SHINE shall establish, implement, and maintain procedures to control examination security and integrity;
>
> c. An authorized representative of SHINE shall approve the required examinations and tests before they are submitted to the Commission for review and approval;
>
> d. SHINE shall establish acceptance criteria for preparation and approval of written examinations and operating tests, and submit the acceptance criteria to the NRC in writing no later than 120 days before the first scheduled examination date;
>
> e. SHINE shall submit any subsequent changes to the acceptance criteria to the NRC in writing no later than 120 days before any scheduled examination dates;
>
> f. SHINE must receive Commission approval of its proposed written examinations and operating tests; and
>
> g. In lieu of conditions (a) through (f) and upon written request from an authorized representative of SHINE pursuant to 10 CFR 55.31(a)(3), the Commission shall, for SHINE, prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and the operating tests required by 10 CFR 55.45. In addition, the Commission may exercise its

discretion to itself prepare, proctor, and grade the required written examinations and operating tests for SHINE.

Chapter 8 – Training Review and Evaluation

Chapter 8, "Training Review and Evaluation," of the SHINE licensed operator initial training program contains information on periodic program review. Based on its review, the NRC staff finds that the information in chapter 8 is not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 9 – Records

Chapter 9, "Records," of the SHINE licensed operator initial training program contains information on recordkeeping. Based on its review, the NRC staff finds that the information in chapter 9 is not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Conclusion

The NRC staff reviewed the SHINE licensed operator initial training program. The staff determined that the program is either consistent with or not contrary to the NRC's regulations, is consistent with the applicable guidance, and is appropriate for the SHINE facility. Therefore, the staff concludes that in accordance with 10 CFR 50.34(b)(6)(i), SHINE has included information concerning licensed operator and licensed senior operator qualifications requirements. The staff also approves the SHINE licensed operator initial training program.

In order to reach the above conclusions regarding the SHINE licensed operator continuing training program and the SHINE licensed operator initial training program, the NRC staff, in part, compared these programs against the NRC's regulations. The NRC's regulations in 10 CFR Part 55 often refer specifically to power reactors or to test or research reactors. However, the SHINE facility is neither a power reactor nor a test or research reactor as those terms are used in the NRC's regulations. As discussed above, though, the NRC has acknowledged the similarities of the SHINE facility and test and research reactors. Therefore, in order to support its review of the SHINE operating license application and ensure that the activities authorized by the operating license can be conducted without endangering the health and safety of the public and to provide regulatory certainty for the conduct of these activities, the staff determined that the licensed operator requirements of 10 CFR Part 55 applicable to test and research reactor licensees, with the exception of 10 CFR 55.40, must apply at the SHINE facility. Accordingly, the conditions in every nuclear power reactor operating license issued under 10 CFR Part 50 that are generally related to licensed operators at facilities with 10 CFR Part 50 operating licenses, 10 CFR 50.54, paragraphs (i), (i-1), (k), and (l) must also be conditions in the SHINE operating license. Taken together, the NRC conditions the SHINE operating license as follows:

> SHINE must comply with the requirements of 10 CFR Part 55, "Operators' Licenses," to the same extent as would a test and research/non-power reactor licensee, with the exception of 10 CFR 55.40, "Implementation." In lieu of 10 CFR 55.40, SHINE will prepare, proctor, and grade the written examinations required by 10 CFR 55.41

and 55.43 and will prepare the operating tests required by 10 CFR 55.45, subject to the following conditions:

a. SHINE shall prepare the required examinations and tests in accordance with the content requirements of 10 CFR 55.41(b), 55.43(b), and 55.45(a);

b. Pursuant to 10 CFR 55.49, SHINE shall establish, implement, and maintain procedures to control examination security and integrity;

c. An authorized representative of SHINE shall approve the required examinations and tests before they are submitted to the Commission for review and approval;

d. SHINE shall establish acceptance criteria for preparation and approval of written examinations and operating tests, and submit the acceptance criteria to the NRC in writing no later than 120 days before the first scheduled examination date;

e. SHINE shall submit any subsequent changes to the acceptance criteria to the NRC in writing no later than 120 days before any scheduled examination dates;

f. SHINE must receive Commission approval of its proposed written examinations and operating tests; and

g. In lieu of conditions (a) through (f) and upon written request from an authorized representative of SHINE pursuant to 10 CFR 55.31(a)(3), the Commission shall, for SHINE, prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and the operating tests required by 10 CFR 55.45. In addition, the Commission may exercise its discretion to itself prepare, proctor, and grade the required written examinations and operating tests for SHINE.

This license shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(i), (i-1), (k), and (l).

12.4.11 Startup Plan

The NRC staff evaluated the sufficiency of SHINE's startup plan, as presented in SHINE FSAR section 12.11, using the applicable guidance and acceptance criteria from section 12.11, "Startup Plan," in NUREG-1537, Parts 1 and 2 and from the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 12.11 describes at a high-level the tests necessary to verify key system parameters required for the safe handling of nuclear material and operation of the facility. SHINE FSAR section 12.11.1, "Administration of the Startup Testing Program," describes testing that will occur in accordance with a startup test schedule to ensure that all required systems are tested to confirm operability prior to facility startup. SHINE FSAR section 12.11.1 states that SHINE will use approved test procedures that will describe the personnel qualifications, conduct of testing, documenting of deficiencies, and corrective actions. Test results will be documented, including comparison of test data with acceptance criteria and disposition of any discrepancies. Along with test procedures, SHINE FSAR section 12.11.1 states that SHINE will use approved test plans to conduct pre-operational testing. The test plans will describe testing methods and objectives, acceptance criteria, hazards controls, and instructions for accomplishing the test. Subsequent to the completion of testing, SHINE will submit a startup report to the NRC in accordance with the timeframe established in SHINE proposed TS 5.8.4, "Startup Report." The startup report will contain the information described in SHINE FSAR section 12.11.1.2, "Startup Test Report."

SHINE FSAR sections 12.11.2.1, "Facility Startup Tests," and 12.11.2.2, "Irradiation Unit Startup Tests," provide an overview of the facility and IU startup tests, which involve tests in the following areas:

- Preparation for uranium handling
- Receipt, unpacking, and internal transfer of uranium
- Preparation of uranyl sulfate
- Preparation for reuse
- Process vessel vent system
- Transfer of target solution
- Packaging at end of solution life
- Radiation measurements
- Ventilation systems
- Electrical systems
- Instrumentation and controls
- Tritium purification system
- Detector calibration
- IU fill and drain systems
- Subcritical assembly system nuclear physics parameters
    - Uranium concentration
    - Critical height
    - Calculational bias
    - Temperature coefficients
    - Void coefficient
    - Flux distribution
- Neutron driver assembly system

- Target solution vessel off-gas system
- Primary closed loop cooling system

The NRC staff determined that although the SHINE FSAR does not provide detailed information on the testing methods and acceptance criteria, it does state that SHINE will develop acceptance criteria using the applicable design specifications, design documents, drawings, TSs, manufacturer instructions, etc. SHINE stated that it will describe these acceptance criteria in test plans for the tests listed in SHINE FSAR sections 12.11.2.1 and 12.11.2.2. For the startup tests described in SHINE FSAR sections 12.11.2.1 and 12.11.2.2, SHINE referenced design details in the following FSAR sections to support the development of the startup test acceptance criteria:

- Section 4a2.3, “Neutron Driver Assembly System,”
- Section 4a2.6, “Nuclear Design,”
- Section 4a2.8, “Gas Management System,”
- Section 4b.2, “Radioisotope Production Facility Biological Shield,”
- Section 4b.4, “Special Nuclear Material Processing and Storage,”
- Section 5a2.2, “Primary Closed Loop Cooling System,”
- Section 7.2.1, “System Description,”
- Section 7.4.5, “Highly Integrated Protection System Design,”
- Section 9a2.1, “Heating, Ventilation, and Air Conditioning Systems,”
- Section 9a2.7, “Other Auxiliary Systems,”
- Section 9b.2, “Handling and Storage of Target Solution,”
- Section 9b.6, “Cover Gas Control in the Radioisotope Production Facility,” and
- Section 9b.7, “Other Auxiliary Systems.”

The NRC staff determined that the applicant provided references to applicable sections of the SHINE FSAR that describe the design details to support the development of the startup plan acceptance criteria. Additionally, the staff determined that the applicant identified startup tests to measure operational nuclear physics parameters, to perform radiation surveys to compare with expected values, for handling uranium and target solution, and to calibrate detectors based on manufacturer instructions.

SHINE FSAR sections 12.11.2.1.1 through 12.11.2.1.4 and sections 12.11.2.1.6 and 12.11.2.1.7 describe the plan for preparation, receipt, unpacking, transfer, reuse, and packaging of uranium. The SHINE FSAR details the uranium testing to include verifying concentration, enrichment, temperature, pH, and volume. Before the initial receipt of uranium, the availability and calibration of required testing equipment are verified. Based on the above, the NRC staff finds that SHINE has plans for receiving, handling, and performing QA checks on uranium. Further, the staff finds that SHINE testing equipment will be calibrated to support testing the uranium. SHINE FSAR section 12.11.2.1.5, “Process Vessel Vent System,” describes that process vessel vent system (PVVS) operational parameters are measured and compared to design parameters. SHINE identifies the key parameters as temperatures, pressures, flow rates, and effective operation of the carbon guard and delay beds. Based on the above, the NRC staff also finds that the PVVS is tested prior to routine operations. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.1.8, “Radiation Measurements,” describes that the installed radiation monitors, such as the continuous airborne monitor and facility stack release monitor, are calibrated and tested prior to startup. Further, radiation measurements are taken and compared to expected values. SHINE FSAR section 12.11.2.1.8 also states that area radiation measurements are taken to confirm the adequacy of the biological shielding. Based on the above, the NRC staff finds that area and effluent radiation surveys will be conducted to confirm expected values and to verify the adequacy of the biological shield. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.1.9, “Ventilation Systems,” describes that the ventilation system parameters, such as pressures, temperatures, and flowrates, used to control airborne contamination are measured and compared to expected values. Based on the above, the NRC staff finds that ventilation systems will be appropriately tested before routine operations. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.1.10, “Electrical Systems,” states that startup testing verifies that the UPSS is capable of providing power to safety-related equipment in the absence of offsite power or the nonsafety-related standby generator. Based on the above, the NRC staff finds that the electrical systems will be appropriately tested before routine operations. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.1.11, “Instrumentation and Controls,” states that the testing of instrumentation and controls systems includes calibration, establishing and verifying setpoints, and testing system actuations. Further, SHINE FSAR section 12.11.2.1.11 states that detectors are calibrated in accordance with the manufacturer instructions or as described in SHINE FSAR section 12.11.2.2.1. The instrumentation and controls acceptance criteria are developed based on design details in SHINE FSAR chapter 7. Based on the above, the NRC staff finds that the instrumentation and controls systems will be appropriately tested before routine operations. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.1.12, “Tritium Purification System,” states that TPS leak rates are measured and compared to predetermined acceptance criteria, which are developed based on design details provided in SHINE FSAR section 9a2.7. Based on the above, the NRC staff finds that the tritium purification system will be appropriately tested before routine operations. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.2.1, “Detector Calibration,” states that detectors are calibrated using an isotopic method in accordance with implementing procedures. Detector calibration acceptance criteria are developed based on manufacturer instructions and are provided in test plans. Based on the above, the NRC staff finds that detectors will be appropriately tested before routine operations. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.2.2, “Irradiation Unit Fill and Drain Systems,” states that the IU fill and drain mechanisms are tested to include key parameters such as fill flow rate and dump valve timing. Further, the measured dump valve opening time and time to empty the TSV with one dump line are compared to the acceptance criteria. Based on the above, the NRC staff finds that the IU fill and drain systems will be appropriately tested before routine operations. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.2.3, “Subcritical Assembly System Nuclear Physics Parameters,” states that the subcritical assembly system nuclear physics parameters are tested in order to develop appropriate operational parameters, such as uranium concentration and TSV fill height, and to ensure the operability of the SSCs. SHINE plans to measure uranium concentration by using a controlled approach towards criticality (1/M approach). SHINE will also use a series of tests to determine critical target solution height in the TSV, neutronic bias, temperature coefficients, void coefficients, and flux distribution. These measured values will be compared to acceptance criteria developed based on design information in the SHINE FSAR. Based on the above, the NRC staff finds that the critical mass will be appropriately determined and that measurements are planned to appropriately determine operational nuclear physics parameters with the results compared to acceptance criteria. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.2.4, “Neutron Driver Assembly System,” states that the neutron driver is tested for operability, stability, and neutron yield prior to placement in the IU cell. The neutron driver is run without target solution in the TSV to evaluate the stability of the neutron flux prior to operation with target solution. The neutron driver startup test acceptance criteria are developed based on design details provided in SHINE FSAR section 4a2.3 and are provided in test plans. Based on the above, the NRC staff finds that the neutron driver assembly system will be appropriately tested before routine operations and that appropriate measurements are planned to determine operational nuclear physics parameters. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.2.5, “Target Solution Vessel Off-Gas System,” states that TSV off-gas system (TOGS) parameters are tested in order to characterize operational parameters, such as TOGS water holdup and worth, and to ensure the operability of safety functions. TOGS pressure boundary leak integrity, sweep gas flow rate, and effectiveness of iodine removal are measured and compared to predetermined acceptance criteria. TOGS is tested for its leak tightness to prevent the release of radioactive material. TOGS is also tested for its ability to maintain the sweep gas flow rate within setpoints and to produce an IU cell safety actuation and an IU Cell Nitrogen Purge if outside setpoints. The iodine removal function is also tested to ensure that iodine removal is performing adequately. The hydrogen recombination and heat removal functions are tested to demonstrate the recombiner efficiency and cooling capacity. The reactivity worth of TOGS water holdup will be measured. The TOGS startup test acceptance criteria are developed based on design details provided in SHINE FSAR sections 4a2.6 and 4a2.8 and are provided in test plans. Based on the above, the NRC staff finds that TOGS will be appropriately tested before routine operations and that appropriate measurements are planned to determine operational nuclear physics parameters. Therefore, this information is sufficient for the issuance of an operating license.

SHINE FSAR section 12.11.2.2.6, “Primary Closed Loop Cooling System,” states that primary closed loop cooling system (PCLS) parameters are tested in order to determine operational parameters, such as PCLS reactivity worth, and to ensure operability of safety functions. The PCLS is tested for its ability to maintain temperature and flow rate within limits and to produce a

Driver Dropout and an IU Cell Safety Actuation if outside setpoints. Additionally, PCLS worth is measured. Filling PCLS is calculated to result in a negative reactivity insertion that is measured by filling the TSV with the PCLS empty then filling the PCLS while measuring neutron flux. The PCLS startup test acceptance criteria are developed based on design details provided in SHINE FSAR sections 4a2.6 and 5a2.2 and are provided in test plans. Based on the above, the NRC staff finds that the PCLS will be appropriately tested before routine operations and that appropriate measurements are planned to determine operational nuclear physics parameters. Therefore, this information is sufficient for the issuance of an operating license.

The NRC staff reviewed the SHINE startup plan. The staff determined that there is reasonable assurance that SHINE will develop appropriate startup plan acceptance criteria based on the approved applicable design specifications as described in the SHINE FSAR, design documents, drawings, TSs, and manufacturer instructions, as stated in SHINE FSAR section 12.11, and that SHINE proposed to perform appropriate tests to demonstrate operability. The staff finds that the information meets the acceptance criteria in NUREG-1537 and the ISG augmenting NUREG-1537 and is appropriate for the SHINE facility, and that the implementation of the startup plan will provide reasonable assurance that the facility is operating as described and analyzed in the SHINE FSAR.

12.4.12 Environmental Reports

SHINE FSAR section 12.12 is vacated. By letter dated November 16, 2021, SHINE submitted Revision 7 of its operating license stage supplement to its construction permit stage environmental report for the SHINE facility. The NRC staff's evaluation of the environmental, economic, technical, and other benefits against the environmental and other costs of the proposed action of deciding whether to issue an operating license for the SHINE facility, based, in part, on SHINE's supplemental environmental report, is documented in NUREG-2183, Supplement 1.

12.4.13 Material Control and Accounting Plan

The NRC staff evaluated the sufficiency of Revision 5 of SHINE's Material Control and Accounting (MC&A) Plan (ML22188A055), as described in SHINE FSAR section 12.13, "Material Control and Accounting Plan," against the applicable regulatory requirements.

Under 10 CFR 70.22(b), an applicant for a license to possess SNM or to possess and use at any one time and location SNM in a quantity exceeding one effective kilogram must submit, as part of its application for a license, a full description of its program for control and accounting of the SNM that will be in its possession under its license to show how compliance with the requirements of 10 CFR 74.31, "Nuclear material control and accounting for special nuclear material of low strategic significance," 10 CFR 74.33, "Nuclear material control and accounting for uranium enrichment facilities authorized to produce special nuclear material of low strategic significance," 10 CFR 74.41, "Nuclear material control and accounting for special nuclear material of moderate strategic significance," or 10 CFR 74.51, "Nuclear material control and accounting for strategic special nuclear material," as applicable, will be accomplished. Of those requirements, 10 CFR 74.31 will not apply because the SHINE facility is a production and utilization facility that will be licensed pursuant to 10 CFR Parts 50 or 70 and will not possess more than one effective kilogram of SNM of low strategic significance; 10 CFR 74.33 will not apply because SHINE will not be authorized to possess equipment capable of enriching uranium or to operate an enrichment facility; and 10 CFR 74.51 will not apply because SHINE will not be authorized to possess five or more formula kilograms of strategic SNM. SHINE will, however, be authorized to possess SNM of moderate strategic significance. Therefore, to comply with 10 CFR 70.22(b), the SHINE MC&A Plan must show how compliance with the requirements of 10 CFR 74.41 will be accomplished. Accordingly, the SHINE MC&A Plan describes how SHINE's program for the control and accounting of SNM meets the performance objectives of 10 CFR 74.41(a) and the system features and capabilities requirements of 10 CFR 74.41(c).

As an initial matter, SHINE has not yet submitted its application for a license to possess SNM and to possess and use at any one time and location SNM in a quantity exceeding one effective kilogram, which means that 10 CFR 70.22, "Contents of applications," (b) does not currently apply to SHINE. The NRC staff, however, understands that SHINE intends to submit a 10 CFR Part 70 application. As the staff understands it, upon submitting its 10 CFR Part 70 application, SHINE intends to combine this application with its 10 CFR Part 50 application in accordance with 10 CFR 50.31, "Combining applications." Given that, and the fact that SHINE has submitted its MC&A Plan as part of its 10 CFR Part 50 application, the staff is reviewing that plan now against the relevant regulatory requirements.

Chapter 1 – Introduction

Chapter 1, "Introduction," of the SHINE MC&A Plan contains the purpose and scope of the MC&A Plan, facility description, process description, and a description of the forms of SNM to be processed at the SHINE facility. The information in this chapter is supplemental and administrative in nature. Based on its review, the NRC staff finds that the information in chapter 1 is acceptable because it is administrative in nature, not contrary to the NRC's regulations, and adequately describes the facility processes and the SNM processed at the facility in sufficient detail for the staff to review the rest of the SHINE MC&A Plan.

Chapter 2 – General Performance Objectives

The purpose of the general performance objectives in 10 CFR 74.41(a) is to maintain current information, verify the presence of all SNM held by the licensee, and to detect the occurrence of any significant loss, including possible theft or diversion. To maintain current information, the applicant should have in place a program that provides timely, accurate, and reliable information about the quantity and location of SNM in its possession (10 CFR 74.41(a)(1)). To meet the requirements of 10 CFR 74.41(a)(2)-(3), the applicant should have a formalized program to promptly investigate and resolve an anomaly that may indicate a possible loss of SNM. Resolution of such anomalies means that the applicant has made a rapid determination about whether an actual loss of a significant quantity of SNM has occurred, including possible theft or diversion. If the NRC or other government agency deems it necessary to conduct an investigation of actual (or highly suspected) events concerning missing material, the licensee should provide any information it deems relevant to the recovery of material involved in a loss, theft, or diversion, as required by 10 CFR 74.41(a)(4).

SHINE addressed the general performance objectives throughout the SHINE MC&A Plan. An overview of the basis for the SHINE MC&A program is described in chapter 2, "General Performance Objectives." Chapter 4, "Measurements," and chapter 5, "Measurement Control System," describe the measurement program and controls that ensure that SNM quantities are accurate, current, and reliable. Chapter 7, "Physical Inventory Program," describes the inventory program that confirms the quantities and presence of all SNM at the facility. Chapter 8, "Item Control Program," describes controls in place to ensure current knowledge on SNM in items, and to ensure that items are stored, handled, and measured in a manner that will ensure detection of unauthorized or unrecorded removal of SNM. Chapter 13, “Resolving Indications of Loss, Theft, Diversion or Misuse of Special Nuclear Material,” describes how SHINE will investigate and resolve indications of loss, theft, diversion, or misuse of SNM. Chapter 14, “Aiding Investigation and Recovery of Missing Special Nuclear Material,” describes SHINE’s program for aiding the investigation and recovery of missing SNM. Chapter 15, “Recordkeeping,” describes how SHINE establishes and maintains records that demonstrate how the general performance objectives and system capabilities are met.

The NRC staff reviewed SHINE’s strategy for meeting the general performance objectives as provided in the SHINE MC&A Plan. This review is discussed throughout this section of the SER. On the basis of that review, the staff determined that SHINE’s overall MC&A program includes processes and procedures to ensure accurate, current, and reliable information on all SNM; to confirm the presence of SNM; to investigate and resolve anomalies; to permit rapid determination of whether a significant loss of SNM has occurred; and to generate information to aid in the investigation and recovery of missing SNM. The staff finds that SHINE’s program for meeting the overall general performance objectives includes the appropriate components to meet the requirements in 10 CFR 74.41(a) and is, therefore, acceptable.

<u>Chapter 3 – Management Structure</u>

Under 10 CFR 74.43, “Internal controls, inventory, and records,” paragraph (a) and (b)(1)-(4), licensees subject to 10 CFR 74.41 must implement internal controls laid out in 10 CFR 74.43(b)(1)-(4) that relate to management structure. The management structure requirements are meant to separate the performance of key MC&A functions from each other to incorporate checks and balances that increase MC&A system reliability and make the theft or diversion of SNM less likely. These functions are then overseen by a single individual as specified by 10 CFR 74.43(b)(2). This separation at the performance level is also meant to free MC&A management personnel from conflicts of interest with other major functions, such as production, and ensure independence of action and objectiveness of decisions. An effective management structure also relies on the adequate review, approval, and use of written MC&A procedures, and the training and qualification of personnel in key positions to maintain a high level of safeguards awareness.

Chapter 3, “Management Structure,” of the SHINE MC&A Plan describes the management structure, including the facility organization, MC&A organization, procedures, and training and qualifications. Section 3.2, “Facility Organization,” and section 3.3, “MC&A Organization,” of the SHINE MC&A Plan describe the various facility organizations as they relate to MC&A and discuss the positions responsible for the MC&A functions, including accounting, measurement, control, and custodianship. Chapter 3 also discusses the overall responsibility for MC&A, independence from manufacturing responsibilities, and separation of key responsibilities, which ensures that the individual with overall responsibility for the MC&A program will function with independence of action and objectiveness of decisions. Section 3.3.5, “MC&A Procedures,” provides information related to the adequate review, approval, and use of written procedures which cover all aspects of the MC&A program. MC&A procedures are listed in appendix 16.4, “List of MC&A Procedures,” of the SHINE MC&A Plan. Section 3.4, “Training and Qualification Requirements,” describes MC&A training for the general employee, training and qualification for employees with specific MC&A tasks, and minimum qualifications for positions with significant MC&A responsibilities. SHINE stated that personnel who work in key positions involving MC&A are trained to maintain a high level of safeguards awareness.

The NRC staff finds that the plan for the management structure for the SHINE facility provided in chapter 3 of the SHINE MC&A Plan incorporates clear overall responsibility for MC&A functions, independence from production and manufacturing, separation of key responsibilities, and overall responsibility for MC&A vested in a single individual at a level sufficient to ensure independence of action and objectiveness of decisions to meet the requirements in 10 CFR 74.43(b)(1)–(2). SHINE's plan for review, approval, and use of written procedures, and assurance that personnel who work in key positions are trained to a high level of safeguards awareness meets the requirements of 10 CFR 74.43(b)(3)–(4). Therefore, SHINE's plan for these internal controls is acceptable.

Chapter 4 – Measurements

Under 10 CFR 74.45, "Measurements and measurement control," paragraph (b), licensees must establish, maintain, and use a program for the measurement of all SNM (both element and fissile isotope) received, produced, transferred between internal control areas, on inventory, or shipped, discarded, or otherwise removed from inventory, with certain exceptions. Licensees must develop and follow approved written procedures related to reference standards, measurement system calibrations, performing measurements, obtaining samples, performing laboratory analyses, and recording, reviewing, and reporting measurements.

Chapter 4, "Measurements," of the SHINE MC&A Plan describes the SHINE SNM measurement program. Systems are in place for quantifying the mass of all SNM received, shipped, discarded, transferred between internal control areas (ICAs), or listed in the physical inventory. Section 4.1, "Measurement Points," lists the items/containers that will be onsite and the measurements to be taken. Section 4.1 also shows in table 4-1a measurements of SNM between ICAs. Section 4.2, "Measurement Systems," describes the various measurement systems used at the SHINE facility, including analytical measurements, sampling, mass measurements, volume, and nondestructive assay (NDA) measurements. Section 4.4, "Measurement Procedures," states that approved, written procedures are used for all accountability measurement methods, including sampling. Approved written procedures are also used for control and reference standards and for calibrating measurement systems.

The NRC staff finds that SHINE's plan for the measurement program provided in chapter 4 of the SHINE MC&A Plan includes sufficient detail on the measurement points and measurement systems that will be used at the SHINE facility, and on the program for the development and use of written procedures for all aspects of its measurement program, for the staff to determine that it meets the requirements in 10 CFR 74.45(b). Additionally, although the SHINE MC&A plan did not explicitly address SNM "otherwise removed from inventory" this would be accounted for because all material removed from inventory would have a measured value on inventory. Further, although SHINE would produce very small quantities of plutonium, these quantities are so small they would not be measured, they would be calculated. Therefore, while the SHINE MC&A Plan does not address SNM produced by SHINE, it does not need to because SHINE will not produce any SNM that would be measured. It is, therefore, acceptable. The calculated quantities of plutonium are discussed in section 4.1.3, "Quantity of Pu," of the SHINE MC&A Plan.

Chapter 5 – Measurement Control System

Under 10 CFR 74.45(c)(1)–(11), licensees must ensure that measurement systems used to establish SNM accountability quantities are controlled by a formal measurement control program that ensures that measurement quality is maintained and that measurement uncertainty values are estimated. Chapter 5 of the SHINE MC&A Plan describes the measurement control program.

Under 10 CFR 74.45(c)(1) licensees must assign responsibility for planning, developing, coordinating, and administering a measurement control program to an individual who has no direct responsibility for performing measurements or for SNM processing or handling, and who holds a position at an organizational level which permits independence of action and has adequate authority to obtain all the information required to monitor and evaluate measurement quality.

Section 5.1, “Organization and Management,” and chapter 3, “Management Structure” (as discussed above), of the SHINE MC&A Plan provides a description of the organization and management of the measurement control program, which includes personnel from the MC&A organization that are responsible for the oversight and implementation of the program, as well as the personnel outside of the MC&A organization that are responsible for performing measurement control activities. SHINE stated that the MC&A Manager is responsible for implementing the overall MC&A program, including planning and coordination, and for administering the measurement control program. SHINE stated that oversight of the measurement control program is provided by the MC&A organization, which is independent of the organizations that perform measurements and measurement control activities.

The NRC staff finds that the organization and management of the measurement control program for the SHINE facility provided in section 5.1 and chapter 3 of the SHINE MC&A Plan are sufficiently independent from performing measurements and from SNM processing and handling to meet the measurement control requirement of 10 CFR 74.45(c)(1) and are, therefore, acceptable.

Under 10 CFR 74.45(c)(2) licensees must ensure that any contractor who performs MC&A measurement services conforms with the applicable measurement control requirements in 10 CFR 74.45(c)(5), (6), (7), (10), and (11), and that conformance includes reporting of sufficient measurement control data to allow the licensee to calculate the associated measurement uncertainties.

Section 5.1 of the SHINE MC&A Plan states that outside contractors and offsite laboratories used to provide measurement services for SHINE are reviewed to ensure that measurement control systems are in place and adequate to meet the requirements of 10 CFR 74.45(c)(2). SHINE also stated that the outside contractor program is audited annually. Additionally, section 10.5, “Assessment of Outside Contractor,” of the SHINE MC&A Plan states that the outside contractor or laboratory’s measurement services will be assessed as part of the independent assessment of the SHINE MC&A program, as described in chapter 10, “Assessment and Review of the MC&A Program,” of the SHINE MC&A Plan.

The NRC staff finds that SHINE’s plan for evaluating and reviewing contractors that provide MC&A measurement services for SHINE provided in sections 5.1 and 10.5 of the SHINE MC&A Plan is sufficiently comprehensive to meet the measurement control requirement in 10 CFR 74.45(c)(2) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(3) licensees must identify potential sources of sampling error and ensure that samples are representative by performing process sampling tests using well characterized materials to establish or verify the applicability of utilized procedures for sampling SNM and for maintaining sample integrity during transport and storage. Licensees are also required to conduct sampling tests whenever a new sampling procedure or technique is used, or new sampling equipment is installed; a sampling procedure, technique, or sampling equipment is modified; or sample containers, sample transport methods, or sample storage conditions are modified.

Section 4.2.5, "Sampling Systems," of the SHINE MC&A Plan describes the potential sources of sampling error and the performance of sampling tests to ensure that solutions are homogeneous and samples are representative. SHINE stated that sampling tests are also performed when modifications are made to a sampling system, a new sampling procedure is used, a sampling technique is modified, sample containers are modified, or sample storage is modified. The NRC staff understands a sampling technique or system, as those terms are used by SHINE, to include sampling equipment and sampling transportation methods. This is similar to the use of the term "measurement system," as defined in 10 CFR 74.4, where measurement system is defined as "all the apparatus, equipment, instruments and procedures used in performing a measurement." While there is no definition of "sampling system" in 10 CFR 74.4, analogous reasoning would define sampling system as all of the apparatus, equipment, instruments, and procedures used in sampling.

The NRC staff finds that SHINE's plan for sampling tests in section 4.2.5 of the SHINE MC&A Plan includes sufficient descriptions of possible sampling errors, sampling tests, and when sampling tests would be used to allow the staff to determine that the program meets the measurement control requirement in 10 CFR 74.45(c)(3) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(4) licensees must establish and maintain a measurement control program so that for each inventory period the standard of error for the inventory difference (SEID) is less than 0.125 percent of the active inventory and assure that any MC&A measurements performed under contract are controlled so that the licensee can satisfy this requirement.

Chapter 5, "Measurement Control System," and section 6.2.2, "Estimating the Standard Error of the Inventory Difference," of the SHINE MC&A Plan state that measurement uncertainty is controlled so that the SEID, based on all measurement contributions, is less than 0.125 percent of the active inventory. Chapter 5 also states that the same measurement control requirements must be met for outside contractors or offsite laboratories providing accountability measurement services, and that these outside organization measurement programs are subject to review before use and by annual audits.

The NRC staff finds that SHINE's plan for establishing and maintaining a measurement control program provided in chapters 5 and 6, "Statistics," of the SHINE MC&A Plan presents sufficient explanation of its approach for controlling measurement uncertainty to allow the staff to determine that the program meets the measurement control requirement in 10 CFR 74.45(c)(4) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(5) licensees must generate current data on the performance of each measurement system used during each material balance period in order to establish measured values and uncertainties, including bias, variance components for calibration, sampling, and replicate measurements.

Section 3.3.2, "Nuclear Material Measurement Responsibilities," of the SHINE MC&A Plan states that the measurement control program coordinator has responsibility for oversight of MC&A measurements and implementation of the measurement control program. Chapter 5 of the SHINE MC&A Plan describes the activities involved in monitoring measurement systems, including calibrations; use of control standards to ensure systems are in control and to estimate bias; and the use of replicate samples and measurements to estimate sampling uncertainties and random errors. Section 5.1 of the SHINE MC&A Plan states that the MC&A organization is responsible for analyzing measurement control data and evaluating measurement performance. Section 3.3 of the SHINE MC&A Plan states that Operations and Radiation Protection generate the source data upon which the records in the accounting system are based, including measurement and measurement control data. Section 5.1 of the SHINE MC&A Plan also states that Operations, Radiation Protection, and the Laboratories are responsible for performing control measurements and providing the control measurement results to the MC&A organization. Chapter 6 of the SHINE MC&A Plan describes the statistical methods used to determine measurement uncertainties and to identify biases.

The NRC staff finds that SHINE’s plan for generating and monitoring current measurement control data provided in chapters 3, 5, and 6 of the SHINE MC&A Plan includes sufficient details on generating the data, estimating and controlling bias and measurement uncertainties through calibration, sampling, and replicates to allow the staff to determine that the program meets the measurement control requirement in 10 CFR 74.45(c)(5) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(6) licensees must use standards on an ongoing basis for the calibration and control of all measurement systems used for SNM accountability. Additionally, 10 CFR 74.45(c)(6) requires that licensees ensure that:

- Calibrations are repeated whenever any significant change occurs in a measurement system or when program data indicate a need for recalibration;
- Calibrations and control standard measurements are based on standards whose assigned values are traceable to certified reference standards or certified standard reference materials; and
- Control standards are representative of the process material or items being measured by the measurement system in question.

Section 5.2, “Calibrations,” of the SHINE MC&A Plan describes the use of calibration standards and methods for laboratory instruments, scales and balances, and tanks and other vessels. SHINE stated that calibrations are repeated when a significant change to a measurement system occurs and when control standard measurements fail to meet acceptance criteria. Chapter 5 and section 4.2 of the SHINE MC&A Plan state that calibration standards are traceable to nationally recognized standards.

Section 5.3, “Control Standards,” of the SHINE MC&A Plan describes the use of control standards to ensure that measurement systems are in control. SHINE stated that control standard measurements are used to verify the performance of each measurement system that is not point-calibrated, and the control standards are traceable to nationally recognized standards. SHINE also stated that control standards are representative of the process material being measured.

The NRC staff finds that SHINE’s plan for the use of calibration and control standards in sections 5.2 and 5.3 of the SHINE MC&A Plan sufficiently utilizes these standards to meet the measurement control requirements in 10 CFR 74.45(c)(6) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(7) licensees must conduct control measurements to provide current data for the determination of random error behavior. The program must also, on a predetermined schedule, include the following, as appropriate:

- Replicate analyses of individual samples;
- Analysis of replicate process samples;
- Replicate volume measurements of bulk process batches;
- Replicate weight measurements of process items and bulk batches, or alternatively, the use of data generated from the replicate weighing of control standard weights as derived from the control standard program; and
- Replicate nondestructive assay (NDA) measurements of individual process containers or items, or alternatively, the use of data generated from the replicate measurements of NDA control standards as derived from the control standard program.

Section 5.4, "Replicate Measurements," of the SHINE MC&A Plan describes the replicate measurement program used to determine random error behavior. SHINE discussed the use of duplicate or replicate samples to estimate combined analytical plus sampling error. SHINE stated that for mass measurements, replicate measurements are taken of control standards. SHINE stated that NDA replicates are not taken due to the low quantity of SNM in waste measured by NDA. SHINE also stated that volume replicates are not taken since the replicates would not be independent of each other and would therefore not be statistically appropriate.

The NRC staff finds that SHINE's plan for the replicate program to determine random error behavior provided in section 5.4 of the SHINE MC&A Plan includes sufficient description of its approach to conducting control measurements, including limitations due to small quantities of SNM in some material areas, to allow the staff to determine that the program meets the measurement control requirement in 10 CFR 74.45(c)(7) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(8) licensees must use all measurements and measurement controls generated during the current material balance period for the estimation of the SEID.
Under 10 CFR 74.45(c)(9) licensees must evaluate with appropriate statistical methods all measurement system data generated pursuant to 10 CFR 74.45(c)(5) to determine significant contributors to the measurement uncertainties associated with inventory differences and shipper-receiver differences so that if SEID exceeds specified limits established in 10 CFR 74.45(c)(4), the cause of the excessive SEID can be identified for corrective action with respect to controlling the standard error within applicable limits.

Section 6.2.2, "Estimating the Standard Error of the Inventory Difference," of the SHINE MC&A Plan describes the approach used to determine the various components of the SEID. SHINE stated that the SEID takes into account all measurement error contributions to the components of the inventory difference, and that measurement uncertainty is controlled so that SEID does not exceed 0.125 percent of active inventory. Determination of the measurement errors, both random and systematic, is described in section 6.1.2, "Estimating Random Uncertainty," and section 6.1.3, "Estimating Systematic Uncertainty." Section 6.1, "Determination of Measurement Uncertainties," of the SHINE MC&A Plan states that measurement uncertainties are estimated using measurement control data (control standards and replicates) as described in chapter 5 of the SHINE MC&A Plan. SHINE stated that established statistical techniques are used to analyze measurement data to provide random and systematic error variances in the measurement method. Section 7.7, "SEID Limit and Response Actions," of the SHINE MC&A Plan states that if a calculated SEID exceeds the limit of 0.125 percent of active inventory, an investigation will be initiated to determine which measurement systems(s) were the source of the excessive SEID.

The NRC staff finds that SHINE's plan for the use of measurements and measurement controls to estimate SEID along with its plan for the use of appropriate statistical methods to evaluate all measurements and measurement controls in estimating the SEID in chapters 5, 6, and 7 of the SHINE MC&A Plan includes appropriate data and calculations to meet the measurement control requirements in 10 CFR 74.45(c)(8) and (9), including calculating SEID and identifying the cause of excessive SEID for corrective action, and is, therefore, acceptable.

Under 10 CFR 74.45(c)(10) licensees must establish and maintain a statistical control system, including control charts, formal statistical procedures, and control limits (established at the 0.05 and 0.001 significance levels or their equivalent) designed to monitor the quality of each measurement device or system. Under 10 CFR 74.45(c)(11) licensees must promptly investigate and take any appropriate corrective action whenever a control datum exceeds an 0.05 control limit, and whenever a control datum exceeds an 0.001 control limit, the measurement system that generated the datum shall immediately be placed out-of-service with respect to MC&A measurements until the deficiency has been corrected and the system brought into control within the 0.05 control limits.

Section 5.5, "Control Limits," of the SHINE MC&A Plan states that control limits are established at the 0.05 (warning limit) and 0.001 (alarm limit) significance levels, and that statistical analyses are performed to evaluate a measurement system's performance, including the use of control charts. SHINE described the response activities when control limits are exceeded, including remeasurements when the warning limits are exceeded and removal of the measurement system from service when the control standard result is out-of-control (exceeds the alarm limit). SHINE stated that the system will not be returned to service until the measurement system has been returned to statistical control. Section 3.3.2 of the SHINE MC&A Plan states that the measurement control coordinator monitors control standard results from measurement systems to ensure that no accountability values were established using an out-of-control system. Section 5.1, "Organization and Management," of the SHINE MC&A Plan states that all facility procedures that address measurement include a section on measurement control, if applicable, and are subject to approval by the MC&A Manager.

The NRC staff finds that SHINE's plan to establish and maintain a statistical control system to monitor the quality of each measurement system provided in sections 3.3.2, 5.1, and 5.5 of the SHINE MC&A Plan includes procedures, control charts, and the appropriate calculations, alarm levels, and alarm responses to meet the measurement control requirements in 10 CFR 74.45(c)(10) and (11) and is, therefore, acceptable.

<u>Chapter 6 – Statistics</u>

Proper use of statistics is important to ensure that the regulatory requirements in 10 CFR 74.43, "Internal controls, inventory, and records," and 10 CFR 74.45, "Measurements and measurement control," are met. An effective statistical program will ensure that measurement uncertainties are estimated and propagated; the inventory difference (ID) and SEID are properly determined; and bias corrections are appropriately estimated and applied.

Chapter 6 of the SHINE MC&A Plan describes the use of statistics in the SHINE MC&A program. This chapter describes how both random and systematic measurement uncertainties are determined and the sources of the uncertainties. Calculation of the ID and SEID are described in section 6.2, “Determination of Inventory Statistics,” of the SHINE MC&A Plan. SHINE described the calculation of the active inventory (used in evaluating the SEID) and stated that common items are appropriately removed from the active inventory equation. Section 6.3, “Bias Corrections,” of the SHINE MC&A Plan describes how SHINE corrects for bias and states that significant biases are corrected in each measurement value or as a total in the inventory difference equation.

The NRC staff finds that SHINE’s statistical programs include the appropriate consideration of uncertainties and use of calculations and meet the system capabilities requirements in 10 CFR 74.43 and 10 CFR 74.45. Therefore, SHINE’s statistical programs are acceptable.

Chapter 7 – Physical Inventory Program

The regulations in 10 CFR 74.43(c)(1)-(8) describe licensee requirements related to inventory control and physical inventories. Chapter 7 of the SHINE MC&A Plan describes the physical inventory program for the SHINE facility.

Under 10 CFR 74.43(c)(1) licensees must provide unique identification for each item on inventory and maintain inventory records showing the identity, location, and quantity of SNM for these items.

Section 7.1, “General Description,” of the SHINE MC&A Plan provides a general description of the physical inventory. SHINE stated that a book inventory list includes all SNM items that records indicate should be present, and that the list indicates the current status of all items. Section 8.3, “Item Identity Controls,” of the SHINE MC&A Plan indicates that all SNM containers have a unique identity that cannot be altered. Section 15.1, “Description of Records,” of the SHINE MC&A Plan describes the Item History Form, which is the primary record used to account for SNM. The form includes item identity, current location, and quantity of SNM.

The NRC staff finds that the item identity controls used for item control and inventory control, as provided in sections 7.1, 8.3, and 15.1 of the SHINE MC&A Plan, include the item identity, location, and quantity to meet the inventory control requirement in 10 CFR 74.43(c)(1) and are, therefore, acceptable.

Under 10 CFR 74.43(c)(2) licensees must document all transfers of SNM between designated ICAs within the licensee’s site.

Section 3.6, “Material Control Boundaries,” of the SHINE MC&A Plan describes the ICAs to be used to facilitate control of SNM. SHINE stated that records are prepared to document movement of SNM between the areas. Section 3.3.4, “Nuclear Material Custodians,” of the SHINE MC&A Plan states that the nuclear material custodians are responsible for ensuring that transfers of SNM out of the area to which they are assigned have been approved and for ensuring that all activities involving SNM are documented. Section 15.1 of the SHINE MC&A Plan describes the primary forms used to document the history and movement of SNM items.

The Item History Form follows the item, including location, from receipt and throughout its existence. The SNM Transfer Form records the relocation of items.

The NRC staff finds that the transfer documentation controls used for item control and inventory control, as provided in sections 3.6, 3.3.4, and 15.1 of the SHINE MC&A Plan, including assigning transfer control responsibilities to nuclear material custodians, provide for the documentation of all transfers of SNM to meet the inventory control requirement in 10 CFR 74.43(c)(2) and are, therefore, acceptable.

Under 10 CFR 74.43(c)(3) licensees must maintain and follow procedures for the tamper-safing of containers or vaults containing SNM, if tamper-safe seals are to be used for assuring the validity of prior measurements. The procedures must include control of access to, and distribution of, unused seals and to records showing the date and time of seal application.

SHINE's tamper-safing program is described in chapter 11, "Tamper-Safing," of the SHINE MC&A Plan. The NRC staff's review of this program can be found in "Chapter 11 – Tamper-Safing" of this section of the SER.

Under 10 CFR 74.43(c)(4) licensees must maintain and follow procedures for confirming the validity of prior measurements associated with unencapsulated and unsealed items on ending inventory.

Section 11.1, "Characteristics of Tamper-Safing Devices," of the SHINE MC&A Plan states that tamper-indicating devices (TIDs) are used on containers of SNM to ensure that no tampering has occurred with the contents. SHINE stated that TIDs are used on containers of SNM that are stored onsite and when they are in transit. Section 8.4, "Storage Controls," of the SHINE MC&A Plan describes storage of SNM items and states that the containers are tamper-safed. Section 7.3, "Typical Inventory Composition," of the SHINE MC&A Plan states that any SNM items that were measured prior to the inventory-taking are not re-measured if a TID was applied and the TID remains intact. In addition, any SNM included in the inventory that has not previously been measured is measured for the inventory. Section 7.5, "Conducting Physical Inventories," of the SHINE MC&A Plan states that during inventory-taking, the TID integrity and identification number are confirmed, and that any discrepancies that are identified during the inventory are investigated and resolved. Based on these measures, the SHINE MC&A plan indicates that there will be no unencapsulated or unsealed items on ending inventory.

The NRC staff finds that SHINE's program for confirmation of the validity of prior measurements used for item control and inventory control, as provided in sections 11.1, 8.4, 7.3, and 7.5 of the SHINE MC&A Plan, includes the use of TIDs to ensure that no items are unencapsulated or unsealed on ending inventory. This meets the inventory control requirement in 10 CFR 74.43(c)(4) and is, therefore, acceptable.

Under 10 CFR 74.43(c)(5) licensees must maintain and follow physical inventory procedures to ensure that the requirements in 10 CFR 74.43(c)(5)(i)–(vi) are met. Under 10 CFR 74.43(c)(6) licensees must conduct physical inventories according to written instructions which meet the requirements in 10 CFR 74.43(c)(6)(i)-(iv).

Concerning the inventory procedure requirements in 10 CFR 74.43(c)(5), section 7.1 of the SHINE MC&A Plan states that all aspects of SHINE's physical inventory program are contained in the SHINE MC&A procedure, "Physical Inventory Taking." Chapter 7 of the SHINE MC&A Plan describes the physical inventory program, including the general description, organization, procedures, inventory composition, and conduct of the inventory. Sections 7.3 and 7.5 of the SHINE MC&A Plan state that the physical inventory is a measured inventory, that any SNM not previously measured is measured for inventory, and that every item is accounted for and no item is counted more than once by using controlled inventory tags. Cutoff procedures for transfers and processing, and for records and reports, are established as described in sections 7.3 and 7.5 of the SHINE MC&A Plan. As stated in section 7.3 of the SHINE MC&A Plan, any SNM not previously measured is measured for the inventory, and the measurements are completed as soon as possible after the inventory listing. Section 7.5 of the SHINE MC&A Plan states that following the physical inventory, the book and inventory records are reconciled with, and adjusted to, the results of the physical inventory for each internal control area.

Concerning the inventory written instructions requirements in 10 CFR 74.43(c)(6), section 7.5 of the SHINE MC&A Plan states that detailed inventory instructions are issued prior to the start of each inventory and are approved by the MC&A manager. Section 7.5 of the SHINE MC&A Plan also states that facility staff with inventory responsibilities are named in the instructions and trained to perform their inventory activities. SHINE stated that the instructions include a timeline of activities including cutoff times for SNM movement and processing, steps taken to clean out processing equipment, and the timing and performance of various inventory steps. Section 7.3 of the SHINE MC&A Plan provides a list of every inventory stratum and how those strata are handled during inventory. Section 7.3 also states that SNM items measured prior to inventory are not remeasured if a TID was applied at the time of measurement and if inspection of the item and the TID indicates that the contents (measured quantity and its limit of error) are intact. If there is evidence of tampering, the contents will be remeasured. The inventory instructions identify specific points where measurements should be made and detail any deviation from normal inventory procedures. As discussed in the previous paragraphs, the SHINE MC&A Plan also includes normal inventory procedures.

The NRC staff finds that the inventory procedures and instructions used for inventory control, as described in sections 7.1, 7.3, and 7.5 of the SHINE MC&A Plan, sufficiently address the inventory control requirements in 10 CFR 74.43(c)(5) and (6) and are, therefore, acceptable.

Under 10 CFR 74.43(c)(7) licensees must conduct physical inventories of all SNM possessed at intervals not to exceed nine calendar months. Under 10 CFR 74.43(c)(8) licensees must, within 60 calendar days after the start of the physical inventory required by 10 CFR 74.43(c)(7), calculate, for the material balance period terminated by the physical inventory, the ID and associated SEID for both element and isotope; reconcile and adjust the book record of quantity of element and isotope, as appropriate, to the results of the physical inventory; and investigate and report to the Director, NRC Office of Nuclear Material Safety and Safeguards, any occurrence where the ID or the SEID exceed limits specified in 10 CFR 74.43(c)(8)(iii) and include a statement of the probable reasons for the excessive inventory difference and the corrective actions taken or planned. The regulations in 10 CFR 74.13, "Material status reports," require, in part, licensees to submit material balance reports and physical inventory listings for each physical inventory performed within 60 calendar days of the beginning of the physical inventory. The regulations in paragraph (b) of 10 CFR 74.17, "Special nuclear material physical inventory summary report," require, in part, licensees to report the results of each physical inventory using NRC Form 327, "Special Nuclear Material (SNM) and Source Material (SM) Physical Inventory Summary Report," not later than 60 calendar days from the start of each physical inventory required by 10 CFR 74.43(c)(7).

Chapter 7 of the SHINE MC&A Plan provides a description of the physical inventory program for the SHINE facility. Section 7.1 of the SHINE MC&A Plan states that a physical inventory of all

SNM at the facility is conducted at intervals not to exceed 9 calendar months, and that differences between the accounting records and the physical inventory are investigated and reconciled. Details of the physical inventory process, including reconciliation activities to align the accounting records and the physical inventory, are provided in section 7.5 of the SHINE MC&A Plan.

Section 7.1 of the SHINE MC&A Plan states that material balance reports (Department of Energy/NRC Form 742, misidentified in the MC&A Plan as material status reports)—which are a type of material status report—and physical inventory listings and the inventory summary report (NRC Form 327) are submitted within 60 days of the start of the physical inventory in the proper formats. Calculation of the ID and the associated SEID are described in section 6.2 of the SHINE MC&A Plan. Section 7.6, "Inventory Limits and Response Actions," of the SHINE MC&A Plan describes the calculation of the ID limits and response actions when the ID exceeds the limits specified in 10 CFR 74.43(c)(8)(iii), including reporting to the NRC. Section 7.7 of the SHINE MC&A Plan states that if the SEID exceeds its 10 CFR 74.43(c)(8)(iii) control limit an investigation will be conducted and the NRC will be notified. Finally, as stated in chapter 7 of the SHINE MC&A Plan, calculation of ID and SEID; relevant reconciliation activities; and investigation and reporting of SEID and ID exceeding relevant limits will be completed within 60 calendar days after the start of each physical inventory.

The NRC staff finds that SHINE's plan for conducting inventories and reporting results of the inventories, as provided in chapter 7 and section 6.2 of the SHINE MC&A Plan, includes sufficient explanation of how and when SHINE will conduct inventories and the associated reporting to allow the staff to determine that the program meets the inventory control requirements in 10 CFR 74.43(c)(7) and (8), 10 CFR 74.13, and 10 CFR 74.17 and is, therefore, acceptable.

Chapter 8 – Item Control Program

Under 10 CFR 74.43(b)(5) licensees must establish, document, and maintain an item control program to protect against and detect unauthorized and unrecorded removal of items, or of material from items. This includes providing current knowledge of SNM items with respect to identity, element and isotope content, and stored location. Further, 10 CFR 74.43(b) exempts certain items from the requirements of 10 CFR 74.42(b)(5). An item, as defined in 10 CFR 74.4, "Definitions," means any discrete quantity or container of SNM or source material, not undergoing processing, having a unique identity and also having an assigned element and isotope quantity.

Chapter 8 of the SHINE MC&A Plan describes the item control program at the SHINE facility. The organizational responsibilities for the item control program are provided in section 8.1, "Organization," as well as section 3.3.1, "Nuclear Material Accounting Responsibilities," section 3.3.3, "Nuclear Material Control Responsibilities," and section 3.3.4 of the SHINE MC&A Plan. A general description of the item control program is provided in section 8.2, "General Description," of the SHINE MC&A Plan which states that the item control program is designed to provide current knowledge of items and ensures the detection of unauthorized or unrecorded removal of SNM. Chapter 8 of the SHINE MC&A Plan also describes item identity and storage controls, which ensures that items have unique identities and are protected during storage, and item monitoring procedures, which confirm that items are stored and identified as indicated in the records. Section 8.6, "Investigation and Resolution of Item Discrepancies," of the SHINE MC&A Plan states the type of discrepancies identified by item monitoring tests and that all discrepancies are investigated and resolved. Other sections of the SHINE MC&A Plan discuss activities that support item control. Sections 9.1, “Receiving Procedures,” and 9.5, “Shipments,” of the SHINE MC&A Plan discuss controls for receipts and shipments to ensure that they are properly tracked and controlled. Chapter 11 of the SHINE MC&A Plan discusses tamper-safing, which ensures the integrity of the contents of items. Chapter 12, “Designation of Material Balance Areas, Item Control Areas, and Custodians,” of the SHINE MC&A Plan discusses the designation of material balance areas (MBAs) and custodians to facilitate SNM control. Chapter 15, “Recordkeeping,” of the SHINE MC&A Plan discusses recordkeeping, including the use of two forms: the item history form to track an item throughout its existence and the SNM transfer form to document relocations of SNM.

The NRC staff finds that SHINE’s program for item control for the SHINE facility, as provided in chapters 8, 9, “Receiving and Shipping Program,” 11, 12, and 15 of the SHINE MC&A Plan, adequately describes how the program provides for current status, protection, and detection of missing SNM items to allow the staff to determine that the program meets the item control requirements in 10 CFR 74.43(b)(5), as modified by the 10 CFR 74.43(b)(6) exemption, and is, therefore, acceptable.

Chapter 9 – Receiving and Shipping Program

Under 10 CFR 74.43(b)(7) licensees must conduct and document shipper-receiver comparisons for all SNM receipts-on both an individual batch basis and total shipment basis-and ensure that any shipper–receiver difference (SRD) that is statistically significant and exceeds twice the estimated standard deviation of the difference estimator and 200 grams of plutonium or uranium (U)-233, or 300 grams of U-235, is investigated and resolved.

Chapter 9 of the SHINE MC&A Plan describes the conduct of shipper–receiver comparisons, including receiving procedures and how the receiver’s values are determined. Section 9.3, “Evaluation of Shipper-Receiver Differences,” of the SHINE MC&A Plan discusses the statistical evaluation of SRDs, including how the combined standard error is determined, and the criteria for finding an SRD significant. Investigation and resolution of significant SRDs is described in section 9.4, “Resolution of Significant Shipper-Receiver Differences,” of the SHINE MC&A Plan, including steps taken to investigate a significant SRD and possible causes. SHINE stated that any SRD that is statistically significant and exceeds twice the estimated standard deviation of the difference estimator and 300 grams of U-235, for both total receipt and individual containers, is investigated and resolved. Section 15.1 of the SHINE MC&A Plan states that MC&A records include records related to the calculation of SRDs.

The NRC staff finds that SHINE’s program for conducting shipper–receiver comparisons for the SHINE facility, as provided in chapter 9 of the SHINE MC&A Plan, adequately addresses the calculation of SRD and resulting actions to meet the shipper–receiver requirement in 10 CFR 74.43(b)(7) and is, therefore, acceptable.

Chapter 10 - Assessment and Review of the MC&A Program

Under 10 CFR 74.43(b)(8) licensees are required to perform an independent assessment of the MC&A program at least every 18 months. This assessment must assess the performance of the MC&A program, review its effectiveness, and document management’s action on prior assessment recommendations and identified deficiencies. The assessment must also include a review and evaluation of any contractor who performs SNM accountability measurements for the licensee.

Chapter 10 of the SHINE MC&A Plan describes the assessment and review of the SHINE MC&A program. Chapter 10 describes the makeup and responsibilities of the assessment team, a comprehensive list of the areas to be reviewed, the review process, including timing of the review and distribution of the report, and the review and response to the report findings. SHINE stated that the assessment evaluates the performance and overall effectiveness of the SHINE MC&A program every 18 months, and documents management action on prior assessment recommendations and deficiencies. SHINE also stated that the assessment includes an evaluation of any contractor who performs SNM accountability measurements for SHINE.

The NRC staff finds that SHINE's program for independent assessment of the MC&A program for the SHINE facility, as provided in chapter 10 of the SHINE MC&A Plan, sufficiently describes the approach to allow the staff to determine that the assessment meets the assessment program requirement in 10 CFR 74.43(b)(8) and is, therefore, acceptable.

Chapter 11 – Tamper-Safing

Under 10 CFR 74.43(c)(3) licensees must maintain and follow procedures for tamper-safing of containers or vaults containing SNM, if tamper-safe seals are to be used for assuring the validity of prior measurements. The procedures must include control of access to, and distribution of, unused seals and records showing the date and time of seal application.

Chapter 11 of the SHINE MC&A Plan describes the tamper-safing program. SHINE described the types of TIDs used at the SHINE facility and the testing of the TIDs to ensure that their removal would be detected. SHINE further described TID control and usage, inventory of unused and unissued TIDs, the proper application of TIDs, and the training of authorized users in the application and destruction of TIDs. Chapter 11 of the SHINE MC&A Plan also describes the records that are prepared to document TID activities. The SHINE tamper-safing program ensures that procedures are maintained and followed for tamper-safing, and includes control of access to, and distribution of, unused seals and records showing the date and time of seal application.

The NRC staff finds that SHINE's tamper-safing program for the SHINE facility, as provided in chapter 11 of the SHINE MC&A Plan, adequately describes the use of TIDs to allow the staff to determine that the program meets the tamper-safing requirement in 10 CFR 74.43(c)(3) and is, therefore, acceptable.

Chapter 12 – Designation of Material Balance Areas, Item Control Areas, and Custodians

As discussed above, because of the material that SHINE expects to possess, it is governed by 10 CFR 74.41, 10 CFR 74.43, and 10 CFR 74.45. Although these regulations do not require MBAs, item control areas, and the designation of custodians, SHINE has voluntarily decided to designate an MBA and to designate custodians as part of its MC&A Plan. That said, regulations related to measurements in 10 CFR 74.45(b) and to inventory in 10 CFR 74.43(c) do require "internal control areas," and licensees use ICAs in some form to facilitate the control of SNM.

Chapter 12 of the SHINE MC&A Plan describes the designation of material control boundaries - which is a generic term SHINE uses to refer to both MBAs and ICAs - and custodians. Due to the size of the SHINE facility, only one MBA is designated. However, to facilitate control, localize losses, and aid in the resolution of MC&A anomalies, the one MBA is divided into five ICAs. Chapter 3 of the SHINE MC&A Plan contains additional information on ICAs and custodial responsibilities. The ICAs are characterized by the form of material and by the physical location of the material. The SHINE MC&A Plan also states that custodial responsibility is assigned to one individual for each ICA.

As noted above, SHINE is not required to identify MBAs, item control areas, or designate custodians. That said, nothing in the regulations prevents SHINE from going beyond the regulatory requirements. The NRC staff reviewed the SHINE MC&A Plan and finds that SHINE's plan for the designation of MBAs, ICAs, and custodians for the SHINE facility, as provided in chapters 12 and 3 of the SHINE MC&A Plan, is consistent with the related regulatory requirements.

Chapter 13 – Resolving Indications of Loss, Theft, Diversion, or Misuse of Special Nuclear Material

Under the general performance objectives in 10 CFR 74.41(a)(2) and (3) licensees should be able to promptly conduct investigations and resolve anomalies indicating a possible loss of SNM, and rapidly determine whether an actual loss of a significant quantity of SNM, as defined in 10 CFR 74.41(a)(3)(i)-(ii), has occurred.

Chapter 13 of the SHINE MC&A Plan describes the resolution program. SHINE described methods and procedures for identifying indicators and the actions taken when an alarm occurs. Chapter 13 provides a list of the types of indicators investigated, describes the information needed for an investigation, and describes the steps taken in the investigation and resolution process. SHINE described the criteria for determining that an indicator is resolved, the timing of the investigation, and notifications to the NRC. Chapter 13 also describes response actions for unresolved indicators, including escalating the response actions and the level of management involved, and conducting a possible cleanout inventory. Section 13.2, "System and Procedures for Investigating and Resolving Loss Indicators," of the SHINE MC&A Plan states the time allowed for resolution, and states that if the indicator is true or SHINE is unable to determine that it is not true, notification is made to the NRC in accordance with 10 CFR 74.11, "Reports of loss or theft or attempted theft or unauthorized production of special nuclear material." Section 13.2 of the SHINE MC&A Plan defines "true" and "not true" indicators such that they align with the reporting requirements in 10 CFR 74.11. Section 13.4, "Documentation Requirements," of the SHINE MC&A Plan states the documentation required for the investigation and resolution of an indicator.

The NRC staff finds that SHINE's resolution program for the SHINE facility, as provided in chapter 13 of the SHINE MC&A Plan, adequately describes its criteria and process for resolving indications to allow the staff to determine that the program meets the resolution program requirements in 10 CFR 74.41(a)(2) and (3) and 10 CFR 74.11 and is, therefore, acceptable.

Chapter 14 – Aiding Investigation and Recovery of Missing Special Nuclear Material

The general performance objective in 10 CFR 74.41(a)(4) requires licensees to generate information to aid in the investigation and recovery of missing SNM in the event of an actual loss.

Chapter 14, "Aiding Investigation and Recovery of Missing Special Nuclear Material," of the SHINE MC&A Plan describes the program for aiding investigation and recovery of missing SNM. SHINE described the types of information available to aid in the investigation and recovery, lists the sources of information indicating that a loss or theft may have occurred, and lists additional information that may be useful in resolving indications of missing SNM. Chapter 14 of the SHINE MC&A Plan states that records are prepared and maintained for all activities and are available to the NRC and any other government investigators to assist in any investigation relating to actual or suspected missing material.

The NRC staff finds that SHINE's program for providing information to aid in the investigation and recovery of missing SNM, as provided in chapter 14 of the SHINE MC&A Plan, is sufficiently complete to meet the investigational aid requirement in 10 CFR 74.41(a)(4) and is, therefore, acceptable.

<u>Chapter 15 – Recordkeeping</u>

Under 10 CFR 74.43(d)(5) licensees must establish and maintain records that demonstrate that the general performance objectives of 10 CFR 74.41(a)(1)–(4) and the system capabilities of 10 CFR 74.43(b) and (c) and 10 CFR 74.45(b) and (c) have been met. Further, in accordance with 10 CFR 74.43(d)(5), licensees must retain these records for a minimum of 3 years (or longer if specifically required by 10 CFR 74.19(b), 10 CFR Part 75, "Safeguards on Nuclear Material—Implementation of Safeguards Agreements between the United States and the International Atomic Energy Agency," or by a specific license condition). Additionally, under 10 CFR 74.43(d)(1)–(3) licensees must maintain records documenting receipt, shipment, disposal, and current inventory associated with all possessed SNM; quantities of SNM added to and removed from process; and all shipper–receiver evaluations associated with SNM receipts.

Under 10 CFR 74.43(d)(4) licensees must retain records pertaining to the receipt and disposal of SNM until the Commission terminates the license. In addition to meeting the recordkeeping requirements of 10 CFR 74.43(d), the licensee's MC&A system must, in accordance with 10 CFR 74.41(c)(1) and (2), incorporate checks and balances that are sufficient to detect the falsification of data and reports that could conceal diversion of SNM by: (1) a single individual, including an employee in any position or (2) collusion between two individuals, one or both of whom have authorized access to SNM.

Chapter 15 of the SHINE MC&A Plan describes the recordkeeping program. SHINE listed the records, forms, reports, and procedures that are considered to be MC&A records; listed records generated by other facility organizations that are necessary for MC&A; and described retention periods for the records. SHINE stated that MC&A records, forms, reports, and procedures are retained for a minimum of 3 years or longer if specifically required by 10 CFR Part 75, and that records pertaining to receipt and disposal of SNM are retained until the NRC terminates the license. Chapter 15 of the SHINE MC&A Plan describes the program and controls for ensuring an accurate and reliable record system, including: access to records; storage controls; redundancy of records; controls to protect computerized records; and checks and balances to detect destruction or falsification of records, such as signature by two individuals. In addition, section 3.3, section 3.5, "MC&A Program Description," and section 3.7, "Commitments and Acceptance Criteria," of the SHINE MC&A Plan describe the SHINE MC&A program and organizational elements that ensure that checks and balances are in place to detect the falsification of data and reports that could conceal diversion of SNM.

The NRC staff finds that SHINE's recordkeeping program, as provided in chapter 15 and chapter 3 of the SHINE MC&A Plan, includes the appropriate records, retention periods, and checks and balances to meet the recordkeeping requirements in 10 CFR 74.43(d) and 10 CFR 74.41(c)(1) and (2) and is, therefore, acceptable.

Chapter 16 – Appendix

Chapter 16, "Appendix," of the SHINE MC&A Plan contains supplemental information including: site layout; production facility layout; organization chart; list of MC&A procedures; list of MC&A forms; item history form; and SNM transfer form. The information in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information in chapter 16, "Appendix," of the SHINE MC&A Plan is acceptable because it is administrative in nature and not contrary to the NRC's regulations.

Conclusion

The NRC staff evaluated the sufficiency of the SHINE MC&A Plan, as described in SHINE FSAR section 12.13 and provided in Revision 5 of the SHINE MC&A Plan, against the applicable regulatory requirements. The staff determined that the SHINE MC&A Plan describes acceptable methods for achieving the general performance objectives in 10 CFR 74.41(a) and the system features and capabilities requirements of 10 CFR 74.43 and 10 CFR 74.45. Therefore, the staff concludes that the SHINE MC&A Plan is acceptable.

12.4.14 Cybersecurity

There are currently no NRC regulations regarding cybersecurity that apply to non-power production and utilization facilities intending to produce Mo-99 like the SHINE facility. Therefore, in SRM-SECY-18-0063, the Commission directed the NRC staff to address cybersecurity at these facilities through the subsequent development of appropriate license conditions based on the facilities' operating license applications. The staff determined that the best approach to develop such risk-informed site-specific license conditions to establish an adequate level of protection for the SHINE facility would be to use, as a starting point, the cybersecurity requirements for similar types of facilities.

The NRC staff reviewed the SHINE FSAR to determine if it includes an adequate level of cybersecurity protections to ensure that, in accordance with 10 CFR 50.57(a)(6), the issuance of an operating license for the SHINE facility will not be inimical to the common defense and security or to the health and safety of the public. The staff also performed a regulatory audit to determine what cybersecurity practices are being applied at the SHINE facility. The staff issued RAIs to SHINE to help gather further information, to which SHINE provided responses (ML21315A003). After completing this review, the staff determined that additional cybersecurity program elements were needed to provide reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks.

To ensure adequate protection at the SHINE facility, and consistent with SRM-SECY-18-0063, the NRC staff drew upon its review of the SHINE FSAR and lessons learned from the cybersecurity programs at nuclear power reactor facilities and the draft fuel cycle facility cybersecurity rulemaking (ML17018A218), to develop a list of important cybersecurity program elements applicable to the SHINE facility. These elements are included in the below risk-informed license condition that allows SHINE to apply a graded approach to cybersecurity based on the consequences of concern specific to the SHINE facility. The term "consequences of concern" is explained below. Specifically, the license condition requires SHINE to have a cybersecurity plan that describes how the facility's cybersecurity program provides reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks. The license condition also requires that the cybersecurity program elements described in the cybersecurity plan include the elements determined by the staff to be important and applicable to the SHINE facility. The staff determined that this license condition, in addition to the supplemental information provided by SHINE that is discussed immediately below, will ensure, in part, that the issuance of the operating license will not be inimical to the common defense and security or to the health and safety of the public. Therefore, the issuance of a SHINE operating license, as conditioned, in part, by the below license condition, meets the requirements of 10 CFR 50.57(a)(6).

On July 6, 2022, SHINE submitted a revision to its responses to NRC staff RAIs related to cybersecurity (ML22223A066) that provides information regarding the design, administrative, and programmatic controls that the SHINE cybersecurity plan will address. This includes how consequences of concern will be identified, how critical digital assets (CDAs) will be determined, how cybersecurity controls will be applied, and other programmatic controls to ensure that the cybersecurity program is documented and maintained. The NRC staff determined that, through the combination of this information and the below cybersecurity license condition, once the SHINE cybersecurity plan is implemented, there will be sufficient cybersecurity program elements in place to provide reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks. The staff also reviewed the consequences of concern identified by SHINE in its July 6, 2022, revised responses to RAIs and determined that protecting CDAs associated with these consequences of concern provides reasonable assurance that issuance of the operating license will not be inimical to the common defense and security or to the health and safety of the public.

A consequence of concern is an event that occurs as a result of the compromise of a CDA that has the potential to adversely impact the public health and safety or the common defense and security. Licensees must identify and document those digital assets that, if compromised by a cyberattack, would result in a consequence of concern. Such digital assets that are then determined to be CDAs must be protected by the application of appropriate cybersecurity controls. A consequence of concern can be active or latent. In the case of an active consequence of concern, the compromise of the digital asset from a cyberattack directly results in a radiological or chemical exposure exceeding the safety criteria limits specified in a licensee’s FSAR. In the case of a latent consequence of concern, a digital asset is compromised but there is no direct impact on a safety, security, or safeguards function until a secondary event occurs (i.e., an initiating event separate from the cyberattack). The combination of the compromise of the digital asset from the cyberattack (i.e., the latent consequence of concern) and the secondary event must both occur for there to be a significant impact on public health and safety or common defense and security.

For facilities intending to produce Mo-99 such as the SHINE facility, the following consequences of concern must be considered (but may not necessarily apply):

> Latent Safeguards: The concern involves the compromise as a result of a cyberattack of a digital asset performing a security function, which would allow a malicious actor to exploit the degraded security function that was put in place to prevent the unauthorized removal of SNM of moderate strategic significance or the loss of MC&A for SNM of moderate strategic significance.
>
> Active Safety: In this situation, the cyberattack compromises the function of a digital asset and directly leads to safety-related consequences as defined in the safety criteria found in the licensee’s FSAR.

Latent Safety or Security: The attack renders one or more digital assets incapable of performing its intended function. When called upon to respond to an event, separate from the cyberattack, the digital asset does not operate as expected and therefore the supported safety or security function is compromised, resulting in safety-related consequences like above, or loss or unauthorized disclosure of classified information or classified matter. In addition, MC&A functions whose compromise could lead to a latent safety consequence of concern, would need to be protected from a cyberattack.

Based on the above, the SHINE operating license is conditioned as follows:

The licensee must have a cybersecurity plan that describes how the facility's cybersecurity program provides reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks. The cybersecurity program elements described in the cybersecurity plan must include but are not limited to the following:

(1) Establishing a team with working knowledge in information and digital system technology, facility operations, engineering, safety, and the facility's physical security and emergency preparedness to identify the relevant consequences of concern, including latent safeguards, active safety, and latent safety or security consequences of concern, as applicable, as defined in the NRC safety evaluation of the SHINE facility operating license application, and make informed cybersecurity decisions. Alternatively, establish equivalent individual roles and responsibilities in the cybersecurity plan that ensure that informed cybersecurity decisions are made.

(2) Identifying digital assets that, if compromised by a cyberattack, would result in a consequence of concern.

(3) Determining which of these assets are critical digital assets (CDAs) that need to be protected to meet the cybersecurity program performance objectives of the facility.

(4) Identifying a set of cybersecurity controls for CDAs and applying them so that there is reasonable assurance that the facility is adequately protected against cyberattacks.

(5) Implementing site-specific defense-in-depth protective strategies that ensure that the failure of a single protective strategy or security control will not result in a consequence of concern by describing how the licensee delays, detects, prevents, responds to, and recovers from cyberattacks on CDAs, as applicable.

(6) Providing temporary compensatory measures to meet the cybersecurity program performance objectives when the cybersecurity controls are degraded.

(7) Establishing and maintaining a configuration management system to ensure that any changes to the facility are monitored and evaluated for potential cybersecurity impacts prior to implementation so that there is

reasonable assurance that the facility is adequately protected against cyberattacks.

(8) Periodically reviewing the effectiveness of the cybersecurity program to provide reasonable assurance that the cybersecurity program performance objectives of the facility are continuously met.

(9) Tracking and reporting cybersecurity events.

The licensee may make changes to the cybersecurity plan provided that the above cybersecurity program elements and the performance objectives of the cybersecurity plan remain met and that these changes are made with the knowledge of the team, or its equivalent, of program element (1).

12.5 Review Findings

The NRC staff reviewed the descriptions and discussions of SHINE's conduct of operations, as described in SHINE FSAR chapter 12, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the conduct of operations and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's conduct of operations are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

13.0 ACCIDENT ANALYSIS

The accident analysis shows that the health and safety of the public and workers are protected, potential radiological and non-radiological consequences have been considered in the event of malfunctions, and the SHINE Medical Technologies, LLC (SHINE, the applicant) facility is capable of accommodating disturbances in the functioning of structures, systems, and components (SSCs). Additionally, the accident analysis demonstrates that the SHINE facility design features, safety limits, limiting safety system settings, and limiting conditions for operation (LCOs) have been selected to ensure that no credible accident could lead to unacceptable radiological consequences to people or the environment.

The accidents analyzed range from anticipated events such as a loss of normal electrical power to a postulated fission product release with radiological consequences that exceed those of any accident considered to be credible. This limiting accident is named the maximum hypothetical accident (MHA). Because the MHA is not expected to occur, the scenario need not be entirely credible. The initiating event and the scenario details need not be analyzed, but the potential consequences should be analyzed and evaluated.

The accident analysis establishes safety limits for SHINE facility operations and provides a technical basis for control of those limits through technical specifications (TSs).

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation by the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final accident analysis of the SHINE irradiation facility (IF) and radioisotope production facility (RPF) (together, the SHINE facility), as presented in chapter 13, "Accident Analysis," of the SHINE final safety analysis report (FSAR) and supplemented by the applicant's responses to staff requests for additional information (RAIs).

13a Irradiation Facility Accident Analysis

Section 13a, "Irradiation Facility Accident Analysis," of this SER provides an evaluation of the final accident analysis of SHINE's IF as presented in SHINE FSAR section 13a2, "Irradiation Facility Accident Analysis," within which SHINE described accident-initiating events and scenarios, as well as the accident analysis and determination of consequences.

13a.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 13a2 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final IF accident analysis. The final IF accident analysis was evaluated to ensure that the analysis is presented in sufficient detail to allow a clear understanding of the facility and that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the operating staff and the public. SSCs were also evaluated to ensure that they would adequately provide for the prevention of accidents and for the mitigation of consequences of accidents. The staff considered the final analysis and evaluation of the design and performance of the SSCs of the SHINE facility, including those SSCs shared by both the IF and RPF, with the objective of assessing the risk to public health and safety resulting from the operation of the facility.

13a.2 Summary of Application

SHINE FSAR section 13a2 identifies and describes the postulated initiating events and credible accidents that form the design basis for the SHINE IF. The FSAR also describes the accident analysis and determination of consequences for the IF. The FSAR provides details on event categories covering the MHA and credible accidents related to the IF, which are insertion of excess reactivity, reduction in cooling, mishandling or malfunction of target solution, loss of offsite power, external events, mishandling or malfunction of equipment, large undamped power oscillations, detonation and deflagration in the primary system boundary, unintended exothermic chemical reactions other than detonation, system interaction events, and facility-specific events.

13a.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR section 13a2 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final IF accident analysis for the issuance of an operating license.

13a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's IF accident analysis are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.57, "Issuance of operating license."
- 10 CFR Part 20, "Standards for Protection Against Radiation."
- 10 CFR 70.61, "Performance requirements."

13a.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power

Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

- NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," issued June 2015.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff's use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in Appendix B, "References," of this SER.

13a.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR section 13a2, as supplemented, to assess the sufficiency of the final SHINE IF accident analysis for the issuance of an operating license. The sufficiency of the final accident analysis is determined by ensuring that it meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 13a.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The results of this technical evaluation are summarized in section 13a.5, "Review Findings," of this SER.

The review covered the methodology for analyzing the systems and operating characteristics of the SHINE facility that could affect its safe operation or shutdown. It includes the identification of limiting accidents within each design-basis accident (DBA) category, an analyses of accident progression, and evaluation of the radiological and chemical exposure consequences. For each accident category, a review of its effects on designed barriers, protective systems, operator responses, and mitigating features were examined. The analysis of potential radiological consequences to the public, the facility control room operators and staff, and the environment were evaluated against the applicable accident dose criteria. Chemical exposure consequences to the same receptors were evaluated against the applicable chemical exposure criteria. These analyses use the most conservative operational condition or operating mode to determine potential radiological and chemical exposure consequences. The information and analyses presented demonstrate that the SHINE facility system designs, safety limits, limiting safety system settings, and LCOs were selected to ensure that the consequences of analyzed accidents do not exceed acceptable radiological or chemical design criteria.

The primary potential consequences resulting from the operation of the SHINE facility are radiological. The DBAs are postulated accidents that a nuclear facility must be designed and built to withstand without loss to the SSCs necessary to ensure public health and safety. They can be thought of as loosely defined ‘classes’ of accidents that bound a number of facility processes, activities, or accident sequences identified through a type of risk-assessment, to identify the limiting event selected for detailed quantitative radiological consequence analysis. They are not intended to be actual event sequences, but rather to be surrogates to enable deterministic evaluation of the response of a facility’s engineered safety features. They are intentionally conservative in order to compensate for known uncertainties in accident progression, fission product transport, and atmospheric dispersion.

The DBAs are computed in terms of total effective dose equivalent (TEDE), which are used as “figures-of-merit” to be compared to the applicable control room design and siting criterion. The TEDE is defined in 10 CFR 20.1003, “Definitions,” as the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). For the purposes of design and siting, this allows for a transparent assessment of the performance of minimum necessary design, fabrication, construction, testing, and performance requirements for SSCs. As discussed above, the TEDE value represents the results of a highly stylized deterministic modeling approach of DBAs, which credits only safety-related emergency safety features to transport and mitigate a severe accident source term which represents an accident of exceedingly low probability. It is noted that these TEDE results do not represent actual doses given an event. However, they do help ensure that actual doses received during an accident remain below the occupational dose limits of 10 CFR Part 20, “Standards for Protection Against Radiation.” This would be done in combination with the general as low as is reasonably achievable (ALARA) practices of 10 CFR Part 20.

SHINE presented two types of safety analyses for the NRC staff to review: (1) the SHINE safety analysis (SSA) and (2) traditional DBA radiological consequence analyses. The SSA was developed pursuant to the ISG augmenting NUREG-1537, which endorses the use of integrated safety analysis methodologies as described in 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” and NUREG-1520, “Standard Review Plan for Fuel Cycle Facilities License Applications.” Those methodologies apply the consequence and likelihood criteria of 10 CFR 70.61 to determine credible accident sequences, preventive or mitigative safety features (i.e., engineered and administrative controls, which the applicant refers to as safety-related controls), and the associated quality assurance elements to ensure that those features are available and reliable. The SSA is considered a licensee-controlled document. However, consistent with the ISG augmenting NUREG-1537, the SSA is a part of SHINE’s demonstration that the SHINE facility design and operations will ensure the health and safety of facility personnel and the public. The SSA is also controlled by the SHINE administrative controls TSs as a part of the SHINE Nuclear Safety Program. In its response to NRC staff Request for Confirmatory Information (RCI) 13-9 (ML22304A126), SHINE confirmed that TS 5.5.1, “Nuclear Safety Program,” ensures that the SSA and its supporting documentation will remain accurate and current, including prompt updates when changes are made to the facility, operations, or FSAR descriptions. The SHINE DBA analyses follow guidance found in NUREG-1537, Part 2, chapter 13, “Accident Analyses,” as augmented by the ISG augmenting NUREG-1537, Part 2, which states that the standard review plan and acceptance criteria are applicable to reviewing a description of the accident analyses. SHINE also identified a number of SHINE facility-specific DBAs through the SSA.

Radiological and Design Criterion

Presently, no radiological accident dose criterion is set forth in regulation or guidance to assess the risk to public health and safety and control room operators for non-power production or utilization facilities. In lieu of a standard regulatory accident dose criterion, the standards of 10 CFR Part 20 have been applied for evaluating the effects of a postulated accident, for instance:

- Before January 1, 1994, the accident dose criteria used to license a non-power production or utilization facility were generally compared to the public dose limits of 10 CFR Part 20. Therefore, the accident criteria that the NRC staff generally found to be acceptable for accident analyses were the public dose limits of 0.5 roentgen equivalent man (rem) whole body and 3 rem thyroid for members of the public.

- On January 1,1994, the NRC amended 10 CFR Part 20 to reduce the dose limits to a member of the public to 0.1 rem TEDE with an implementation date of January 1, 1994. In lieu of an accident dose criterion, under 10 CFR 20.1301(d), a licensee or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem.

However, as discussed in NUREG-1537, Part 1, there are several instances in which the NRC staff has accepted very conservative accident analyses that exceed the 10 CFR Part 20 public dose limits discussed above.

The NRC staff described in the *Federal Register*, Volume 82, Number 60, dated March 30, 2017 (82 FR 15643), a proposal to amend the NRC's regulations that govern the license renewal process for non-power production or utilization facilities. The staff stated that it had determined that the public dose limit of 0.1 rem (0.001 sievert (Sv)) TEDE is unduly restrictive to be applied as accident dose criteria for these facilities, other than those subject to 10 CFR Part 100, "Reactor Site Criteria." The staff based this determination on an NRC Atomic Safety and Licensing Appeal Board statement that the standards in 10 CFR Part 20 are unduly restrictive as accident dose criteria for research reactors (Trustees of Columbia University in the City of New York, ALAB-50, 4 AEC 849, 854–855 (May 18, 1972)). Therefore, the staff proposed to amend the regulations in 10 CFR 50.34, "Contents of applications; technical information," to add an accident dose criterion of 1 rem TEDE for non-power production or utilization facilities not subject to 10 CFR Part 100.

The proposed accident dose criterion of 1 rem TEDE is based on the U.S. Environmental Protection Agency's (EPA) Protective Action Guides (PAGs), which were published in the EPA document 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents." In January 2017, the EPA published an update to its PAGs in EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents." The update to the EPA PAGs did not change the basis for the 1 rem TEDE early phase PAG published in 1992. The purpose of the EPA PAGs is to support decisions on protective actions to provide reasonable assurance of adequate protection of the public from unnecessary exposure to radiation.

The EPA PAGs are dose guidelines to support decisions that trigger protective actions such as staying indoors or evacuating to protect the public during a radiological incident. The PAG is defined as the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. The three principles considered in the development of the EPA PAGs were: (1) prevent acute effects; (2) balance protection with other important factors and ensure that actions result in more benefit than harm; and (3) reduce risk of chronic effects. In the early phase of a nuclear incident, which may last hours to days, the EPA PAG recommends the protective actions of sheltering-in-place or evacuation of the public to avoid inhalation of gases or particulates in an atmospheric plume and to minimize external radiation exposures between 1 rem to 5 rem. Therefore, if the projected dose to an individual from a nuclear incident is less than 1 rem, no protective action for the public is recommended.

SHINE chose to adopt an accident dose criterion of 1 rem TEDE based on the proposed rule described in 82 FR 15643 and the EPA PAGs discussed therein. The SHINE-selected radiological siting and design criteria (in lieu of the 10 CFR Part 20 exposure limits) are defined as follows:

- Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 1 rem TEDE for the duration of the accident and

- Radiological consequences to workers do not exceed 5 rem TEDE during the accident.

As also discussed in section 3.4.1.2, "SHINE Facility Nuclear Safety Classification," of this SER, the NRC staff finds this accident dose criterion to be acceptable based on the understanding of the EPA early phase PAGs and the NRC's proposed accident dose criterion of 1 rem TEDE for non-power production or utilization facilities to provide reasonable assurance of adequate protection of the public from unnecessary exposure to radiation. As stated in the proposed rule at 82 FR 15643, "the NRC is proposing to amend its regulations in [10 CFR 50.34] to add an accident dose criterion of 1 rem (0.01 Sv) TEDE for NPUFs [non-power production or utilization facilities] not subject to 10 CFR Part 100." As also stated in the proposed rule, the accident dose criterion of 1 rem (0.01 Sv) TEDE is based on the EPA's PAGs, which in the early phase recommend the protective action of sheltering-in-place or evacuation of the public to avoid inhalation of gases or particulates in an atmospheric plume and to minimize external radiation exposures to 1 rem (0.01 Sv) to 5 rem (0.05 Sv). If the projected dose to an individual from an incident is less than 1 rem (0.01 Sv), then no protective action for the public is recommended. Therefore, the accident dose criterion of 1 rem (0.01 Sv) TEDE provides reasonable assurance of adequate protection of the public from unnecessary exposure to radiation.

SHINE defines the control room operator as the "worker" receptor for calculating radiological consequences to demonstrate compliance with SHINE's General Design Criterion 6 – Control room, which states:

> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

SHINE uses design criteria to ensure that the SSCs within the SHINE facility demonstrate adequate protection against the hazards present. The use of the control room operator as the "worker" receptor assists in ensuring that the SSCs present in the SHINE facility are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public and to control or mitigate the consequences of such accidents. The design criteria are selected to cover:

- The complete range of IF and RPF operating conditions.
- The response of SSCs to anticipated transients and potential accidents.
- Design features for safety-related SSCs including redundancy, environmental qualification, and seismic qualification.
- Inspection, testing, and maintenance of safety-related SSCs.
- Design features to prevent or mitigate the consequences of fires, explosions, and other man-made or natural conditions.
- Quality standards.
- Analyses and design for meteorological, hydrological, and seismic effects.
- The bases for TSs necessary to ensure the availability and operability of required SSCs.

In addition to the siting and design criteria mentioned above, SHINE has additional "SHINE safety criteria" that assist in achieving an acceptable level of safety by ensuring that events are highly unlikely or by reducing their consequences to less than the SHINE safety criteria. The SHINE safety criteria are:

- An acute worker dose of 5 rem or greater TEDE.
- An acute dose of 1 rem or greater TEDE to any individual located outside the owner-controlled area.
- An intake of 30 milligrams or greater of uranium in a soluble form by any individual located outside the owner-controlled area.
- An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could lead to irreversible or other serious, long-lasting health effects to a worker or could cause mild transient health effects to any individual located outside the owner-controlled area.
- Criticality where fissionable material is used, handled, or stored (with the exception of the target solution vessel).
- Loss of capability to reach safe shutdown conditions.

The SHINE radiological-related safety criteria of acute worker dose and individual located outside the owner-controlled area dose of 5 and 1 rem, respectively, are bound by the control room design and siting criteria of 5 and 1 rem, respectively, using the TEDE methodology.

The SHINE safe shutdown safety criterion ensures that the facility is designed to automatically shut down the irradiation process, place the target solution into a safe condition, and stabilize accident conditions without immediate operator actions.

Based on the above, the NRC staff finds the SHINE radiological and design criterion to be an acceptable basis for the SHINE facility accident analysis.

SHINE Safety Analysis Methodology

The NRC staff evaluated the SHINE SSA using the guidance and acceptance criteria from the ISG augmenting NUREG-1537, Part 2, which endorses the use of integrated safety analysis methodologies as described in 10 CFR Part 70 and NUREG-1520. Those methodologies apply the consequence and likelihood criteria of 10 CFR 70.61 to determine credible accident sequences, preventive or mitigative safety features (i.e., engineered and administrative controls, which the applicant refers to as safety-related controls), and the associated quality assurance elements (also referred to as management measures) to ensure that those features are available and reliable. Those consequence criteria include radiological consequences as well as chemical consequences for chemical hazards directly associated with NRC licensed radioactive material. Given the nature of the SHINE facility and processes, the chemical consequence criteria are part of ensuring that the activities authorized by the license can be conducted without endangering the health and safety of the public (10 CFR 50.57(a)(3)) and facility personnel. The chemical consequence criteria also form a part of the bases and evaluations showing that safety functions will be accomplished (10 CFR 50.34(b)(2)). As stated in the ISG augmenting NUREG-1537, Part 1, applicants may propose alternate accident analysis methodologies, consequence and likelihood criteria, safety features, and methods of assuring the availability and reliability of the safety features.

SHINE FSAR section 13a2 states that SHINE's SSA applies a methodology based on NUREG-1520 to the SHINE IF and RPF. The applicant used its SSA methodology to identify and evaluate credible accident sequences. The accident categories include the following, evaluated for the IF and RPF as appropriate:

- Excess reactivity insertion
- Reduction in cooling
- Mishandling or malfunction of target solution
- Loss of offsite power
- External events, including natural phenomenon events
- Mishandling or malfunction of equipment
- Large undamped power oscillations
- Detonation and deflagration in the primary system boundary
- System interaction events
- Facility-specific events

- Inadvertent nuclear criticality in the RPF
- Hazardous chemical accidents

In its SSA, the applicant also identified and evaluated safety-related controls for accident prevention or mitigation, including the methods for ensuring their availability and reliability. There are some differences between SHINE's methodology and the methodology described in NUREG-1520, as noted below. Additionally, while SHINE is a first-of-a-kind facility, the applicant makes use of engineering judgement and operating experience of similar systems and components and similar types of activities in industrial and nuclear applications in its evaluations of the accident sequences and safety-related controls. The NRC staff's review of the applicant's methodology is described below.

The SSA considers routine activities, non-routine activities, and external events that could initiate accident sequences, such as normal and abnormal operations and maintenance activities. The SSA assesses those activities using the following steps:

- Identification and evaluation of facility hazards;
- Identification of credible accident sequences associated with the hazards;
- Assessment of radiological and chemical consequences and likelihoods associated with the accident sequences;
- Identification and description of safety-related controls to prevent the identified accident sequences or mitigate their consequences; and
- Identification of reliability management measures to ensure safety-related controls can perform their intended safety functions.

Among the hazards identified and considered are fissile material hazards for criticality accidents. As described in SHINE FSAR section 3.1, "Design Criteria," criticality is considered in the SHINE safety criteria. SHINE's SSA methodology includes identification and evaluation of such accidents and controls for those accidents. A description of this process is provided in SHINE FSAR section 13a2 and is evaluated below.

Identification and Evaluation of Facility Hazards

SHINE identifies and evaluates facility hazards using common hazard evaluation methods such as Hazard and Operability Analysis (HAZOP) and Failure Modes and Effects Analysis (FMEA). The NRC staff finds that these methods have the necessary capabilities for assessments to satisfy 10 CFR Part 70 requirements when used in accordance with appropriate selection criteria (see NUREG-1513, "Integrated Safety Analysis Guidance Document" (Agencywide Documents Access and Management System Accession No. ML011440260), and section 3.4.3.2(5) of NUREG-1520). The staff used these same criteria to evaluate SHINE's use of these methods as part of SHINE's implementation of 10 CFR Part 70 methodologies to demonstrate compliance with 10 CFR Part 50 requirements. The results of SHINE's hazard evaluation identify those hazards that have the potential to harm the public, facility occupants, or the environment. The results also recommend engineered or administrative controls that may be applied to prevent or mitigate the hazards.

Identification of Credible Accident Sequences Associated With the Hazards

SHINE applied the results of the hazard evaluation to develop process hazards analyses and the associated credible accident sequences. SHINE designated an initiating event for each sequence that SHINE determined according to the applicable failures, process deviations (including human errors), or external events derived from the hazard evaluation.

SHINE defined credible accident sequences as those that do not meet the following conditions:

a. An external event for which the frequency of occurrence can conservatively be estimated as less than once in a million years.

b. A process deviation that consists of a sequence of many unlikely events or errors for which there is no reason or motive. In determining that there is no reason for such errors, a wide range of possible motives, short of intent to cause harm, must be considered.

c. A convincing argument exists that, given physical laws, process deviations are not possible, or are extremely unlikely. The validity of the argument is not dependent on any feature of the design or materials controlled by the TSs or safety-related SSCs or activities.

These criteria are similar to the sets of qualities described in NUREG-1520 that could define an event as not credible. For item c above, the terminology used by the applicant has been adapted to recognize that the license includes TSs, which address those items described in section 13a2 of the SHINE FSAR. The intent is that the argument for an event not being credible cannot depend upon the exercise or implementation of any kind of control. This includes any feature controlled by license condition or TS or by safety-related SSCs or activities, which include engineered or administrative (specific administrative controls, in the applicant's terminology) safety-related controls (among which are those that meet the applicant's safe-by-design definition) or reliability management measures. The NRC staff finds that this intent is consistent with the intent of the set of qualities described in NUREG-1520.

Assessment of Radiological and Chemical Consequences and Likelihoods

SHINE defined consequence and likelihood categories in order to calculate a risk index for each credible accident sequence. The risk index methodology is based on risk index values described in NUREG-1520 where accident sequences with risk indices above a certain limit require safety controls (i.e., safety-related controls, in SHINE's terminology). The SHINE consequence categories designate indices based on deterministic intermediate and high consequence limits for radiological and chemical exposures of the public and facility occupants. SHINE determined these limits based on the SHINE safety criteria.

The SHINE safety criteria define the intermediate consequence limits. An exception is that the SHINE safety criteria include the high consequence limit on soluble uranium intake. The NRC staff notes that 10 CFR 70.61(c) doesn't include a soluble uranium intake limit for intermediate consequences; the limit is in 10 CFR 70.61(b), which means an event leading to an intake in excess of that amount would be a high consequence event. However, with SHINE's approach of reducing the likelihood of both high and intermediate consequence events to highly unlikely, the staff finds SHINE's use of the soluble uranium intake limit to be acceptable. The staff finds that the high consequence limits align with those specified in 10 CFR 70.61(b).

The radiological safety criteria and intermediate consequence limits use dose limit values that are noticeably less than those in 10 CFR 70.61(c) and do not include a separate release criterion like is in 10 CFR 70.61(c). As this is not an application for a 10 CFR Part 70 license, the applicant need not commit to the limits in 10 CFR 70.61 but can propose and justify alternate performance criteria (see section 13b.1 of Part 2 of the ISG augmenting NUREG-1537). In this case, the applicant has selected radiological safety criteria and intermediate consequence limits with dose limit values that are lower than those in 10 CFR 70.61(c). These limits are 5 rem TEDE for workers and 1 rem TEDE for the public. The public accident dose limit is evaluated at the controlled area boundary as discussed in section 13a.4 of this SER. The applicant has not selected a separate release criterion, instead using the public dose criterion to cover the radiological consequences from a release. The NRC staff finds that the dose criterion is an appropriate criterion for accidents for the SHINE facility.

With regard to consequences for workers, SHINE FSAR section 13a2 states that radiological consequences for facility staff are determined for control room operators, but chemical consequences for facility staff are determined for control room operators and other personnel in the controlled area, consistent with the approach in 10 CFR Part 70. The approach for radiological consequences is consistent with the requirements and regulatory criteria for the safety analyses for a 10 CFR Part 50 license. The NRC staff notes that while the FSAR only addresses radiological doses to control room operators, the SSA does include radiological dose to other personnel in the radiologically controlled area, which is consistent with 10 CFR Part 70 for evaluating consequences to any individual that would receive an occupational dose as defined in 10 CFR 20.1003.

SHINE designated three likelihood categories: not unlikely, unlikely, and highly unlikely. For each category, SHINE established corresponding likelihood indices and annual event frequency limits. The NRC staff finds that the defined indices and frequency limits align with table A-6, “Example Likelihood Index Limit Guidelines,” of NUREG-1520. SHINE determined the likelihood of credible accident sequences from the initiating event frequency and may include other factors such as component failures or human error. For each credible accident sequence, SHINE evaluated the uncontrolled risk by combining the applicable consequence and likelihood indices without crediting any safety-related controls. This evaluation results in a risk index value which determines whether the risk of the postulated accident sequence is acceptable. Acceptable risks are:

- High and intermediate consequence events that are highly unlikely or
- Low consequence events in any likelihood category.

For nuclear criticality safety, the applicant treated criticality accidents as high consequence events (see SHINE FSAR section 6b.3, “Nuclear Criticality Safety”). Thus, such events must be highly unlikely to have acceptable risk. The applicant defined highly unlikely for criticality accident events as meeting the double contingency principle. As noted in section 3.4.3.2(9) of NUREG-1520, double contingency addresses several reliability and availability qualities, and where the applicable qualities are each present to an appropriate degree, a system of safety-related controls (in NUREG-1520 these controls are called items relied on for safety) possessing double contingency protection can be an acceptable definition of “highly unlikely.” In considering the definition of double contingency, the NRC staff notes that sometimes more than a two-fold redundancy may be needed. The staff evaluation of nuclear criticality safety is in chapter 6, “Engineered Safety Features,” of this SER.

The applicant also defined and applied an approach called “safe-by-design” (SBD) to defining a criticality accident event as highly unlikely. SHINE FSAR table 13a2.1-4, “Failure Frequency Index Numbers,” includes a description of the characteristics for a component or feature to qualify as SBD. The SBD qualification applies only to passive design components or features that are passive engineered controls (PEC) that meet the following criteria:

a. The PEC’s dimensions fall within established single parameter limits or can be shown by calculation to be subcritical, considering bounding process conditions and including the use of the approved subcritical margin.

b. The PEC has no credible failure mechanisms (e.g., bulging, corrosion, leakage) that could disrupt the credited design characteristics.

c. The PEC’s design characteristics are controlled so that the only potential means to effect a change that might result in a failure to function would be to implement a design change.

The control of the PECs that are credited as SBD includes the applicant’s configuration management program, a description of which is given in TS 5.5.4, “Configuration Management.” This program is one of several developed to ensure the availability and reliability of safety-related controls and that the facility design and operations are consistent with the safety analyses (see also reliability management measures discussion below). This program includes evaluation of changes in accordance with SHINE’s 10 CFR 50.59, “Changes, tests, and experiments,” change control program. Also, in its response to NRC staff RCI 13-9, SHINE confirmed that TS 5.5.1 ensures that the SSA and its supporting documentation will remain accurate and current, including prompt updates when changes are made to the facility, operations, or FSAR descriptions. Since the SBD component or feature is a PEC, the item is safety-related and so the applicant’s TS 5.5.4 configuration management program applies to these items. Additionally, as described in the applicant’s Quality Assurance (QA) Program Description (QAPD), these items will be controlled to Quality Level 1 (QL-1), the highest level in the applicant’s graded approach to quality in its QAPD.

Since the applicant’s method allows for qualification of items as SBD alone to be relied on to determine that a criticality accident sequence is highly unlikely, the NRC staff finds that the reliability management measures, including the applied QA elements, applied to such items need to have a commensurately high degree of rigor. This is due to the significance of the risk reduction credited for being SBD. The staff notes that the applicant’s QAPD follows ANSI/ANS-15.8-1995, “Quality Assurance Program Requirements for Research Reactors.” As described in NUREG-1537 and the ISG augmenting NUREG-1537, Parts 1 and 2, the NRC accepts a QA program that follows ANSI/ANS-15.8-1995 (as endorsed in Regulatory Guide (RG) 2.5, Revision 1, “Quality Assurance Program Requirements for Research and Test Reactors” ML093520099) as fulfilling the QA requirements of 10 CFR Part 50 for the applicant’s type of facility. The staff evaluation of the SHINE QAPD is in chapter 12 of this SER.

The applicant’s method also allows for applying a failure frequency index number (FFIN) of -5 to accident sequences besides criticality accident sequences for which SBD is applied. The NRC staff notes that this aspect of the applicant’s method also varies from the approach described in NUREG-1520. The applicant indicated that an FFIN of -5 was applied to a limited number of accident sequences. In most cases, the uncontrolled accident sequence involves multiple failures or conditions to occur coincident with an initiating event. Thus, the FFIN for the uncontrolled accident event includes the individual contributions of each failure or condition necessary to result in an accident sequence having radiological or chemical consequences. In other instances, the applicant performed calculations that demonstrate the frequency of the event to be sufficiently low or otherwise provided information to justify the use of this FFIN. Based on this information, the applicant's method allows limited use of an FFIN of -5 for accident sequences beyond those criticality accident sequences that involve SBD. Based on a review of these accident sequences, the staff finds that the method requires appropriate evaluations and considerations for applying this FFIN. The staff's finding is also based on considerations of the applicant's overall accident analysis approach for the requested 10 CFR Part 50 license.

Identification and Description of Safety-Related Controls to Prevent the Identified Accident Sequences or Mitigate their Consequences

For accident sequences with unacceptable risk indices, SHINE designated engineered and administrative controls to reduce the risk to acceptable levels. Engineered controls include passive and active controls. SHINE referred to these engineered and administrative controls as safety-related controls. SHINE confirmed the reduction in risk by reassessing the accident sequence after applying the controls. The reduction in risk can be achieved by decreasing the likelihood of occurrence and/or reducing the resulting consequences. SHINE may also identify defense-in-depth (DID) controls to provide additional risk reduction margin. SHINE did not credit these DID controls for the purposes of evaluating the risk of an accident sequence.

The NRC staff finds that the applicant's method for determining failure frequency and probability indices is, with the exceptions already noted above and some other changes, consistent with the method described in NUREG-1520. However, since this facility is a first-of-a-kind for which the reliability of human actions has not been studied to the same degree as for power reactors or typical fuel cycle facilities, it was unclear to the staff that some of the indices that SHINE's method allows for administrative controls, including enhanced administrative controls, would be justifiable for those controls. The applicant did explain that while the SHINE facility is a first-of-a-kind, some of the administrative controls are similar in nature to those at other facilities. Additionally, in selecting the index for failure probability (SHINE FSAR table 13a2.1-5, "Failure Probability Index Numbers"), the applicant selected the higher index from the index range applicable for the type of administrative control (i.e., an index of -2 for an enhanced administrative control). The staff finds the applicant's method for assigning failure frequency and probability indices to be acceptable based on the applicant selecting the highest index in the index range and in consideration of the applicant's overall accident analysis approach. Additionally, in evaluating SHINE's method for determining failure frequency and probability indices, the staff considered SHINE's process to maintain the SSA, which will ensure that the SSA reflects the actual performance of the administrative safety-related controls. In its response to NRC staff RCI 13-9, SHINE confirmed that TS 5.5.1 ensures that the SSA and its supporting documentation will remain accurate and current, including prompt updates when changes are made to the facility, operations, or FSAR descriptions. Thus, based on these considerations, the staff finds that SHINE's failure frequency and probability index method is acceptable.

The NRC staff also finds that the applicant's method for determining failure probability indices allows for engineered controls to be given a failure probability index number of -4 or -5. While this is consistent with the method described in NUREG-1520, the method in NUREG-1520 and in the applicant's FSAR (SHINE FSAR table 13a2.1-5) indicates that these index values can rarely be justified by evidence. In reviewing the accident sequences and information provided in the SHINE RAI response dated January 29, 2021 (ML21029A101), Enclosure 3 (ML21029A105), the staff finds that the limited application of these index values along with the justifications for their application in those instances indicate appropriate consideration was taken in assigning such index values. Further, in evaluating SHINE's method of determining failure probability indices, the staff considered SHINE's process to maintain the SSA per TS 5.5.1, which will ensure that the SSA reflects the actual performance of the engineered safety-related controls. Thus, based on these considerations, the staff finds that the applicant's method for assigning failure frequency and probability indices is acceptable.

Identification of Reliability Management Measures

SHINE applied reliability management measures to ensure the availability and reliability of safety-related controls. SHINE defined reliability management measures as programmatic administrative controls applied to ensure that the credited control can perform its intended safety function. Reliability management measures include activities such as design control, surveillance, procedures, training, and preventive maintenance. The applicant established programs for development and implementation of specific reliability management measures for the engineered and administrative safety-related controls. These programs include the applicant's QA program described in its QAPD and the following programs in section 5, "Administrative Controls," of the TSs:

- TS 5.2, "Review and Audit."
- TS 5.4, "Procedures."
- TS 5.5.1, "Nuclear Safety Program."
- TS 5.5.2, "Training and Qualification."
- TS 5.5.4, "Configuration Management."
- TS 5.5.5, "Maintenance of Safety-Related SSCs."
- TS 5.7, "Required Actions."
- TS 5.8, "Reports."
- TS 5.9, "Records."

In its review of the applicant's SSA methodology, the NRC staff reviewed the descriptions of the reliability management measures and programs, including descriptions of specific reliability management measures for the safety-related controls identified for several accident sequences. The programs for these measures include those programs that the staff would expect to be in place for providing specific measures to ensure the reliability and availability of the safety-related controls that are credited for accident prevention and mitigation (e.g., TS 5.5.1). In terms of the QA program, the staff recognizes that the applicant's QA program includes a graded approach. In this approach, the full QA program is applied to safety-related items and activities. This means that the safety-related controls, both engineered and administrative, that the applicant relies on to prevent or mitigate accidents will be controlled to QL-1. The staff finds that this is acceptable and appropriate since treating these controls and characteristics at the highest QA level ensures that these controls and characteristics are maintained, reliable, and available as analyzed and credited in the applicant's safety analysis.

In reviewing the different accident types, the NRC staff identified instances where it appeared that items and activities that are reliability management measures were being identified as administrative safety-related controls or identified as defense-in-depth controls. As reliability management measures ensure that safety-related controls are available and reliable, they are not themselves safety-related controls, but they are necessary to ensure that the safety-related controls perform as evaluated in the applicant's analyses. Thus, a modification of a reliability management measure for a particular safety-related control can result in a change to the safety-related control's performance, reflected in its risk index, and so affect whether accident sequences relying on that safety-related control have been adequately prevented or mitigated. This means that modification of a safety-related control's reliability management measures can result in an increase in frequency, likelihood, or consequence of an accident or malfunction. Change control programs include evaluation of increases in frequency, likelihood, and consequence. In its response to NRC staff RCI 13-9, SHINE confirmed that the SSA and its supporting documentation will remain accurate and current, which the staff considered in its review of SHINE's SSA methodology, including reliability management measures.

Having clear distinctions and descriptions of the reliability management measures and the safety-related controls they support is important. For example, an administrative safety-related control may be a particular facility staff action to ensure that a system parameter is maintained within an acceptable range. The procedures for performing that action would be a reliability management measure that ensures that the control is properly performed (and so is available and reliable). Training on that procedure would be an additional reliability management measure. Other items used to ensure that the facility staff's action is performed correctly or that the equipment that the facility staff use to perform that action is appropriate and functioning correctly would also be reliability management measures. Additionally, if an item is necessary to ensure that a safety-related control is available and reliable, it is a reliability management measure and cannot be treated as defense-in-depth. Thus, the applicant revised its SSA to ensure that reliability management measures are not identified as specific administrative controls and are not used as defense-in-depth controls. In its review of selected accident sequences and descriptions of safety-related controls, the NRC staff finds that there are a few instances of items identified as defense-in-depth controls that seem to be more like reliability management measures. However, these particular items do not appear to also be associated with supporting other safety-related controls for the evaluated accident sequences. Thus, the staff finds that the applicant's SSA method adequately distinguishes reliability management measures from safety-related controls.

Conclusion

The NRC staff reviewed the SSA methodology and the following accident types to assess the applicant's implementation of its methodology:

- Facility-specific events,
- Mishandling or malfunction of equipment,
- External events, and
- Selected accident events that could lead to criticality.

The NRC staff finds that SHINE FSAR chapter 13 and the SSA methodology are consistent with the ISG augmenting NUREG-1537, Part 2, in that the SSA methodology reviews the systems and operating characteristics of the SHINE facility that could affect safe operation or shutdown. Furthermore, the staff finds that SHINE FSAR chapter 13 and the SSA methodology demonstrate that the applicant applied the SSA methodology to identify limiting accidents, analyze the evolution of the scenarios, evaluate the consequences, designate safety-related controls, and establish quality assurance measures.

The SSA and the SSA methodology are an important part of SHINE's safety program. An effective and adequate SSA and safety program are those that reflect the as-built and as-operated facility and demonstrate that it ensures the health and safety of personnel and the public. Chapter 12 of this SER includes the NRC staff's evaluation of SHINE's QAPD. In its response to NRC staff RCI 13-9, SHINE confirmed that the Nuclear Safety Program as described in TS 5.5.1 will ensure that the SSA and its supporting documentation will remain accurate and current. As noted above, the staff considered the outcome of those reviews in its evaluation of SHINE's SSA methodology and its implementation.

The NRC staff determined that the SSA methodology demonstrates an adequate basis for the final design and satisfies the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2, allowing the staff to make the following findings, with the considerations identified above:

(1) The various methodologies that SHINE described (e.g., HAZOP, FMEA, etc.) are accepted accident analysis approaches.

(2) The definitions of accident likelihood, consequence severity, and the risk categories are comparable to the guidance in NUREG-1520 and are acceptable for use in the SSA.

(3) The SSA methodology provides reasonable assurance that SHINE has identified intermediate and high consequence accidents and established safety-related controls to decrease the likelihood of occurrence to highly unlikely and/or reduce the consequence to low.

(4) The SSA methodology supports the adequate identification of capabilities and features to prevent or mitigate potential accidents and protect the health and safety of the public and workers.

Based on these findings, the NRC staff concludes that the accident analysis methodology, as described in SHINE FSAR chapter 13 and implemented in the SSA, is sufficient to demonstrate that the proposed equipment, facilities, and administrative controls to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property.

SHINE Design-Basis Accidents

SHINE Design-Basis Accident Methodology

SHINE FSAR chapter 13 provides the DBA analyses which are evaluated against the siting and control room design criterion. These analyses evaluate the design and performance of SSCs of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility. The analyses assist in determining the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of SSCs provided for the prevention and mitigation of accident consequences. Therefore, SHINE identified the postulated initiating events and credible accidents that form the design-basis for the facility, consisting of the irradiation units (IUs) and supporting systems and the RPF.

SHINE elected to utilize the following sources of information to develop applicable DBAs:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.
- NUREG/CR-6410, “Nuclear Fuel Cycle Facility Accident Analysis Handbook*,”* dated March 1998, which presents a methodology to compute radiological consequences utilizing the so-called “five-factor formula.”
- NUREG-1520, Revision 2, “Standard Review Plan for Fuel Cycle Facilities License Applications,” issued June 2015.
- NUREG/CR-2858, “PAVAN: An Atmospheric-Dispersion Program for Evaluating Design-Basis Accidental Releases of Radioactive Materials from Nuclear Power Stations,” issued November 1982.
- Regulatory Guide 1.145, Revision 1, “Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants,” issued February 1983.
- The SSA document that incorporated information from the SHINE process hazard analysis method within the safety analysis, hazard and operability studies, failure modes and affects analyses, and experience of the hazard analysis team.

For non-power reactors, the MHA is generally analyzed because it would involve a scenario involving irradiated fuel and probably include the release of fission products to the environment. The NRC staff notes that, in many cases, non-power reactor accidents do not result in fission product releases to the environment. However, SHINE identified numerous DBAs that result in fission product releases to the environment. The DBA releasing fission products to the environment resulting in the highest offsite public consequences is considered the facility's maximum creditable accident. SHINE also identified DBAs that result in releases of non-fission product radioactive material to the environment. These accidents involve releases of tritium.

The NRC staff review process can be generally divided into six parts, which are a review of: (1) selected bounding DBAs; (2) applicable accident source terms; (3) major SSCs of the facility that are intended to mitigate the radiological consequences of a DBA; (4) characteristics of fission product releases from the proposed site to the environment; (5) the meteorological characteristics of the proposed site; and (6) the total calculated radiological consequence dose at the site boundary from the bounding DBAs.

The NRC staff generally does not accept DBA analyses that credit facility features that:

a. are not safety-related;

b. are not covered by TSs;

c. do not meet single-failure criteria; or

d. rely on the availability of offsite power.

Safety-related - Those SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public or to control or mitigate the consequences of such accidents are classified as safety-related SSCs. Safety-related SSCs are designed, constructed, and operated to remain functional during normal conditions and during and following design-basis events. SSCs that perform an engineered safety feature function are also classified as safety-related. The NRC staff finds that the application of SHINE's design criteria discussed in SHINE FSAR chapter 3, "Design of Structures, Systems, and Components," reflect the design features of safety-related SSCs which include redundancy, environmental qualification, seismic qualification, and procedures for inspection, testing, and maintenance.

Technical Specifications - The NRC staff reviewed SHINE proposed TSs, which provide LCOs of the facility pursuant to 10 CFR 50.36. Consistent with NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, the staff confirmed that the SSCs credited in the accident analysis are designated as safety-related and included within TSs. The engineered controls credited for prevention or mitigation are incorporated into TS section 3.0, "Limiting Conditions for Operation and Surveillance Requirements." The safety margins contained within the DBAs are products of specific values and limits contained in the facility's TSs and other values, such as assumed accident or transient initial conditions or assumed safety system response times. Specific TSs have been established for:

- A process variable, design feature, or operating restriction that is an initial condition of a DBA or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier.

- An SSC that is part of the primary success path and which functions or actuates to mitigate a DBA or transient that either assumes the failure of or presents a challenge to the integrity of a fission product barrier.

Single Failure - The Single Failure Criterion is applied when developing DBAs as a design and analysis tool which has the direct objective of promoting reliability through the enforced provision of redundancy in those systems that must perform a safety-related function. The Single Failure Criterion, as applied in DBA analyses, is a requirement that a system that is designed to carry out a defined safety function must be capable of carrying out its mission despite the failure of any single active component within the system or in an associated system that supports its operation. Application of this criterion involves a systematic search for potential single failure points and their effects on the system. The objective is to search for design weaknesses that could be overcome by increased redundancy, use of alternate systems, or use of alternate procedures. In general, only those systems or components that are judged to have a credible chance of failure are assumed to fail when the Single Failure Criterion is applied. Consistent with NUREG-1537 and the ISG augmenting NUREG-1537, the NRC staff confirmed that SHINE had designed the protection systems for high functional reliability consistent with SHINE Design Criterion 15, "Protection system reliability and testability," which ensures that redundancy and independence designed into the protection systems are sufficient to ensure that: (1) no single failure results in loss of the protection function and (2) removal from service of any component or channel does not result in loss of the required minimum redundancy unless the acceptable reliability of operation of the protection system can be otherwise demonstrated.

Emergency Power - Loss of normal electrical power and consequent reduction in cooling will not lead to a challenge to the primary boundary. A loss of normal electric power should not compromise safe IU shutdown. Consistent with NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, the NRC staff confirmed that the emergency electrical power is provided by a common safety-related uninterruptible electrical power supply system (UPSS) and a common non-safety-related standby generator system. The purpose of the UPSS is to provide a reliable source of power to the redundant divisions of safety-related alternating current (AC) and direct current (DC) components required to ensure and maintain safe facility shutdown and prevent or mitigate the consequences of design-basis events. The UPSS consists of two independent trains, each consisting of a 125 volts-direct current (VDC) battery subsystem with associated charger, inverter, and distribution system. This UPSS is capable of delivering required emergency power for the required duration during normal operations and accident conditions. The staff finds that this is consistent with SHINE Design Criteria 27, "Electric power systems," and 28, "Inspection and testing of electric power systems," which specify that onsite and offsite electric power systems, and their inspection and testing, be provided to permit functioning of safety-related SSCs. The safety functions of the onsite and offsite electric power systems are to provide sufficient capacity and capability to ensure that: (1) target solution design limits and primary system boundary design limits are not exceeded as a result of anticipated transients and (2) confinement integrity and other vital functions are maintained in the event of postulated accidents. The UPSS is designed to have sufficient independence, redundancy, and testability to perform its safety functions assuming a single failure. Provisions are included to minimize the probability of losing electric power from the UPSS as a result of or coincident with, the loss of power from the offsite electric power system. In addition, the SHINE facility is also equipped with a standby generator system that is not safety-related and, thus, not credited in the accident analysis. This system is, however, available as a normal backup power supply for selected asset protection loads in the event of a loss of offsite power.

The NRC staff confirmed consistency with NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, with respect to SHINE's DBAs accident analysis by reviewing that:

- Credible accidents were categorized, and the most limiting accident in each group was chosen for detailed analyses.

- Each DBA sequence started with an initiation and ended in a stabilized condition.

- The primary boundary consists of all structures that prevent the release of fission products in solution and the fission gases generated during operation and that its integrity will be maintained under all credible accidents analyzed.

- The IU was assumed to be operating normally under applicable TSs before the initiating event.

- Instruments, controls, and automatic protective systems were assumed to be operating normally or to be operable before the initiating event.

- The single malfunction that initiates the event was identified.

- Credit was taken during the scenario for normally operating systems and protective actions and the initiation of emergency safety features required to be operable by TSs.

- The sequence of events and the components and systems damaged during the accident scenario were clearly discussed.

- The applicant identified the limiting phenomena that would release radionuclides within the facility and to the outside environment. For the SHINE facility, this includes:

  - Thermal-hydraulic safety limits;
  - Precipitation of fission products;
  - Precipitation of target solution (uranium);
  - Detonation or deflagration of combustible gas mixtures; and
  - Excessively high radiolytic gas release.

- Reactivity limits and the functional designs of control and safety-related systems should prevent loss of primary boundary integrity during credible accidents involving insertion of some fraction of excess reactivity. The analyses should include applicable reactivity feedback coefficients and automatic protective actions.

- The applicant analyzed potential power instabilities, including unstable (growing) power oscillations that are large and undamped and that the IU will return to a stable state such that the integrity of the primary boundary is not challenged.

- The mathematical models and analytical methods employed, including assumptions, approximations, validation, and uncertainties, were clearly stated.

- The radiation source terms were presented or referenced.

- The potential radiation consequences to the facility staff and the public were presented and compared with acceptable limits.

The NRC staff reviewed the DBA analysis inputs to confirm that the most restrictive values of facility parameters were selected from the range of design values possible so that the postulated radiological consequences would be maximized. Other considerations included:

- The range of values applicable during an accident that may vary from accident to accident which could differ from the range that applies during normal operations.
- The use of different parameter values in different portions of the analyses and, when needed, sensitivity analysis to determine the limiting value.
- Facility parameters associated with a TS LCO which specifies a range, or a value with a tolerance band where the most restrictive value should be used.
- Situations where and how some parameters may change value during the accident. In these cases, the calculation should either assume the most restrictive value for the entire duration or the calculation should be performed in time steps, with the appropriate parameter values used for each time step.
- For parameters based on the results of less frequent surveillance testing, for example, efficiency testing of charcoal filters, the degradation that may occur between periodic tests should be considered in establishing the analysis value.
- Analysis parameters affected by density changes that occur in the process stream. With regard to specified volumetric flow rates as LCOs, the density used should be consistent with the density that is assumed in the surveillance procedure that demonstrates compliance with the LCOs.

General Description the SHINE Facility Safety and Design Features, and Design Bases

Other chapters of the SHINE FSAR contain discussions and analyses of the facility as designed for normal operation. NUREG-1537 necessitates a discussion that considers how the facility has been designed to ensure the safe operation and shutdown of the facility to avoid undue risk to the health and safety of the public, the workers, and the environment. Therefore, this section of this SER provides an overview of SHINE’s methodology in designing the SSCs and the operating characteristics of the facility that could affect its safe operation and shutdown. The purpose of this section is to provide context on how the SSCs are credited within the DBAs.

The SHINE facility is divided into two major process areas: (1) the IF and (2) the RPF. The IF and the RPF are side-by-side within a single structure, separated by a central wall. Descriptions of each are as follows:

Irradiation Facility: includes eight IUs with each containing, among other components, a subcritical assembly system which includes the target solution vessel (TSV) and TSV dump tank, light water pool system, and the TSV off-gas system (TOGS).

Radioisotope Production Facility: consists of several process areas that prepare target solution, extract and purify the radioisotope products, and process waste streams. The major process systems are the uranium receipt and storage system, target solution preparation system, target solution staging system, vacuum transfer system, process vessel vent system, radioactive liquid waste storage system, and the radioactive liquid waste immobilization system. The RPF also includes the supercell, which is comprised of several internal cells, including the molybdenum extraction areas, purification areas, an iodine and xenon purification and packaging cell, process vessel vent system equipment, and packaging areas, that form one hot cell structure.

Irradiation Facility Operations and Systems

For a facility such as the SHINE facility, margin to safety is large and few credible accidents can be sufficiently damaging to result in the release of radioactive materials to the unrestricted area. The target solution is low-enriched uranium (LEU) in the form of a uranyl sulfate held within the TSV. During operation, the target solution is close to ambient temperature and pressure. The primary system boundary acts as the primary fission product boundary and is defined by the TSV, TSV dump tank, TOGS, and associated components. Within the IU, the target solution is irradiated in a subcritical assembly by neutrons produced by a fusion-neutron source. After irradiation, the target solution is then processed in the RPF to extract and purify molybdenum-99 (Mo-99) and other medical isotopes. Radioactive waste materials are processed and/or converted to solid wastes for shipment to offsite disposal facilities.

The radiologically controlled area (RCA) incorporates both the IF and RPF, which are located within a single seismic Category 1 structure. The radioactive material present in the RCA is located in the following areas:

- Irradiation Facility:
  - IU cells,
  - TOGS shielded cells,
  - Tritium purification system (TPS) area,
  - RCA ventilation equipment areas.
- Radioisotope Production Facility:
  - Target solution preparation and storage areas,
  - Supercell,
  - Target solution hold tanks,
  - Carbon delay beds,
  - Radioactive liquid waste storage tanks,
  - Radioactive liquid waste immobilization.

Within the RCA, the facility is designed as a series of confinement boundaries that establish a low-leakage barrier against the uncontrolled release of radioactivity to the environment. The confinement systems provide active and passive protection and are designed to limit the release of radioactive material to occupied or uncontrolled areas during and after DBAs to mitigate the consequences to facility staff, the public, and the environment.

The IF uses two confinement systems:

1. Primary Confinement Boundary and

2. Tritium Confinement Boundary.

The RPF uses three confinement systems:

1. Process Confinement Boundary,

2. Hot cells and gloveboxes, and

3. RCA ventilation isolations.

Primary System Boundary

The TSV, TSV dump tank, TOGS, and associated components make up the primary system boundary. The primary system boundary is designed, fabricated, erected, and tested to have an extremely low probability of abnormal leakage, of rapidly propagating failure, and of gross rupture. The primary system boundary has a design pressure of 100 pounds per square inch (psi). The TSV, TSV dump tank, and most components of TOGS have a design temperature of 200 degrees Fahrenheit (°F). The TOGS hydrogen recombiners, recombiner condensers, and the interconnecting piping have a design temperature of 650°F to accommodate the heat produced by the hydrogen recombination process that results in normally elevated temperature within these components.

Primary Confinement Boundary

The primary confinement boundary contains the primary system boundary, which contains the fission products. The primary confinement boundary consists predominantly of the IU cell, the TOGS shielded cell, and the IU cell and TOGS cell heating, ventilation, and air conditioning (HVAC) enclosures. The primary confinement boundary is primarily passive, and the boundary for each IU is independent from the others. During normal operations, the primary confinement boundary is operated within a normally closed atmosphere without connections to the facility ventilation system, except through the primary closed-loop cooling system (PCLS) expansion tank. The closed-loop ventilation units, radiological ventilation zone 1 (RVZ1) recirculating subsystem (RVZ1r), circulate and cool the air within the IU cell and the TOGS cell. Each subsystem is equipped with a cooling coil and high-efficiency particulate air (HEPA) and carbon filters to remove contaminants in the circulated air. There are no normally open external connections between the RVZ1r subsystem and the main RVZ1 system. The PCLS expansion tank connection to the RVZ1 exhaust subsystem (RVZ1e) provides a vent path for radiolysis gases produced in the PCLS and light water pool, to avoid the buildup of hydrogen gas. The PCLS expansion tank is located in the IU cell but draws air from the TOGS cell atmosphere. A small line connecting the IU cell and TOGS cell atmospheres creates a flow path from the IU cell, into the TOGS cell, and out through the PCLS expansion tank to RVZ1e. This flow path normally maintains the cells at a slightly negative pressure. The connection to RVZ1e is equipped with redundant dampers or valves that close on a confinement actuation signal, isolating the cells from RVZ1. The IU and TOGS shielded cells are equipped with removable shield plugs which allow entry into the confined area. Gaskets and other non-structural features are used, as necessary, to provide sealing where separate structural components meet.

The primary confinement boundary shield plug gaskets are maintained in accordance with SHINE’s Maintenance Program, and inspected, repaired, and replaced in accordance with approved maintenance procedures. The content of these procedures is controlled in accordance with SHINE TS section 5.4. Each piping system capable of excessive leakage that penetrates the primary confinement boundary is equipped with one or more isolation valves that serve as active confinement components, except for the nitrogen purge supply system supply and process vessel ventilation system (PVVS) connections that may remain open to sweep gas through the primary system boundary to prevent damage from excessive hydrogen accumulation. Shield plug performance will be verified during startup testing in accordance with approved startup test plans. This testing will be done by slightly pressurizing the confinement and verifying that leakage rates are within acceptance criteria based on the analytical limits. The analytical limit for leak rate out of the IU cell is 6E+04 standard cubic centimeters per minute (sccm) at 0.5 Kilopascal (kPa) differential pressure. The analytical limit for leak rate out of the TOGS cell is 4E+04 sccm at 24 inches of water column (6 kPa) differential pressure. The reliability of the shield plugs will be verified via periodic inspection and testing in accordance with SHINE TS section 3.4, “Confinement,” which includes an LCO for the primary confinement boundary. LCO 3.4.5 includes a surveillance requirement of the IU cell and TOGS cell shield plugs to verify operability upon each installation of the shield plugs.

There are three digital instrumentation and control systems that monitor and control various operations throughout the IF and RPF. The process integrated control system (PICS) is a non-safety-related digital control system that monitors and controls various operations throughout the IF and RPF. The TSV is protected by the TSV reactivity protection system (TRPS). All other engineered safety feature functions are monitored and controlled within the engineered safety features actuation system (ESFAS).

The purpose of the TRPS is to monitor process variables and provide automatic initiating signals in response to off-normal conditions, providing protection against unsafe IU operation during the IU filling, irradiation, and post-irradiation modes of operation. The TRPS is designed to end the event and place the target solution in a safe shutdown condition without the need for operator action. Each IU has its own TRPS. The major safety function of the TRPS is to monitor variables associated with the IU during the IU filling, irradiation, and post-irradiation modes of operation and to trip the neutron driver and actuate the engineered safety features (see SHINE FSAR table 7.4-1, “TRPS Monitored Variables”). This is executed by an “Irradiation Unit Cell Safety Actuation” signal when specified setpoints, based on analytical limits, are reached or exceeded. An IU Cell Safety Actuation signal causes a transition of the TRPS to Mode 3 operation (shutdown) which isolates the primary system boundary and the primary confinement boundary via transition of each component to its de-energized state. The parameters indicating a release of radioactive material into the primary confinement boundary are: (1) high RVZ1e IU cell radiation indicating a release of fission products; (2) high TPS target chamber supply pressure; and (3) high TPS target chamber exhaust pressure indicating a release from the neutron driver assembly system. If sufficient radioactive material reaches the radiation monitors in the RVZ1 exhaust duct, the ESFAS will isolate the radiological ventilation system building supply and exhaust. The TRPS also transmits status and information signals to the non-safety-related maintenance workstation and to the PICS for display in the control room, trending, and historical purposes. In the event of a DBA that results in a release from the primary system boundary to the primary confinement boundary, confinement is achieved through the TRPS, the radiological ventilation system, and the passive confinement structures provided by the steel and concrete comprising the walls, roofs, and penetrations of the IU cell and TOGS shielded cell.

The ESFAS monitors process variables and provides automatic initiating signals in response to off-normal conditions, providing protection against unsafe conditions in the SHINE facility (see SHINE FSAR table 7.5-1, “ESFAS Monitored Variables”). The ESFAS is a plant-level protection system not specific to any operating unit or process. The two major safety functions of the

ESFAS are to provide: (1) sense and command functions necessary to maintain the facility confinement strategy and (2) process actuation functions as required by the safety analysis. The actuation functions can be initiated throughout the SHINE facility via the use of radiation monitoring and other instrumentation. If at any point a monitored variable exceeds its predetermined limits, the ESFAS automatically initiates the associated safety function.

On a Safety Actuation single from the TRPS and/or ESFAS, the primary confinement boundary isolates, the normal flow of materials passes through the mezzanine RVZ1 exhaust filter banks before being released to the environment (radiological ventilation system filtration is not safety-related and is not credited in the accident analysis). The setpoint and locations for fission product radiation monitors are presented in SHINE TS table 3.7.1-a, “Safety-Related Radiation Monitoring Instruments.” The setpoint limits for item g. and item h. in TS table 3.7.1-a for tritium are less than or equal to 927 Ci/m^3 and 0.96 Ci/m^3 of tritium, respectively. These setpoint provides margin to an analytical limit of 15 times the normal background level. SHINE TS 3.7, “Radiation Monitoring Systems and Effluents,” ensures that radiation levels within the facility and radiation released to the environment are within allowable limits. Meanwhile, the redundant fail-open TSV dump valves actuate, and the target solution is gravity-fed down to the geometrically favorable TSV dump tank within the light water pool system. The TSV dump valves are provided to drain the TSV, either as part of the process prior to transferring the target solution downstream for processing within the RPF, or as a safety-related feature utilized as part of a planned response in the event of an IU abnormal or accident condition. Once the target solution is in the TSV dump tank, it is passively cooled by the light water pool.

The light water pool is safety-related and serves two primary functions: shielding and cooling. It is a concrete structure lined with stainless steel designed as Seismic Category I to remain functional after the design-basis earthquake without the loss of liner integrity that could compromise its water retention capability. The pool is approximately 15 feet deep filled with approximately 19,000 gallons of water. It is designed with sufficient thermal mass to provide decay heat removal capacity to cool the target solution during normal operation and abnormal events. The minimum acceptable water levels for normal operation provide adequate radiological shielding and equipment cooling for TSV operation at the licensed power limit. These water levels are assumed for normal operation and within the analyses for loss of cooling conditions. SHINE TS 3.3, “Coolant Systems,” LCO 3.3.1, indicates that verification of light water pool level occurs prior to entering Mode 1 and shall be greater than or equal to 14 feet, relative to the bottom of the pool. This pool depth is consistent with the limiting physical configuration with respect to radiological dose.

Tritium Confinement Boundary

The tritium confinement boundary is defined by portions of the TPS. Tritium in the IF is confined using active and passive features of the TPS. The TPS gloveboxes and secondary enclosure cleanup subsystems are credited passive confinement barriers. The TPS gloveboxes enclose TPS process equipment. The process equipment of the secondary enclosure cleanup subsystem is a credited passive confinement barrier. The TPS gloveboxes are maintained at negative pressure relative to the TPS room and have a helium atmosphere. The TPS gloveboxes provide confinement in the event of a breach in the TPS process equipment that results in a release of tritium from the isotope separation process equipment.

The TPS gloveboxes include isolation valves on the helium supply, the glovebox pressure control exhaust, and the vacuum/impurity treatment subsystem process vents. The TPS has isolation valves on the process connections to the neutron driver assembly system target chamber supply and exhaust lines. The TPS neutron driver assembly system interface lines themselves are part of the credited tritium confinement boundary up to the interface with the primary confinement boundary. When the isolation valves for a process line or glovebox close, the spread of radioactive material is limited to the glovebox plus the small amount between the glovebox and its isolation valves. The liquid nitrogen supply and exhaust lines and the gaseous nitrogen pneumatic lines for the TPS equipment are credited to remain intact during a DBA and the internal interface between the gloveboxes and nitrogen lines serves as a passive section of the tritium confinement boundary.

Upon detection of high TPS exhaust to facility stack tritium concentration or high TPS glovebox tritium concentration, the ESFAS automatically initiates a TPS isolation. The active components required to function to maintain the confinement barrier are transitioned to their safe de-energized state by the ESFAS.

Process Confinement Boundary

The process confinement boundary includes two areas: (1) the supercell confinement, which includes the extraction, purification, and packaging hot cells and the PVVS hot cell and (2) the below grade confinement, which confines the PVVS delay beds, the target solution hold, storage, and waste tanks, the pipe trench and valve pits, and the waste processing tanks. Gaskets and other non-structural features are used, as necessary, to provide sealing where components meet (e.g., shield plugs and inspection ports). Each vault is equipped with a concrete cover plug fabricated in multiple sections with one or more inspection ports that allow remote inspection of the confined areas without personnel access. Each valve pit is equipped with a concrete cover plug fabricated in multiple sections with one inspection port. The pipe trench is equipped with concrete cover plugs fabricated in multiple sections with some having inspection ports. The pipe trench, vaults, and valve pits with equipment containing fissile material are equipped with drip pans and drains to the radioactive drain system. The below grade confinement is primarily passive. Most process piping that passes through the confinement boundary is entering or exiting another confinement boundary. Process piping for auxiliary systems entering the boundary from outside confinement is provided with manual or automatic isolation capabilities. In the event of a DBA that results in a release within the process confinement boundary, radioactive material is confined primarily by the structural components of the boundary. If sufficient radioactive material reaches the radiation monitors in the RVZ1 exhaust duct, ESFAS will isolate the radiological ventilation system building supply and exhaust.

Process Vessel Vent Isolation

The PVVS captures or provides holdup for radioactive particulates, iodine, and noble gases generated within the RPF and primary system boundary. The system draws air from the process vessels through a series of processing components that remove the radioactive components by condensation, acid adsorption, mechanical filtration with HEPA filters, and adsorption in carbon beds. Two sets of carbon beds are used; the guard beds located in the supercell and the delay beds located in the carbon delay bed vault. The PVVS guard and delay beds are equipped with isolation valves that isolate the affected guard bed or group of delay beds from the system and extinguish any fire. The isolation valves also serve to prevent the release of radioactive material to the environment. The delay beds are equipped with sensors to detect fires, which provide indication to ESFAS. The isolation valves close within 30 seconds of the receipt of the actuation signal. The redundancy in the beds and the ability to isolate individual beds allow the PVVS to continue to operate following an isolation.

Hydrogen gas is produced by radiolysis in the target solution during and after irradiation. During normal operation, the PVVS removes radiolytic hydrogen and radioactive gases generated within the RPF and primary system boundary. If the PVVS becomes unavailable, the buildup of hydrogen gas is limited using the combustible gas management system, which uses the nitrogen purge system (N2PS), process system piping, and the PVVS to establish an inert gas flow through the process vessels.

Nitrogen Purge System

The combustible gas management system uses the N2PS, primary system boundary (PSB) piping, and the PVVS to establish an inert gas flow through the IUs. One of the functions of the TOGS is to maintain PSB hydrogen concentrations below values that could result in a hydrogen explosion overpressure capable of rupturing the PSB during normal, shutdown, and initial accident conditions. For long-term hydrogen gas mitigation during and after an accident, or if TOGS is unavailable, the N2PS provides sweep gas to dilute hydrogen within the TSV headspace, TSV dump tank, and TOGS piping and maintain the hydrogen gas concentration. Upon initiation of an IU Cell Nitrogen Purge, active components required to function to establish and maintain the N2PS flow path are transitioned to their de-energized (safe) state by the TRPS and the ESFAS.

Resupply of the N2PS occurs within 3 days, which is considered to be a safety-related maintenance activity in accordance with SHINE TS 5.4. The procedures would be performed by the SHINE emergency response organization (ERO) whose members are trained and qualified to perform their duties in accordance with SHINE TS 5.5.2.

The SHINE ERO is described in the SHINE Emergency Plan. Members of the ERO receive training in accordance with the requirements of the plan, to include recovery actions required by the SSA. Control room operators are members of the onsite ERO and receive training on the emergency plan and emergency response actions. The directions for performing or ensuring the performance of credited administrative or personnel actions are contained within standard operating procedures performed by or under the direction of licensed operators, maintenance procedures, or emergency response procedures. The content of these procedures is controlled in accordance with SHINE TS 5.4.

Supercell

The supercell is a set of hot cells in which isotope extraction, purification, and packaging is performed, and gaseous waste is handled. The supercell provides shielding and confinement of airborne radioactive materials during normal operation and in the event of a release. The RVZ1 draws air through each individual confinement box, from the general RPF area, to maintain negative pressure inside the confinement, minimizing the release of radiological material to the facility. Filters and carbon adsorbers on the ventilation inlets and outlets control the release of radioactive material. The supercell ventilation exhaust ductwork is fitted with radiation monitoring instrumentation to detect off-normal releases to the confinement boxes. The active components required to function to maintain the confinement barrier are actuated by the ESFAS. Upon indication of a release exceeding setpoints, isolation dampers or valves on both the inlet and outlet ducts isolate the hot cells from the ventilation system. Contaminated air is confined to the supercell by the confinement boxes, the ventilation exhaust dampers or valves, and the process isolation valves. Additionally, the actuation signal closes isolation valves on the molybdenum extraction and purification system (MEPS) heating loops and conducts a vacuum transfer system (VTS) Safety Actuation. As part of the VTS Safety Actuation, connections to the supercell from the facility chemical reagent system (FCRS) skid isolate, closing the MEPS and iodine and xenon purification and packaging (IXP) supply valves.

Radiologically controlled area ventilation isolations

The radiological ventilation systems include supply air, recirculating, and exhaust subsystems required to condition the air and provide the confinement and isolation needed to mitigate DBAs. The SHINE facility utilizes three ventilation systems in the RCA to maintain the temperature and humidity and to progress air from areas with the least potential for contamination to areas with the most potential for contamination. These systems and sub-systems are as follows:

- Radiological ventilation zone 1 (RVZ1)
  - RVZ1 recirculating subsystem (RVZ1r)
  - RVZ1 exhaust subsystem (RVZ1e)
- Radiological ventilation zone 2 (RVZ2)
  - RVZ2 exhaust subsystem (RVZ2e)
  - RVZ2 supply subsystem (RVZ2s)
  - RVZ2 recirculating subsystem (RVZ2r)
- Radiological ventilation zone 3 (RVZ3)

Radiological Ventilation Zone 1

RVZ1 provides ventilation and humidity control for ventilation zone 1 within the RCA. Subsystem RVZ1r provides cooling for systems within the IU cell and the TOGS cell. RVZ1r recirculates, filters, and cools air within the IU cell and the TOGS cell. The system includes two fan coil units and associated ductwork and dampers per each set of IU/TOGS cells. Each set of RVZ1r units is located within the cooling room and forms a portion of the confinement boundary for the IU/TOGS cells that it serves. RVZ1r provides sampling, ventilation, and cleanup connections for the primary confinement.

Subsystem RVZ1e provides exhaust air from the areas with a high potential for contamination in the SHINE facility. The air is filtered and directed out of the facility through the exhaust stack. The subsystem includes fans, filters, ductwork, dampers, and HEPA filter banks. It also includes the necessary transfer ductwork to allow makeup from the RCA general area into the exhausted areas.

RVZ1e is designed to maintain ventilation zone 1 areas at a lower pressure than ventilation zone 2 areas. The design inhibits backflow with the use of backflow dampers at the discharge of the RVZ1e and RVZ2e exhaust fans in order to minimize the spread of contamination. RVZ1e ductwork provides sampling locations for radiation detectors, fire detection equipment, stack release monitoring, and an exhaust stack connection point for RVZ2e and the PVVS.

Radiological Ventilation Zone 2

RVZ2 provides ventilation and humidity control for ventilation zone 2 rooms within the RCA. RVZ2s supplies conditioned outside air into the RCA to provide ventilation and to make up for RVZ1e and RVZ2e exhaust volumes. The system includes air handling units, filters, ductwork, and dampers. RVZ2s provides cooling, heating, and humidification for all systems within ventilation zone 2 as well as maintains the quality control lab and analytical labs at positive pressure with respect to the ventilation zone 2 general area.

RVZ2r recirculates, filters, and conditions air within the RCA. The system includes air handling units (AHUs), filters, ductwork, and dampers. The RVZ2r AHUs are located within the RCA. RVZ2r provides additional cooling for systems within ventilation zone 2. RVZ2r is also used to cool air being supplied to the supercell, which reduces the flow rate required to cool the equipment within the supercell. The filters and bubble-tight dampers on the inlet side of the supercell are part of RVZ1e.

RVZ2e exhausts air from the general areas of the RCA. It provides an exhaust path for the quality control (QC) laboratory and analytical testing laboratory fume hoods within the RCA and maintains the QC laboratory and analytical testing laboratory at positive pressure with respect to the ventilation zone 2 general area. The system is designed to maintain the RCA at a lower pressure than areas outside of the RCA. The RVZ2e design inhibits backflow within ductwork that could spread contamination. The subsystem includes fans, filters, ductwork, dampers, and HEPA filter banks. It also includes the necessary transfer ductwork to allow makeup from the RCA general area into the exhausted rooms. RVZ2e ductwork provides sampling locations for ESFAS radiation detectors and fire detection equipment.

Radiological Ventilation Zone 3

RVZ3 provides ventilation and humidity control for ventilation zone 3 rooms within the RCA. RVZ3 transfers air from the non-radiological area ventilation zone 4 (FVZ4) to ventilation zone 3 then from ventilation zone 3 to ventilation zone 2 via engineered pathways. RVZ3 receives air from RVZ2s in the IF exit labyrinth.

During upset and accident conditions, affected sections of the RVZ1e, RVZ2s, and RVZ2e ventilation systems are isolated as required for the specific event or indication. The IU cell exhaust flow path of RVZ1e provides ventilation of the IU cell and TOGS cell via PCLS expansion tank headspace. This path is equipped with safety-related radiation monitoring instrumentation (see SHINE TS table 3.7.1-a, “Safety-Related Radiation Monitoring Instruments”) and redundant isolation valves (see SHINE TS 3.4, “Confinement”). Between the RVZ1e IU cell radiation instrumentation and RVZ1e IU cell ventilation valves is an isolation lag tank. The isolation lag tank of the RVZ1e provides an exhaust gas delay time greater than the closing time of the valves. If radiation measurements exceed predetermined limits (15 times background), the TRPS initiates an IU Cell Safety Actuation, which closes the RVZ1e IU cell ventilation valves. The RVZ1e has safety-related redundant bubble-tight dampers that are situated as near to the confinement boundary as practical and close in a failsafe condition (see SHINE TS 3.4). Upon loss of power, loss of signal, or ESFAS initiation of confinement, dampers seal the affected confinement areas within 30 seconds.

Radioisotope Production Facility Operations and Systems

Operations within the RPF involving special nuclear material (SNM) include the uranium receipt and storage system (URSS), target solution preparation system (TSPS), the MEPS, the IXP system, the quality control and analytical testing laboratories (LABS), the target solution staging system (TSSS), the VTS, the radioactive liquid waste storage (RLWS) system, the radioactive liquid waste immobilization (RLWI) system, and the radioactive drain system (RDS). The operations that do not involve SNM but that pose a radiological or chemical hazard from radiochemical operations and operations with hazardous chemicals include the molybdenum isotope packaging system (MIPS), the PVVS, and the FCRS. Other systems in the RPF that do not have direct radiological or chemical hazards are evaluated for impact on the systems listed above.

The URSS receives, thermally oxidizes (if needed), repackages, and stores LEU prior to target solution preparation in the TSPS. The TSPS prepares low-enriched uranyl sulfate solution, which, once qualified for use, is referred to as target solution. The URSS and TSPS are both classified as both an operation with unirradiated SNM and an operation with hazardous chemicals. Due to the presence of uranium, both the URSS and TSPS pose criticality, radiological, and chemical hazards.

The MEPS separates the molybdenum from the irradiated target solution and purifies the resulting product. The extraction portion of the MEPS is an operation involving irradiated target solution processed for radioisotope extraction and contains significant quantities of uranium. Due to the presence of uranium, the MEPS extraction process is analyzed for criticality hazards. In addition, the extraction process involves radiological and chemical exposure hazards. The purification portion of MEPS, as well as isotope packaging operations in MIPS, are considered radiochemical operations, but pose a lesser hazard than extraction operations because these processes are physically separated from the extraction operations and involve smaller quantities of radioactive material.

The IXP system separates iodine from acidic solutions and purifies the resulting product. The separation operations handle irradiated target solution processed for radioisotope extraction and contain significant quantities of uranium. Due to the presence of uranium, the IXP process has the potential for criticality. In addition, the IXP has radiological and chemical exposure hazards.

The LABS are used to analyze samples of target solution, radioisotope products, and other process fluids. The operations in the LABS involve small amounts of SNM, radiochemicals, and hazardous chemicals. Due to the presence of uranium, the LABS are analyzed for criticality hazards. In addition, the LABS involve radiological and chemical exposure hazards.

The TSSS receives both irradiated target solution from the radioisotope extraction processes and unirradiated target solution from the TSPS. The TSSS allows for the target solution to be sampled prior to reuse or disposal, and stages target solution for transfer to the IF or the waste system. The system is categorized as irradiated target solution processed for reuse or waste disposal. Due to the presence of uranium, the TSSS has the potential for criticality as well as radiological and chemical exposure hazards.

The VTS serves as the transfer system for irradiated target solution between RPF tanks and for transfers between the RPF and the IF. The system also provides the capability to sample tank contents in the TSSS and the RLWS. The system performs operations involving irradiated target solution processed for reuse or waste disposal. Due to the presence of uranium, the VTS has the potential for criticality as well as radiological and chemical exposure hazards.

The RLWS serves as a waste system for solutions resulting from the processing of licensed material, and target solution batches or portions thereof that will no longer be used in facility processes. The RLWS involves operations with irradiated target solution processed for waste disposal. Due to the presence of uranium, the RLWS has the potential for criticality. In addition, this process has radiological and chemical exposure hazards.

The RLWI serves as a waste immobilization system for solutions received from the RLWS. The RLWI involves operations with irradiated target solution processed for waste disposal. Due to the presence of uranium, the RLWI has the potential for criticality. In addition, this process has radiological and chemical exposure hazards.

The RDS collects leakage and overflow of process fluids, including target solution, from process tanks and vessels and from hot cells. Fluids collected in the RDS can be returned to production or transferred to the RLWS for disposal. The RDS involves operations with irradiated target solution processed for reuse or for waste disposal. Due to the presence of uranium, the RDS has the potential for criticality as well as radiological and chemical exposure hazards.

The PVVS handles the off-gas resulting from the processes of the IF and RPF. The PVVS is classified as a radiochemical operation and poses a radiological hazard. This process contains radionuclides removed from the off-gas.

The FCRS stores and supplies reagents to the processes of the RPF. The FCRS is classified as an operation with hazardous chemicals and poses a chemical hazard. The system contains no SNM or radionuclides.

The supercell is designed as a confinement boundary. Hot cell exhaust ventilation (RVZ1) is equipped with radiation monitors (i.e., the RVZ1 supercell area 1-10 radiation monitors) that provide a signal to ESFAS to isolate the affected cell and limit the amount of target solution introduced into the cell, hot cell inlet (RVZ2) and outlet (RVZ1) ventilation ducts are equipped with ESFAS-controlled redundant isolation dampers, hot cell outlet (RVZ1) ducts are equipped with carbon filters, and ESFAS-controlled IXP extraction pump breakers, VTS vacuum transfer pump breakers, and VTS vacuum break valves are provided to limit the amount of target solution introduced into the affected hot cell. Due to the presence of uranium, the supercell has the potential for criticality as well as radiological and chemical exposure hazards.

The pipe trench and tank vault are designed as a confinement boundary. The RDS drains prevent the accumulation of target solution in the pipe trench. The RDS sump tank liquid detection sensor detects fluid in-leakage and provides a signal to ESFAS to stop any in-process transfers of solution within the facility via opening ESFAS-controlled VTS vacuum transfer pump breakers and VTS vacuum break valves. The RVZ1 and RVZ2 building exhausts are equipped with radiation monitors (i.e., the RVZ1 and RVZ2 RCA exhaust radiation monitors) that provide a signal to ESFAS to isolate the building ventilation supply and exhaust dampers on high radiation. Due to the presence of uranium, the pipe trench and tank vaults has the potential for criticality as well as radiological and chemical exposure hazards.

Accident Analysis Consequence Methodology

SHINE generally followed the NUREG/CR-6410 methodology to compute radiological consequences recommended in the ISG augmenting NUREG-1537, Part 1. SHINE calculation document, CALC-2018-0048, Revision 8, “Radiological Dose Consequences” (ML22301A149), provides the SHINE FSAR chapter 13 supporting analysis. The purpose of this document is to determine the dose consequences to a SHINE facility control room operator and a member of the public for fourteen DBAs. The methodology is presented as a multi-step process as follows: (1) calculation of radionuclide inventories; (2) definition of the accident-specific materials-at-risk (MAR); (3) identification of transport methods of radionuclides; (4) development of accident source terms; (5) assessment of meteorological conditions; and (6) determination of radiological consequences. The NRC staff followed the NUREG/CR-6410 methodology when reviewing

SHINE's accident analysis and supporting calculations to assess the acceptability of safety-related SSCs to mitigate radiological consequences. The methodology utilizes the so-called "five-factor formula" to derive accident-specific source terms, $ST_A(i)$, as follows:

$$ST_A(i)[\text{Ci}] = MAR(i)[\text{Ci}] \times DR \times ARF(i) \times LPF(i) \times RF(i) \qquad \text{(Equation 1)}$$

where:

$ST_A(i)$ = accident-specific airborne source term for nuclide(i);
MAR(i) = material at risk for nuclide(i);
DR = damage ratio, assumed to be 1.0;
ARF(i) = airborne release fraction for nuclide(i);
LPF(i) = leak-path factor for nuclide(i); and
RF = respirable fraction(i), assumed to be 1.0.

The MAR is the amount of hazardous material available to be acted on by a given physical stress. Depending on the magnitude and scope of the stress, the MAR may range from the total inventory of a facility to a subset of the inventory in one operation. The DR is the fraction of MAR actually impacted by a given physical stress from a specific event. The ARF is the fraction of impacted material (MAR x DR) that can be suspended to become available for airborne transport following a specific set of induced physical stresses. The RF is the fraction of the material-of-concern initially suspended in the air and present as particles that can be inhaled into the human respiratory system. The LPF is the quantitative value that expresses the fraction of initially airborne material that successfully escapes the facility. For particles, the LPF primarily depends on three parameters: (1) the flow rate of the aerosol through the facility; (2) the particle sizes; and (3) the areas available for deposition of contaminants.

The SHINE accident analysis combines the leak-path factor, airborne release fraction, and atmospheric dispersion factors into a single receptor activity fraction (RAF), which represents the fraction of a tracer that is present in a control volume at a specific time interval.

Radionuclide Inventories

SHINE calculation document, CALC-2018-0010, Revision 2, "Bounding Fission Product Inventories and Source Terms," provide the safety basis fission product inventories and safety basis source terms for the SHINE facility. The safety basis source terms are intended to be used in bounding calculations for shielding and safety analysis. In addition to providing source terms, these calculations also evaluate the effects of the statistical uncertainties of the Monte Carlo N-Particle (MCNP)-calculated neutron fluxes and cross sections on the final source terms.

For most accident scenarios, the MAR was derived from the TSV target solution inventory at the end of a time period of continuous 30-day irradiation cycles (normal operation is 5.5 days) with a downtime between cycles. A conservative constant power level of 137.5 kilowatts (kW) was used for the analysis, which is 110 percent of the licensed-limit design operating power. The 110 percent increase in power has a near linear increase in MAR radionuclide inventory and a subsequent similar increase in computed radiological consequence. SHINE assumed this increase in power level to accommodate known uncertainties and error limits of the nuclear systems. Uncertainties in generating the target solution MAR could include target solution void profiles, target solution temperature profiles, core configuration (solution height and uranium concentration), and geometrical tolerances of the TSV. These sources of uncertainty are negligible and modeling the power as 110 percent of the licensed-limit is adequate because the transmutation calculation in ORIGEN-S is held at a constant power level meaning that the neutron flux will be as high as necessary to reach the given power level. During actual operation of the SHINE system, the high time-averaged neutron flux signal, as described in SHINE FSAR section 7.4.4.1.3, “High Time-Averaged Neutron Flux,” protects against exceeding analyzed TSV power levels.

The TSV inventory calculation includes effects from fission, transmutation, activation, and decay. There is no partitioning due to extraction between irradiation cycles. The calculation contains time steps from the start of irradiation through the end of the irradiation cycle and additional time steps that account for decay post-shutdown, as needed. This period was selected for the irradiation cycle based on the anticipated replacement period for target solution. Most of the peak halogen and noble gas radionuclide concentrations occur at the end of the last irradiation cycle. The percent difference for all halogen and noble gas activities at their maximum compared to shutdown is less than 1 percent, except for radon-222, which is being built into the system from the uranium-238 decay chain. SHINE demonstrated a very large margin between the MAR and normal operations. The applicant identified the bounding and nominal activities and maximum generation rates of iodine-131 at the end of the last irradiation cycle. SHINE explained that the net-generation rate of iodine-131 is higher in the nominal case for the last cycle because the nominal case accounts for removal of iodine (and other elements) between irradiation cycles, where the bounding case assumes that there is no removal of any elements between cycles and with the large inventory in the bounding case, decay losses are comparable to generation (i.e., the system is approaching saturation). The NRC staff finds that the MAR MHA source term is about 158 times higher than the calculated nominal inventory for iodine-131 which is the primary dosimetric radionuclide contributing to TEDE. The NRC staff finds this source term to be conservative due to the bounding nature of the assumption used to derive it, which considers longer irradiation times and no extraction between cycles.

SHINE utilized the Los Alamos National Laboratory developed code, Monte Carlo N-Particle 5 (MCNP5), version 1.60 to calculate the neutron flux spectrums and cross sections in the target solution and PCLS. To compute material information for the target solution and PCLS water, following irradiation and decay, SHINE also utilized three modules of the Oak Ridge National Laboratory code, Standardized Computer Analyses for Licensing Evaluation (SCALE), version 6.1.2: (1) COUPLE was used to generate neutron data libraries from the MCNP5 tally results for input in ORIGEN-S; (2) ORIGEN-S was used to simulate nuclide fission, transmutation, and decay; and (3) OPUS was used to request information from other SCALE modules. The NRC staff finds these computer codes to be acceptable for the purpose of developing radionuclide inventories to derive a bounding SHINE-specific MAR. The staff reviewed the applicable safety-basis SHINE calculation documents, which include validation for reactivity in solution systems for the TSV and estimated neutron fluence and target solution burnup over the length of target solution recovery. The staff finds that SHINE utilized the codes discussed above appropriately to derive the safety basis source term, or MAR. SHINE performed an uncertainty analysis on the MAR source term using SHINE Best Estimate Neutronics Model to evaluate the statistical errors of the MCNP-calculated neutron fluence cross sections used in the ORIGEN-S to develop 95 percent confidence, 95th percentile upper tolerance bounds by nuclide. The modeling produced nuclide-dependent multiplication factors ranging from an approximately 0 to a 35 percent increase in the nuclide inventory per nuclide. For the radionuclides that were increased, the average increase was approximately 2.5 percent, and the total estimated increase in inventory was approximately 1 percent. The staff finds the use of conservative assumptions and the treatment of uncertainty to justify the MAR to be acceptable.

Accident- Specific Materials-At-Risk

Accident-specific MARs were developed for each accident scenario. The starting inventory was selected based on the assumed start-time and then partitioned based on scenario-specific removal mechanisms. For the source term determination, the radionuclides are grouped into three groups: (1) iodine; (2) noble gases; and (3) non-volatiles (all others). For scenarios involving the release of tritium, the available MAR was determined based on the limiting operational values for the affected systems or components. Consistent with NUREG-1537 and the ISG augmenting NUREG-1537, Parts 1 and 2, the NRC staff audited scenario-specific MARs or referenced source documents, as documented in the NRC's audit report dated December 7, 2022 (ML22301A149).

The accident-specific MAR for the MHA, SHINE FSAR section 13a2.2.7, "Mishandling or Malfunction of Equipment," was derived to assess the consequences of a TOGS malfunction leading to the TOGS gas inventory being released into the TOGS cell. The analysis deterministically assumes that 25 percent of iodine in the TSV solution is initially within the TOGS. This assumption is based on a "rule-of-thumb" recommendation from NUREG/CR-6410, section 3.4.3, "Estimation of ARF and RF for Nuclear Criticality Accidents," for liquid systems where most of the volatile iodine isotopes are retained in the liquid and 25 percent is released for a criticality accident. It is assumed that the iodine in solution is predominantly volatile (i.e., I_2) and that aqueous to gas partitioning occurs rapidly, causing 100 percent of the iodine inventory to be released to TOGS post shutdown. SHINE conservatively assumes that 100 percent of the safety-basis MAR is released. However, for the SHINE facility, when a transient or event occurs that initiates the TRPS IU Cell Safety Actuation signal, for instance on a high neutron flux level signal (source, wide range, and time-averaged), the TSV is designed to dump the target solution into the favorable geometry dump tank to protect the primary system boundary. The physical phenomena of transporting radionuclides from the target solution are not those from a prompt critical event, but rather from well understood processes such as the evolution of iodine due to the low pH of the target solution and the radiolytic generation of hydrogen, which can cause early and long-term release of iodine and non-volatiles through bubble burst. SHINE modeled these processes within its accident analysis as more long-term releases utilizing models and recommendations from the experimental studies performed at the Oak Ridge National Laboratory contained in NUREG/CR-5950 (ORNL/TM-12242), "Iodine Evolution and pH Control" (ML063460464). The NRC staff finds these modeling assumptions to be conservative and acceptable.

The NRC staff performed a number of confirmatory calculations. Among those were inventory calculations, simplified iodine evolution and transport calculations using the assumed elevated iodine inventory. An additional calculation to estimate the transient iodine concentration in the TOGS system during operation and following shutdown that factors in the reduction in iodine inventory due to evolution during operation was considered but ultimately not performed because SHINE could meet its safety criteria limits even assuming the elevated iodine inventory.

Radionuclide Transport Method within Confinement

SHINE's evaluation of the transport of radioactive material is generally consistent with the methods described in NUREG/CR-6410 when developing control volumes and leak path factors (LPFs). The model yields the fraction of a given radionuclide that is released to the environment. To support this method, the NRC staff audited scenarios and analyses which identified the control volumes and leakage paths.

Identify control volumes and leakage paths.

SHINE identified the control volumes, leakage paths, and heat sinks that define the model geometry. The performance of this step establishes the geometric information for the LPF calculations including: gas and liquid volumes, surface areas for deposition, flow path areas and characteristics that influence leakage, elevations, surface areas for liquid and air heat sinks, and system information for ventilation rates and filtering. The control volumes used in the analysis include the source volume, the building volume, and the environment. Leakage paths are treated as junctions between the control volumes.

The analysis considers each part of the facility as a fixed volume that the material is free to disperse into. Dispersion within these volumes is assumed to be instantaneous. Each volume is connected by one or more junctions which allow flow in one direction at a volumetric flow rate, either pressure-driven or constant. Counter-current flow, or flow back into the previous control volume, is not considered in this calculation. The NRC staff determined that this is a conservative modeling decision.

SHINE identified scenarios that can be organized into four leak-path combinations that include: release location, initial confinement, secondary confinement, and release to environment. These control volumes and leak-path combinations are:

1. Confinement by IU cell or concrete cell -> IF building -> environment;

2. Confinement by glovebox -> TPS room -> IF building -> environment;

3. Confinement by hot cell -> RPF building -> environment; and

4. Confinement by concrete vault -> RPF building -> environment.

The NRC staff finds SHINE’s identification of control volumes and leak paths based on the thirteen leak-path scenarios to be acceptable, as it is consistent with NUREG/CR-6410, which presents the methodology to compute radiological consequences utilizing the five-factor formula.

Quantify scenario progression source histories

The performance of this step quantifies initial sources and source rate histories for radionuclides and other mass and energy sources that drive material transport. To do so, the specific physical phenomena for each scenario are defined. This includes the accident initiator and source volume location to quantify the amount or rate at which materials and energy can be released. Where pertinent, this also includes the amounts or rates at which gases and aerosols are evolved. It also includes the initial conditions including gas temperature and pressure, liquid mass and temperature, as appropriate, and initial released activity. Further rates of activity release are also specified for evolution of iodine and non-volatile evolution. The most pertinent quantification is the identification of the physical form of the radionuclides to be tracked: non-condensable gases, condensable species, and/or aerosols.

For each scenario, the initial MAR comprised of individual radionuclides is assumed to be released instantaneously. Once released, all noble gas radionuclides are released to the gas space. Iodine is partitioned between gas and liquid depending on the pH level of the solution and temperature. The rest of the radionuclides are considered to be in condensed form, either dissolved in the solution, in liquid form, or in solid form. The radionuclides in condensed form can become airborne due to bubble bursting, spray leak, or spill, and be transported to the environment with gas flows.

When present, radioactive iodine is demonstrated to be the dominant contributor to radiological dose to the worker and public. The transport of iodine species involves two main processes in order to estimate the contribution of iodine to the total dose: (1) the radiolytic conversion of iodine from I- to I2 and (2) the partitioning of I2 between the aqueous and gas phases. To derive iodine reduction factors, SHINE utilized the following modeling assumptions and guidance:

- Iodine partitioning was calculated using equations based on the definitions found in NUREG/CR-5950, "Iodine Evolution and pH Control."

- Bursting bubble aerosols were treated using a linear relationship between entrainment coefficients and the volumetric flow rate with entrainment coefficients consistent with the small amount of dissolved materials present in the target solution.

- Spray and free-fall aerosols used a constant airborne release fraction found in NUREG/CR-6410.

- Radiolysis was treated as either an instantaneous release of hydrogen or as sentrainment with source generation based on decay power inputs for long-term scenarios.

During normal operations in the IU cell, iodine isotopes are removed from the TSV gas space through the operation of the TOGS. The two types of iodine removal occur at two different steps in the process. One occurs during normal irradiation of the target solution in the TSV. The other occurs during the time period that the target solution sits in the TSV dump tank after a normal irradiation period. The TOGS contains a zeolite bed on one train through which the off-gas from the target solution is moved. The zeolite bed preferentially removes iodine isotopes from the gas stream.

All scenarios containing iodine use isotope reduction factors that account for TOGS running during normal operations. Scenarios that are downstream from the IU cell take an additional removal factor of iodine due to the operation of the TOGS during the post-irradiation TSV dump tank hold time.

In its response to NRC staff RCI 13-3 (ML22304A126), SHINE confirmed that the SHINE calculation CALC-2018-0048, Appendix B, "Justification for Treatment of Iodine," contains the justification for the removal factors that were utilized in this calculation as well as the isotope-specific reduction factors. The NRC staff reviewed the iodine isotope-specific reduction factors applied in the DBA dose calculations. Table 13-1 provides a list for each DBA scenario that assumes iodine removal factors for the IU, the TSV dump tank, or both.

Table 13-1: Design-Basis Accident Scenarios Utilizing Iodine Removal Factors

Scenario Number	Irradiation Reduction Factor	Dump Tank Reduction Factor
1a	x	
1b	x	
3	x	
9a	x	x
9b	x	x
10	x	
11	x	x
12	x	x
14	x	x

The NRC staff performed a series of confirmatory calculations to derive the iodine removal factors that SHINE utilized in its DBA dose calculation. The staff finds that SHINE's quantify scenario progression for each of the thirteen leak-path scenarios is acceptable as it is consistent with NUREG/CR-6410, which presents the methodology to compute radiological consequences utilizing the five-factor formula.

Quantify leakage rates between volumes

SHINE defined leakage rates between volumes driven by pressure, gas density differences, and barometric breathing and used the outcome of this sub-step to establish expressions for removal rates in the LPF model. The gas pressure in each volume is determined using a combination of conservation laws for mass and energy, temperature-dependent specific heats, and the ideal gas law. Pressure-driven flow through each junction was calculated using the standard compressible flow equation for pressure-driven flow. Pressure-driven flow through shielding cover plug gaps was calculated using the equation for plane Poiseuille flow. In the absence of pressure-driven flow, counter-current flow was assumed to be induced and was calculated based on the difference in pressure from one side of the cover plug to the other. There is no assumed flow from the IF to the RPF or vice versa; all material in the IF or RPF control volumes exits the SHINE facility to the environment. The NRC staff determined that the assumption of no flow between the IF and the RPF is conservative.

The NRC staff determined that SHINE's quantification of leakage rates between volumes for each of the thirteen leak-path scenarios is acceptable as it is consistent with the ISG augmenting NUREG-1537, Part 2 and NUREG/CR-6410, which presents the methodology to compute radiological consequences utilizing the five-factor formula.

Quantify removal mechanisms

SHINE established expressions for removal rates of radionuclides for use in the LPF model, specifically, iodine adsorption, non-volatile aerosol deposition, and removal by filters along flow paths. Removal by aerosol settling was evaluated using Stokes' law and the calculated equilibrium particle size for a hygroscopic particle. The use of the equilibrium particle size is valid based on the time scale of the accident sequences and is found to be acceptable by the NRC staff. Consideration of removal by filters in the accident flow paths was done by assigning decontamination factors for noble gases, iodine, and aerosols to each filter. Removal due to barometric breathing was based on an analysis of the peak-to-peak magnitude of environmental pressure fluctuations. Eight years of pressure data were collected and analyzed to provide a bounding estimate of the barometric breathing flow rate for the facility.

The NRC staff determined that SHINE's quantification of removal mechanisms of radionuclides for use in the LPF model scenarios is acceptable as it is consistent with NUREG/CR-6410.

Development Accident Source Terms

SHINE developed accident source terms for each of the thirteen accident scenarios using the five-factor formula described in NUREG/CR-6410. Radioactive decay of the MAR for various times after the initiation of an accident was included in the source term development. SHINE's LPF model combines the ARF and LPF terms which represent the time-dependent leakage of radionuclides. The ARF multiplied by LPF values are calculated for the leakage from the source volume to the building for the control room operator (duration of the event), worker dose (10 minutes), and the source volume to the environment for the public dose (duration of the event). The tritium-related events assume that the functional secondary enclosure cleanup component of the TPS train will be able to begin recovery operations within 10 days of the initiating event. The RF and DR are conservatively set at 1.0.

Assessing meteorological conditions

SHINE developed short-term atmospheric dispersion (χ/Q) factors for an effluent release from the SHINE site. The results are used to assess the consequences of an accident release. SHINE's approach utilized a Gaussian plume diffusion model with a building vent release to compute the nuclide concentrations and consequent doses external to the facility. This methodology conservatively assumes that the release occurs at ground level. Factors were developed at the offsite public dose locations and the control room. Details on the meteorological measurements used to calculate the χ/Q values can be found in chapter 2, "Site Characteristics," of this SER.

The χ/Q values are calculated at each receptor location as a function of time following the effluent release. The χ/Q values are calculated for periods of 0-2 hours, 0-8 hours, 8-24 hours, 1-4 days, and 4-30 days following the effluent release. The calculations are performed with the NRC computer program, PAVAN, which implements the guidance provided in RG 1.145.

The atmospheric dispersion χ/Q values utilized in the SHINE accident analysis are provided in SHINE's response to NRC staff RAI 13-3 (ML ML20357A084), Enclosure 3 (ML20357A087) and NRC staff RCI 13-6 (ML22304A126); and CALC-2018-0048, Revision 6, table 3-1, "95th Percentile Site Boundary χ/Q values," and reproduced in the table 13-2 below.

Table 13-2: 95th Percentile Atmospheric Dispersion χ/Q Values

Locations	Time Bin (hours)				
	0-2	2-8	8-24	24-96	96-720
Public χ/Q Values (s/m^3)	5.66E-3	3.45E-3	2.70E-3	1.58E-3	7.31E-4
Control Room χ/Q Values (s/m^3)	1.40E-2	1.09E-2	4.61E-3	2.99E-3	2.33E-3

Determination of Radiological Consequences

SHINE computed the radiological consequences for each of the thirteen DBAs for the facility worker (i.e., control room operator, RCA worker) or member of the public. The radiological consequences are computed using the NUREG/CR-6410 methodology discussed above in conjunction with dosimetry methodologies utilizing Federal Guidance Report (FGR) No. 11, “Limiting Values of Radionuclides Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,” and FGR No. 12, “External Exposure to Radionuclides in Air, Water, and Soil,” dose conversion factors, which are consistent with the dose-based criteria and limits specified in 10 CFR Part 50 and 10 CFR Part 20 in terms of TEDE. Assumptions for each receptor and applied dosimetry methodologies are described below.

Control Room Operator Receptor Radiological Consequence Assumptions:

The volume of the control room is conservatively estimated to be 350 m^3 based on the dimensions of the control room minus estimated sizes of the equipment in the control room. SHINE assumed no cross contamination from the IF and the RPF as the control room is not part of the RCA. Therefore, the radionuclide flow path from the MAR source to the control room is accident-dependent but generally flows to the environment and to the FVZ4 using the control room atmospheric χ/Q values. The FVZ4 is responsible for delivering air to the control room and many other rooms in the non-RCA of the SHINE facility where approximately 20 percent of the FVZ4 inlet flow is delivered to the control room. The FVZ4 is assumed to continue running after all initiating events as it is not safety-related. Material that reaches the control room is assumed to instantaneously diffuse within the control room volume. The ventilation system is assumed to continue running after all initiating events for a period of 30 days. The breathing rate for control room operators is assumed to be 3.50E-04 m^3/s based on Regulatory Guide 1.195, “Methods and Assumptions for Evaluating Radiological Consequences of Design Basis Accidents at Light-Water Nuclear Power Reactors” (ML031490640), for the duration of the scenario. Control room occupancy factors sourced from RG 1.195, item 4.2.6 are in table 13-3below.

Table 13-3: Control Room Occupancy Factors

	Control Room Occupancy Factors		
	0-24 hours	24-96 hours	96-720 hours
Occupancy Factor	1.0	0.6	0.4

The NRC staff finds that the assumptions made to compute radiological consequences to the control room operator are conservative and appropriate when demonstrating that the SHINE Design Criterion 6 is met, which permits the control room operator to perform its intended functions under accident conditions.

Public Receptor Radiological Consequence Assumptions:

The public radiological consequences are computed by modeling the radionuclide flow path from the MAR source to the environment in combination with the siting public atmospheric χ/Q values over a 30-day period. The breathing rate for the public receptor is 3.50E-04 m^3/s based on RG 1.195 for the duration of the scenario.

The NRC staff finds that the assumptions made to compute radiological consequences to the public are conservative and appropriate when demonstrating the SHINE public dose acceptance criterion of 1 rem TEDE.

Total Effective Dose Equivalent:

The TEDE is defined as the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures. Both 10 CFR Part 50 and 10 CFR Part 20 refer to the dosimetry methodologies defined by the International Commission on Radiological Protection (ICRP) in Publication 26, “Recommendations of the ICRP,” and in Publication 30, “Limits for Intakes of Radionuclides by Workers.” The ICRP 30 dosimetry methodologies are applied in:

- 10 CFR Part 50 – through the TEDE criteria (defined in 10 CFR 50.2, “Definitions”) for the design, construction, and operation of the facility under normal and accident conditions.
- 10 CFR Part 20 – through the TEDE limits (defined in 10 CFR 20.1003) to establish standards and practices for radiation protection purposes for occupational and public health during normal operation.

Additionally, 10 CFR Part 20, Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” provides direction on how to determine external and internal exposures. Among other things, this appendix provides an appropriate method to compute dose based on ICRP 30 tissue weighting factors. These tissue weighing factors are directly codified by 10 CFR 20.1003 within the table labeled, “Organ Dose Weighting Factors.”

Acceptable practices for computing DBA radiological consequences in terms of TEDE are to apply the exposure-to-committed effective dose equivalent coefficients for inhalation of radioactive material found in table 2.1 of FGR No. 11. The coefficients in the column headed “effective” yield doses corresponding to the committed effective dose equivalent. These tables are derived from the data provided in ICRP Publication 30 and have been found acceptable to the NRC staff as they meet the applicable regulatory requirements. Likewise, the exposure-to-effective dose equivalent factors for external exposure of radioactive material apply FGR No. 12. Therefore, compliance with the dose-related regulations of 10 CFR Part 50 and 10 CFR Part 20 is demonstrated when applying the exposure-to-dose conversion factors of FGR Nos. 11 and 12.

The NRC staff reviewed the dosimetry methodology applied by SHINE to compute radiological consequences of DBAs to be evaluated against the applicable accident dose criteria. To compute radiological consequences in compliance with 10 CFR Part 50 and 10 CFR Part 20, SHINE utilized the exposure-to-dose conversion factors of FGR Nos. 11 and 12. The NRC staff finds this approach acceptable because it complies with the applicable regulations.

Irradiation Facility Design-Basis Accidents

SHINE identified for the IF credible DBA scenarios that range from anticipated events, such as a loss of electrical power, to events that are still credible, but considered unlikely to occur during the lifetime of the facility. For each accident scenario, SHINE identified:

- limiting initiating event, initial conditions, and boundary conditions;
- sequence of events for functions and actions that change the course of the accident or mitigate the consequences of the accident;
- damage to equipment or the facility that affects the consequences of the accident;
- potential radiation source term and radiological consequences; and
- safety controls to prevent or mitigate the consequences of the accident.

The IF DBA categories that bound credible accident sequences are as follows:

- Maximum hypothetical accident (SHINE FSAR subsection 13a2.1.1);
- Insertion of excess reactivity (SHINE FSAR subsection 13a2.1.2);
- Reduction in cooling (SHINE FSAR subsection 13a2.1.3);
- Mishandling or malfunction of target solution (SHINE FSAR subsection 13a2.1.4);
- Loss of offsite power (LOOP) (SHINE FSAR subsection 13a2.1.5);
- External events (SHINE FSAR subsection 13a2.1.6);
- Mishandling or malfunction of equipment (SHINE FSAR subsection 13a2.1.7);
- Large undamped power oscillations (SHINE FSAR subsection 13a2.1.8);
- Detonation and deflagration in the primary system boundary (SHINE FSAR subsection 13a2.1.9);
- Unintended exothermic chemical reactions other than detonation (SHINE FSAR subsection 13a2.1.10);
- System interaction events (SHINE FSAR subsection 13a2.1.11); and
- Facility-specific events (SHINE FSAR subsection 13a2.1.12).

The DBA TEDE results for the public and the control room operator are listed in table 13-4 below.

Table 13-4: Irradiation Facility and Radioisotope Production Facility Accident Dose Consequences

Accident Category (Bounding Scenario)	Public TEDE (mrem)	Control Room TEDE (mrem)
Irradiation Facility		
Insertion of Excess Reactivity	No consequences	No consequences
Reduction in Cooling	No consequences	No consequences
Mishandling or Malfunction of Target Solution		
• Primary system boundary leak into an IU cell	440	771
Loss of Offsite Power (LOOP)	No consequences	No consequences
External Events	292	588
Mishandling or Malfunction of Equipment - MHA	727	1,940
Large Undamped Power Oscillations	No consequences	No consequences
Detonation and Deflagration in the Primary System Boundary	No consequences	No consequences
Unintended Exothermic Chemical Reactions other than Detonation	No consequences	No consequences
System Interaction Events	No consequences	No consequences
Facility-Specific Events		
• Tritium Release into an IU Cell	37	74
• Tritium Release into the Tritium Purification System Glove box	798	1,380
Radioisotope Production Facility		
Spill of Target Solution in the Supercell	42	76
Spill of Eluate Solution in the Supercell	88	122
Spill of Target Solution in the RPF Piping Trench	22	40
Spill of Target Solution from a Tank	24	42
Spill of Waste Solution in RLWI	557	1,880
PVVS Carbon Delay Bed Fire (Beds 1/2/3)	117	8
PVVS Carbon Delay Bed Fire (Beds 4/5/6/7/8)	686	48
PVVS Carbon Guard Bed Fire	546	1,390

13a.4.1 Maximum Hypothetical Accident

As described in SHINE FSAR sections 13a2.1.1 and 13a2.2.1, “IF Maximum Hypothetical Accident,” SHINE considered an MHA for the IF as well as the RPF. SHINE identified the MHA as the failure of the TSV TOGS pressure boundary resulting in a release of off-gas into the TOGS cell. This is a credible fission product-based DBA that bounds the radiological consequences for all other DBA categories except for the special-case tritium release DBA. The NRC staff’s review of the MHA event is in section 13a.4.7 of this SER.

13a.4.2 Insertion of Excess Reactivity

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR sections 13a2.1.2 and 13a2.2.2, "Insertion of Excess Reactivity," examine the modes of operation including the fill process, the cold target solution prior to starting the neutron driver, and irradiation operations after the neutron driver is activated. The TSV is expected to operate in a subcritical condition during all modes of operation through a combination of automatic safety systems and administrative controls, including a passive standpipe overflow system and fill rate limits. The effective neutron multiplication factor (k_{eff}) is expected to be at a maximum at the end of the filling mode. The k_{eff} will be reduced during irradiation operations due to void and temperature feedback in the target solution.

The subcritical assembly system, including the TSV and TSV dump tank, is designed to operate in a subcritical state without the availability of excess reactivity. As such, there are no reactivity control systems in the SHINE system. However, as applicable to the TSV, the excess reactivity insertion event during the startup process and post-irradiation mode of the TSV has been identified as a potential initiating event that can challenge the integrity of the pressure system boundary by causing increased power density, temperature, and pressure. The insertion of excess reactivity does not result in radiological consequences.

When in Mode 1 (Startup) and Mode 3 (Post-Irradiation (Shutdown)), the subcritical assembly is not being driven by the neutron driver and excess reactivity could lead to inadvertent criticality and unplanned fission power generation, temperature increase, and gas generation. When in Mode 2 (Irradiation), the subcritical assembly is being driven by the neutron driver where excess reactivity would result in an increase in power, temperature, and gas generation.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that the credible insertion of excess reactivity accident scenarios were categorized and that the most limiting accident in each group was chosen for detailed analysis. These scenarios are:

- Increase in the target solution density during operations (e.g., due to pressurization).
- Target solution temperature reduction during fill/startup (e.g., excessive cooldown).
- Target solution temperature reduction during irradiation (e.g., excessive cooldown).
- High reactivity and power due to high neutron production at cold conditions.
- Moderator addition due to cooling system malfunction (e.g., cooling water in-leakage).
- Additional target solution injection during fill/startup and irradiation operations.
- Realistic, adverse geometry changes.

- Reactivity insertion due to moderator lumping effects (e.g., voiding in the cooling system).

- Inadvertent introduction of other materials into the TSV (e.g., uranium solids introduction or precipitation of uranium from target solution).

- Concentration changes of the TSV target solution (e.g., through boiling or evaporation).

- Failure to control temperature during inverse subcritical multiplication factor (1/M) measurements at startup.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions and that the accident sequence started with an initiator and ended in a stabilized condition. Before the event, the IU was assumed to be operating normally under applicable TSs. When the TSV is being filled, it is filled to an approximate k_{eff} of near 1 at a cold startup temperature range of 59°F to 77°F (15 degrees Celsius (°C) to 25°C). During steady-state irradiation operations, the TSV is in a subcritical state with a nominal k_{eff} of slightly less than when filled. The TSV operates with the neutron driver in-service with a source strength yielding a maximum value of 125 kW power within the target solution. The operating TSV maximum average temperature is below 176°F (80°C). During all modes of operations, the target solution has high negative temperature and void coefficients.

Following a TRPS signal, the TSV is designed to dump the target solution on high neutron flux level (source, wide range, and time-averaged) to protect the primary system boundary. Additionally, the TRPS is designed to dump the TSV contents on high PCLS temperature, low PCLS temperature, and low PCLS flow. The redundant, fail-open TSV dump valves ensure that target solution can be dumped and are cycled each irradiation cycle.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as Scenario 4, “High Reactivity and Power Due to High Neutron Production at Cold Conditions.” This scenario can occur due to excess tritium injection into the neutron driver assembly system (NDAS) during cold conditions as a result of a TPS control system or component failure during startup before the TSV is at operating temperature. This scenario can also occur if the NDAS neutron production drops to a lower flux than expected due to focusing issues, electrical arcing, or other malfunctions. This loss of neutron source during irradiation results in a decrease in void fraction and a target solution cooldown in the TSV. If the NDAS neutron production were to rapidly return to full output subsequent to a loss of void fraction and cooldown, excessive power generation could occur that could challenge target solution power density limits or primary system boundary integrity.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events for the insertion of excess reactivity event. The event is initiated when the accelerator ceases to produce source neutrons because of an upset event. The TRPS detects the loss of neutron production and begins a delay time prior to initiating a TSV reactivity protection system driver dropout, which would cause the NDAS high voltage power supply breakers to open, terminating the irradiation process by the accelerator. The PCLS continues to function and cool the target solution in the TSV. As the system reduces in power, voids collapse in the target solution, causing a reactivity increase. After the loss of neutron production, target solution cooling results in a temperature decrease of less than 7°C. This results in a reactivity increase. The accelerator output is restored just prior to the TRPS Driver Dropout actuation signal. Power increases to a level that is greater than the steady-state power before the upset occurred. This power level would result in a TRPS IU Cell Safety Actuation on high wide range neutron flux equivalent to fission power. This limit provides margin to an analytical limit of 240 percent fission power (i.e., 300 kW).

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls that protect from excessive power resulting in damage to the pressure system boundary. They are the actuation signals from the TRPS on high flux in Mode 1 and Mode 2, which are:

- Low power range neutron flux;
- TRPS Driver Dropout, resulting in redundant NDAS high voltage power supply breakers opening;
- Redundant high voltage power supply (HVPS) breakers on neutron driver;
- High wide range neutron flux; and
- TRPS IU Cell Safety Actuation on high wide range neutron flux.

The TRPS prevents challenges to the integrity of the pressure system boundary as no design limits are exceeded. No equipment damage results from the postulated insertion of excess reactivity event. No releases of radioactive material are expected to occur as a result of the postulated insertion of excess reactivity event. Therefore, because no design limits are exceeded and no damage to the pressure system boundary is expected, there are no radiological consequences to the workers or the public.

The limiting reactivity insertion event has been identified and analyzed and the consequences of this event are within the dose acceptance limits and bounded by the MHA. The TSV attains a stable condition following the limiting event. Radiation doses to the public and workers are thus within acceptable limits and the safety and health of the workers and public are adequately protected.

The NRC staff reviewed the results of SHINE’s insertion of excess reactivity event analyses, as discussed above. The staff finds that the results of the analyses demonstrate that a credible insertion of excess reactivity in the IF would result in no design limits being exceeded and no radiological consequences to the workers and public. Therefore, the staff concludes that SHINE’s insertion of excess reactivity event analyses are acceptable.

13a.4.3 Reduction in Cooling

The NRC staff evaluated the sufficiency of the applicant’s descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, “Accident Analyses,” of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR sections 13a2.1.3 and 13a2.2.3, “Reduction in Cooling,” evaluate a reduction in PLCS cooling flow. The reduction in cooling event during normal operations is identified as a potential initiating event which can challenge the operation on the subcritical assembly system.

The subcritical assembly system components evaluated with reduced cooling were the neutron multiplier, the TSV, and the TSV dump tank. These components are cooled by the PCLS and light water pool during irradiation operations to maintain target solution average temperature at 125 kW of heat generation in the TSV. The PCLS is designed to remove 170 kW and to reject heat to the RPF cooling system, which in turn is cooled by the process chilled water system. The PCLS, RPF cooling system, and the process chilled water system are supplied by offsite power; therefore, a loss of coolant flow occurs due to power failure and could also occur due to failure of a pump, inadvertent valve closure, or a pipe break. The light water pool provides a large heat capacity for passively rejecting heat from the TSV dump tank during shutdown operations. The temperature rise in the light water pool after a specified decay heat period, assuming the pool is at its minimum allowable level, is described in SHINE FSAR section 4a2.4.2.2.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that the credible reduction in cooling accident scenarios were categorized and that the most limiting accident in each group was chosen for detailed analysis. These scenarios are:

- Loss of normal power resulting in loss of PCLS and de-energized neutron driver.

- Loss of PCLS cooling due to blockage, malfunction, or operator error where the neutron driver remains operating.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions and that the accident sequence started with an initiator and ended in a stabilized condition. The initial conditions and assumptions for the reduction in cooling events are that the TSV is operating normally at steady-state in Mode 2 with a thermal power being generated as 137.5 kW which is 10 percent above the licensed thermal power of 125 kW. The PCLS is providing greater than the minimum flow rate at a temperature less than the maximum supply temperature of 77°F. It is assumed that the TSV was filled to the minimum cold fill volume at the maximize power density. The average target solution temperature is up to 175°F. Target solution decay heat is based on end-of-life target solution conditions, which generates the highest decay heat.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as Scenario 2, “Loss of PCLS Cooling,” because in this scenario the accelerator operation could continue with reduced cooling flow. This scenario postulates a loss of PCLS flow without a loss of offsite operating power, resulting in continued operation of the neutron driver at full power which continues to generate heat.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events for the reduction in cooling DBA. It is initiated by a PCLS cooling flow being reduced, resulting in increased TSV temperature. A low PCLS flow or high temperature signal (77°F (25°C)) initiates a TRPS Driver Dropout actuation signal, which causes the NDAS high voltage power supply breakers to open, terminating the irradiation process by the accelerator. After a 180 second delay, an IU Cell Safety Actuation is initiated, opening the redundant TSV dump valves and draining the target solution to the TSV dump tank. The light water pool is the heat sink for removal of decay heat from the target solution in the TSV dump tank.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls to prevent a reduction in cooling event and that ensure that the target solution in the TSV does not boil:

- TRPS Driver Dropout on loss of PCLS flow and high PCLS temperature.

- TRPS IU Cell Safety Actuation on low PCLS flow rate and high PCLS temperature.
- Light water pool.
- NDAS HVPS breakers.
- Redundant TSV dump valves.

The TRPS is designed to end the event and place the target solution in a safe shutdown condition without the need for operator action. The system prevents challenges to the integrity of the pressure system boundary as no design limits are exceeded. If the PCLS supply temperature exceeds the maximum operating limit of 77°F (25°C) or its flow rate is below the minimum operating limit, the TRPS indicates an IU Cell Safety Actuation where the target solution is transferred to the TSV dump tank and passively cooled by the light water pool. No equipment damage results from the postulated reduction in cooling event. No releases of radioactive material are expected to occur as a result of the event. Therefore, because no design limits are exceeded and no damage to the pressure system boundary is expected, there are no radiological consequences to the workers or the public.

The NRC staff reviewed the results of SHINE's reduction in cooling event analyses, as discussed above. The staff finds that the consequences of the event have been analyzed and are bounded by the MHA. Further, the staff finds that radiation doses to the public and workers will be within acceptable limits and that the safety and health of the workers and public will be adequately protected. Therefore, the staff concludes that SHINE's reduction in cooling event analyses are acceptable.

13a.4.4 Mishandling or Malfunction of Target Solution

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR sections 13a2.1.4 and 13a2.2.4, "Mishandling or Malfunction of Target Solution," describe the IF as containing a liquid target solution that may include radioactive fission products. This accident category includes events that involve the mishandling of the target solution and the failure of the primary system boundary within the IF. The solution may be contained within the target solution hold tank, the TSV, TSV dump tank, or any of the associated piping.

The design of the TSV is to hold the liquid target solution which generates fission products while being normally irradiated during Mode 2 of operation. The primary system boundary which consists of the TSV, the TSV dump tank, the TOGS, and associated connected piping and piping components contains all fission products produced during irradiation. The mishandling or malfunction of a target solution event during normal operations is identified as a potential initiating event, which could release fission products from the irradiated target solution in the TSV, while being transferred, or in the storage area. Mishandling and malfunction of target solution events fall broadly into two categories. The first is spills or leaks that cause target solution to migrate into unintended locations. The second is changes in the physical or chemical form of the target solution that results in adverse effects.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed a series of credible scenarios of mishandling of, or malfunction involving, target solution by postulating the following scenarios:

- Failure of the pressure system boundary below the level of the light water pool.
- Failure of the TSV to the PCLS pressure boundary resulting in in-leakage to the TSV.
- Failure of the RPF cooling system to the pressure system boundary interface.
- Failure of the TSV to the PCLS pressure boundary resulting in target solution leakage to the PCLS.
- Failure in the TOGS causing high pressure in the TSV during fill mode.
- Target solution leakage into a valve pit.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions and that the accident sequence started with an initiator and ended in a stable condition. Prior to the event, the pressure system boundary does not a contain significant pressure source. Leakage between the pressure system boundary and the light water pool will normally flow from the pool to the pressure system boundary should a break occur. The primary confinement boundary isolates the primary system boundary from the rest of the facility by robust walls, ceilings, and floors. Penetrations for piping, ducts and electrical cables, and shield plugs are sealed to limit the release of radioactive materials from the facility. Integrated leak rate from the primary confinement boundary is less than that assumed in the dose analysis. The primary confinement is cooled by the RVZ1r recirculating air ventilation system. The primary confinement is ventilated to the RVZ1e exhaust system through the PCLS expansion tank. The IF tanks and piping that have the potential to contain fissile material, except the TSV, are designed with passive measures that prevent an inadvertent criticality with the most reactive uranium concentration. Drains that lead from the pipe trenches and tank vaults are designed with a geometry that prevents an inadvertent criticality of the leaked target solution.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as Scenario 1a, “Failure of the PSB Below the Level of the Light Water Pool.” For this scenario, a failure in the pressure system boundary below the light water pool surface is assumed to result in target solution leakage from the primary system to the light water pool. The target solution mixes with the pool water and noble gases, volatile fission products, and particulates evolve into the IU cell gas space. Some of the radionuclides would then leak through the primary confinement boundary into the building and then into the environment.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified that this sequence of events is initiated by a failure of the primary system boundary, which leads to mixing of irradiated target solution within the IU cell light water pool. Radioactive material that enters the gas space above the light water pool is then confined by the primary confinement boundary. Gaskets and other non-structural features are used, as necessary, to provide sealing where components meet (e.g., shield plugs and inspection ports). Some radioactive material is transported into the IF through minor leakage paths around penetrations in the primary confinement boundary. Detection of airborne radiation in RVZ1e (15 times background fission product) actuates the primary confinement boundary isolation valves and an IU trip within 20 seconds of detection (see SHINE FSAR table 7.4.1, "TRPS Monitored Variables"). A time delay is provided by the holdup volume in RVZ1e to prevent radioactive gases from exiting through RVZ1e prior to isolation. The radioactive material is then dispersed throughout the IF and exits the facility to the environment through building penetrations. Detection of high radiation in the RCA actuates ventilation dampers between the RCA and the environment and minimizes the transport of radioactive material to the environment. No operator actions are required to reach a stable condition or to mitigate dose consequences.

Following the failure of the primary system boundary, it is assumed that the MAR is instantly well-mixed with the light water pool and that gases immediately evolve out of the pool and into the IU cell gas space. For the purposes of the accident analysis, it is assumed that the nitrogen purge system is operating and causes pressurization of the IU cell. Radiation transport is driven by pressure-driven flow between the IU cell and the IF. Reduction in the MAR occurs during the release due to adsorption of iodine onto the IU cell walls and other surfaces until equilibrium conditions are established. The majority of the MAR is transported to the IF through primary confinement boundary leakage. Transport to the environment occurs through leakage around penetrations in the RCA boundary.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident, which are:

- primary confinement boundary;
- ventilation radiation monitors;
- RVZ1e IU ventilation isolation mechanisms; and
- holdup volume in the RVZ1e.

Consistent with NUREG-1537, Part 2, the NRC staff determined that SHINE identified the radiation source term as being the TSV radionuclide inventory as described in "Accident Analysis Consequence Methodology," of section 13a.4 of this SER. The entire radionuclide inventory in the TSV is deterministically assumed to be instantaneously released to the light water pool and dispersed uniformly throughout the pool. The iodine in the TSV is assumed to be fully dissolved into the target solution prior to the initiating event where none is present in the gas space of the TSV. The iodine dissolved in the pool water is partitioned according to the pool pH, temperature, and the pool and gas volumes. The pool pH used in the radiological dose calculation bounds the minimum pool pH calculated for nominal conditions. The minimum pool pH was calculated using the bounding low pool volume at bounding low pool pH mixed with the bounding high target solution volume at a bounding low pH.

Deposition of iodine on the walls of the IU cell due to the temperature difference of the warm gas and the cold walls is also credited as a removal mechanism. As iodine is deposited on the cell walls, more iodine is evolved from the light water pool and into the gas space. The iodine partitioning determines the transport of volatile iodine out of the pool. Some radionuclides deposited in the light water pool are released to the gas space as an aerosol when radiolytically-generated hydrogen gas bubbles burst at the pool surface. Radiolysis becomes a long-term source of both non-volatiles and iodine. Once the MAR is released into the gas space of the IU cell, there are several paths through which leakage could occur. The primary leak-path would be around the IU cell plug perimeter. As discussed in section 13a.4 "Accident Analysis

Consequence Methodology,” of this SER, all potential leak paths are modeled as a single leakage junction to the IF.

The applicant also considered the consequences of target solution mishandling events, such as excessive leakage or spillage that could potentially initiate an unintended criticality event in an area or location where it could pose a threat to facility workers. The MHA bounds the accidental dose consequences of such postulated events. Therefore, radiological doses to the workers and the public will be within acceptable limits, and the health and safety of the staff and public will be adequately protected.

The NRC staff reviewed the results of SHINE’s mishandling or malfunction of target solution event analyses, as discussed above. The staff finds that the consequences of the event have been analyzed and are bounded by the MHA. Further, the staff finds that radiation doses to the workers and the public will be within acceptable limits and that the health and safety of the workers and public will be adequately protected. Therefore, the staff concludes that SHINE’s mishandling or malfunction of target solution event analyses are acceptable.

13a.4.5 Loss of Electrical Power

The NRC staff evaluated the sufficiency of the applicant’s descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, “Accident Analyses,” of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR sections 13a2.1.5 and 13a2.2.5, “Loss of Off-Site Power,” examine a LOOP at the facility for an extended period of time with conservative operating conditions as an event that bounds all other loss of power events for the facility. A UPSS is available to supply battery power for safety-related loads.

The LOOP event during normal operations is identified as a potential initiating event which could result in partial or complete loss of power to the facility and potentially challenge the primary system boundary in the IF. A LOOP is defined as zero voltage/power supplied by the utility, loss of a phase, phase reversal, sustained overvoltage, or sustained undervoltage. When there is loss of phase, phase reversal, sustained overvoltage, or sustained undervoltage the facility automatically disconnects from the power utility.

The design of the normal electrical power supply system (NPSS) is as a single overall electrical power system serving the SHINE facility as well as the site and support buildings. The NPSS consists of the normal power service entrances from the electric utility from two separate feeds and a distribution system.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed a series of credible scenarios resulting from a LOOP. The analysis examines the variety of reasons related to the reliability and operation of the transmission system, stress during peak grid load conditions, severe weather effects from high wind, tornado, or ice and snowstorms, a seismic event, or equipment failure in the supplying substation. Additionally, SHINE assessed loss of power resulting from failure, or malfunction of, the facility NPSS such as the facility transformers or switchgear. It is assumed that a complete LOOP occurs from causes that are external to the SHINE facility or common cause failures in the NPSS. A LOOP may occur during any combination of operating modes within the IF and the RPF. Postulated LOOP scenarios are the following:

1. Degradation (reliability) of the transmission system.

2. Electrical grid stress during peak load conditions.

3. Severe weather effects from high wind, tornado, ice or snowstorms.

4. Seismic event.

5. Equipment failure in the supplying substation.

6. Failure or malfunction of facility transformers or switchgear.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as a complete LOOP. This would potentially occur due to severe weather or a seismic event that damages substation equipment or associated transmission lines. For this scenario, the initial conditions and assumptions are that all eight TSVs are in Mode 2 (Irradiation) with the maximum source term and decay heat levels. The irradiation power is assumed to be 137.5 kW, which is 10 percent above maximum operating power. The average target solution temperature in the TSV is at the limit of 176°F (80°C). Bulk target solution temperature in the TSV is at the limit of 176°F (80°C). The initial light water pool temperature is assumed to be 95°F (35°C). Complete loss of PCLS flow at the time of the initiating event is also assumed. The light water pool level is assumed to be not less than the level specified in SHINE FSAR section 13a2.1.5.1, “Identification of Causes, Initial Conditions, and Assumptions,” which provides a passive heat sink sufficient to remove decay and residual heat from the target solution. Hydrogen concentration in the TSV and TOGS is assumed to be maintained within operating limits prior to the event. The TOGS mainstream low flow limit has been conservatively calculated by SHINE to be sufficient to maintain the hydrogen concentration within the TSV headspace at less than 4.0 percent during normal operations, which prevents a deflagration that could challenge PSB integrity. The UPSS is assumed to be available and thus to provide sufficient battery capacity for essential loads for its required runtime as described in SHINE FSAR table 8a2.2-1, “UPSS Load List.” Resupply of N2PS is assumed to occur within 3 days following a LOOP, which is considered to be a safety-related maintenance activity in accordance with SHINE TS 5.4. The procedures would be performed by the SHINE ERO whose members are trained and qualified to perform their duties in accordance with SHINE TS 5.5.2.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE assessed that the sequence of events for a long-term LOOP, during normal operations, will start with the UPSS automatically maintaining power supply to the 125 VDC UPSS buses A and B. Each NDAS HVPS deenergizes and the associated irradiation processes are secured. The TSV dump valves open, draining the target solution in the TSVs to their respective TSV dump tanks. The PCLS loses power to its pumps and forced convection cooling ceases while heat is removed by natural convection to the light water pool. Hydrogen generation in the TSV dump tanks continues to occur due to radiolysis from the decay of fission products. The TOGS blowers and recombiner heaters operate on UPSS power for at least 5 minutes. The blowers continue forced flow through the TOGS recombiners for a short period of time as hydrogen production levels decrease and bubbles leave the target solution. The N2PS begins passively injecting nitrogen gas into the primary system boundary. Nitrogen gas is injected in the eight subcritical assembly systems via a connection to the TSV dump tank. The nitrogen gas purges the primary system boundary of hydrogen leaving through a vent connection from the TOGS to the PVVS system header. The gas then passes through the PVVS carbon delay beds which have a minimum efficiency for iodine of 99 percent for removal of fission product gases before release to the environment. The N2PS has enough nitrogen capacity for 72 hours, after which the system is resupplied.

For transfer operations of target solution from the TSV dump tanks to the RPF, the VTS operation is automatically secured. Nitrogen gas sweeps RPF process tank and lift tank headspaces to dilute radiolytic hydrogen. Nitrogen from the N2PS is routed to the PVVS carbon beds for removal of fission product gases before release to the environment.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident, which are:

- UPSS;
- NDAS HVPS breakers;
- N2PS;
- TSV dump valves; and
- Light water pool.

The safety-related functions of the equipment supplied by the UPSS are uninterrupted; therefore, the safety-related functions continue to be performed to place the target solution in a safe shutdown condition without the need for operator action. Irradiation processes stop and the target solution is drained from operating TSVs to their respective TSV dump tanks. Decay heat is removed by natural convection to the light water pool. The combustible gas management system eliminates the risk of a release of radioactive material due to deflagration. The combined systems prevent challenges to the integrity of the pressure system boundary as no design limits are exceeded. No equipment damage results from the postulated LOOP event. No releases of radioactive material are expected to occur as a result of the event. Therefore, because no postulated LOOP event result in the loss of safety functions of the equipment supplied by the UPSS, no design limits are exceeded, and no damage to the pressure system boundary is expected, there are no radiological consequences to the workers or the public.

The NRC staff finds that SHINE’s analysis considered the effects of the radiolytic decomposition of the target solution and the formation of fission gases, addressed the system response to gas formation, and evaluated the potential for the decomposed gases to react explosively. Further, the staff finds that SHINE’s analysis was carried out for a sufficient duration of time to demonstrate that the IU reaches a stable state, and that the MHA bounds the dose consequences of such postulated events. Therefore, radiological doses to the workers and the public will be within acceptable limits and the health and safety of the workers and public will be adequately protected.

The NRC staff reviewed the results of SHINE’s loss of electrical power event analyses, as discussed above. The staff finds that the results of the analyses demonstrate that credible loss of electrical power events would result in no design limits being exceeded and no radiological consequences to the workers and public. Therefore, the staff concludes that SHINE’s loss of electrical power event analyses are acceptable.

13a.4.6 External Events

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR sections 13a2.1.6 and 13a2.2.6, "External Events," identify seismic events, tornados or high winds, and a small aircraft crash as external events that can credibly affect the IF. The external events represent natural or man-made events that occur outside the facility and have the potential to impact facility SSCs and challenge the primary system boundary in the IF. The SHINE facility structure is designed to withstand credible external events. Most of the analyzed accidents involving credible external events are prevented by the facility structure or the seismic qualification of affected SSCs. SSCs, including their foundations and supports, that are required to perform their safety function(s) in the event of a design-basis earthquake (DBE) are classified as Seismic Category I. SSCs that are co-located with a Seismic Category I SSC and required to maintain their structural integrity in the event of a DBE to prevent unacceptable interactions are classified as Seismic Category II. Seismic Category II SSCs are not required to remain functional in the event of a DBE.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed a series of credible scenarios for external events by postulating the following scenarios:

1. Several seismic event scenarios.

2. Severe weather events.

3. Transportation accidents, including small aircraft crash into the IF or RPF, toxic gas releases, or explosions.

4. External flooding.

5. External fires from natural sources.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions and that the accident sequence started with an initiator and ended in a stabilized condition. Prior to an external event occurring, the SHINE facility is assumed to be running at nominal conditions.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as Scenario 3, "Seismic Event Causing Multiple NDAS Failures." This scenario may cause the failure of one or more NDAS units. A failure of the NDAS vacuum boundary within the IU would result in a release of tritium and sulfur hexafluoride (SF_6) gas into the IU cell. The accident analysis assumes the simultaneous failure of all eight NDASs so as to bound the maximum allowable operating state in the IF.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events for a seismic event causing multiple NDAS failures during normal operations. This sequence is that first the IU cells become slightly pressurized due to the mass of the released SF_6 gas. The IU and TOGS shielded cells are equipped with removable shield plugs which allow entry into the confined area. Gaskets and other non-structural features are used, as necessary, to provide sealing where separate structural components meet. Some tritium released from the NDASs is transported into the IF through penetrations in the primary confinement boundary and then to the environment. A detection of high TPS target chamber supply pressure or high TPS target chamber exhaust pressure actuates the primary confinement boundary isolation valves and minimizes the transport of radioactive material to the environment and the IU trips within 20 seconds of detection. A sufficient time delay is provided by the holdup volume in RVZ1e to prevent radioactive gases from exiting through RVZ1e prior to isolation. The primary confinement boundary and components are assumed to remain intact and perform their mitigation function with respect to radionuclide transport from the IU cells to the IF. Failure of the NDAS vacuum boundary does not cause subsequent damage to equipment. While the NDAS vacuum boundary integrity is not seismically qualified to maintain integrity, the NDAS is designed to maintain structural integrity during and following a DBE. After the initial IU cell pressurization has reached equilibrium, leakage between the IU cells and the IF is driven primarily by barometric breathing. The MAR includes each of the eight NDASs containing the maximum tritium inventory of tritium gas.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident, which are:

- Primary confinement boundary;
- TPS Train Isolation on high TPS target chamber supply pressure or high TPS target chamber exhaust pressure;
- Ventilation isolation mechanisms; and
- Holdup volume in the RVZ1e.

The NRC staff finds that SHINE's analysis considered the potential system interactions between the IUs and the RPF for external events. The staff finds that the MHA bounds the dose consequences of the postulated external events scenarios. Therefore, radiological doses to the workers and the public will be within acceptable limits, and the health and safety of the workers and public will be adequately protected.

The NRC staff reviewed the results of SHINE's external events analyses, as discussed above. The staff finds that the results of the analyses demonstrate that credible external events would result in radiological consequences to the workers and public bounded by the MHA. Therefore, the staff concludes that SHINE's external events analyses are acceptable.

13a.4.7 Mishandling or Malfunction of Equipment

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR sections 13a2.1.7 and 13a2.2.7, "Mishandling or Malfunction of Equipment," examine scenarios where the mishandling or malfunction of equipment could lead to an accident where workers or the public are exposed to radiation. This includes scenarios where the PSB is not maintained. Scenarios related to the mishandling or malfunction of equipment that could lead to a release of target solution are reviewed in section 13a.4.4 of this SER. This section of this SER examines those scenarios that could lead to radiation exposure including the release of radioactive gases.

SHINE reviewed the category of DBAs that involve the mishandling or malfunction of equipment during normal operations and that could challenge the PSB in the IF. Within this category, SHINE also identified the MHA for the SHINE facility as a failure of the TSV TOGS pressure boundary resulting in a release of off-gas into the TOGS cell. This is a credible fission product-based DBA that bounds the radiological consequences to the public of all credible fission product-based accident scenarios.

SHINE identified the mishandling or malfunction of equipment during normal operations as a potential initiating event that could challenge the PSB in the IF. The waste gases from the irradiation of the target solution are of two major types: (1) the hydrogen and oxygen produced by the radiolysis of water in the target solution and (2) radioactive fission product gases. Failure of the TOGS portion of the PSB could allow the escape of hydrogen or fission product gases into the primary confinement boundary and the RCA. SHINE included analyses of this event and other potential mishandling or malfunction of equipment events, excluding the detonation or deflagration of hydrogen within TOGS and other exothermic chemical reactions within the PSB, which are discussed in sections 13a.4.9 and 13a.4.10, respectively, of this SER.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed the mishandling or malfunction of equipment events within two broad categories. The first is spills or leaks that cause target solution to migrate into unintended locations (reviewed in section 13a.4.4 of this SER). The second is changes in the physical or chemical form of the target solution that result in adverse effects. Within this category, three specific initiating events were considered:

1. Failure of the TOGS pressure boundary resulting in release of off-gas into the TOGS cell.

2. Failure of the TOGS vacuum tank.

3. TOGS vacuum makeup valve fails open.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the events the system is assumed to be under normal operational conditions. Fission product gases (e.g., Kr, Xe, and halogens) produced during irradiation operations are retained within TOGS until the target solution batch irradiation cycle is completed. As the TOGS circulates sweep gas during the irradiation cycle, a portion of the iodine is removed by the zeolite beds, and hydrogen and oxygen are recombined by the catalytic recombiners, but no other gases are removed or purged. Each IU is assumed to be operated on an irradiation cycle of 30 days with a minimum time for target solution residing in the TSV dump tank following irradiation. The MAR for these events is conservatively assumed to be the inventory at shutdown, at the end of the irradiation cycle, with the most limiting burnup. The IUs are operated independently, so that an event on one TOGS does not affect another TOGS or IU cell. The TOGS cells are isolated from the rest of the facility by robust walls, ceiling, and floor. The physical separation of individual TOGS prevents malfunctions in one TOGS from affecting the others. Penetrations for piping, ducts, and electrical cables are sealed to limit the release of radioactive materials from the confinement boundary. The TOGS cells are cooled by a recirculating air ventilation system and are isolated from all other facility ventilation systems. A single ventilation connection from the PCLS expansion tank to the RVZ1e subsystem is provided for hydrogen gas removal from the cooling systems and is isolated on a high radiation signal in the RVZ1e ventilation duct. The primary confinement boundary is assumed to be intact and perform a mitigation function with respect to radionuclide transport from the IU cell to the IF.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as Scenario 1, "Failure of the TOGS Pressure Boundary Resulting in Release of Off-Gas into the TOGS Cell." Consistent with NUREG-1537, Part 2, the staff confirmed that SHINE identified the sequence of events for this scenario with the initiating event being a break of the TOGS line downstream of the TOGS blower and the subsequent release of noble gases and iodine into the TOGS cell. The N2PS then actuates and pressurizes the TOGS cell through the leak in the TOGS pressure boundary. The gases in the TOGS cell leak into the IF and then into the environment.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident, which are:

- Primary confinement boundary;
- Ventilation radiation monitors;
- N2PS;
- Ventilation isolation mechanisms; and
- Holdup volume in the RVZ1e.

Prior to the event, iodine is assumed to be fully dissolved within the TSV with none present in the TSV gas space. The TSV inventory at the end of multiple years of continuous 30-day irradiation cycles with a downtime between cycles is assumed. The power level used for the analysis is 137.5 kW, which is 110 percent of design operating power. The initial radiation source term MAR is assumed to be 25 percent of the TSV target solution inventory at the end of the multiple years of continuous 30-day irradiation cycles with a specified downtime between cycles. It is assumed that the iodine in solution is predominantly the volatile (I2) species and that aqueous to gas partitioning occurs rapidly, causing 100 percent of the iodine inventory to be released to TOGS post-shutdown. To model this, the iodine MAR was multiplied by 4, essentially assuming that 100 percent of the MAR is used for the dose calculation. One hundred percent of the noble gases and iodine is assumed to be present in the TOGS gas space while it is operating. Non-volatiles are not included in this accident sequence because the system is designed as a gas-handling system.

The NRC staff evaluated SHINE's analysis of the MHA scenario for compliance with regulations, adherence to acceptable dose consequence analysis assumptions and methods as described in the above applicable regulatory codes, guides, and standards, and approved precedents. The staff also performed confirmatory accident radiological dose calculations where appropriate. The staff determined that SHINE assumed that the SSCs important to safety function as designed and that radioactive material is held up temporarily in the primary confinement boundary and then released from the building. SHINE used realistic methods to compute external radiation doses and dose commitments resulting from inhalation by the control room operator. SHINE used realistic but conservative methods to compute potential doses and dose commitments to the public in the unrestricted area. The staff determined that the methods used for calculating doses from inhalation and direct shine of gamma rays from dispersing plumes of airborne radioactive material are acceptable. The duration of the accident considered for the calculation of radiological doses is 30 days for the facility control room operator and 30 days for the public.

The calculated doses for the MHA scenario are the following:

- Control room operator – 1940 mrem (1.94 rem)
- Maximally exposed member of the public – 727 mrem (0.727 rem)

These doses are within the SHINE-selected radiological siting and design criteria of (1) radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material of not to exceed 1 rem TEDE for the duration of the accident and (2) radiological consequences to workers of not to exceed 5 rem TEDE during the accident, which the NRC staff found acceptable in section 13a.4 of this SER.

The NRC staff reviewed the results of SHINE's mishandling or malfunction of equipment event analyses, as discussed above. Due to the assumptions of the scenario being bounding, the doses calculated will likely not be exceeded by any accident considered credible. Thus, even for the MHA, whose consequences bound all fission product-based credible accidents at the facility, the NRC staff finds that the health and safety of the workers and public are adequately protected. Therefore, the staff concludes that SHINE's mishandling or malfunction of equipment event analyses are acceptable.

13a.4.8 Large Undamped Power Oscillations

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR sections 13a2.1.8 and 13a2.2.8, "Large Undamped Power Oscillations," describe the conditions when power oscillations may occur in the TSV in response to natural fluctuations in the target solution that result in fluctuations in reactivity. The large undamped power oscillations event during normal operations is identified as a potential initiating event that could challenge the PSB in the IF. Large undamped power oscillations are power oscillations that grow over time due to positive reactivity feedback effects and that challenge the design limits of the subcritical assembly. The design of the TSV is a subcritical assembly which can experience power oscillations within reactivity variations within the target solution. Also, the neutron driver output can oscillate which can lead to power variations. Therefore, SHINE evaluated the TSV for large undamped power oscillations as a potential event that could occur during irradiation operation due to reactivity variations in the target solution that lead to fluctuations in the k_{eff} within the irradiated target solution.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed the large undamped power oscillations event by postulating the following scenarios:

1. TOGS failure results in variations in TSV gas pressure.
2. Variations in the neutron driver voltage, current, tritium concentration, or other parameter results in variations in the fusion-neutron production rate.

3. Failure in the PCLS temperature control loop or RPF cooling system supply results in temperature oscillations.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident, which are:

- The design and safety characteristics of the TSV to resist undamped power oscillations;
- IU Cell Safety Actuation initiated by TRPS;
- TRPS high neutron flux trips; and
- TSV dump valves and TSV dump tank.

The analyses for the large undamped power oscillations event assume that negative temperature and void coefficients are within license limits and that the TRPS neutron flux setpoints are within TS limits. During startup, irradiation, and shutdown operations, TOGS regulates gas pressures in the PSB to maintain pressures within the acceptable range. Increased gas pressures in the TSV reduce void fraction, leading to positive reactivity addition. Excessive TSV power oscillations from TOGS pressure oscillations are prevented by redundant TRPS high neutron flux IU Cell Safety Actuation signals. The neutron driver has variability in neutron production rates due to normal variations in beam current and focusing, voltages, and tritium gas concentrations. These variations lead to corresponding variations in fission power in the subcritical assembly system. The TRPS high wide range neutron flux IU Cell Safety Actuation signal prevents excessive TSV power oscillations that challenge design limits should the neutron driver return to full power rapidly following a reduced power transient. The PCLS provides cooling water to the TSV and, therefore, temperature variations in the PCLS directly lead to TSV temperature variations. PCLS provides constant cooling water inlet temperature to the TSV. The TRPS high neutron flux IU Cell Safety Actuation signals prevent excessive TSV power oscillations from PCLS temperature variations. Therefore, there are no large undamped power oscillations that result from PCLS operation.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE demonstrated that power oscillations that may occur are self-limiting as a result of the inherent design and safety characteristics associated with the TSV, operating parameters, and system response to transients. SHINE’s analyses identified that these large undamped oscillation scenarios do not result in damage to the PSB. Large power oscillations that could potentially challenge design limits are prevented by TRPS setpoints on high neutron flux. No operator actions are required to dampen power oscillations. When a TRPS high neutron flux setpoint is exceeded, the neutron driver is automatically de-energized, the TSV dump tank valves automatically open, and the target solution is dumped, by force of gravity, into the favorable geometry TSV dump tank. Therefore, power oscillations that may occur in the subcritical assembly are self-limiting as a result of the inherent design and safety characteristics of the subcritical assembly, operating parameters, and system response to transients.

The TRPS is designed to end a large undamped power oscillations event and place the target solution in a safe shutdown condition without the need for operator action. The TRPS prevents challenges to the integrity of the PSB as no design limits are exceeded. No equipment damage results from the postulated large undamped power oscillations event and no releases of radioactive material are expected to occur as a result of the event. Therefore, because no design limits are exceeded and no damage to the PSB is expected, there are no radiological consequences to the workers or the public.

The NRC staff reviewed the results of SHINE's large undamped power oscillations event analyses, as discussed above. The staff finds that the applicant evaluated the potential for large undamped power oscillations and demonstrated that these events can be readily detected and suppressed so that the TSV reaches a stable state. The applicant considered the potential for positive feedback to arise due to system interaction. The staff finds that the power oscillations at the SHINE facility should be stable or can be readily detected and suppressed so that the consequences are bounded by the MHA. The staff finds that radiological doses to the workers and the public are within acceptable limits and that the health and safety of the workers and public are adequately protected. Therefore, the staff concludes that SHINE's large undamped power oscillations event analyses are acceptable.

13a.4.9 Detonation and Deflagration

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR sections 13a2.1.9 and 13a2.2.9, "Detonation and Deflagration in the Primary System Boundary," examine the effects of a possible hydrogen detonation or deflagration within the PSB on the IF. Irradiating the target solution produces significant quantities of hydrogen and oxygen through radiolysis and small amounts of fission product gases. The TOGS is designed to control the level of hydrogen and oxygen so that a deflagration or detonation does not occur. The hydrogen and oxygen are recombined, condensed, and returned as water to the TSV by the TOGS.

The detonation and deflagration in the PSB event during normal operations is identified by SHINE as a potential initiating event that could challenge the PSB in the IF. The design of the TOGS is the primary control for mitigating hazards associated with the gases evolved from the irradiation of the target solution. Functional requirements for the TOGS include maintaining the concentration of hydrogen to less than the lower flammability limit, recombining the hydrogen and oxygen, and returning the recombined water back to the TSV. The TOGS functions largely as a closed loop during the irradiation process, with gas additions and removals as needed to maintain proper functioning. The TOGS is purged as needed to the PVVS via the VTS.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed the detonation and deflagration in the PSB event by postulating the following scenarios:

1. Target solution off-gas system failure resulting in hydrogen deflagration.

2. PCLS radiolysis resulting in hydrogen deflagration.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions. A hydrogen deflagration produces a maximum overpressure condition of 65 pounds per square inch absolute (psia). Each TSV is serviced by a dedicated and independent TOGS. For this event, it is assumed that a single TOGS fails, allowing hydrogen to accumulate in the TSV and TSV dump tank. The target solution is assumed to be at steady-state conditions at 110 percent of the licensed power limit when the TOGS failure occurs. This is conservative since it results in the maximum hydrogen generation rate in the target solution.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as Scenario 1, “TOGS Failure Resulting in Hydrogen Deflagration.” A TOGS failure may occur due to flow blockage or failure of the TOGS blowers, loss of sweep gas flow to the TSV dump tank, or overfilling the TSV which causes a reduction of available headspace and sweep gas flow. The loss of TOGS functionality allows the hydrogen gas concentration to increase in the headspace in the TSV and/or TSV dump tank. The hydrogen gas may ignite and cause a deflagration in the PSB.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events for a failure of the TOGS resulting in hydrogen deflagration during normal operations. The failure of a single TOGS blower will result in a complete loss of flow through the affected train and total loss of TSV dump tank flow. The other single TOGS blower continues to operate normally. The TRPS detects the loss of flow and executes an IU Cell Safety Actuation and IU cell N2PS actuates. The IU Cell Safety Actuation opens the TSV dump valves and NDAS HVPS breakers, terminating the irradiation process. Hydrogen generation in the TSV and TSV dump tank continues due to radiolysis caused by delayed fission and decay radiation. Hydrogen evolution from the target solution occurs at an increased rate as target solution voids collapse. Within 4 seconds, N2PS is at full flow to the TSV dump tank. Hydrogen and other gases are vented to PVVS through the combustible gas management system exhaust point. Gases pass through the PVVS carbon guard and carbon delay beds before being exhausted from the building at the safety-related exhaust point. The remaining TOGS blower continues operation for a minimum of 5 minutes. The combined action of the remaining TOGS blower and the N2PS maintains the peak hydrogen concentration as described in the SHINE FSAR; therefore, the peak pressure will not exceed the design pressure of the PSB if a deflagration were to occur and no radiological materials would be released. Detonations cannot occur because this peak hydrogen concentration is less than the lower detonation limit. As delayed fission and decay of short-lived radionuclides decline, the production and evolution of hydrogen declines following shutdown and draining of the TSV to the TSV dump tank. The N2PS continues to provide sweep gas for diluting and removing any remaining hydrogen for a period of 72 hours. Resupply of N2PS within 3 days is considered to be a safety-related maintenance activity in accordance with SHINE TS 5.4. The procedures would be performed by the SHINE ERO whose members are trained and qualified to perform their duties in accordance with SHINE TS 5.5.2.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident, which are:

- TOGS capable of maintaining hydrogen concentration within design limits, assuming the worst case single active failure following an IU trip;
- TOGS low-flow trips (TRPS function);
- TOGS oxygen sensor, which detects incipient degradation or failure;

- TOGS demister high temperature trips (TRPS function), which detect incipient degradation or failure of N2PS;
- TSV fill line isolation valves mode-permissive interlock;
- TSV overflow lines to the TSV dump tank;
- TSV dump tank level sensors (TRPS function);
- TSV dump tank low-flow sensors (TRPS function);
- TSV target solution dump on dump tank level sensors (TRPS function);
- PCLS expansion tank flame arrestor;
- N2PS;
- Radiation detection in RVZ1e exit from PCLS expansion tank; and
- Isolation valves in RVZ1e exit from PCLS expansion tank.

The system prevents challenges to the integrity of the PSB as no design limits are exceeded. If hydrogen deflagration occurs at the peak calculated hydrogen concentration, the PSB remains intact. Damage to other primary system components internal to TOGS in the affected train may occur; however, such damage will not result in any release of radiological material. No releases of radioactive material are expected to occur as a result of the detonation and deflagration in the PSB events described above. Therefore, because no design limits are exceeded and no damage to the PSB is expected, there are no radiological consequences to the workers or the public.

The NRC staff reviewed the results of SHINE's detonation and deflagration in the PSB event analyses, as discussed above. The staff finds that the applicant evaluated the consequences of potential deflagrations or detonations of combustible gases within the PSB. Further, the staff finds that the assumptions regarding the impact of potential deflagrations or detonations on PSB integrity are valid. The staff finds that the MHA bounds the dose consequences of the limiting credible detonation within the PSB. The staff finds that the radiological doses to the workers and the public will be within acceptable limits and the health and safety of the workers and public will be adequately protected. Therefore, the staff concludes that SHINE's detonation and deflagration in the PSB event analyses are acceptable.

13a.4.10 Unintended Exothermic Chemical Reactions Other Than Detonation

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

As described in SHINE FSAR sections 13a2.1.10 and 13a2.2.10, "Unintended Exothermic Chemical Reactions Other than Detonation," there is no potential for the target solution to undergo any significant exothermic chemical reactions. The unintended exothermic chemical reactions other than detonation event during normal operations is identified by SHINE as a potential initiating event that could challenge the PSB in the IF. The FSAR examines safety aspects of exothermic chemical reactions that challenge the PSB integrity in the IF, other than hydrogen deflagrations and detonations, which are discussed in section 13a.4.9 of this SER.

Consistent with NUREG-1537, Part 2, the NRC staff finds that SHINE identified credible unintended exothermic chemical reactions other than the detonation scenarios. Specifically, SHINE systematically analyzed the uranium metal-water reaction in the neutron multiplier assembly event. Possible causes of breaches of the neutron multiplier assembly cladding that would allow water to come into direct contact with the natural uranium metal in the neutron multiplier assembly include corrosion of the neutron multiplier cladding, uranium metal-cladding interaction due to radiation-induced growth, or other mechanical damage incurred during maintenance. Such a breach may occur at any time during the lifecycle of the neutron multiplier allowing water intrusion over an extended period of time.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions. The PCLS provides cooling to the TSV and the neutron multiplier and transfers gases produced from radiolysis to the expansion tank. The neutron multiplier radionuclide inventory is developed assuming 30 years of continuous operation at 137.5 kW, which is 110 percent of the licensed power limit.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as Scenario 1, "Uranium Metal-Water Reaction in the Neutron Multiplier Assembly." Water intrusion is assumed to result in an exothermic uranium metal-water reaction in the neutron multiplier assembly. This reaction would generate hydrogen gas inside the neutron multiplier cladding shell. An accumulation of hydrogen gas could result in a deflagration under certain conditions. These conditions include sufficient oxygen concentration, an ignition source, or autoignition temperatures being reached. In this scenario, the hydrogen produced is prevented from potential deflagration by using certain materials within the neutron multiplier. Hydrogen gas that migrates into the PCLS stream from the neutron multiplier leak accumulates in the expansion tank, which is vented to the RVZ1e.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events, following the assumed cladding breech, that result in an exothermic uranium metal-water reaction generating hydrogen. The presence of certain material in the neutron multiplier inhibits a potential deflagration. Small amounts of hydrogen gas migrate into the PCLS and travel to the PCLS expansion tank, along with hydrogen normally generated in the PCLS itself via radiolysis. The expansion tank is vented to RVZ1e to prevent hydrogen accumulation in that tank. Small amounts of fission products from the multiplier also migrate into the PCLS water. The presence of fission products in excess of normal operating levels is detected via in-line radiation monitoring installed in the exhaust of the PCLS expansion tank.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident to be the design of the neutron multiplier which inhibits deflagration.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE evaluated the consequences of potential unintended exothermic chemical reactions (other than explosions) that could occur within the PSB. As a precursor to this event, an excess of gases could accumulate in the PSB and subsequently react with oxygen to release heat. The heat could increase pressure within the PSB or induce thermal stress on the PSB.

The NRC staff reviewed the results of SHINE's unintended exothermic chemical reactions other than detonation event analyses, as discussed above. The staff finds that the applicant identified the types of possible exothermic reactions and evaluated their consequences. The staff finds that the MHA bounds the dose consequences of the limiting unintended exothermic chemical reaction within the PSB. The staff finds that the radiological doses to the workers and the public will be within acceptable limits and the health and safety of the workers and public will be adequately protected. Therefore, the staff concludes that SHINE's unintended exothermic chemical reactions other than detonation event analyses are acceptable.

13a.4.11 System Interaction Events

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

As described in SHINE FSAR sections 13a2.1.11 and 13a2.2.11, "System Interaction Events," the applicant considered events that could result from system interactions within the IF and interactions between the IF and RPF. The system interaction events during normal operations are identified by SHINE as potential initiating events that could challenge the PSB in the IF. SHINE identified three categories of system interaction events. Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed the credible system interaction events, which were categorized as follows:

1. Functional Interactions:

    a. loss of offsite power;
    b. reduction; and
    c. loss of ventilation:
        i. loss of normal ventilation to the IU or TOGS and
        ii. loss or normal ventilation to primary cooling rooms.

2. Spatial Interactions:

    a. fires;
    b. exothermic chemical reaction;
    c. internal flooding; and
    d. dynamic effects.

3. Human-Intervention Interactions.

SHINE defined "Functional Interactions" to be interactions between systems or subsystems that result from a common interface. A functional interaction exists if the operation of one system can affect the performance of another system or subsystem. An adverse functional interaction exists when the operation and/or performance of an (initiating) system adversely affects the operation and/or performance of an SSC as it performs its safety-related function. Functional interaction events are those that may result from failures in support systems or other shared systems that could result in an adverse impact on the PSB.

SHINE defines "Spatial Interactions" to be interactions resulting from the presence of two or more systems in a location. Spatial interactions include a single event that could impact the operation of the adjacent systems, or the failure of one system that may impact the operation of another system.

SHINE defines “Human-Intervention Interactions” to be adverse system interactions caused by human errors in the RPF, which can cause adverse system performance in the subcritical assembly during irradiation operations.

The identified system interaction events are discussed in other sections of the SHINE FSAR and evaluated in other sections of this SER, with the exception of the following scenarios:

1. Loss of normal ventilation to the IU or TOGS.

2. Loss of normal ventilation to primary cooling rooms.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events for the loss of normal ventilation to the IU or TOGS as being caused by a failure of an RVZ1 blower or cooler, including a loss of cooling water. Loss of normal ventilation to individual IUs or TOGSs may also be caused by a failed-shut or mispositioned damper or other equipment failure. A loss of cooling may cause instrumentation inaccuracies or failures which may lead to TOGS maloperation or loss of function. This can result in a potential deflagration and release of radiological material. The protections in place to prevent a TOGS failure due to a loss of normal ventilation are redundant and environmentally qualified TOGS instrumentation (e.g., low-flow) that initiates a TRPS signal if TOGS failures are detected. The TRPS signal opens redundant TSV dump valves draining target solution to the TOGS dump tank and shuts down the IU. Decay heat from the target solution is removed by the light water pool.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events for the loss of normal ventilation to primary cooling rooms as being caused by a failure of an RVZ2 blower or cooler, including a loss of cooling water. Loss of normal ventilation to individual primary cooling rooms may also be caused by a failed-shut or mispositioned damper or other equipment failure. A failure of normal ventilation may lead to increased environmental temperatures within the primary cooling room with a potential for increased instrument inaccuracies or failure. The consequences of an RVZ2 failure leading to equipment malfunction may result in TSV overcooling causing a reactivity insertion in the TSV, which is discussed in the excess reactivity insertion event section of this SER.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified that the safety controls in place to prevent TSV malfunctions related to ventilation failures are redundant low- and high PCLS temperature trip that initiates a TRPS signal. The TRPS signal opens redundant TSV dump valves draining target solution to the TSV dump tank and shuts down the IU. Decay heat from the target solution is removed by the light water pool system.

There are no unique initial conditions or assumptions associated with system interaction events. Based on the preventive controls, the failure of normal ventilation does not have radiological consequences, and no further analysis is necessary.

The NRC staff reviewed the results of SHINE’s system interaction events analyses, as discussed above. The staff finds that the applicant considered potential system interactions between the IF and the RPF. Further, the staff finds that the MHA bounds the dose consequences of these postulated events. The staff finds that the radiological doses to the workers and the public will be within acceptable limits and the health and safety of the workers and public will be adequately protected. Therefore, the staff concludes that SHINE's system interaction events analyses are acceptable.

13a.4.12 Facility-Specific Events

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

As described in SHINE FSAR sections 13a2.1.12 and 13a2.2.12, "Facility-Specific Events," the applicant considered facility-specific events during normal operations that could challenge the PSB in the IF. Identified facility-specific accident scenarios are associated with the neutron driver assembly system, the TPS, and potential damage resulting from heavy load drops.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed the credible facility-specific events, which were categorized as follows:

- NDAS Events:

    1. Inadvertent exposure to neutrons within the IU;
    2. Inadvertent exposure to neutrons within the NDAS service cell;
    3. Catastrophic failure of the NDAS; and
    4. NDAS vacuum boundary failure.

- TPS Events:

    1. TPS piping failure due to deflagration;
    2. Release of tritium into the IF due to glovebox deflagration;
    3. Release of tritium to the facility stack;
    4. Excessive release of tritium from the tritium storage bed; and
    5. Release of tritium into the IF due to TPS-NDAS interface line mechanical damage.

- Heavy Load Drop Events:

    1. Heavy load drop into an open IU cell;
    2. Heavy load drop onto an in-service IU cell; and
    3. Heavy load drop onto TPS equipment.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions for accident scenarios involving the NDAS. The NDAS was assumed to contain the bounding inventory of tritium gas for full power. The NDAS pressure vessel was assumed to contain the maximum inventory of SF_6 gas. The primary confinement boundary for an affected IU cell is operable, including the RVZ1e radiation detection and isolation valves.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions for accident scenarios involving the TPS. The TPS glovebox confinement is operable, including the confinement isolation valves. The glovebox has a helium atmosphere. Automatic isolation valves are installed in the system to isolate sections of the system to minimize system release. Leakage of tritium from the glovebox enclosure or the external piping is detected by the continuous airborne monitoring system or other leakage detection systems to provide alarms for facility personnel evacuation. The TPS-NDAS interface lines were assumed to contain the maximum inventory of tritium gas.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions for accident scenarios involving heavy load drops. An IU cell was assumed to be in maintenance when either the IU cell shielding plug is removed with the TSV and neutron diver assembly system is empty or an IU cell was assumed to be in-service when the IU cell shielding plug is in place.

Consistent with NUREG-1537, Part 2, the NRC staff determined that most of the facility-specific events do not have radiological consequences. The events that do have radiological consequences are related to the release of tritium into the facility from the neutron driver assemblies or from the TPS. Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as TPS Scenario 1, "TPS Piping Failure due to Deflagration."

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events, which begin with the initiating event of a vacuum boundary component failure in the NDAS, which is assumed to instantaneously release tritium and SF_6 gas into the IU cell. The IU cell becomes slightly pressurized due to the mass of the released SF_6 gas. Tritium is then transported into the IF through penetrations in the confinement boundary and then to the environment. A detection of high TPS target chamber supply pressure or high TPS target chamber exhaust pressure actuates the primary confinement boundary isolation valves and the ventilation dampers between the RCA and the environment and minimizes the transport of radioactive material to the environment and the IU trips within 20 seconds of detection. A sufficient time delay is provided by the holdup volume in RVZ1e to prevent radioactive gases from exiting through RVZ1e prior to isolation. Personal dosimeters, local radiation alarms, and alarms in the facility control room notify facility personnel of radiation leakage.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident, which are:

- Primary confinement boundary (IU cell plugs and seals);
- TPS Train Isolation on high TPS target chamber supply pressure or high TPS target chamber exhaust pressure;
- IU cell ventilation isolations;
- Holdup volume in the RVZ1e; and
- Emergency procedures.

In addition, TPS glovebox deflagration is prevented by the use of helium in the TPS glovebox gas space, and it is being designed with a minimum volume to prevent deflagration conditions.

The NRC staff reviewed the results of SHINE's facility-specific events analyses, as discussed above. The staff finds that the applicant's analysis considered potential facility-specific events. Further, the staff finds that the MHA bounds the dose consequences of these postulated events.

The staff finds that the radiological doses to the workers and the public will be within acceptable limits, and the health and safety of the workers and public will be adequately protected. Therefore, the staff concludes that SHINE's facility-specific events analyses are acceptable.

13a.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the final SHINE IF accident analysis, as described in SHINE FSAR section 13a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the accident analysis of the IF and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20, and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the final SHINE IF accident analysis are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

13b Radioisotope Production Facility Accident Analysis

Section 13b, "Radioisotope Production Facility Accident Analysis," of this SER provides an evaluation of the final accident analysis of SHINE's RPF as presented in SHINE FSAR section 13b, "Radioisotope Production Facility Accident Analyses," within which SHINE described accident -initiating events and scenarios, as well as the accident analysis and determination of consequences.

13b.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 13b against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final RPF accident analysis. The final RPF accident analysis was evaluated to ensure that the accident analysis is presented in sufficient detail to allow a clear understanding of the facility, and that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the operating staff and the public. SSCs were also evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents. The staff considered the final analysis and evaluation of the design and performance of the SSCs of the SHINE facility, including those SSCs shared by both the IF and RPF, with the objective of assessing the risk to public health and safety resulting from the operation of the facility.

13b.2 Summary of Application

SHINE FSAR section 13b identifies and describes the postulated initiating events and credible accidents that form the design basis for the SHINE RPF. The FSAR also describes the accident analysis and determination of consequences for the RPF. The FSAR provides details on event categories covering the MHA and credible accidents related to the RPF, which are loss of electrical power, external events, RPF critical equipment malfunction, RPF inadvertent nuclear criticality, RPF fire, and analyses of accidents with hazardous chemicals.

13b.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR section 13b against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final RPF accident analysis for the issuance of an operating license.

13b.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's RPF accident analysis are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report."
- 10 CFR 50.36, "Technical specifications."
- 10 CFR 50.40, "Common standards."

- 10 CFR 50.57, “Issuance of operating license.”
- 10 CFR Part 20, “Standards for Protection Against Radiation.”

13b.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

As stated in the ISG augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, IEEE standards, ANSI/ANS standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

13b.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR section 13b, as supplemented, to assess the sufficiency of the final SHINE RPF accident analysis for the issuance of an operating license. The sufficiency of the final accident analysis is determined by ensuring that it meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 13b.3, “Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The results of this technical evaluation are summarized in section 13b.5, "Review Findings," of this SER.

13b.4.1 Accident Initiating Events

SHINE identified for the RPF credible DBA scenarios that range from anticipated events, such as a loss of electrical power, to events that, while still credible, are considered unlikely to occur during the lifetime of the facility. Within the RPF, irradiated target solution is processed for radioisotope extraction and purification. Other processes occurring within the RPF include target solution processes for reuse, waste handling, and product packaging. SHINE performed the accident analysis of the RPF using the same methodology as the accident analysis of the IF described in "Accident Analysis Consequence Methodology," of section 13a.4 of this SER.

Processes that are conducted in the RPF fall into the following categories:

- Operations with SNM:
  - Irradiated target solution processed for radioisotope extraction;
  - Irradiated target solution processed for reuse or for waste disposal; and
  - Operations with unirradiated SNM.
- Radiochemical operations.
- Operations with hazardous chemicals.

The RPF DBA categories that bound credible accident sequences are as follows:

- MHA (SHINE FSAR section 13b.2.1);
- Loss of Electrical Power (SHINE FSAR section 13b.2.2);
- External Events (SHINE FSAR section 13b.2.3);
- RPF Critical Equipment Malfunction (i.e., Mishandling or Malfunction of Equipment) (SHINE FSAR section 13b.2.4);
- RPF Inadvertent Nuclear Criticality (SHINE FSAR section 13b.2.5);
- RPF Fire (SHINE FSAR section 13b.2.6); and
- Hazardous Chemical Accidents (SHINE FSAR section 13b.3).

Table 13-5 of this SER lists the DBA TEDE results for the public and the control room operator.

13b.4.3 Maximum Hypothetical Accident

SHINE identified the MHA as the failure of the TSV TOGS pressure boundary resulting in a release of off-gas into the TOGS cell within the IF. This is a credible fission product-based DBA that bounds the radiological consequences for all other DBA categories except for the special-case tritium release DBA. The NRC staff's review of the MHA event is in section 13a.4.7 of this SER.

13b.4.4 Loss of Normal Electric Power

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 13b.2.2, "Loss of Electrical Power," describes that the LOOP event was evaluated in the accident analysis as an initiating event for a number of critical equipment malfunction scenarios. A facility-wide LOOP results in automatic actuation of multiple facility engineered safety features, which act to ensure that the risk associated with radiological or chemical releases is reduced to within acceptable limits. The facility-wide LOOP does not result in system or component failures within the RPF that result in unacceptable radiological or chemical consequences. The facility-wide LOOP analyses are further discussed in section 13a.4.5 of this SER.

13b.4.5 External Events

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 13b.2.3, "External Events," identifies seismic events, severe weather, flooding, and external fires as external events that can credibly affect the RPF. The external events represent natural or man-made events that occur outside the facility and have the potential to impact facility SSCs and challenge the integrity of the RPF process tanks containing irradiated uranyl sulfate. The SHINE facility structure is designed to withstand credible external events. Most of the analyzed accidents involving credible external events are prevented by the facility structure or the seismic qualification of affected SSCs. SSCs, including their foundations and supports, that are required to perform their safety function(s) in the event of a DBE are classified as Seismic Category I. SSCs that are co-located with a Seismic Category I SSC and required to maintain their structural integrity in the event of a DBE to prevent unacceptable interactions are classified as Seismic Category II. Seismic Category II SSCs are not required to remain functional in the event of a DBE. The facility-wide external events analyses are further discussed in section 13a.4.6 of this SER.

13b.4.6 Mishandling or Malfunction of Equipment

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 13b.2.4, “RPF Critical Equipment Malfunction,” presents the evaluation of a mishandling or malfunction of equipment that leads to a loss of control of radiological material within the RPF. Two types of solutions are present in the RPF supercell: (1) irradiated target solution and (2) product eluate solutions. Spills of these solutions are analyzed to determine their radiological consequences. Multiple scenarios were identified as having potential radiological consequences and were selected for additional evaluation.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed a series of credible scenarios of mishandling of, or malfunction involving, target solution and product eluate solutions by postulating the following scenarios:

- Scenario 1 - Spill of Target Solution in the Supercell (MEPS Column Misalignment)
- Scenario 2 - Spill of Target Solution in the Supercell (MEPS Overpressurization)
- Scenario 3 - Spill of Molybdenum Eluate Solution in the Supercell (Overfill or Drop of Rotovap Flask)
- Scenario 4 - Spill of Target Solution in the Supercell (IXP Column Misalignment)
- Scenario 5 - Spill of Target Solution in the Supercell (IXP Overpressurization)
- Scenario 6 - Spill of Target Solution in the Supercell (Liquid Nitrogen Leak in IXP Hot Cell)
- Scenario 7 - Spill of Iodine Solution in the Supercell (Overfill or Drop of Iodine Solution Bottle)
- Scenario 8 - Spill of Target Solution in the Pipe Trench from a Single Pipe
- Scenario 9 - Spill of Target Solution in the Pipe Trench from Multiple Pipes
- Scenario 10 - Spill of Target Solution in a Tank Vault (Hold Tank Leak or Rupture)
- Scenario 11 - Spill of Target Solution in a Tank Vault (Hold Tank Deflagration)
- Scenario 12 - Spill of Target Solution in a Tank Vault (Seismic Event)
- Scenario 13 - Spill of Molybdenum Eluate in the Supercell (Deflagration)
- Scenario 14 - Target Solution Leaking out of the Supercell (MEPS Preheater Tube Leak)
- Scenario 15 - Extraction Column Three-Way Valve Misalignment
- Scenario 16 - Spill of Target Solution in a Valve Pit (Pipe Rupture or Leak)

- Scenario 17 - Spill of Radioactive Liquid Waste in the RLWI Shielded Enclosure

- Scenario 18 - Heavy Load Drop onto RLWI Shielded Enclosure or Supercell

- Scenario 19 - Heavy Load Drop onto a Tank Vault or Pipe Trench Cover Block

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenario as Scenario 17, “Spill of Radioactive Liquid Waste in the RLWI Shielded Enclosure,” where the event is caused by a break and leak within the RLWI enclosure of the immobilization feed tank or RLWI system piping containing waste solution.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the events the system was assumed to be under normal operational conditions. A 380-liter batch of waste solution (diluted target solution) is present in the RLWI system immobilization feed tank at the time of the initiating event. The volume of solution in this scenario is based on the volume of the immobilization feed tank with a conservative scaling factor to account for the highest allowable concentration of radionuclides. The waste solution was assumed to have been irradiated using the assumptions in SHINE FSAR section 13a2.2, “Accident Analysis and Determination of Consequences,” and been held for decay for 35 days post-shutdown. The post-shutdown hold time is based on the minimum hold time needed to reduce waste activity to within dose consequence limits and establishes an administrative control.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation for this event, which are:

- Waste solution holdup times in the RLWS before processing in the RLWI;

- Concentration controls applied to waste solutions;

- Heavy load drop controls; and

- Facility personnel evacuate the immediate area within 10 minutes after receipt of electronic dosimeter or local radiation alarms.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that that SHINE applied a conservative MAR for this scenario by using 380 liters of waste solution at 35 days post-shutdown. The concentration of radionuclides for the waste solution was determined by multiplication of the ratio of the maximum uranium concentration permitted in the RLWI to the nominal uranium concentration of target solution. The action of the TOGS during the period when the original target solution was held in the TSV dump tank removes more than 67 percent of the iodine present in the solution at shutdown. It is assumed that 35 percent of the post-shutdown iodine inventory is released to the RLWI enclosure during the event.

The NRC staff reviewed the results of SHINE’s RPF critical equipment malfunction event analyses, as discussed above. The staff finds that SHINE’s analyses considered potential critical equipment malfunctions within the RPF. Further, the staff finds that the MHA bounds the dose consequences of the limiting credible event. The staff finds that the radiological doses to the workers and the public will be within acceptable limits and the health and safety of the workers and public will be adequately protected. Therefore, the staff concludes that SHINE’s RPF critical equipment malfunction event analyses are acceptable.

13b.4.7 Inadvertent Nuclear Criticality in the Radioisotope Production Facility

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 13b.2.5, "RPF Inadvertent Nuclear Criticality," evaluates inadvertent nuclear criticality events in the accident analysis using the same methodology as non-criticality accidents. Nuclear criticality safety is achieved through the use of preventative controls throughout the RPF, which reduces the likelihood of a criticality accident to highly unlikely. Further discussion of the criticality safety bases for RPF processes is included in SHINE FSAR section 6b.3 and the NRC staff's review in section 6b.4.3 of this SER.

13b.4.8 Radioisotope Production Facility Fire

The NRC staff evaluated the sufficiency of the applicant's descriptions and discussions of this DBA category using the guidance and acceptance criteria from chapter 13, "Accident Analyses," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

As described in SHINE FSAR section 13b.2.6, "RPF Fire," SHINE evaluated fires within the RPF for internal fire risks based on the fire hazards analysis (FHA). The FHA documents the facility fire areas, with each area individually evaluated for fire risks. Internal facility fires are generally evaluated as an initiating event for the release of radioactive material.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE systematically analyzed credible fire events and categorized them into three scenarios, as follows:

- PVVS Carbon Delay Bed Fire (Beds 1/2/3)
- PVVS Carbon Delay Bed Fire (Beds 4/5/6/7/8)
- PVVS Carbon Guard Bed Fire

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the most limiting scenarios as Scenario 2, "PVVS Carbon Delay Bed Fire (Beds 4/5/6/7/8)" for the public and Scenario 3, "PVVS Carbon Guard Bed Fire" for the worker.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that prior to the event the system was assumed to be under normal operational conditions. The PVVS is operating normally, with nominal flow through a carbon guard bed and carbon delay beds. The affected carbon beds contains iodine from RPF process streams.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the sequence of events where an upset or malfunction in the PVVS may result in high moisture or high temperature flow through the carbon guard bed. The high moisture or high temperature results in ignition of the carbon bed absorber material. The ignition of the carbon beds results in an exothermic release of stored radioactive material to the PVVS downstream of the guard bed. For Scenario 3, radioactive material is captured by the downstream carbon delay bed and filtered. It is assumed that one percent of the released radioactive material is released through the PVVS and the facility stack to the environment.

Consistent with NUREG-1537, Part 2, the NRC staff confirmed that SHINE identified the safety controls credited for mitigation of the dose consequences for this accident as PVVS delay bed filtration.

The NRC staff reviewed the results of SHINE's RPF fire event analyses, as discussed above. The staff finds that SHINE's analyses considered potential RPF fires. Further, the staff finds that the MHA bounds the dose consequences of the limiting credible event. The staff finds that radiological doses to the workers and the public will be within acceptable limits, and the health and safety of the workers and public will be adequately protected. Therefore, the staff concludes that SHINE's RPF fire event analyses are acceptable.

13b.4.9 Analyses of Accidents with Hazardous Chemicals Produced from Licensed Material

The NRC staff evaluated the sufficiency of the applicant's analysis of accidents with hazardous chemicals produced from licensed material, as presented in SHINE FSAR section 13b.3, "Analyses of Accidents with Hazardous Chemicals," in part, by reviewing the chemical process description, chemical accidents description, and consequences estimates using the guidance and acceptance criteria from section 13b.2, "Chemical Process Safety for the Radioisotope Processing Facility," of the ISG augmenting NUREG-1537, Part 2.

SHINE proposed safety criteria in SHINE FSAR section 3.1 that include requirements for chemical safety for both individuals outside the controlled area (i.e., the public) and facility workers. The NRC staff's chemical safety review focused primarily on potential accident sequences involving chemical hazards that could impact the public.

Potential chemical exposure scenarios in the RPF were identified and evaluated by SHINE to assess chemical hazards and necessary controls. The evaluation used the limited inventories of chemicals used in the RPF as identified in table 13b.3-1, "Quantities of In-Process Hazardous Chemicals," of the SHINE FSAR.

The NRC staff reviewed the SHINE hazard identification and analysis methodology discussed in SHINE FSAR section 13a2. The methodology includes consideration of chemical hazards. The methodology considers all modes of operation for potential process upsets and accident sequences. SHINE's implementation of the methodology leads to the identification of safety-related controls that are relied on to limit or prevent potential accidents or mitigate their consequences. It also identifies programmatic administrative controls that ensure the availability and reliability of identified safety systems.

The NRC staff also reviewed the SHINE implementation of the accident analysis methodology as it relates to the identification and analysis of chemical hazards. The more detailed identification and analysis of chemical hazards is documented in the SHINE SSA summary. The consequences of accidents involving chemical hazards are presented in CALC-2018-0049, Revision 4, "Chemical Dose Analysis for Hypothetical Accidents in the SHINE Medical Production Facility" (ML22301A149). The SHINE analysis concludes that all offsite chemical exposures consequences were limited (i.e., concentrations were less than protective action criteria one [PAC-1] levels) and that only a few chemical accidents would result in RCA workers exposure to chemical concentrations greater than PAC-1 levels, but in all cases less than PAC-2 levels. SHINE FSAR table 13b.3-2, "Hazardous Chemical Source Terms and Concentration

Levels," identifies the hazardous chemicals, release location, source term, and concentrations to the control room operator and at the site boundary.

The NRC staff reviewed the chemical accident scenarios identified in the SHINE FSAR and in the SHINE SSA summary and found them to be reasonable and consistent with facility description, chemical process description, and process equipment information presented in the SHINE FSAR about the RPF and the various RPF processes. The staff notes that the quantities of process chemicals is limited, the volume of process vessels is small, and the cells that contain the irradiated material processing operations are shielded.

The NRC staff also reviewed information about the consequences of accident scenarios involving the release of hazardous chemicals. The consequences are a function of the amount of material released, the release rate, and the dilution/dispersion of the hazardous chemical as it moves from the release point to the point of contact with the receptor.

The NRC staff reviewed the methods that SHINE used to estimate release quantities and the concentrations of hazardous chemicals to offsite receptors for the postulated accident sequences. The staff finds that the methods used are consistent with guidance provided in NUREG/CR-6410, which is recommended in the ISG augmenting NUREG-1537, Part 1. Independent calculations by the staff confirmed the concentrations presented by SHINE for site boundary and offsite receptors and support the SHINE conclusion that the chemical hazards to off-site personnel from RPF operations are minimal. The staff notes that it previously reached this same general conclusion of limited potential impact to the public for the Cintichem facility, which recovered Mo-99 from irradiated material and was previously licensed by the NRC as documented in Inspection Report 70-687/87-04 (ML20236S788). This conclusion is also consistent with an environmental analysis conducted by the U.S. Department of Energy (DOE) when it evaluated the environmental impact of Mo-99 production and recovery at DOE facilities (DOE/EIS-0249F, Medical Isotopes Projection Project: Molybdenum-99 and Related Isotopes, April 1996).

In addition to reviewing the consequences of chemical accidents to offsite individuals, the NRC staff reviewed the SHINE method for predicting concentrations of hazardous chemicals to RCA workers. The SHINE method assumes instantaneous release and mixing of the hazardous material into the RCA room volume. An actual release would occur over some time and so the predicted concentrations are conservatively higher than what would occur during a release period. In addition, worker evacuation is generally expected and so the actual exposure duration would be less than the 1-hour period associated with the PAC-2 concentrations used in the SHINE analysis. The staff finds that there is reasonable assurance that actual RCA worker exposure to hazardous materials will be below PAC-2 levels for 1 hour, and that exposure will not exceed the chemical exposure criteria identified in SHINE FSAR section 3.1 (i.e., concentrations that would present the potential for irreversible or other serious, long-lasting health effects to a worker).

The NRC staff also reviewed the method used to predict the concentration of hazardous material in the control room. The general scenario identified in the SHINE analysis involves the release of a chemical from a rollup door that is on the eastern edge (right side) of the south side of the SHINE facility. The SHINE analysis assumes that the chemical released from the rollup door would be diluted as it moves to the ventilation intakes, which are at a higher elevation than the rollup door and to the left of the door.

The transport of material from a release point on the right side of the southern face of the building to an intake point that is higher and near the center of the same side of the building involves complex flow processes that are influenced by many factors including wind speed and direction and the position of the release point and intake locations.

SHINE used the ALOHA (Areal Locations of Hazardous Atmospheres) code to predict control room concentrations. The ALOHA code does not specifically model the flow arrangement described in the SHINE accident sequence. SHINE described the flow arrangement as a release and intake on a common wall. The SHINE ALOHA analysis assumed Gaussian dispersion over the short distance and used an ALOHA feature that calculates an indoor air concentration in a downwind building based on an assumed building air change rate.

The NRC staff analyzed the meteorological transport processes to gain insight into any conservatism in the SHINE ALOHA analysis for control room workers. In order to evaluate the reasonableness of the control room concentrations calculated by SHINE using the ALOHA code, the staff compared the χ/Q value used in the SHINE ALOHA analysis with other χ/Q values developed by SHINE using NRC guidance specifically intended for control room habitability analysis. The staff reviewed the SHINE ALOHA results presented in CALC-2018-0049, Revision 4 and found that the ALOHA analysis used a χ/Q value of around 3 sec/m^3. This was compared to the χ/Q that SHINE developed in a separate calculation performed to support control room habitability analysis (CALC-2020-0018, Revision 0, “Atmospheric Dispersion for Control Room Habitability Calculations” ML22301A149). This separate analysis considered a southeasterly wind given the relative location of the rollup door and the ventilation intake structures and used the ARCON96 code to estimate the χ/Q for transport from the rollup door to the ventilation intake structure. This separate SHINE analysis estimated the χ/Q to be 1.4 x 10^{-2} sec/m^3 for scenarios of less than 2 hours duration. The staff reviewed this SHINE ARCON96 analysis and finds it to be conservative.

The NRC staff compared the ARCON96 χ/Q values developed by SHINE with other near-field χ/Q reported values such as DOE reviews of models and methods for developing a χ/Q for workers at 100 meters. This review identified a conservative χ/Q of 3.5x10^{-3} for a collocated worker at 100 meters. The DOE analysis (Technical Report for Calculation of Atmospheric Dispersion at Onsite Locations for Department of Energy Nuclear Facilities, NSRD-2015-TD01) also examined different methods for estimating χ/Q at 100 meters including those in ARCON96 and ALOHA and found the recommended default value of 3.5 x 10^{-3} sec/m^3 to be conservative when there was a building wake. The staff also reviewed a report prepared by the Center for Nuclear Waste Regulatory Analysis, “Summary of Near-Field Methods for Atmospheric Release Modeling” (ML072500257). This report also examined different models for estimating χ/Q at short distances. The most conservative χ/Q identified in this analysis for F stability class and 1 m/sec wind speed was about 5 x 10^{-2} sec/m^3 if there was no building and 9 x 10^{-3} sec/m^3 if there was a building. The χ/Q from the analysis using the ARCON code was about 6 x 10^{-4} sec/m^3 assuming that there was a building.

The NRC staff finds the SHINE ARCON96 χ/Q value of 1.4 x 10^{-2} sec/m^3 to be appropriate and conservative because it considers winds from the southeast and takes into consideration the effects of the building which contains both the release point and the intake point. It is also consistent with other analyses of dispersion over short distances with building turbulence effects. Because the SHINE ALOHA analysis uses a higher χ/Q value, the staff determined the SHINE ALOHA dispersion analysis to be conservative by a factor of about 200 (3/1.4 x 10^{-2} sec/m^3).

The NRC staff also reviewed the effect of the air exchange rate used in the SHINE ALOHA analysis, which was assumed to be 1.2 air exchanges per hour. The SHINE ALOHA analysis predicted indoor (i.e., control room) concentrations that were reduced by up to a factor of 50 when compared to the outdoor concentration predicted in the ALOHA analysis. The SHINE report CALC-2018-0048, Revision 6, presents information on the volume of the control room and the ventilation flow through that room. The document estimates the control room volume as 350 m^3 and the ventilation flow through this volume as being approximately 2600 m^3 per hour. The control room has about seven air exchanges per hour which is higher than the 1.2 value used in the SHINE ALOHA analysis. The higher exchange rate means that there will be less reduction of the indoor air concentration compared to the outdoor concentration that was calculated in the SHINE ALOHA analysis.

To understand the effect of this higher air exchange rate, the NRC staff performed an independent ALOHA analysis. The staff repeated the SHINE ALOHA analysis for nitric acid and produced results that were consistent with the SHINE analysis for the air exchange rate of 1.2. When the staff repeated the analysis with the higher air exchange rate, the staff's predicted indoor air concentration was essentially the same as the outdoor air concentration. The staff determined that the SHINE ALOHA analysis used a non-conservative air exchange rate when estimating control room concentrations following chemical releases. However, the staff finds that the non-conservatism in this parameter is offset by the conservatism in the χ/Q value.

The NRC staff's review of the SHINE estimate of control room concentration concluded that the SHINE estimates of control room concentrations were conservative because of the ALOHA dilution/dispersion analysis (χ/Q) was conservative and compensated for the non-conservative estimate of air exchange rate for the SHINE control room. Based on its review, the staff has reasonable assurance that the design will meet the design criteria identified in SHINE FSAR section 3.1 when considering the chemical exposure of control room operators.

The NRC staff also reviewed the chemical process safety controls identified in the SHINE FSAR section 13b.3. The confinement barrier controls are of a general nature that lack the specificity of the controls identified in the SSA.

The NRC staff finds that the SHINE SSA identified and analyzed chemical hazards against the SHINE design criteria related to public health and safety, which are presented in SHINE FSAR section 3.1. The staff's review and independent analysis led the staff to conclude that there is reasonable assurance that the design meets the requirements of 10 CFR 50.40 for protection of the public health and safety from process chemical hazards.

The NRC staff review of the analysis of consequences for hazardous chemical events to workers, both those in the control room and those in the RPF, is discussed above. The staff finds that there is reasonable assurance that the design meets the design criteria SHINE established for worker chemical safety in SHINE FSAR section 3.1 and that worker and public health and safety are protected. Therefore, the staff concludes that the results of SHINE's hazardous chemical accidents analyses are acceptable.

13b.4.10 Proposed Technical Specifications

In accordance with 10 CFR 50.34(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed TSs for the SHINE facility related to the RPF accident analysis.

The proposed TS 5.5.8, “Chemical Control,” states the following:

> The SHINE chemical control program ensures that on-site chemicals are stored and used appropriately to prevent undue risk to workers and the facility. The chemical control program implements the following activities, as required by the accident analysis:
>
> 1. Control of chemical quantities permitted in designated areas and processes;
>
> 2. Chemical labeling, storage and handling; and
>
> 3. Laboratory safe practices.

TS 5.5.8 requires that the chemical control program implement controls on chemical quantities, labeling, storage, handling, and safe laboratory practices. The NRC staff finds that the implementation of these controls will help manage the chemical process thereby minimizing the possibility of a significant chemical release and ensuring public health and safety. Therefore, the staff finds that TS 5.5.8 is acceptable.

13b.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the final SHINE RPF accident analysis, as described in SHINE FSAR section 13b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the accident analysis of the RPF and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the final SHINE RPF accident analysis are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

14.0 TECHNICAL SPECIFICATIONS

The principal purpose of technical specifications (TSs) is to maintain system performance and safe operation. This is accomplished by addressing limiting or enveloping conditions of design and operation ensuring that emphasis is placed on the safety of the public, the facility staff, and the environment. TSs are typically derived from the analyses and evaluation included in a facility's final safety analysis report (FSAR).

This chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the proposed TSs for the SHINE irradiation facility (IF) and radioisotope production facility (RPF) (together, the SHINE facility), as presented in chapter 14, "Technical Specifications," of the SHINE FSAR and in SHINE's proposed TSs and supplemented by the applicant's response to the staff's requests for additional information (RAIs).

14.1 Areas of Review

The NRC staff reviewed SHINE FSAR chapter 14 and SHINE's proposed TSs against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the proposed TSs. The staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items included in the proposed TSs for the SHINE facility, with special attention given to those items that may significantly influence the final design.

The specific areas of review for this chapter of the SER are those TSs proposed for the SHINE IF and RPF. Within these areas of review, the NRC staff assessed whether SHINE's proposed TSs, including relevant safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation, surveillance requirements, design features that affect the function, availability, or reliability of structures, systems, or components (SSCs), and administrative controls would ensure the availability of SSCs.

14.2 Summary of Application

The principal purpose of TSs is to maintain system performance and safe operation emphasizing the safety of the public, the facility staff, and the environment. The summary provided below applies to both the SHINE IF and RPF.

SHINE FSAR chapter 14 states that the proposed TSs for the SHINE IF and RPF were developed following the format and content guidance of American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.1-2007, "The Development of Technical Specifications for Research Reactors," and using the applicable guidance of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content" (Agencywide Documents Access and Management System No. ML042430055), and Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria" (ML042430048), and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors" (ML12156A069), and "Final Interim Staff Guidance Augmenting

NUREG 1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors” (ML12156A075). It further states that normal operation of the SHINE facility within the limits of the proposed TSs will not result in offsite radiation exposure in excess of the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection Against Radiation,” and that the observance of the proposed TSs limits the likelihood and consequences of malfunctions.

The NRC staff reviewed SHINE’s proposed TSs submitted by letter dated January 26, 2022 (ML22034A612), Enclosure 6 (ML22034A633). Based upon audit discussions, SHINE submitted revised proposed TSs to the NRC on August 31, 2022 (ML22249A148), Enclosure 8 (ML22249A129). The discussion in this chapter of the SER uses the most recent revision of the proposed TSs. The proposed TS 1.2, “Format,” states that the usage rules in TS 3.0, “Limiting Conditions for Operation and Surveillance Requirements,” and the descriptions of logical connectors and completion times in TS 1.4, “Logical Connectors and Completion Times,” are based on the guidance provided in NUREG-1431, “Standard Technical Specifications: Westinghouse Plants,” Volume 1, “Specifications” (ML21259A155).

14.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 14 and SHINE’s proposed TSs against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the proposed TSs for the issuance of an operating license.

14.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE’s proposed TSs are as follows:

- 10 CFR 50.34, “Contents of applications; technical information,” paragraph (b), “Final safety analysis report.”
- 10 CFR 50.36, “Technical specifications.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR 50.57, “Issuance of operating license.”
- 10 CFR Part 20, “Standards for Protection Against Radiation.”

14.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.

- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

- ANSI/ANS 15.1-2007, “The Development of Technical Specifications for Research Reactors.”

As stated in the ISG augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, ANSI/ANS standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; NUREG-1431, Volume 1; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

14.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the content of SHINE’s proposed TSs, as supplemented, to determine whether the requirements in 10 CFR 50.36, “Technical specifications,” are met with respect to the TSs being derived from the analyses and evaluation included in the SHINE FSAR and that they include items in the categories of: (1) safety limits (SLs), limiting safety system settings (LSSSs), and limiting control settings; (2) limiting conditions for operation (LCOs); (3) surveillance requirements (SRs); (4) design features (DFs); and (5) administrative controls. Additionally, the staff reviewed the proposed TSs to ensure their general consistency with the format and guidance in chapter 14, “Technical Specifications,” of NUREG-1537, Parts 1 and 2, chapter 14, “Technical Specifications,” of the ISG augmenting NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.1-2007. For general TS applicability and usage in LCO 3.0.1 and SR 3.0.1, SHINE proposed similar content as used in NUREG-1431, Volume 1, which is the standard technical specifications for Westinghouse nuclear power reactor plants. The staff also noted that SHINE submitted TS bases that provide the reasons for the proposed TSs.

The NRC staff audited SHINE’s proposed TSs to gain a complete understanding of the information provided in the operating license application with respect to TSs and to focus on TS format, clarity, and consistency with regulatory guidance. During the audit, the staff reviewed

SHINE's proposed TSs in their entirety to ensure that the applicable guidance and acceptance criteria were met. The information that the staff audited is documented in an audit report dated September 12, 2022 (ML22220A261). The staff's approach to the audit was to group the staff's comments and information into four categories based on significance. The four categories, from least to most significant, were for the staff to: (1) gain an understanding of the proposed TSs; (2) provide observations and recommend format changes to promote consistency; (3) provide regulatory or guidance directed changes; and (4) identify a TS deviation or exception that is not adequately explained or justified.

For the majority of SHINE's proposed TSs, the NRC staff's review of the TSs is documented in the chapter of this SER that is most relevant to those TSs. For those reviews, the staff focused on TS parameters and values from a technical perspective to ensure safety. In this chapter of the SER the staff specifically reviews TS 1.3, "Definitions"; TS 1.4, LCO and SR 3.0.1; LCO and SR 3.8.4 since they were not addressed in chapter 6, "Engineered Safety Features," of this SER; and TS 3.9, "Startup Testing." The staff also reviews the SHINE proposed DFs in TS 4.0, "Design Features," that were not evaluated in other chapters of this SER. With respect to the SHINE proposed administrative controls TSs in TS 5.0, "Administrative Controls," the staff's review focused mainly on the more safety significant of those TSs. Although this chapter of the SER concentrates on these proposed TSs, the staff has reviewed all of SHINE's proposed TSs and, between this chapter and the other chapters of this SER, all of the proposed TSs are discussed as appropriate.

SHINE included definitions in proposed TS 1.3 to provide for the uniform interpretation of the terms and phrases used in the TSs and to be generally consistent with the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. SHINE's proposed TS definitions include minor modifications to some definitions in the guidance and some additional facility-specific definitions. The NRC staff reviewed the TS definitions and finds that they are either appropriate facility-specific definitions or are consistent with applicable guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff concludes that TS 1.3 is acceptable.

SHINE proposed the use of the logical connectors "AND" and "OR" in TS 1.4. These logical connectors are used throughout the SHINE LCOs and SRs to discriminate between required actions and completion times under the conditions when an LCO or SR is not met. TS 1.4 explains the meaning of these logical connectors and the rationale for identifying the order to complete the required action(s) in a specific LCO. The "AND" connector is used to indicate that all associated actions must be completed while the "OR" connector is used to indicate that only one of the associated actions must be completed. Required actions are also sometimes nested where the physical arrangement (indentation) indicates the successive nature and order of required actions.

Based on the information provided by SHINE TS 1.4, the NRC staff finds that SHINE's proposed implementation of logical connectors is consistent with the guidance in NUREG-1431, Volume 1. Because SHINE appropriately uses logical connectors to state a condition, completion time, surveillance, or frequency, the staff concludes that TS 1.4 is acceptable.

Proposed LCO 3.0.1 provides general requirements and specific allowances for LCO application, completion of required actions, and test exceptions. Additionally, LCO 3.0.1.2 requires the associated conditions and actions for a TS to be addressed individually and independently of other LCOs, conditions, and actions unless otherwise stated. ANSI/ANS 15.1-2007 provides that deviations from LCOs may be allowed under specified conditions, such as the use of actions statements. SHINE's proposed TSs contain action statements that are immediately initiated upon the discovery that an LCO is not met. The NRC staff also reviewed the general LCO usage and applicability requirements in NUREG-1431, Volume 1 to determine whether the usage and applicability requirements in LCO 3.0.1 are consistent with them. The staff finds that LCO 3.0.1 ensures that LCOs will be met during the Modes of applicability for the LCOs and that when an LCO and corresponding actions are not met or provided, immediate action is initiated to place the facility in a Mode or condition in which the LCO is not applicable. Additionally, the staff finds that LCO 3.0.1.4 identifies channels that may be rendered inoperable using administrative controls for the purpose of completing recovery actions. The staff determined that LCO 3.0.1 provides appropriate LCO practices and is consistent with the guidance in NUREG-1537, ANSI/ANS 15.1-2007, and NUREG-1431, Volume 1. Because LCO 3.0.1 clearly identifies the LCO application and usage, describes actions when an LCO is not met, and identifies specific channels that may be rendered inoperable to complete recovery actions, the staff concludes that it is acceptable.

The proposed SR 3.0.1 provides general requirements for surveillance application, performance frequency, identification of surveillances that require entry into the Mode of applicability or condition to perform the surveillance, and surveillance testing. The NRC staff finds that SR 3.0.1 helps to maintain the quality of SSCs within specifications. Further, the staff finds that SR 3.0.1 specifies the conduct of SRs required to allow operational flexibility that does not impact the safe operation of the facility. NUREG-1537 and ANSI/ANS 15.1-2007 provide guidance that SRs define the frequency and scope of the surveillance activities required to ensure that LCOs are acceptably maintained. The staff determined that SR 3.0.1 provides appropriate surveillance practices and is consistent with the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff concludes that SR 3.0.1 is acceptable.

The proposed TS 3.8, “Facility-Specific,” LCO 3.8.4 and SR 3.8.4 state the following:

LCO 3.8.4	The concentration of uranium present in the second uranium liquid waste tank and the liquid waste blending tank shall be less than 25 gU/L.
Applicability	At all times
Action	According to Table 3.8.4
SR 3.8.4	1. Uranium concentration in the first uranium liquid waste tank shall be measured and verified to be below the limit in accordance with the requirements of the criticality safety program and prior to transfer of liquid to the second uranium liquid waste tank. 2. Uranium concentration in the second uranium liquid waste tank shall be measured and verified to be below the limit in accordance with the requirements of the criticality safety program and prior to transfer of liquid o the liquid waste blending tank. 3. Uranium concentration in the liquid waste blending tank shall be measured and verified to be below the limit in accordance with the requirements of the criticality safety program.

The proposed TS Table 3.8.4, “Waste Tank Uranium Concentration Actions,” states the following:

	Condition and Action	Completion Time
1.	If uranium concentration is above the limit in either the second uranium liquid waste tank or the liquid waste blending tank, Stop transfers of solution to the liquid waste blending tank AND Dilute solution in the liquid waste blending tank until the uranium concentration is verified to be below the limit.	 Immediately 6 hours

LCO 3.8.4 specifies that the concentration of uranium present in the second uranium liquid waste tank and the liquid waste blending tank shall be less than 25 grams of uranium per liter at all times. The NRC staff finds that this LCO and associated actions would ensure that the uranium concentration in the second uranium liquid waste tank, which is designed with a favorable geometry, is below the uranium concentration limit specified in SHINE’s nuclear criticality safety program to prevent a potential criticality event in the non-geometrically favorable liquid waste blending tank. Therefore, the staff finds LCO 3.8.4 acceptable.

SR 3.8.4.1 and SR 3.8.4.2 require uranium concentration measurements in both the first and second uranium liquid waste tanks prior to transfer of the liquid to the liquid waste blending tank. Further, SR 3.8.4.3 requires sampling the liquid in the liquid waste blending tank to verify that the uranium concentration is below the limit specified in SHINE’s nuclear criticality safety program. The NRC staff finds that measuring and verifying the uranium concentration in both the first and second uranium liquid waste tanks, as well as the liquid waste blending tank, ensures that the liquid can be safely transferred and stored in the liquid waste blending tank. Therefore, the staff finds SR 3.8.4 acceptable.

The proposed TS 3.9, LCOs 3.9.1 through 3.9.3 and SRs 3.9.1 through 3.9.3, and the proposed TS table 3.9.1, “Actions for Mode 1 Startup Testing Exceptions,” TS table 3.9.2, “Actions for Mode 2 Startup Testing Exceptions,” and TS table 3.9.3, “Actions for Mode 2 Initial NFDS [Neutron Flux Detection System] Calibration,” describe activities and testing to support startup testing in Mode 1 and Mode 2. The NRC staff finds that these LCOs, SRs, and tables specify exceptions to other LSSSs and LCOs provided that sufficient actions are taken to ensure that testing activities can be safely accomplished during startup testing in Mode 1 and Mode 2. Therefore, the staff finds LCOs 3.9.1 through 3.9.3 and SRs 3.9.1 through 3.9.3 acceptable.

The NRC staff reviewed the following SHINE proposed DFs in TS 4.0 that were not evaluated in other chapters of this SER:

DF 4.1.1	1. The SHINE Facility is owned and operated by SHINE Technologies, LLC and is located at 4021 S. U.S. Highway 51, Janesville, WI, 53546. The SHINE Facility includes the Main Production Facility, N2PS structure, resource building, material staging building, and the storage building. 2. The nearest distance from a potential release point from the Main Production Facility to the site boundary is 756 ft. 3. The site boundary corresponds to the property line around the perimeter of the SHINE site and encompasses approximately 91 acres of land. The owner controlled area is the area within the site boundary. 4. The operations boundary is the area within the site boundary where the Shift Supervisor or the designee has direct authority over all activities. The controlled access area fence and the perimeter walls of the Main Production Facility, the material staging building, the storage building, and the resource building constitute the SHINE operations boundary. The operations boundary is the emergency planning zone.

DF 4.1.2	1. The building free volume of the irradiation facility is approximately 13,400 m3. 2. The building free volume of the radioisotope production facility is approximately 18,000 m3. 3. The accident dose effluent release height is 0 feet above grade. 4. The normal effluent release height is 67 feet above grade.

DF 4.1.4	Supercell ventilation is designed with a maximum flowrate of 40 air exchanges per hour (ACH) for extraction and purification cells.

DF 4.1.6	Irradiation cell biological shield (ICBS) and production facility biological shield (PFBS) features are provided to maintain radiation exposure to workers and the public within acceptable limits as required by 10 CFR 20.

The NRC staff finds that these DFs provide a general description of the SHINE site and facility including building volumes and features of the supercell ventilation. The staff finds that DF 4.1.1, DF 4.1.2, DF 4.1.4, and DF 4.1.6 appropriately implement the guidance in ANSI/ANS 15.1-2007 to provide a general description of the site, building volumes, ventilation flow rates, and effluent release heights that are important to safety. Therefore, the staff finds DFs 4.1.1, 4.1.2, 4.1.4, and 4.1.6 acceptable.

With respect to the proposed TS 5.0, the NRC staff focused its review on the following administrative controls TSs.

The proposed TS 5.1.1, “Structure,” and TS figure 5.1.1, “SHINE Operational Organization Chart,” describe the SHINE organizational structure, functional responsibilities, and levels of authority. The NRC staff finds that TS 5.1.1 and TS figure 5.1.1 help ensure that the SHINE organizational structure, including the communication and reporting lines, is appropriately defined and properly delineated in the TSs. The staff also finds that by delineating the SHINE organizational structure, TS 5.1.1 and TS figure 5.1.1 appropriately implement the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.1.1 and TS figure 5.1.1 acceptable.

The proposed TS 5.1.2, “Responsibility,” describes the authority and responsibility of the SHINE organizational members identified in TS figure 5.1.1. The NRC staff finds that by clearly defining the responsibilities of personnel as they relate to the facility, TS 5.1.2 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.1.2 acceptable.

The proposed TS 5.1.3, “Facility Staffing Required,” states the following:

1. The minimum staffing when the facility is not Secured shall be:
    a. A Senior Licensed Operator present in the facility,

    b. A Licensed Operator or second Senior Licensed Operator present in the control room, and

    c. An additional designated person present at the facility able to carry out prescribed written instructions.

    Unexpected absence of the position described in 5.1.3.1.a for as long as 30 minutes to accommodate a personal emergency may be acceptable provided immediate action is taken to designate a replacement.

    Unexpected absence of the position described in 5.1.3.1.c for as long as two hours to accommodate a personal emergency may be acceptable provided immediate action is taken to obtain a replacement.

The proposed TS 5.1.3 describes the minimum staffing required when the SHINE facility is not secured as defined in TS 1.3. Specifically, TS 5.1.3 requires, when the SHINE facility is not secured the minimum shall be: an NRC-licensed senior operator in the facility, either an NRC-licensed operator or second NRC-licensed senior operator in the control room, and an additional designated person at the facility able to carry out prescribed written instructions. TS 5.1.3 also provides exceptions to the minimum staffing requirements to accommodate personal emergencies. The NRC staff finds that TS 5.1.3.1.a helps ensure that a senior licensed operator is present at the facility to provide supervision. Excepting this requirement for an unexpected absence of the senior licensed operator for a personal emergency for up to 30 minutes meets the intent of the guidance in ANSI/ANS 15.1-2007. The staff also finds that by requiring a senior licensed operator to be present at the facility when the facility is not secured, TS 5.1.3.1.a appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. The staff finds that TS 5.1.3.1.b helps ensure appropriate staffing at the facility and is consistent with the regulation at 10 CFR 50.54(k), which states that “[a]n operator or senior operator licensed pursuant to [10 CFR Part 55] shall be present at the controls at all times during the operation of the facility.” The staff finds that the designation of an additional person at the facility able to carry out prescribed written instructions helps ensure the prompt implementation of the emergency plan. Excepting this requirement for an unexpected absence of the additional person for a personal emergency for up to 2 hours is consistent with the guidance in ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.1.3 acceptable.

The introductory text to the proposed TS 5.2, “Review and Audit,” requires SHINE to have a review and audit committee (RAC) to ensure that there is appropriate technical expertise for review and audit activities, which ensure that facility deficiencies that affect nuclear safety are immediately reported to Level 1 management. The proposed TS 5.2.1, “Composition and Qualifications,” requires that the Diagnostics General Manager (Level 1 Alternate) or designee be the chair of the RAC and appoint additional members to the RAC. TS 5.2.1 also requires a minimum number of RAC members with qualifications over a broad spectrum of technical, operational, and managerial expertise, where the facility operations personnel do not constitute a majority. TS 5.2.1 allows the RAC chair to appoint non-SHINE employees in certain circumstances if expertise is not available from SHINE employees. The NRC staff finds that by establishing a method for the independent assessment of operations and establishing requirements for the committee responsible for review and audit activities, the introductory text to TS 5.2 and TS 5.2.1 appropriately implement the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds the introductory text to TS 5.2 and TS 5.2.1 acceptable.

The proposed TS 5.2.2, “Charter and Rules,” requires that the charter for the RAC require at least one meeting per year; require at least one-half its committee membership be present (where the facility operations personnel, including the Director of Plant Operations (Level 2), do not constitute a majority of those present) to achieve a quorum; and require distribution of meeting minutes to its members within 3 months. TS 5.2.2 requires a majority vote of members for approval. The NRC staff finds that TS 5.2.2 helps ensure that RAC functions are appropriately conducted in accordance with an established charter, and that the RAC follows appropriate rules related to meeting frequency, quorum, and timely distribution of meeting minutes. The staff also finds that the requirement that facility operations personnel not be a majority in order to achieve an RAC quorum helps ensure independence of the RAC. Additionally, the staff finds that by establishing rules for the RAC and requiring the RAC to operate in accordance with its charter, TS 5.2.2 appropriately implements the guidance of NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.2.2 acceptable.

The proposed TS 5.2.3, “Review Function,” identifies items that require review by the RAC, and also requires that written reports of RAC reviews be submitted to the Level 1 management within 3 months following the completion of a review. The NRC staff finds that TS 5.2.3 helps ensure that the scope of RAC reviews is appropriate and includes items that relate to facility safety, and that RAC review findings are reported in a timely manner. The staff also finds that by defining the RAC’s review function, TS 5.2.3 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.2.3 acceptable.

The proposed TS 5.2.4, “Audit Function,” imposes requirements for audits, including that audits be performed by an individual without immediate responsibility for the area being audited; that audits be performed (annually or biennially, as specified) of facility operations for conformance with the TSs and license, of the retraining and requalification program, of corrective actions, of the emergency plan and its implementing procedures, of the radiation protection plan, of the quality assurance program description, of the physical security plan, and a triennial review of the nuclear criticality safety program and the SHINE Safety Analysis Summary report. Further, TS 5.2.4 requires that deficiencies identified by audits be entered into SHINE's corrective action program and that any deficiencies uncovered that affect nuclear safety be immediately reported to the Level 1 management; and that follow-up written reports of audit findings be submitted to the Level 1 management and the RAC members within 3 months after the completion of an audit. The NRC staff finds that TS 5.2.4 helps ensure that audits are conducted with appropriate independence, that the scope of audits is appropriate and includes important items relating to facility safety, and that audit findings are reported in a timely manner. The staff also finds that by establishing requirements related to audits, TS 5.2.4 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Additionally, the audit intervals specified in TS 5.2.4 are consistent with the recommended intervals provided in ANSI/ANS 15.1-2007, section 6.2.4, as applicable. Therefore, the staff finds TS 5.2.4 acceptable.

The proposed TS 5.7.1, "Safety Limit Violation," requires specific actions to be taken if one of the SLs in TS 2.1 is exceeded. TS 5.7.1.1 requires that the SHINE facility operations related to medical isotope production be shut down immediately and that operations not be resumed until authorized by the NRC. TS 5.7.1.2 requires prompt reporting of the violation to Level 2 management or designated alternates. TS 5.7.1.3 requires reporting of the violation to the NRC. TSs 5.7.1.4 and 5.7.1.5 require the preparation and RAC review of a safety limit violation report, and that any follow-up report be submitted to the NRC when authorization is sought to resume operation of the SHINE facility. The NRC staff finds that TS 5.7.1 helps ensure that SHINE will take appropriate actions in the event of an SL violation, including reporting, analysis, corrective actions, and documentation of the violation, and also helps ensure that the facility will not be restarted until it is safe to do so, and it has been determined that recurrence of the violation is unlikely. The staff notes that the SL violation report is required to be prepared and submitted within 14 days in accordance with TS 5.8.2.1.a. The staff finds that TS 5.7.1 helps ensure that SHINE meets the requirements in 10 CFR 50.36(c)(1)(i)(A) related to follow-up actions for a SL violation. The staff also finds that by listing specific actions that must be taken if an SL is exceeded, TS 5.7.1 appropriately implements the guidance in NUREG-1-537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.7.1 acceptable.

The proposed TS 5.8.1, "Operating Reports," requires SHINE to submit, within 30 days of the end of the calendar year (30 days from December 31), a report to the NRC providing information related to facility operations during the previous 1-year period. TS 5.8.1 also specifies the minimum information that is required to be included in each such report. The NRC staff finds that TS 5.8.1 helps ensure that important information regarding facility operations is provided to the NRC at intervals that are appropriate to allow timely NRC review. The staff also finds that by specifying requirements related to annual operating reports, TS 5.8.1 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007, including guidance related to the content of annual reports. Therefore, the staff finds TS 5.8.1 acceptable.

The proposed TSs 5.9.1, "Lifetime Records," 5.9.2, "Five Year Records," and 5.9.3, "Records to be retained for at least one certification cycle," provide requirements for record retention at the SHINE facility. TS 5.9.1 specifies records that must be maintained until the facility license is terminated. TS 5.9.2 specifies records that must be maintained for 5 years (or for the life of the component involved if less than 5 years). TS 5.9.3 specifies records related to licensed operators that must be maintained for the term of each operators' license. The NRC staff finds that TSs 5.9.1, 5.9.2, and 5.9.3 help ensure that SHINE maintains important records and retains them for appropriate time periods. The staff finds that TSs 5.9.1, 5.9.2, and 5.9.3 appropriately implement the guidance in NUREG-1537 and ANSI/ANS 15.1-2007 related to recordkeeping requirement TSs, and that TS 5.9.2.7 helps ensure SHINE's compliance with the 10 CFR 50.59(d) requirement to retain records of changes in procedures for 5 years. Therefore, the staff finds TSs 5.9.1, 5.9.2, and 5.9.3 acceptable.

Although its review of the proposed TS 5.0 did not focus on the following TSs, the NRC staff did review these TSs that were not evaluated in other chapters of this SER:

5.1.4 Selection and Training of Personnel

SHINE establishes and maintains training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. ANSI/ANS 15.4-2016 is used in the selection and training of personnel and compliance is maintained with 10 CFR Part 55, as it pertains to non-power facilities. This includes initial and requalification training programs for Licensed Operators. The Training Manager (TM) reports to the Director of Corporate Support (DCS) and is responsible for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety. Records of personnel training and qualification are maintained.

In general, personnel have the combination of academic training, job-related experience, health, and skills commensurate with their level of responsibility that provides reasonable assurance that decisions and actions during normal and abnormal conditions are such that the facility is operated in a safe manner.

Additional information is detailed in FSAR Subsection 12.1.4 for the minimum qualification level of personnel.

5.4 Procedures

1. Procedures for the operation and use of the SHINE Facility provide appropriate direction to ensure that the facility is operated normally within its design basis, and in compliance with technical specifications. Procedures also provide guidance for addressing abnormal and emergency situations. These procedures are controlled and monitored to ensure that the content is technically correct, and the wording and format are clear and concise.

2. Revisions to the procedures for the operation and use of the SHINE Facility are initiated and tracked through the document control processes. The process required to make changes to procedures, including substantive and minor permanent changes, and temporary deviations to accommodate special or unusual circumstances during operation shall be documented and shall include a screening for 10 CFR 50.59 applicability.

3. SHINE shall prepare, review, and approve written procedures for the following topics:

   a. startup, operation, and shutdown of the IU;

b. target solution fill, draining, and movement within the SHINE Facility;

c. maintenance of major components of systems that may have an effect on nuclear safety;

d. surveillance checks, calibrations and inspections required by the technical specifications;

e. personnel radiation protection, consistent with applicable regulatory guidance. The procedures shall include management commitment and programs to maintain exposures and releases as low as reasonably achievable in accordance with ANSI/ANS 15.11-2016, Radiation Protection at Research Reactor Facilities;

f. administrative controls for operations and maintenance and for the conduct of irradiations that could affect nuclear safety;

g. implementation of required plans (e.g., emergency, security); and

h. use, receipt, and transfer of byproduct material.

4. The specific procedures within these topic areas are developed in accordance with the SHINE QAPD.

5. SHINE shall review and approve written procedures prior to initiating any of the activities listed above. The procedures shall be reviewed by the SHINE review and audit committee and approved by Level 2 management or designated alternates, and such reviews and approvals shall be documented in a timely manner.

6. Substantive changes to procedures related to the activities listed above shall be made effective only after documented review by the SHINE review and audit committee and approval by Level 2 management or designated alternates.

7. Prior to a new or revised procedure being issued for use, the procedure is verified and validated to ensure it will accomplish its intended purpose.

8. The extent of detail in a procedure is dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error. A controlled copy of all operations procedures is maintained in the control room.

5.5.1 Nuclear Safety Program

The SHINE nuclear safety program documents and describes the methods used to minimize the probability and consequences of accidents resulting in radiological or chemical release. The program applies a graded approach to the design and management of processes to assure plant safety through risk reduction and satisfaction of SHINE's performance goals. The safety program accomplishes these goals through development and maintenance of the accident analysis, identification of safety-related controls credited for the prevention or mitigation of accidents, and establishment of programmatic administrative controls to ensure reliability of the credited controls.

5.5.2 Training and Qualification

The SHINE training and qualification programs are established as described in Section 5.1.4.

5.5.4 Configuration Management

The SHINE configuration management program provides oversight and control of design information, safety information, and records of modifications that might impact the ability of safety-related SSCs to perform their functions. The configuration management program is applied to all safety-related SSCs and is used to evaluate each change to the SHINE Facility for the potential to affect safety-related SSCs. The configuration management program is used to maintain consistency among the design requirements, the physical configuration and the facility documentation, and ensures changes are made in accordance with 10 CFR 50.59 and the administrative controls and reviews specified by this program.

Table 5.5.4 lists controls derived from the accident analysis not otherwise included in Sections 3, 4, or 5 of the technical specifications. SHINE maintains these controls under the configuration management program.

5.5.5 Maintenance of Safety-Related SSCs

The SHINE maintenance program, which includes inspection, testing, and maintenance, ensures that the safety-related SSCs are available and reliable when needed. The maintenance program includes corrective maintenance, preventative maintenance, surveillance and monitoring, and testing. The maintenance program includes the following activities to ensure that safety-related SSCs can perform their functions as required by the accident analysis:

1. Inspection and maintenance of Confinement boundaries;

2. Corrective maintenance or inspections following safety-related system or component actuations or adverse conditions;

3. Overhead crane maintenance and requirements for usage;

4. Safety-related electrical equipment preventive maintenance; and

5. Other inspections and surveillances deemed necessary to ensure the continued functionality of safety-related SSCs.

5.5.6 Fire Protection

The SHINE fire protection program documents and describes the methods used to minimize the probability of and the consequences of fire. The fire protection program ensures, through defense-in-depth, that a fire will not prevent the performance of necessary safety-related functions and that radioactive releases to the environment, in the event of fire, will be minimized. The fire protection program implements the following activities to prevent and mitigate potential fire events in the SHINE Facility:

1. Periodic surveillances;

2. Control of hot work;

3. Control of transient combustibles;

4. Control of physical design characteristics of the facility relied on to prevent or mitigate the effects of fires; and

5. Maintenance of the fire hazards analysis and safe shutdown analysis for the facility.

5.5.7 Nuclear Criticality Safety

The SHINE nuclear criticality safety program ensures that workers, the public, and the environment are protected from the consequences of a nuclear criticality event. The nuclear criticality safety program complies with applicable national consensus standards, as clarified by Regulatory Guide 3.71, Revision 3, Nuclear Criticality Safety Standards for Fuels and Material Facilities, and is described in FSAR Subsection 6b.3.1.

The nuclear criticality safety program evaluates the fissionable material operations in the SHINE Facility and establishes appropriate criticality safety controls which are described in the criticality safety evaluations and the accident analysis. The criticality safety controls are preventative in nature and comply with the preferred hierarchy of controls: passive controls over active controls and engineered controls over administrative controls.

A criticality accident alarm system (CAAS) is provided for the SHINE Facility. The CAAS meets the requirements of 10 CFR 70.24(a) and follows the guidance of ANSI/ANS 8.3-1997. Maintenance and testing of the CAAS is performed in accordance with ANSI/ANS 8.3-1997. The CAAS is further described in FSAR Subsection 6b.3.3.

5.7.2 Occurrence of Events Requiring a Special Report.

In the event of an occurrence requiring a special report as specified in Section 5.8.2.1, other than a violation of a safety limit:

1. The affected processes or areas of the facility shall be returned to normal conditions or shut down. If it is necessary to shut down processes to

correct the occurrence, operation of those affected processes shall not be resumed unless authorized by Level 2 management or designated alternates.

2. The occurrence shall be reported to Level 2 management or designated alternates and to the NRC.

3. The occurrence shall be reviewed by the RAC at its next scheduled meeting.

5.8.2 Special Reports

Special reports are used to report unplanned events as well as planned major facility and administrative changes. Special reports will follow the schedule below:

1. There will be a report not later than the following working day by telephone and confirmed in writing by electronic mail or similar conveyance to the NRC Operations Center, to be followed by a written report to the NRC Document Control Desk that describes the circumstances of the event within 14 days of any of the following:

   a. Violation of a safety limit;

   b. Release of radioactivity from the site above allowed limits;

   c. Operations with actual Safety System settings for required systems less conservative than the limiting safety system settings specified in Section 2.2;

   d. Operation in violation of limiting conditions for operation established in Section 3, unless prompt remedial action is taken as permitted in Section 3;

   e. A Safety System component malfunction that renders or could render the Safety System incapable of performing its intended safety function.

      If the malfunction or condition occurs during Modes or conditions in which the LCO is not applicable, then no report is required.

      Where components or systems are provided in addition to those required by the technical specifications, the failure of the extra components or systems is not considered reportable provided that the minimum numbers of components or systems specified or required perform their intended safety function;

   f. Abnormal and significant degradation of the PSB (including minor leaks);

g. Abnormal and significant degradation in the PCLS and the light water pool (excluding minor leaks); and

h. An observed inadequacy in the implementation of administrative or procedural controls such that the inadequacy causes or could have caused the existence or development of an unsafe condition with regard to operations.

2. There shall be a written report within 30 days to the NRC Document Control Desk of the following:

   a. Permanent changes in the facility organization involving Level 1 or Level 2 management, and

   b. Significant changes in the transient or accident analysis as described in the FSAR.

5.8.3 Additional Event Reporting Requirements

1. Events which meet the reporting requirements of 10 CFR 70.50 or 10 CFR 70.52 shall be reported to the NRC as prescribed in the applicable regulation.

2. SHINE shall report to the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:

   a. An inadvertent nuclear criticality.

   b. An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

   c. An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could endanger the life of a worker or could lead to irreversible or other serious, long-lasting health effects to any individual located outside the owner controlled area.

   d. An event or condition such that no credited controls, as documented in the SHINE Safety Analysis, remain available and reliable, in an accident sequence evaluated in the SHINE Safety Analysis.

3. SHINE shall report to the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:

   a. Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that described in the SHINE Safety Analysis, and which results in inadequate controls in place to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

b. Loss or degradation of credited controls, as documented in the SHINE Safety Analysis, other than those items controlled by a limiting condition of operation established in section 3 of the technical specifications, that results in failure to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

c. An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that could lead to irreversible or other serious, long-lasting health effects to a worker, or could cause mild transient health effects to any individual located outside the owner controlled area.

d. Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more safety-related structures, systems or components.

4. SHINE shall concurrently report to the NRC Operations Center any event or situation, related to the health and safety of the public or on-site personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made.

5.8.4 Startup Report

SHINE shall conduct startup testing in accordance with the Startup Testing Program, as described in FSAR Section 12.11. Following completion of startup testing, SHINE will submit a Startup Report to the NRC Document Control Desk that identifies the startup tests performed.

The Startup Report shall be submitted within 6 months of the completion of all startup testing activities.

Based on its review, the NRC staff finds that the SHINE proposed administrative controls TSs provide a description of the organizational structure, program and procedure requirements, reporting requirements, and facility-specific controls. The staff finds that TS 5.0 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007 to help ensure that the SHINE facility is operated safely. Therefore, the staff finds TS 5.0 acceptable.

The regulation at 10 CFR 50.36(a)(1) states, in part, that a summary statement of the bases or reasons for TSs, other than those covering administrative controls, shall also be included in the application for an operating license, but shall not become part of the TSs. Consistent with 10 CFR 50.36(a)(1), the applicant submitted TS bases that provide the reasons for the proposed TSs. The NRC staff determined that the TS bases are consistent with the proposed TSs and provide the purpose for each proposed TS. Therefore, the staff concludes that 10 CFR 50.36(a)(1) is met with respect to TS bases.

14.5 Review Findings

The NRC staff reviewed SHINE's proposed TSs. The proposed TSs define certain features, characteristics, organizational and reporting requirements, and conditions governing the operation of the SHINE facility. The staff reviewed the format and content of the proposed TSs for consistency with the guidance in ANSI/ANS 15.1-2007, NUREG-1431, Volume 1, and NUREG-1537 and finds that they are appropriately consistent with this guidance. The staff also specifically evaluated the content of the proposed TSs to determine if they meet the requirements in 10 CFR 50.36. Based on its review, the staff determined that:

(1) As required by 10 CFR 50.36(a)(1), the SHINE operating license application includes a summary statement of the bases or reasons for the proposed TSs, other than those covering administrative controls.

(2) As required by 10 CFR 50.36(b), the SHINE operating license application includes proposed TSs derived from the analyses and evaluation included in the SHINE FSAR, as supplemented.

(3) SHINE's proposed TSs include (1) SLs on the wall temperature and differential pressure across the primary system boundary and the pressure within process tanks containing irradiated uranyl sulfate and connected piping, which are the important process variables necessary to reasonably protect against the uncontrolled release of radioactivity and (2) LSSSs, which are settings for the automatic protection systems related to those variables having significant safety functions, so chosen to prevent exceeding the SLs, that satisfy 10 CFR 50.36(c)(1)(i)(A) and (ii)(A).

(4) SHINE's proposed TSs include LCOs, which are the lowest functional capability or performance levels of equipment required for safe operation of the facility, for each item that meets one or more of the criteria specified in 10 CFR 50.36(c)(2)(ii).

(5) SHINE's proposed TSs include SRs, which are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within SLs, and that the LCOs will be met, that satisfy 10 CFR 50.36(c)(3).

(6) SHINE's proposed TSs include design features, which are those features of the facility such as materials of construction and geometric arrangements, which, if altered or modified, would have a significant effect on safety, that satisfy 10 CFR 50.36(c)(4).

(7) SHINE's proposed TSs include administrative controls, which are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the facility in a safe manner, that satisfy 10 CFR 50.36(c)(5).

(8) SHINE's proposed TSs include requirements for initial notification, written reports, and records that satisfy 10 CFR 50.36(c)(1), (2), and (7) and requirements for special reports that the staff deemed necessary in accordance with 10 CFR 50.36(c)(8).

(9) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that SHINE's proposed TSs meet the requirements of 10 CFR 50.36 and concludes that normal operation of the SHINE facility within the limits of the TSs will not result in radiation exposures in excess of the limits in 10 CFR Part 20 for members of the public or for workers. The staff also concludes that the proposed TSs provide reasonable assurance that the facility will be operated as analyzed in the SHINE FSAR, as supplemented; that adherence to the TSs will limit the likelihood of malfunctions and the potential accident scenarios analyzed in SHINE FSAR chapter 13, "Accident Analysis," and discussed in chapter 13, "Accident Analysis," of this SER; that facility operation will be in accordance with the applicable regulations and meet regulatory requirements for the issuance of an operating license; and that the conduct of activities by the applicant will not endanger the public or workers.

15.0 FINANCIAL QUALIFICATIONS

Financial qualifications (FQs) for an application for an operating license establish whether the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first five years of operation of the facility and indicate the source(s) of funds to cover these costs. The applicant must also submit information related to the funding for decommissioning; foreign ownership, control, or domination (FOCD); and nuclear insurance and indemnity.

This chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) describes the review and evaluation by the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of SHINE's FQs and information submitted related to the funding for decommissioning, FOCD, and nuclear insurance and indemnity, as presented in chapter 15, "Financial Qualifications," of the SHINE final safety analysis report (FSAR) and Enclosure 2 of the SHINE operating license application, "General and Financial Information" (Agencywide Documents Access and Management System Accession No. ML19211C143), Enclosure 2 (ML19211C089).

15.1 Areas of Review

Chapter 15 of this SER provides the NRC staff's evaluation of SHINE's FQs and information submitted related to the funding for decommissioning, FOCD, and nuclear insurance and indemnity.

The NRC staff reviewed SHINE FSAR section 15.2, "Financial Ability to Operate the SHINE Facility," section 15.3, "Financial Ability to Decommission the SHINE Facility," section 15.4, "Foreign Ownership, Control, or Domination," and section 15.5, "Nuclear Insurance and Indemnity," and Enclosure 2 of the SHINE operating license application against applicable statutory and regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the operating license application with respect to FQs, funding for decommissioning, FOCD, and nuclear insurance and indemnity for the issuance of an operating license.

Areas of review included (1) estimates for total annual operating costs for each of the first five years of operation of the SHINE facility and sources of funds to cover these costs, (2) a cost estimate for decommissioning the facility, the method that will be used to cover this cost estimate, and the means of periodically adjusting this cost estimate and associated funding level, (3) information related to FOCD, and (4) information related to insurance and indemnity. Although the applicant provided in SHINE FSAR section 15.1, "Financial Ability to Construct the SHINE Facility," information related to FQs for constructing the SHINE facility, this information is not required in an operating license application and the issue was previously reviewed by the NRC staff as part of its review of the SHINE construction permit application.

15.2 Summary of Application

SHINE FSAR section 15.1 references updated information already submitted to the NRC related to SHINE's financial ability to construct its facility.

SHINE FSAR section 15.2 presents information to demonstrate that SHINE possesses, or has reasonable assurance of obtaining, the funds necessary to cover estimated operation costs for the period of the operating license. SHINE provides estimates for total annual operating costs for each of the first five years of operation of the facility and indicates the sources of funds to cover these costs.

SHINE FSAR section 15.3 presents information on the estimated cost to decommission the facility, the method to provide funds for decommissioning, and the means of periodically adjusting the decommissioning cost estimate and associated funding level.

SHINE FSAR section 15.4 and Enclosure 2 of the SHINE operating license application present information regarding the corporate identity of SHINE, including its state of incorporation, address, directors and principal officers, and relevant citizenship information, as well as whether it is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government or acting as an agent or representative of another person in filing its application.

SHINE FSAR section 15.5 provides that the nuclear insurance and indemnity requirements of the Price-Anderson Act (section 170 of the Atomic Energy Act of 1954, as amended (AEA)) apply to SHINE and that those requirements will be satisfied.

15.3 Statutory and Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 15 against the applicable statutory and regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the information provided by SHINE for the issuance of an operating license.

15.3.1 Applicable Statutory and Regulatory Requirements

The applicable statutory and regulatory requirements for the evaluation of SHINE’s FQs and information submitted related to the funding for decommissioning, FOCD, and nuclear insurance and indemnity are as follows:

- AEA § 103, “Commercial Licenses,” paragraph d.
- AEA § 170, “Indemnification and Limitation of Liability.”
- Title 10 of the *Code of Federal Regulations* (10 CFR) 50.33, “Contents of applications; general information.”
- 10 CFR 50.38, “Ineligibility of certain applicants.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR 50.57, “Issuance of operating license.”
- 10 CFR 50.75, “Reporting and recordkeeping for decommissioning planning.”
- 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements.”

15.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

15.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the information presented in SHINE FSAR chapter 15 and Enclosure 2 of the SHINE operating license application to assess the sufficiency of SHINE’s FQs and information submitted related to the funding for decommissioning, FOCD, and nuclear insurance and indemnity for the issuance of an operating license. The sufficiency of this information is determined by ensuring that it meets applicable statutory and regulatory requirements and guidance and acceptance criteria, as discussed in section 15.3, “Statutory and Regulatory Requirements and Guidance and Acceptance Criteria,” of this SER. The findings of this evaluation are described in section 15.5, “Review Findings,” of this SER.

15.4.1 Financial Ability to Construct the SHINE Facility

Consistent with the regulatory requirements discussed in section 15.3.1, "Applicable Statutory and Regulatory Requirements," of this SER, the NRC staff reviewed the information regarding SHINE's financial ability to construct the SHINE facility, as described in SHINE FSAR section 15.1, using the guidance and acceptance criteria from section 15.1, "Financial Ability to Construct a Non-Power Reactor," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The NRC staff previously concluded in its SER for the SHINE construction permit application that SHINE is financially qualified to construct the SHINE facility (ML16229A140). As part of its operating license application, SHINE referenced updated financial qualification information related to construction that SHINE had provided to the NRC in an application for transfer of control of the SHINE construction permit (ML18347A215) and (ML19071A059), Enclosure 2 ML19071A055). A further determination regarding SHINE's financial ability to construct the SHINE facility is not required under 10 CFR 50.33 for the issuance of an operating license.

15.4.2 Financial Ability to Operate the SHINE Facility

Consistent with the regulatory requirements discussed in section 15.3.1 of this SER, the NRC staff evaluated the sufficiency of SHINE's financial ability to operate the SHINE facility, as described in SHINE FSAR section 15.2, using the guidance and acceptance criteria from section 15.2, "Financial Ability to Operate a Non-Power Reactor," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The applicant supplied financial information for the estimates of operating costs and the sources of funds to cover these costs. The first five years of estimated operating costs are provided in SHINE FSAR table 15.2-1, "Operating Costs for the First Five Years of Operation." These costs are divided into two primary categories: costs of goods sold and organizational expenses. The applicant provided the bases for each of these categories of costs, which include existing contracts and quotes from providers.

Per the application, SHINE intends to cover the estimated operating costs through the sale of medical isotopes, primarily molybdenum-99 (Mo-99). SHINE has entered into contracts to sell Mo-99 to three customers: GE Healthcare; Lantheus Medical Imaging, Inc.; and HTA Co., Ltd. SHINE FSAR table 15.2-2, "Estimated Funding for the First Five Years of Operation," estimates the first five years of Mo-99 sales covered under these contracts (both the minimum and maximum contract revenues), as well as the excess production capacity available within this timeframe, and the minimum projected additional sales needed based on available production capacity. The application also discusses the ability of SHINE to obtain additional financing. The application concludes that, based on existing sales contracts and the facility's excess production capacity that will allow SHINE to expand its existing sales contracts or enter into new sales contracts, the funds necessary to cover operating costs will be obtained.

The NRC staff reviewed the financial ability of the applicant to operate the SHINE facility in accordance with NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2. This guidance provides that an applicant should estimate the first five years of operating costs and give a reliable basis for the estimate and should discuss the sources of funding for operating costs, the amount of funding that is committed, and the amount that is potentially available; the applicant should confirm committed sources and discuss conditions under which potential sources of funding would become committed and how the facility can be safely operated if some potential sources of funding are not realized. The SHINE operating license application satisfies this guidance because the application estimates the first five years of operating costs and discusses the sources of funding for these costs. The staff finds that the estimates of operating costs are reasonable because the applicant gives a reliable basis for them. The staff finds that there is reasonable assurance that the applicant will obtain the funds necessary to cover the estimates of operating costs because the applicant confirms committed sources of contract revenue and discusses the amount of excess production capacity available to cover the remaining operating costs. Finally, the applicant discusses how the safety of the facility will be assured if some potential sources of funding are not realized by stating that in the unlikely event that SHINE fails to obtain additional financing or is unable to establish additional Mo-99 sales contracts, SHINE will not be able to operate the facility.

The Commission has stated that it will accept financial assurances based on plausible assumptions and forecasts, even though the possibility is not insignificant that things will turn out less favorably than expected (ML16195A533). Based on this standard and the information provided by the applicant, the NRC staff concludes that the applicant has shown, by a preponderance of the evidence, that it satisfies 10 CFR 50.33(f) and is financially qualified to carry out the activities for which the operating license is sought.

15.4.3 Financial Ability to Decommission the SHINE Facility

Consistent with the regulatory requirements discussed in section 15.3.1 of this SER, the NRC staff evaluated the sufficiency of SHINE's financial ability to decommission the SHINE facility, as described in SHINE FSAR section 15.3, using the guidance and acceptance criteria from section 15.3, "Financial Ability to Decommission the Facility," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The applicant supplied a decommissioning cost estimate for the SHINE facility of $50,058,000. The estimate considers costs for activities necessary to decommission and release the site for unrestricted use, including planning and preparation, decontamination and dismantling of facility components, equipment and supplies, radioactive waste characterization, waste packaging and shipment, waste disposal, contingency costs, contractor costs, and radiation surveys. The estimate assumes that decommissioning activities begin immediately after radioisotope production activities and operations involving radioactive materials cease. The applicant stated that the method that will be used to cover the decommissioning cost estimate will be to maintain an external escrow account in which deposits will be made periodically, coupled with a surety method, insurance, or some other form of guarantee. Finally, the applicant stated that the decommissioning cost estimate and associated funding level will be adjusted every three years, or when the amounts or types of materials at the facility change. These triennial adjustments will account for inflation, for other changes in the prices of goods and services, for changes in facility conditions or operations, and for changes in expected decommissioning procedures, as well as for other changes at the site such as leaks or spills of radioactive material.

The NRC staff reviewed the decommissioning cost estimate, the method that will be used to cover this estimate, and the means of periodically adjusting this estimate and associated funding level in accordance with NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2. The staff finds that the applicant discussed the decommissioning method to be used for the facility in sufficient detail to permit cost estimates to be developed and that the applicant estimated decommissioning costs and took into account the decommissioning method to be used. Because the applicant adequately addressed and evaluated the activities required to decommission the facility and their costs, the staff concludes that the applicant's estimate of the costs required for decommissioning the facility appears to be reasonable.

The applicant proposed a method of funding decommissioning costs that meets the requirements of the NRC's regulations. Specifically, the applicant identified the NRC-approved external sinking fund method of 10 CFR 50.75(e)(1)(ii) and surety method, insurance, or other guarantee method of 10 CFR 50.75(e)(1)(iii). The applicant also provided a description of the means of adjusting the decommissioning cost estimate and associated funding level periodically over the life of the facility based on actual changes or changes in cost indices. The NRC's regulations require power reactor licensees and non-power reactor licensees to continually provide reasonable assurance that funds will be available for the decommissioning process through certifying to a decommissioning amount, periodically updating that decommissioning amount, and covering that amount by an NRC-approved method. To apply similar requirements to SHINE as committed to in its application, the SHINE operating license will be conditioned as follows:

> The SHINE operating license application provided a decommissioning cost estimate for the SHINE facility. This cost estimate must be adjusted every three years or when the amounts or types of materials at the SHINE facility change, whichever is less, and the adjustment must account for, among others, the factors discussed in the SHINE operating license application, as appropriate. The decommissioning cost estimate, as adjusted, must be covered by the external sinking fund method of 10 CFR 50.75(e)(1)(ii) and/or the surety method, insurance, or other guarantee method of 10 CFR 50.75(e)(1)(iii). The licensee must also comply with the requirements of 10 CFR 50.75(f)–(h) that are applicable to non-power reactor licensees.

The applicant has supplied financial information for decommissioning costs of the facility in accordance with 10 CFR 50.75. The NRC staff has reviewed the decommissioning cost estimate submitted by the applicant and concludes that the cost estimate appears to be reasonable. The applicant has indicated the method or methods to be used to provide funds for decommissioning and has provided a description of the means of adjusting the cost estimate and associated funding level periodically over the life of the facility. The staff has reviewed the applicant's information provided on decommissioning funding assurance and finds that the applicant's financial assurance method to be used to provide funds for decommissioning is acceptable, and that the applicant's means of adjusting the cost estimate and associated funding level periodically over the life of the facility appears to be reasonable. The staff notes that any adjustment of the decommissioning cost estimate should incorporate, among other things, changes in costs resulting from the availability of disposal facilities. The above license condition ensures that these findings will be maintained. Therefore, the staff concludes that the applicant has provided reasonable assurance that funds will be available to decommission the SHINE facility.

15.4.4 Foreign Ownership, Control, or Domination

Consistent with the statutory and regulatory requirements discussed in section 15.3.1 of this SER, the NRC staff evaluated the sufficiency of SHINE's description of FOCD considerations, as presented in Enclosure 2 of the SHINE operating license application and SHINE FSAR section 15.4, using the guidance and acceptance criteria from section 15.4, “Foreign Ownership, Control, or Domination (FOCD),” of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with AEA § 103d. and 10 CFR 50.33(d) and 10 CFR 50.38 and the guidance in the ISG augmenting NUREG-1537, Parts 1 and 2, the NRC staff reviewed whether the application included all of the 10 CFR 50.33(d) information that is applicable to the applicant and a statement as to whether the applicant is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

According to the application, SHINE is not owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. SHINE is a single member, Delaware limited liability company, owned and controlled by Illuminated Holdings, Inc. (Illuminated), a Delaware corporation. The application states that to the best of SHINE’s knowledge, current shareholders holding 1 percent or more of Illuminated stock are U.S. citizens or entities owned or controlled by U.S. citizens. The NRC staff notes that one individual on the Illuminated Board of Directors (BOD) is a foreign citizen (Canadian). The staff recognizes that a single foreign BOD member cannot exercise control over SHINE based on the makeup of the SHINE BOD. The staff conducted an independent analysis, including open-source research and verification of the information provided in the application related to the ownership of SHINE, and found no evidence of FOCD.

Based on the above, the NRC staff finds that the level of detail provided on FOCD considerations for operation of the SHINE facility is reasonable and satisfies the requirements of 10 CFR 50.33(d) and that the issuance of the operating license does not raise any issues related to FOCD within the meaning of AEA § 103d. and 10 CFR 50.38. Therefore, the staff concludes that it does not know or have reason to believe that SHINE is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

15.4.5 Nuclear Insurance and Indemnity

Consistent with the statutory requirements discussed in section 15.3.1 of this SER, the NRC staff evaluated the sufficiency of SHINE’s description of nuclear insurance and indemnity considerations, as described in SHINE FSAR section 15.5, using the guidance and acceptance criteria from section 15.5, “Nuclear Insurance and Indemnity,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

By letter dated August 27, 2018 (ML18239A219), SHINE provided that section 170 of the AEA states that each license issued under section 103 of the AEA (including a SHINE operating license) shall have as a condition of the license a requirement that the licensee have and maintain financial protection of such type and in such amount as the NRC shall require to cover public liability claims. Section 170 of the AEA also states that the NRC shall, with respect to licenses for which it requires financial protection of less than $560 million, agree to indemnify and hold harmless the licensee from public liability arising from nuclear incidents that is in excess of the level of financial protection required of the licensee up to a specified amount. Section 170 of the AEA describes the considerations for the NRC’s determination of the acceptable types and amounts of financial protection. SHINE provided that section 170 of the AEA, though, does not directly specify the type or amount of financial protection applicable to the SHINE facility. Moreover, the NRC’s regulations that implement section 170 of the AEA (10 CFR Part 140) do not specify the type or amount of financial protection applicable to the SHINE facility. However, 10 CFR 140.11, “Amounts of financial protection for certain reactors,” does specify financial protection amounts applicable to nuclear reactors, including, at 10 CFR 140.11(a)(2), that nuclear reactors authorized to operate at a thermal power level in excess of 10 kilowatts but not in excess of 1 megawatt are required to have and maintain financial protection in the amount of $1.5 million. And 10 CFR 140.14, "Types of financial protection," specifies the allowable types of financial protection for the amounts of financial protection under 10 CFR Part 140, including under 10 CFR 140.11(a)(2).

SHINE stated that the eight utilization facilities (i.e., the eight irradiation units that make up the irradiation facility (IF)) at the SHINE facility, although not nuclear reactors, are, in total, within the 10 CFR 140.11(a)(2) thermal power level range of 10 kilowatts to 1 megawatt and that the NRC staff has previously acknowledged for safety considerations the similarity of the SHINE facility and non-power reactors with comparable thermal power levels. SHINE also stated that the accident scenarios associated with the SHINE utilization facilities and the SHINE production facility (i.e., the radioisotope production facility (RPF)) are consequentially equivalent for the purpose of applying financial protection because the accident consequences for the IF and RPF are bounded by the same accident dose criterion and because the material at risk associated with the processes within the IF and RPF is largely the same. Therefore, SHINE concluded that the appropriate financial protection amount under section 170 of the AEA for the entire SHINE facility is the $1.5 million amount of 10 CFR 140.11(a)(2).

In its operating license application, SHINE stated that the financial protection requirements of section 170 of the AEA are applicable to SHINE and that SHINE has determined that maintaining financial protection in the amount of $1.5 million, covering each of the eight utilization facilities and the production facility, satisfies these financial protection requirements.

The NRC staff agrees with the analysis in SHINE's August 27, 2018, letter and finds, for the reasons provided in that analysis and discussed above, that section 170 of the AEA applies to the SHINE facility, that the appropriate amount of financial protection for the SHINE facility under section 170 of the AEA is $1.5 million, which is equivalent to the amount required for nuclear reactors in 10 CFR 140.11(a)(2), and that the types of financial protection provided in 10 CFR 140.14 as applying, in part, to the amount required under 10 CFR 140.11(a)(2), are also applicable to SHINE. Therefore, in the exercise of its licensing authority and responsibility and consistent with section 170 of the AEA and 10 CFR Part 140, the NRC conditions the SHINE operating license as follows:

> The licensee shall have and maintain financial protection of such type as provided by 10 CFR 140.14 and in the amount of $1.5 million to cover public liability claims in accordance with Section 170 of the Atomic Energy Act of 1954, as amended.

In its operating license application, SHINE also stated that it will maintain an indemnification agreement with the NRC that extends for the life of the license. Consistent with section 170 of the AEA, the NRC conditions the SHINE operating license as follows:

> The licensee shall execute and maintain an indemnification agreement in accordance with Section 170 of the Atomic Energy Act of 1954, as amended.

Based on the above, the NRC staff concludes that SHINE has provided sufficient information regarding nuclear insurance and indemnity in accordance with section 170 of the AEA.

15.5 Review Findings

The NRC staff reviewed the descriptions and discussions of SHINE's FQs, funding for decommissioning, FOCD, and nuclear insurance and indemnity, as described in SHINE FSAR chapter 15 and Enclosure 2 of the SHINE operating license application, against the applicable statutory and regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of this information and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE has submitted information that demonstrates that it possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license in accordance with 10 CFR 50.33(f);

(2) SHINE will provide reasonable assurance that funds will be available for the decommissioning process in accordance with 10 CFR 50.75;

(3) SHINE has submitted information that satisfies 10 CFR 50.33(d) with respect to FOCD considerations and the NRC does not know or have reason to believe that SHINE is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government in accordance with AEA § 103d. and 10 CFR 50.38; and

(4) SHINE has provided sufficient information regarding nuclear insurance and indemnity in accordance with section 170 of the AEA.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of FQs, funding for decommissioning, FOCD, and nuclear insurance and indemnity are sufficient and meet the applicable statutory and regulatory requirements and guidance and acceptance criteria for the issuance of an operating license and that, therefore, consistent with 10 CFR 50.40, SHINE is financially qualified to engage in the proposed activities in accordance with the NRC's regulations.

16.0 OTHER LICENSE CONSIDERATIONS

The SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR) chapter 16, “Other License Considerations,” states that “[t]he SHINE facility utilizes new and appropriately-qualified components and systems to conduct production operations,” and that “[d]iscussions regarding used components and systems are not applicable to the SHINE facility.” Additionally, SHINE stated that its facility “does not contain equipment or facilities associated with direct medical administration of radioisotopes or other radiation-based therapies,” and that discussions regarding the medical use of the facility are not applicable.

The U.S. Nuclear Regulatory Commission staff evaluated the descriptions and discussions of the SHINE facility in the FSAR and finds that the final design of the SHINE facility does not contain prior use components, contain equipment or facilities associated with direct medical administration of radioisotopes or other radiation-based therapies, or raise other license considerations. Therefore, the staff concludes that an evaluation of the guidelines of NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996, and the “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012, is not required.

17.0 DECOMMISSIONING AND POSSESSION-ONLY LICENSE AMENDMENTS

The SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR) chapter 17, “Decommissioning and Possession-Only License Amendments,” states that a decommissioning report is provided in FSAR section 15.3, “Financial Ability to Decommission the SHINE Facility.” SHINE also stated that because SHINE is not requesting a possession-only license amendment, discussions related to a possession-only license amendment are not applicable to the SHINE facility.

The U.S. Nuclear Regulatory Commission staff evaluation of SHINE’s financial ability to decommission the SHINE facility is described in chapter 15.0, “Financial Qualifications,” of this safety evaluation report. The staff evaluated the descriptions and discussions of the SHINE facility in the FSAR and finds that SHINE is not requesting a possession-only license amendment. Therefore, the staff concludes that an evaluation of the possession-only license amendment guidelines of NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996, and the “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012, is not required.

18.0 HIGHLY ENRICHED TO LOW-ENRICHED URANIUM CONVERSION

The SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR) chapter 18, “Highly Enriched to Low Enriched Uranium Conversion,” states that because the SHINE facility is a new facility that uses low-enriched uranium, discussions related to uranium conversion are not applicable to the SHINE facility.

The U.S. Nuclear Regulatory Commission staff evaluated the descriptions and discussions of the SHINE facility in the FSAR and finds that the final design of the SHINE facility does not utilize highly enriched uranium. Therefore, the staff concludes that an evaluation of the uranium conversion guidelines of NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996, and the “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012, is not required.

APPENDIX A
EVALUATION OF THE SHINE MEDICAL TECHNOLOGIES, LLC PHASED APPROACH TO STARTUP

1.0 THE FACILITY

Section 1, "The Facility," of this appendix to the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) discusses SHINE's proposed phased approach to startup and provides the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff's evaluation of the overall impact of this approach on the SHINE facility.

1.1 Introduction

By letter dated February 26, 2021 (Agencywide Documents Access and Management System Accession No. ML21057A340), SHINE stated that it intends to pursue a phased approach to startup of the SHINE facility. SHINE stated that this approach consists of four phases of process equipment installation and operation. The phases are defined as follows.

Phase 1 consists of the equipment necessary to support operation of irradiation units (IUs) 1 and 2. The anticipated equipment to be installed during Phase 1 includes:

- All auxiliary and support systems, except as noted below for the instances of primary closed loop cooling system (PCLS), light water pool system (LWPS), and radiological ventilation zone 1 (RVZ1) equipment located in the cooling room;
- All radioisotope production facility (RPF) systems except the capability of iodine and xenon purification and packaging (IXP) and radioactive liquid waste immobilization (RLWI) selective removal;
- IUs 1 and 2, including the associated instances of the subcritical assembly system (SCAS), neutron flux detection system (NFDS), target solution vessel (TSV) offgas system (TOGS), PCLS, LWPS, and radiological ventilation zone 1 recirculating system (RVZ1r); and
- Tritium purification system (TPS) train A.

Phase 2 adds the equipment necessary to support operation of IUs 3, 4, and 5. The anticipated equipment to be installed during Phase 2 includes:

- IUs 3, 4, and 5, including the associated instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1r; and
- TPS Train B.

Phase 3 adds the equipment necessary to support operation of IUs 6, 7, and 8. Phase 3 also adds the capability for selective removal in the RLWI system and waste staging. The anticipated equipment to be installed during Phase 3 includes:

- IUs 6, 7, and 8, including the associated instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1r;
- TPS Train C;
- RLWI selective removal components; and
- The material staging building (MATB).

Phase 4 adds the IXP capability.

To incorporate its proposed phased approach to startup, SHINE supplemented its operating license application by letter dated January 27, 2022 (ML22027A353), as supplemented by letters dated May 23, 2022 (ML22143A814), August 1, 2022 (ML22213A049), August 31, 2022 (ML22249A148), September 19, 2022 (ML22263A027), September 20, 2022 (ML22263A344), and September 28, 2022 (ML22271A962) (hereafter, the SHINE Supplement). The SHINE Supplement describes new or different information from the facility descriptions and analyses provided in the SHINE final safety analysis report (FSAR) resulting from the phased approach to startup. In its letter dated August 31, 2022, SHINE revised the information related to its phased approach to startup because of design changes and responses to NRC staff requests for additional information, as follows:

- Updated the disabling of inputs as described in SHINE Supplement section 7.4.5, "Highly Integrated Protection System Design";
- Removed "Group 1," "Group 2," and "Group 3" isolation from the title of the safety function associated with the carbon delay beds in SHINE Supplement section 7.5.3, "Design Basis";
- Revised "High PVVS Carbon Delay Bed Exhaust Carbon Monoxide" to "High PVVS Carbon Delay Bed Exhaust Temperature," as a result of a design change in SHINE Supplement section 7.5.4, "Operation and Performance";
- Described the adequacy of bore hole storage space for waste streams until the MATB is available in Phase 3 in SHINE Supplement section 9b.7.5, "Solid Radioactive Waste Packaging System"; and
- Updated the estimated waste stream and disposal during phased startup activities in SHINE Supplement table 11.2-1, "Estimated As-Generated Annual Waste Stream Summary During Phased Startup Operations," and table-11-2.2, "Estimated As-Disposed Annual Waste Stream Summary During Phased Startup Operations."

This appendix to the SER documents the results of the NRC staff's technical and safety review of the SHINE Supplement and its proposed phased approach to startup.

1.1.1 Areas of Review

For its technical and safety review of SHINE's proposed phased approach to startup, the NRC staff reviewed the information in the SHINE Supplement against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, as discussed below. The staff evaluated the effect of the phased approach to startup on the sufficiency of the SHINE facility description and the design bases, the limits on facility operation, and the safety analysis of the structures, systems, and components (SSCs) and of the facility as a whole presented in the SHINE FSAR.

The NRC staff also reviewed the kinds and quantities of radioactive materials expected to be produced in the operation of the SHINE facility and the means for controlling and limiting radioactive effluents and radiation exposures within the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection Against Radiation,” during the phased approach to startup. Additionally, the staff reviewed the effect of the phased approach to startup on the final analysis and evaluation of the design and performance of SSCs with the objective of assessing the risk to public health and safety resulting from such startup of the facility.

1.1.2 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed the SHINE Supplement against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the proposed phased approach to startup for the issuance of an operating license.

The applicable regulatory requirements for the evaluation of the SHINE Supplement are as follows:

- 10 CFR 50.2, “Definitions.”
- 10 CFR 50.33, “Contents of applications; general information.”
- 10 CFR 50.34, “Contents of applications; technical information,” paragraph (b), “Final safety analysis report.”
- 10 CFR 50.36, “Technical specifications.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR 50.50, “Issuance of licenses and construction permits.”
- 10 CFR 50.54, “Conditions of licenses.”
- 10 CFR 50.57, “Issuance of operating license.”
- 10 CFR Part 50, Appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities.”
- 10 CFR Part 20, “Standards for Protection Against Radiation.”
- 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.”

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.
- NUREG-0711, Revision 3, "Human Factors Engineering Program Review Model," dated November 2012.
- NUREG/CR-7126, "Human-Performance Issues Related to the Design and Operation of Small Modular Reactors," dated June 2012.
- NUREG/CR-7202, "NRC Reviewer Aid for Evaluating the Human-Performance Aspects Related to the Design and Operation of Small Modular Reactors," dated June 2015.
- NUREG-0612, "Control of Heavy Loads at Nuclear Power Plants," dated July 1980.
- NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," dated June 2015.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its Supplement. The staff's use of reactor-based guidance in its evaluation of the SHINE Supplement is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE Supplement. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE Supplement. Additional guidance documents used to evaluate the SHINE Supplement are provided as references in appendix B, “References,” of this SER.

1.2 Summary and Conclusions on Principal Safety Considerations

The NRC staff evaluated the sufficiency of the summary and conclusions on principal safety considerations of the SHINE facility, as presented in SHINE Supplement section 1.2, “Summary and Conclusions of Principal Safety Considerations,” using the guidance and acceptance criteria from section 1.2, “Summary and Conclusions on Principal Safety Considerations,” of NUREG-1537, Parts 1 and 2, and section 1.2, “Summary and Conclusions on Principal Safety Considerations,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement section 1.2 states, in part, that the listing of locations in which radioactive materials are primarily present provided in the SHINE FSAR is not affected by the phased approach to startup, with the exception that the MATB, which is not operational until Phase 3 and, therefore, which does not contain radioactive material during Phases 1 and 2. The NRC staff evaluates the impact of the unavailability of the MATB during Phases 1 and 2 in section 9b, “Radioisotope Production Facility Auxiliary Systems,” and section 11, “Radiation Protection Program and Waste Management,” of this appendix to the SER.

SHINE Supplement section 1.2 states, in part, that the SHINE Safety Analysis (SSA) methodology described in Chapter 13 of the SHINE FSAR was used to evaluate whether any new or different hazards are introduced by the phased approach to startup. The NRC staff evaluates the revised SSA as a result of the phased approach to startup in section 13, “Accident Analyses,” of this appendix to the SER.

1.3 General Description

The NRC staff evaluated the sufficiency of the general description of the SHINE facility, as presented in SHINE Supplement section 1.3, “General Description of the Facility,” using the guidance and acceptance criteria from section 1.3, “General Description,” of NUREG-1537, Parts 1 and 2, and section 1.3, “General Description of the Facility,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement section 1.3 states, in part, that the information provided in SHINE FSAR section 1.3 is not affected by the phased approach to startup, with the exception of the specific number of operational IUs during each phase. SHINE Supplement section 1.3 describes general system isolations and further describes the impact to the IUs, instrumentation and control (I&C) systems, and radiological ventilation from the phased approach to startup. The NRC staff evaluates the general system information in SHINE Supplement section 1.3 in sections 4, “Irradiation Unit and Radioisotope Production Facility Description,” section 5, “Cooling Systems,” section 6, “Engineered Safety Features,” section 7, “Instrumentation and Control Systems,” and section 9, “Auxiliary Systems,” of this appendix to the SER.

1.4 Shared Facilities and Equipment

The NRC staff evaluated the sufficiency of the SHINE shared facilities and equipment, as presented in SHINE Supplement section 1.4, “Shared Facilities and Equipment,” using the guidance and acceptance criteria from section 1.4, “Shared Facilities and Equipment,” of

NUREG-1537, Parts 1 and 2, and section 1.4 of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement section 1.4 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR section 1.4 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER section 1.4, “Shared Facilities and Equipment,” is applicable to the phased approach to startup without further supplementation.

1.5 Comparison with Similar Facilities

The NRC staff evaluated the sufficiency of the comparison of the SHINE facility with similar facilities, as presented in SHINE Supplement section 1.5, “Comparison with Similar Facilities,” using the guidance and acceptance criteria from section 1.5, “Comparison with Similar Facilities,” of NUREG-1537, Parts 1 and 2, and section 1.5, “Comparison with Similar Facilities,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement section 1.5 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR section 1.5 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER section 1.5, “Comparison with Similar Facilities,” is applicable to the phased approach to startup without further supplementation.

1.6 Summary of Operations

The NRC staff evaluated the sufficiency of the SHINE summary of operations, as presented in SHINE Supplement section 1.6, “Summary of Operations,” using the guidance and acceptance criteria from section 1.6, “Summary of Operations,” of NUREG-1537, Parts 1 and 2, and section 1.6 of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement section 1.6 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR section 1.6 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER section 1.6, “Summary of Operations,” is applicable to the phased approach to startup without further supplementation.

1.7 Compliance with the Nuclear Waste Policy Act of 1982

The NRC staff evaluated the sufficiency of SHINE’s compliance with the Nuclear Waste Policy Act of 1982, as presented in SHINE Supplement section 1.7, “Compliance with the Nuclear Waste Policy Act of 1982,” using the guidance and acceptance criteria from section 1.7, “Compliance with the Nuclear Waste Policy Act of 1982,” of NUREG-1537, Parts 1 and 2, and section 1.7 of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement section 1.7 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR section 1.7 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER section 1.7, "Compliance with the Nuclear Waste Policy Act of 1982," is applicable to the phased approach to startup without further supplementation.

1.8 Facility Modifications and History

The NRC staff evaluated the sufficiency of SHINE's description of facility modifications and history, as presented in SHINE Supplement section 1.8, "Facility Modifications and History," using the guidance and acceptance criteria from section 1.8, "Facility Modifications and History," of NUREG-1537, Parts 1 and 2, and section 1.8 of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement section 1.8 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR section 1.8 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER section 1.8, "Facility Modifications and History," is applicable to the phased approach to startup without further supplementation.

1.9 License Condition for the Phased Approach to Startup

By letter dated February 26, 2021 (ML21057A340), as supplemented, SHINE informed the NRC staff of, among other things, its intent to pursue a phased approach to initial operations of the SHINE facility. This approach would consist of four phases of process equipment installation and operation. Phase 1 would include (1) the completion of the entire main production facility structure and the nitrogen purge system structure, (2) IUs 1 and 2 including the associated instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1r, (3) the completion of the RPF with the exception of the installation of the IXP and RLWI selective removal, (4) the installation of TPS train A, and (5) all auxiliary and support systems, except as noted below for the instances of PCLS, LWPS, and RVZ1 equipment located in the cooling room. At the completion of Phase 1, the SHINE facility would be capable of commencing production of molybdenum-99 (Mo-99) using IUs 1 and 2 and TPS Train A.

Phase 2 would include (1) the installation of IUs 3, 4, and 5 and all associated auxiliary and support systems and (2) the installation of TPS Train B. At the completion of Phase 2, the SHINE facility would be capable of producing additional Mo-99 using IUs 3, 4, and 5 and TPS Train B.

Phase 3 would include (1) the installation of IUs 6, 7, and 8 and all associated auxiliary and support systems and (2) the installation of TPS Train C. At the completion of Phase 3, the SHINE facility would be capable of producing additional Mo-99 using IUs 6, 7, and 8 and TPS Train C. Phase 3 would also include the installation of RLWI selective removal components and the MATB.

Phase 4 would include the installation of iodine and xenon purification and packaging components.

By letter dated January 27, 2022 (ML22027A353), SHINE supplemented its operating license application to describe the impacts of its proposed phased approach to startup of the SHINE facility. SHINE explained that the phasing was developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where remaining equipment installation would occur during operation to minimize impacts on the operating portions of the facility. SHINE also explained that each grouping of IUs and their associated auxiliary and support systems and TPS train (i.e., IUs 1 and 2 and TPS Train A; IUs 3, 4, and 5 and TPS Train B; and IUs 6, 7, and 8 and TPS Train C) is capable of operating independently. SHINE specified that isolations at interface points with uninstalled systems would generally consist of one or more valves and blind flanges or caps. To install systems for the subsequent phases, the blind flanges and caps would be removed, and the appropriate process connections would be made. The confinement boundaries for operating systems would not be impacted by installation activities. Similarly, the I&C systems would be installed as part of Phase 1 such that sufficient isolation would exist between the portions of the systems for which construction and installation is complete and are operating and the portions that are still under construction/being installed. Portions of the systems that are not completely constructed/installed when other portions are ready to operate would subsequently be brought online when construction and installation is complete. In the supplement, SHINE FSAR figure 1.1-1, “Physical Layout of Phased Approach to Operation,” which shows the SHINE main production facility and the portions of it that would be installed at each phase.

On August 25, 2022 (ML22105A110), the NRC staff requested additional information on how SHINE intended to satisfy the NRC’s regulations for licensing the SHINE facility under its proposed phased approach to startup. The staff explained that 10 CFR 50.57(a) states that the Commission may issue an operating license upon finding that, among other things, “[c]onstruction of the facility has been substantially completed, in conformity with the construction permit and the application as amended ….” Additionally, 10 CFR 50.57(b) states that “[e]ach operating license will include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety.” Finally, NRC Inspection Procedure (IP) 69022, “Inspections of Operational Readiness during Construction of Non-Power Production and Utilization Facilities” (ML19193A110), provides that licensees are expected to notify the NRC in writing when construction of the facility is substantially complete and to provide to the NRC a complete list of remaining construction and preoperational test activities that must be addressed prior to operation. The IP further states, in part:

> At the time a licensee notifies the NRC that construction is substantially complete, the NRC expects that the safety-related [SSCs] required for initial startup; handling and storage of special nuclear material; shutdown of the facility; and prevention of accidents and the mitigation of consequences of accidents of the [facility] will have been installed at the site. The NRC also expects that the construction and pre-operational tests necessary to ensure the functionality of safety-related SSCs will have been performed and documented by the licensee in accordance with a formal plan. The licensee should have developed the operational test programs necessary

to demonstrate that safety-related SSCs will remain functional during normal conditions and during and following design basis events.

Accordingly, the NRC staff asked SHINE how it interprets the term “facility” in 10 CFR 50.57(a) with respect to the SHINE facility, how it interprets the term “substantially completed” in 10 CFR 50.57(a) with respect to SHINE’s proposed phased approach to startup, and how any SHINE operating license would include appropriate provisions with respect to any “uncompleted items of construction” pursuant to 10 CFR 50.57(b).

By letter dated September 20, 2022 (ML22263A344), SHINE responded that it considers the “facility” as used in 10 CFR 50.57(a) regarding the NRC’s finding of substantial completion to be that described in the SHINE operating license application, as amended, to include the SSCs of the entire facility described in chapter 1 of the SHINE FSAR and that SHINE’s proposed phased approach to startup did not affect this definition of the facility. The NRC staff determined that this interpretation of “facility” in 10 CFR 50.57(a) is acceptable because it is consistent with the history of the licensing of the SHINE facility, which is summarized as follows.

By letters dated March 26, 2013, May 31, 2013, and September 25, 2013 (ML13088A192, ML13172A361, and ML13269A378, respectively), as supplemented, SHINE submitted to the NRC a construction permit application for the SHINE facility. The SHINE construction permit application proposed a single facility for the manufacture of medical radioisotopes that would include both an irradiation facility (IF) and an RPF. In turn, the IF would consist of eight IUs and the RPF would consist of hot cell structures and systems. The NRC staff assigned this application for the SHINE facility to a single docket number, Docket No. 50-608. The staff determined that, although they are not reactors, the IUs within the SHINE facility would achieve a fission rate with a thermal power level comparable to non-power reactors and would also have many safety considerations similar to those of non-power reactors. Therefore, in order to license the IUs using the NRC regulations applicable to non-power reactors, the staff amended the NRC’s definition of “utilization facility” at 10 CFR 50.2 to include “[a]n accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608” (79 *FR* 62329; October 17, 2014). This rulemaking also identified the SHINE facility as a single building in which the IUs and the RPF would be housed. On February 29, 2016 (ML16041A471), the NRC issued a single construction permit under Docket No. 50-608 (Construction Permit No. CPMIF-001) authorizing the construction of the SHINE facility and its eight utilization facilities and one production facility, designed for the production of medical radioisotopes.

SHINE also stated that the construction of the SHINE facility, as defined above, would be substantially completed pursuant to 10 CFR 50.57(a) upon the installation and functional testing of the safety-related SSCs required for initial startup (i.e., Phase 1 operations), the safe handling and storage of special nuclear material, safe shutdown of operational IUs (as defined in technical specifications (TSs)), and the prevention of accidents or the mitigation of consequences of accidents involving installed equipment. SHINE stated that substantial completion of the SHINE facility represents the point in time in which the facility can safely produce medical isotopes (i.e., the facility is functionally complete, as defined in CPMIF-001). The NRC staff determined that this interpretation of “substantially completed” as being prior to the commencement of Phase 1 operations is acceptable because at that time, the SHINE facility would be functionally complete with respect to its purpose, stated in CPMIF-001 as “the production of medical radioisotopes, as described in the [construction permit] application ….” Additionally, as indicated in figure 1.1-1 of the SHINE FSAR, at this time a significant portion of the SHINE facility will be completed, with uncompleted items of construction at discrete locations within the facility.

Regarding uncompleted items of construction, SHINE provided a phase-specific listing of installation and functional testing activities required to support operation of Phase 2, Phase 3, and Phase 4. The NRC staff reviewed this listing and determined that the installation activities are consistent with the phase descriptions provided in the SHINE Supplement. Further, the staff determined that the functional testing activities to support construction completion are consistent with the TS surveillance requirements associated with the equipment to be installed for each phase. Additionally, as explained in sections 4, 6, and 9 of this appendix to the SER, the staff determined that the completion of the uncompleted items of construction during the operation of the SHINE facility, as proposed in the SHINE operating license application and the SHINE FSAR, as amended, would not endanger public health and safety.

Section 50.57(b) of 10 CFR requires each operating license issued by the Commission to include appropriate provisions with respect to uncompleted items of construction and such limitations or conditions as are required to ensure that operation during the period of the completion of such items will not endanger public health and safety. Accordingly, in addition to the NRC staff's determination regarding the reasonableness of SHINE's description of the uncompleted items of construction and the safety of completing the uncompleted items of construction during operation, the staff is imposing a license condition to ensure that the operation of the subsequent phases of the SHINE facility will not be commenced until the associated uncompleted items of construction have been completed and that appropriate NRC oversight of the completion of the uncompleted items of construction is maintained.

The license condition is as follows:

> The licensee shall conduct activities for startup of facility operations in Phases, as described in SHINE Technologies, LLC Application for an Operating License Supplement No. 31, Enclosure 3, "Phased Startup Operations Application Supplement," dated September 28, 2022 (ML22271A962 and ML22271A966), as amended. Operation of Phase 2 or of any subsequent Phase shall not commence prior to satisfaction of conditions (a) and (b) below:
>
> (a) No later than 14 days before the planned commencement of operation of Phase 2, and thereafter no later than 14 days before the planned commencement of operation of each subsequent phase, the licensee shall notify the NRC in writing that all uncompleted items of construction related to that Phase have been completed.
>
> (b) Prior to the operation of Phase 4, the licensee shall provide to the NRC in writing, six months after the issuance of this operating license and every six months thereafter, information on the status and schedule for completion of uncompleted items of construction.

Based on the above, including the imposed license condition, the NRC staff concludes that SHINE's phased approach to startup satisfies 10 CFR 50.57 and is, therefore, acceptable.

2.0 SITE CHARACTERISTICS

Section 2, “Site Characteristics,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the site selection, as presented in SHINE Supplement chapter 2, “Site Characteristics.”

SHINE Supplement chapter 2 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE’s description of site characteristics using the guidance and acceptance criteria from chapter 2, “Site Characteristics,” of NUREG-1537, Parts 1 and 2, and chapter 2, “Site Characteristics,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR chapter 2 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER chapter 2, “Site Characteristics,” is applicable to the phased approach to startup without further supplementation.

3.0 DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

Section 3, “Design of Structures, Systems, and Components,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the design bases of the SSCs, as presented in SHINE Supplement chapter 3, “Design of Structures, Systems, and Components.”

SHINE Supplement chapter 3 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE’s description of the design bases of the SSCs using the guidance and acceptance criteria from chapter 3, “Design of Structures, Systems, and Components,” of NUREG-1537, Parts 1 and 2, and chapter 3, “Design of Structures, Systems, and Components,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR chapter 3 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER chapter 3, “Design of Structures, Systems, and Components,” is applicable to the phased approach to startup without further supplementation.

4.0 IRRADIATION UNIT AND RADIOISOTOPE PRODUCTION FACILITY DESCRIPTION

Section 4, “Irradiation Unit and Radioisotope Production Facility Description,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE IF and RPF, as presented in SHINE Supplement chapter 4a2, “Irradiation Facility Description,” and chapter 4b, “Radioisotope Production Facility Description.”

4a Irradiation Facility Description

Section 4a, “Irradiation Facility Description,” of this appendix to the SER provides the NRC staff evaluation of the final design of the SHINE IF as affected by the proposed phased approach to startup, as presented in SHINE Supplement chapter 4a2.

4a.1 Summary of the Supplement to the Application

SHINE Supplement section 4a2.1, “Summary Description,” identities and describes the systems and equipment that support IF operation at the IU level. The SHINE Supplement further describes the methods of isolation during Phase 1 and Phase 2 operations. For Phase 3 operations, IUs 1–8 are fully operational with supporting systems and equipment as described in SHINE Supplement section 1.1, “Introduction.”

4a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement Chapter 4a2 using the guidance and acceptance criteria from section 4a2, “Aqueous Homogeneous Reactor Description,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement section 4a2.1 states that each IU is designed and operated at the unit level. Each IU contains its own instances of the SCAS, NFDS, TSV, TOGS, neutron driver assembly system (NDAS), irradiation cell biological shield (ICBS), PCLS, LWPS, and RVZ1 equipment. Therefore, each IU can operate independently of the other IUs in the IF, and the descriptions of each IU and the associated nuclear and thermal-hydraulic design are not affected by the phased approach to startup.

SHINE Supplement section 4a2.5, “Irradiation Facility Biological Shield,” states that the ICBS, other than shield plugs, is installed and that IU-specific instances of the shield plugs are installed prior to IU operation to support phased startup operations. The IU cells and the associated primary cooling rooms have biological shields that are designed to allow for maintenance activities to be performed while adjacent IUs are operating, and to meet the as low as is reasonably achievable (ALARA) radiation exposure goals and meet or exceed the requirements in 10 CFR Part 20. This will allow for the IU-specific installation of equipment for the next phase of operation during the preceding phase of operation.

SHINE FSAR section 4a2.1 states that the interfaces to external systems for IUs 3–8 will be isolated during Phase 1 operation. For Phase 2, the interfaces to external systems for IUs 6–8 will be isolated. The isolation at the interfaces is attained by using one or more valves and blind flanges or caps. The systems that are isolated are the vacuum transfer system (VTS), the process vessel vent system (PVVS), the radioisotope process facility cooling system (RPCS), the facility nitrogen handling system (FNHS), the nitrogen purge system (N2PS), and the RVZ1 exhaust lines. Trains B and C of the TPS, which interface with the NDAS in IUs 3–5 and 6–8, respectively, will be implemented in Phases 2 and 3, respectively.

SHINE FSAR section 4a2.1 states that, for each IU, the VTS line to fill the TSV, the VTS line to the TSV dump tank, and the VTS line to the TOGS vacuum all have two isolation valves. The PVVS line that exits the IU cell has one locked closed isolation valve. The FNHS supply lines include one isolation valve. The facility chemical reagent system (FCRS) supply lines include one isolation valve. The N2PS purge lines include one isolation valve and a blind flange or cap. The RPCS interface lines are addressed in chapter 5 of this appendix to the SER and the RVZ1 exhaust lines are addressed in chapter 9 of this appendix to the SER.

SHINE Supplement chapter 13a2, “Irradiation Facility Accident Analysis,” identifies, for the IF, three new accident sequences and the increased likelihood of three existing scenarios related to the proposed phased approach to startup. The new accident scenarios are: (1) improper target solution routing to an uninstalled IU cell; (2) damage to a PVVS to TOGS interface line during installation of the SCAS in an IU; and (3) damage to an installed TPS train during the installation of another TPS train. The existing accident sequences with increased likelihood are: (1) a heavy load drop onto an in-service IU cell or TOGS cell; (2) a heavy load drop on the TPS; and (3) a fire in the IF general area. These are discussed in chapter 13 of this appendix to the SER.

Based on its review, the NRC staff finds that each IU is capable of operating independently of the other IUs and that uncompleted items of construction in the IF can be completed without impacting the operating IUs. The staff also finds that the biological shielding and isolation of systems that interface with the IUs is adequate to allow the completion of uncompleted items of construction during the operation of those IUs.

4a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE’s IF as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 4a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the IF and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4b Radioisotope Production Facility

Section 4b, "Radioisotope Production Facility," of this appendix to the SER provides the NRC staff evaluation of the final design of the SHINE RPF as affected by the proposed phased approach to startup, as presented in SHINE Supplement chapter 4b, "Radioisotope Production Facility Description."

4b.1 Summary of the Supplement to the Application

SHINE Supplement section 4b.1, "Facility and Process Description," states that the RPF and RPF process descriptions provided in SHINE FSAR section 4b.1 are not affected by the proposed phased approach to startup, with the exception of the following:

- The IXP system described in SHINE FSAR subsection 4b.1.3.3 is not available during Phase 1 through Phase 3.
- The RLWI selective removal process described in SHINE FSAR subsection 4b.1.3.8.2 is not available during Phase 1 and Phase 2.
- Solidified waste drums are not transported to the MATB as described in SHINE FSAR subsection 4b.1.3.8.2 during Phase 1 and Phase 2.

SHINE Supplement section 4b.2, "Radioisotope Production Facility Biological Shield," states that the production facility biological shield (PFBS) for the hot cells within the supercell, including the biological shield for the IXP hot cell, is installed prior to Phase 1. However, the IXP system is not installed in the IXP hot cell until Phase 4. During Phase 1 through Phase 3, the supercell confinement boundary is isolated from the IXP hot cell, and the IXP hot cell drain to the radioactive drain system (RDS) is plugged.

SHINE Supplement Section 4b.2 further states that the solid waste drum storage bore holes description provided in the SHINE FSAR is not affected by the phased approach to startup.

SHINE Supplement section 4b.3, "Radioisotope Extraction System," states that the radioisotope extraction process descriptions provided in SHINE FSAR section 4b.3 are not affected by the phased approach to startup, with the exception that the IXP system is not available to extract iodine and xenon and is isolated during Phase 1 through Phase 3. This isolation of the IXP system within the RPF is provided as follows:

- The process line from the molybdenum extraction and purification system (MEPS) is isolated with manual valves and a blind flange or cap.
- The process line to the target solution staging system (TSSS) is isolated with a manual valve and a blind flange or cap.
- The VTS line is isolated with a manual valve and a blind flange or cap.

- Each waste line to the radioactive liquid waste storage system (RLWS) is isolated with a manual valve and a blind flange or cap.

- Each FNHS supply line is isolated with a manual valve and a blind flange or cap.

- Each PVVS vent line is isolated with a manual valve and a blind flange or cap.

- Each FCRS supply line is isolated with a manual valve and a blind flange or cap.

- The radiological ventilation zone 2 (RVZ2) supply air to the IXP elute hold tank (also the N2PS supply) is isolated with a manual valve and a blind flange or cap.

- The RVZ1 cryotrap exhaust line is isolated with a manual valve and a blind flange or cap.

- The molybdenum isotope product packaging system (MIPS) does not receive product from the IXP system.

- The solid radioactive waste packaging system does not receive waste from the IXP system.

SHINE Supplement section 4b.4, “Special Nuclear Material Processing and Storage,” states that the special nuclear material processing and storage description provided in SHINE FSAR section 4b.4 is not affected by the phased approach to startup, with the exception that the IXP system is not available during Phase 1 through Phase 3. During Phase 1 through Phase 3, the IXP system does not extract iodine and xenon, and reagents are not added to target solution by the IXP system. In addition, the IXP system does not contain the special nuclear material (SNM) identified in SHINE FSAR table 4b.4-2.

4b.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 4b using the guidance and acceptance criteria from section 4b, “Radioisotope Production Facility Description,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The NRC staff evaluated the effects of the proposed phased approach to startup on the descriptions associated with the RPF from the standpoint of completeness and allowing safe operation and the completion of uncompleted items of construction during the four phases as described in SHINE Supplement section 4b.1. Specifically, the staff evaluated the descriptions associated with the isolation of the supercell confinement boundary from the IXP hot cell during Phase 1 through Phase 3, the unavailability of the RLWI selective removal process during Phase 1 and Phase 2, and the lack of transport of solidified waste drums to the MATB during Phase 1 and Phase 2.

Since the IXP system described in SHINE FSAR subsection 4b.1.3.3 is not available during Phase 1 through Phase 3, target solution is not directed to the IXP hot cell and the PVVS does not interface with the IXP. In addition, the RLWS system does not collect liquid wastes from the IXP system, and the MIPS does not receive product from the IXP system. The isolation of the IXP hot cell from the RPF will ensure that there are no pathways for radioactive material to enter the IXP system.

Based on the above, the NRC staff finds that accessing the IXP system prior to Phase 4 for purposes such as to install and connect the systems in the IXP to the RPF, will not result in a radiation hazard to the workers from direct or inhalation exposures. Additionally, the staff finds that the description of the IXP system is sufficiently detailed to allow the staff to conduct its safety evaluation addressed in other sections of this appendix to the SER. Therefore, the staff concludes that the description in SHINE Supplement section 4b.1 is in accordance with the ALARA requirement and limits of 10 CFR Part 20, and 10 CFR Part 50, and is consistent with the guidance in the ISG and thus is acceptable.

The NRC staff evaluated the effects of the phased approach to startup on the description of the biological shielding within the RPF from the standpoint of completeness and allowing safe operation and the completion of uncompleted items of construction during the four phases as described in SHINE Supplement section 4b.2. Specifically, the staff evaluated the timing of the installation of the biological shield and the isolation of the supercell confinement boundary from the IXP hot cell during Phase 1 through Phase 3.

The PFBS hot cells (supercell), including the IXP hot cell, is installed prior to Phase 1. However, during Phase 1 through Phase 3, the IXP system is not installed within the IXP hot cell, and the IXP hot cell is isolated from the supercell confinement boundary. Since most shielding and hot cell construction activities will occur prior to operation (i.e., prior to Phase 1), the potential for radiation exposures to construction workers prior to Phase 4 will be minimized in accordance with the ALARA principle. During Phase 1 through Phase 3, the IXP hot cell does not provide a confinement function and the other hot cells are isolated from the IXP hot cell. The IXP hot cell transfer doors to the adjacent hot cell are locked closed and the IXP hot cell drain to RDS is plugged. The IXP hot cell is isolated from radiological ventilation systems. The purpose of these features is to ensure that there is no pathway for radioactive materials to be introduced into the IXP hot cell thereby minimizing the potential for unintentional radiation exposures emanating from the IXP system to workers and the public during Phase 1 through Phase 3 in accordance with the ALARA principle.

Based on the above, the NRC staff finds that the IXP hot cell is adequately isolated during Phase 1 through Phase 3, such that there is no pathway for radioactive materials to be introduced into it thereby protecting the workers from unintentional exposures and the public and environment from any releases of radioactivity. Additionally, the staff finds that the storage waste drum boreholes installed prior to Phase 1 are a stand-alone system and are not affected by the phased approach to startup. The staff also finds that the description provided in SHINE Supplement section 4b.2 is sufficiently detailed to allow the staff to conduct its safety evaluation addressed in other sections of this appendix to the SER. Therefore, the staff concludes that the description in SHINE Supplement section 4b.2 is in accordance with the ALARA requirement and limits of 10 CFR Part 20, and 10 CFR Part 50, and is consistent with the guidance in the ISG and thus is acceptable.

The NRC staff evaluated the effects of the phased approach to startup on the description of the radioisotope extraction process from the standpoint of completeness and allowing safe operation and the completion of uncompleted items of construction during the four phases as described in SHINE Supplement section 4b.3. The only system within the radioisotope extraction system that would be affected by the phased approach to startup is the IXP system, in that it would be isolated during Phase 1 through Phase 3. As discussed above, the staff evaluated the isolation of the interfacing process and supporting system connections to the IXP system during Phase 1 through Phase 3. Specifically, the staff evaluated the isolation methods using valves and blind flanges or caps and determined that there is no pathway for radioactive materials to be introduced into the IXP system during Phase 1 through Phase 3.

Based on the above, the NRC staff finds that unintentional exposure of workers and the public to radioactive material from the radioisotope extraction system will be prevented during the phased approach to startup. Additionally, the staff finds that the description provided in SHINE Supplement section 4b.3 is sufficiently detailed to allow the staff to conduct its safety evaluation addressed in other sections of this appendix to the SER. Therefore, the staff concludes that the description in SHINE Supplement section 4b.3 is in accordance with the ALARA requirement and limits of 10 CFR Part 20, and 10 CFR Part 50, and is consistent with the guidance in the ISG and thus is acceptable.

The NRC staff evaluated the description of the SNM processing and storage systems within the RPF from the standpoint of completeness and allowing safe operation and the completion of uncompleted items of construction during the four phases as described in SHINE Supplement section 4b.4.

The IXP system does not extract iodine and xenon and reagents are not added to target solution by the IXP system during Phase 1 through Phase 3. The IXP system does not contain the SNM identified in SHINE FSAR table 4b.4-2 during Phase 1 through Phase 3. TSSS interfaces with the IXP system are isolated as identified in SHINE Supplement section 4b.3.

Based on the above, the NRC staff finds that unintentional exposure of workers and the public to radioactive material as a result of SNM processing and storage will be prevented during the phased approach to startup. Additionally, the staff finds that the description provided in SHINE Supplement section 4b.4 is sufficiently detailed to allow the staff to conduct its safety evaluation addressed in other sections of this appendix to the SER. Therefore, the staff concludes that the description in SHINE Supplement section 4b.4 is in accordance with the ALARA requirement and limits of 10 CFR Part 20, and 10 CFR Part 50, and is consistent with the guidance in the ISG and thus is acceptable.

4b.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's RPF as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 4b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the RPF and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE’s RPF as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

5.0 COOLING SYSTEMS

Section 5, “Cooling Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE cooling systems, as presented in SHINE Supplement chapter 5a2, “Irradiation Facility Cooling Systems,” and Chapter 5b, “Radioisotope Production Facility Cooling Systems.”

5a Irradiation Facility Cooling Systems

Section 5a, “Irradiation Facility Cooling Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the final design of the SHINE IF cooling systems as affected by the phased approach to startup, as presented in SHINE Supplement chapter 5a2.

5a.1 Summary of the Supplement to the Application

SHINE Supplement section 5a2.2, “Primary Closed Loop Cooling System,” states that each IU is supported by an IU-specific instance of the PCLS during phased startup. Unit-specific instances of PCLS are operational for IUs 1 and 2 in Phase 1, IUs 1 through 5 in Phase 2, and IUs 1 through 8 in Phases 3 and 4. Interfaces between instances of PCLS that have not yet been installed and non-IU-specific supporting systems (i.e., RPCS, facility demineralized water system (FDWS), and RVZ1 exhaust subsystem (RVZ1e)) will be isolated during the phased approach to startup with a manual valve and a blind flange or cap.

SHINE Supplement section 5a2.3, “Radioisotope Process Facility Cooling System,” states that the RPCS is installed to support Phase 1 operations. The RPCS is isolated from uninstalled IU-specific systems (PCLS, TOGS, NDAS cooling cabinets, and RVZ1r IU supplemental cooling) with a manual valve and a blind flange or cap.

SHINE Supplement section 5a2.4, “Process Chilled Water System,” states that the process chilled water system (PCHS) is installed to support Phase 1 operations. The PCHS is a closed chilled system that removes heat from the RPCS from within the radiologically controlled area (RCA) and rejects the heat to the environment. The PCHS is a nonsafety-related system and is not credited with preventing or mitigating any design basis events.

SHINE Supplement section 5a2.5, “Primary Closed Loop Cooling System Cleanup Side Stream,” states that each IU is supported by an IU-specific instance of the PCLS (including an IU-specific instance of the PCLS cleanup side stream) installed to support phased startup. Phased startup of the PCLS is described in SHINE Supplement section 5a2.2.

SHINE Supplement section 5a2.6, “Facility Demineralized Water System,” states that the FDWS is installed to support Phase 1 operations and interface points with IU-specific systems (i.e., the PCLS and LWPS) are isolated to support phased startup (i.e., interfaces with IU-specific systems supporting IUs 3 through 8 are isolated during Phase 1 operation, and interfaces with IU-specific systems supporting IUs 6 through 8 are isolated during Phase 2 operation). The FDWS supply interfaces with the PCLS and LWPS are isolated with a manual valve and a blind flange or cap.

5a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 5a2 using the guidance and acceptance criteria from section 5a2, “Aqueous Homogeneous Reactor Cooling Systems,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

Because the designs of the PCLS and LWPS are IU-specific, the NRC staff finds that the conclusions reached in SER section 5a.4.2, “Primary Cooling System,” are not affected by the proposed phased approach to startup. Additionally, based on its review of SHINE Supplement section 5a2.2, the staff finds that the PCLS and LWPS systems for IUs 3 through 8 will be appropriately isolated from non-IU-specific systems prior to their installation.

Due to the limited number of IUs in operation during Phase 1 and Phase 2, the heat removal capability of the PCHS will exceed the RPCS heat loads generated. Because the PCHS is installed prior to operation, the NRC staff finds that the PCHS can operate as an independent system and meet plant demands during the phased approach to startup.

The PCLS cleanup side stream maintains the required water quality limits of the PCLS. The PCLS cleanup side stream components are in the primary cooling room, directly adjacent to the IU cells. The location, shielding, and radiation monitoring of the water cleanup system are consistent with PCLS design. Because the design of the cleanup system is IU-specific and an integral part of the PCLS, the cleanup system can perform its function through all phases of startup. Therefore, the NRC staff finds that the conclusions reached in SER section 5a.2.5 are not affected by the proposed phased approach to startup.

The FDWS is a non-safety system providing makeup of cooling water loss in the IU-specific instances of the PCLS and LWPS, which occurs gradually from radiolysis and evaporation. Water loss in the PCLS, RPCS, facility chilled water system (FCHS), MEPS hot water subsystem, and PCHS may also occur from off-normal events such as leaks or for maintenance. The FDWS is supplied water from the facility potable water system (FPWS), which is described in SHINE Supplement section 9b.7.7, “Facility Potable Water System,” and is not affected by the phased approach to startup. Therefore, the FDWS supply will be available during phased startup. Because the FDWS is installed to support Phase 1 and interface points with IU-specific systems are isolated, the FDWS can perform its function and the conclusions reached in SER section 5a.2.6 are not affected by the proposed phased approach to startup.

SHINE FSAR section 5a2.3.1, “Design Bases and Functional Requirements,” states that the RPCS rejects heat to the PCHS. Makeup water is supplied by the FDWS. The RPCS removes heat from the:

- PCLS;
- NDAS cooling cabinets;
- TOGS;
- Recirculating heating, ventilation, and air conditioning (HVAC) fan-coil units that are part of RVZ1r;

- Recirculating HVAC fan-coil units that are part of the RVZ2 recirculating cooling subsystem (RVZ2r);
- Target solution preparation system (TSPS);
- PVVS; and
- MEPS.

These system interfaces are also depicted in SHINE FSAR figure 5a2.3-1. The SHINE Supplement indicates that non-IU specific systems that interface with the RPCS, including PCHS, FDWS, PVVS, and all RPF systems, excluding the IXP and RLWI (e.g., MEPS and TSPS), are available for operation in Phase 1.

The NRC staff reviewed SHINE Supplement section 5a2.3 and finds that the RPCS will be appropriately isolated from IU-specific systems prior to their installation. Non-IU-specific systems that interface with the RPCS will be installed with the RPCS prior to Phase 1 and, therefore, no isolations are required.

The NRC staff concluded in SER section 5a.4.3.2, "Radioisotope Process Facility Cooling System Conclusion," that the RPCS meets the acceptance criteria in section 5a2.3, "Secondary Cooling System," of the ISG augmenting NUREG-1537, Part 2, with respect to that the SHINE facility is designed to ensure that the RPCS pressure is maintained higher than the PCLS pressure across the heat exchangers under all anticipated conditions to avoid potential leakage of contaminants to the RPCS, and that the secondary cooling system (i.e., the RPCS) is closed. In its letter dated May 23, 2022, SHINE confirmed that this pressure cascade will be maintained in each RPCS piping configuration employed during the phased approach to startup.

Based on the above, the NRC staff concludes that the conclusions reached in SER section 5a.4.3.2 are not affected by the phased approach to startup.

5a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's IF cooling systems as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 5a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the IF cooling systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF cooling systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

5b Radioisotopes Production Facility Cooling Systems

SHINE Supplement chapter 5b states that the cooling systems are integrated throughout the SHINE facility. Therefore, the summary of the supplement to the application, technical evaluation, and review findings provided in section 5a of this appendix to the SER are applicable to both the IF and the RPF.

6.0 ENGINEERED SAFETY FEATURES

Section 6, “Engineered Safety Features,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE engineered safety features (ESFs), as presented in SHINE Supplement chapter 6a2, “Irradiation Facility Engineered Safety Features,” and chapter 6b, “Radioisotope Production Facility Engineered Safety Features.”

6a Irradiation Facility Engineered Safety Features

Section 6a, “Irradiation Facility Engineered Safety Features,” of this appendix to the SER provides the NRC staff’s evaluation of the final design of the SHINE IF ESFs as affected by the proposed phased approach to startup, as presented in SHINE Supplement chapter 6a2.

6a.1 Summary of the Supplement to the Application

SHINE Supplement section 1.1 states that the phased approach to startup was developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where remaining equipment installation is occurring during different phases to minimize impacts on the operating portions of the facility. Each IU has a dedicated IU cell, TOGS cell, and primary cooling room. This design results in an installation area for the nonoperating IUs that is physically separate from the operating IUs. The IU cells and primary cooling rooms are designed to allow access for maintenance or other operational needs while adjacent IUs are operating.

The phased approach to startup is divided into four phases. Phase 1 brings the Mo-99 production capability online and Phases 2 and 3 increase this capability. During Phase 1, the equipment necessary to support the operation of IUs 1 and 2 are functional and available for operation. During Phase 2, the equipment necessary to support the operation of IUs 1 through 5 are functional and available for operation. During Phase 3, the equipment necessary to support the operation of all IUs (i.e., IUs 1 through 8) are functional and available for operation. Phase 4 adds iodine and xenon production capability. The SHINE Supplement describes the sequence in which the IUs will become operational during the phased approach to startup and the configuration of the IF ESFs during the different phases of startup. SHINE Supplement section 6a2.1, “Summary Description,” states that the summary descriptions provided in SHINE FSAR section 6a2.1 are not affected by the phased approach to startup.

6a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 6a2 using the guidance and acceptance criteria from section 6a2, “Aqueous Homogeneous Reactor Engineered Safety Features,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

In its evaluation, the NRC staff reviewed the pertinent information associated with the proposed phased approach to startup as described in SHINE Supplement chapter 6a2. The specific system-level isolations necessary for safe operation of the facility during the phased approach to startup are described in the applicable sections of this appendix to the SER that address those specific systems.

Primary Confinement Boundary

The SHINE Supplement states that the information provided in SHINE FSAR subsection 6a2.2.1.1, including figure 6a2.2-1, is described on a per IU basis and is, therefore, not affected by the phased approach to startup.

During Phase 1, the primary confinement boundaries for IUs 1 and 2 are operable. The passive confinement provided by physical barriers such as concrete and steel boundaries, and sealed access plugs will be in place for IUs 1 and 2 during Phase 1. The active isolations for the process and ventilation systems will also be in place for IUs 1 and 2 during Phase 1 to respond to any potential accidents/events analyzed in the SHINE FSAR. For the primary confinement boundaries that are not operable in Phase 1, system isolations will be in place to prevent a release of radiological or chemical hazards into the uninstalled IUs. During Phase 2, the primary confinement boundaries for IUs 1 through 5 are operable. A similar sequencing of passive and active isolations will be followed for IUs 1 thorough 5 during Phase 2, including system isolations to prevent a release of radiological or chemical hazards into the uninstalled IUs. The primary confinement boundaries for all 8 IUs will be operational during Phases 3 and 4. The isolation points are further described in SHINE Supplement chapter 4a2 for isolation within the IU and in chapter 4b for isolation points in systems located within the below grade confinement. The NRC staff review of chapters 4a2 and 4b of the SHINE Supplement address these isolation features.

Based on its review, the NRC staff finds that each IU is capable of operating independently of the other IUs and that uncompleted items of construction in the IF can be completed without impacting the operating IUs. The staff also finds that the biological shielding and ESF isolations of systems that interface with the operating IUs including system isolations with the uninstalled IUs is adequate to allow the completion of uncompleted items of construction during the operation of those IUs.

Tritium Confinement Boundary

The information provided in SHINE Supplement subsection 6a2.2.1.2 is described on a per TPS train basis and is not affected by the proposed phased approach to startup. For Phase 1 operations, only Train A of the TPS is installed, which fully and independently supports the operation of IUs 1 and 2. For Phase 2 operations, Trains A and B of the TPS are installed, with Train B fully and independently supporting the operation of the IUs installed as part of Phase 2 (i.e., IUs 3 through 5). For Phases 3 and 4 operations, the TPS trains and IUs are installed in full, with Train C fully and independently supporting the operation of the IUs installed as part of Phase 3 (i.e., IUs 6 through 8).

SHINE FSAR figure 6a2.2-2 is not impacted by the phased approach to startup, with the exception of the number of TPS trains and IUs installed for each phase. SHINE Supplement figure 6a2.2-1, "Tritium Confinement Boundary," provides an update to SHINE FSAR figure 6a2.2-2 to reflect the number of TPS trains and IUs in operation during Phase 1 and Phase 2. The NRC staff finds that the updated figure 6a2.2-1 is consistent with the description of the phased approach to startup of the TPS trains in the SHINE Supplement.

Combustible Gas Management

The SHINE Supplement states that the description of combustible gas management provided in SHINE FSAR section 6a2.2.2 is not affected by the proposed phased approach to startup.

SHINE Supplement figure 6a2.2-2, “Irradiation Facility Combustible Gas Management Functional Block Diagram,” provides an update to SHINE FSAR figure 6a2.2-3 to reflect the number of IUs in operation during Phase 1 and Phase 2. The NRC staff finds that the updated figure is consistent with the description of the phased approach to startup in the SHINE Supplement.

<u>Conclusion</u>

The ESFs and combustible gas management feature descriptions and the updated figures included in the SHINE Supplement provide sufficient detail and clarity to convey the interim configuration of the systems in each of Phases 1, 2, 3, and 4.

Based on its review, the NRC staff finds that each IU is capable of operating independently of the other IUs and that uncompleted items of construction in the IF can be completed without impacting the operating IUs during the phased approach to startup.

6a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE’s IF ESFs as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 6a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the IF ESFs and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE’s IF ESFs as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

6b Radioisotope Production Facility Engineered Safety Features

Section 6b, “Radioisotope Production Facility Engineered Safety Features,” of this appendix to the SER provides the NRC staff evaluation of the final design of the SHINE RPF ESFs as affected by the proposed phased approach to startup, as presented in SHINE Supplement chapter 6b, “Radioisotope Production Facility Engineered Safety Features.”

6b.1 Summary of the Supplement to the Application

To support the installation of the IXP system as part of Phase 4, the IXP hot cell is not part of the supercell confinement in Phases 1, 2, and 3 operations. SSCs are installed to isolate any connections to the IXP system from other installed systems. Isolation is maintained between the IXP cell and the other hot cells using the bubble tight dampers shown in SHINE FSAR figure 9a2.1-3. These dampers remain closed until the IXP cell is in operation to maintain the supercell confinement boundary. SHINE Supplement figure 6b.2-1, “Supercell Confinement Boundary,” provides a block diagram of the supercell confinement boundary in Phases 1, 2, and 3.

The subgrade equipment and confinement, as described in SHINE FSAR Chapter 6b, is installed as part of Phase 1. Isolation capability is provided to segregate the installed subgrade equipment from equipment that is installed as part of subsequent phases. These isolation SSCs remain operational during and following any design-basis accident (DBA), including seismic events and loss of offsite power.

6b.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 6b using the guidance and acceptance criteria from section 6b, “Radioisotope Production Facility Engineered Safety Features and Items Relied on for Safety,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

In its evaluation, the NRC staff reviewed the pertinent information associated with the proposed phased approach to startup as described in SHINE Supplement chapter 6b. The specific system-level isolations necessary for safe operation of the facility during the phased approach to startup are described in the applicable sections of this appendix to the SER that address those specific systems.

SHINE Supplement sections 6b.1, “Summary Description,” and 6b.2, “Detailed Descriptions,” provide a description of the RPF ESFs during the phased approach to startup. The subgrade equipment and confinement, as described in SHINE FSAR chapter 6b, are installed as part of Phase 1. Isolation capability is provided to segregate the installed subgrade equipment from equipment that is installed as part of subsequent phases. These isolation SSCs remain operational during and following any DBA, including seismic events and loss of offsite power. The PVVS isolation and combustible gas management ESFs are not affected by the phased approach to startup. The RPF DBAs, the ESFs required to mitigate the DBAs, and the location of the bases for these determinations provided in SHINE FSAR table 6b.1-1 are not affected by the phased approach to startup.

Confinement

The information provided in SHINE FSAR subsection 6b.2.1 is not affected by the phased approach to startup. The ESFs described in SHINE FSAR figure 6b.1-1 are not affected by the phased approach to startup.

Supercell Confinement

The IXP system equipment is not installed as part of Phase 1, 2, or 3. However, the IXP cell, including the confinement box and bubble tight isolation dampers, are installed. To allow for the installation of the IXP equipment within the IXP hot cell during Phases 1, 2, and 3, the IXP hot cell is isolated from the other nine cells of the supercell and is, therefore, not considered part of the supercell confinement. Isolation of interfacing process and supporting systems to IXP equipment during Phases 1, 2, and 3 is addressed in section 4b of this appendix to the SER. Isolation of ventilation to the IXP hot cell during Phases 1, 2, and 3 is described in section 9a of this appendix to the SER. A complete listing of the IXP hot cell isolations is provided in SER section 4b, “Radioisotope Production Facility.” SHINE Supplement figure 6b.2-1 provides a block diagram of the supercell confinement boundary applicable to Phases 1, 2, and 3.

Below Grade Confinement

As part of Phase 1, the below grade confinement is installed in full, as described in SHINE FSAR subsection 6b.2.1.2, to support initial (i.e., Phase 1) operations of the SHINE facility. The below grade confinement functional block diagram, as described in SHINE FSAR figure 6b.2-2, is not affected by the phased approach to startup.

Process Vessel Vent Isolation

As part of Phase 1, the process vessel vent isolation SSCs are installed in full, as described in SHINE FSAR subsection 6b.2.2, to support initial (i.e., Phase 1) operations of the SHINE facility. The process vessel ventilation isolations are described in the applicable sections of this SER.

Combustible Gas Management

As part of Phase 1, the combustible gas management system is installed in full, as described in SHINE FSAR subsection 6b.2.3, to support initial (i.e., Phase 1) operations of the SHINE facility. The RPF combustible gas management functional block diagram, as described in SHINE FSAR figure 6b.2-3, is not affected by the phased approach to startup.

Conclusion

The NRC staff finds that the description in SHINE Supplement chapter 6b is adequate and acceptable. Based on the above, the staff concludes that the conclusions reached in SER section 6b are not affected by the proposed phased approach to startup. In addition, based on the above, the staff has reasonable assurance that the RPF can operate safely during all four phases and remain unimpacted by the completion of uncompleted items of construction during the four phases.

6b.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE’s RPF ESFs as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 6b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the RPF ESFs and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's RPF ESFs as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

7.0 INSTRUMENTATION AND CONTROL SYSTEMS

Section 7, “Instrumentation and Control Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE I&C systems, as presented in SHINE Supplement chapter 7, “Instrumentation and Control Systems.”

7.1 Summary of the Supplement to the Application

In support of the phased approach to startup, SHINE Supplement chapter 7 states that the I&C systems required for the safe operation of the process equipment in each phase are fully tested and operable. Sufficient isolation exists between operable and non-operable portions of the systems to ensure that the non-operable portions do not impact the safe operation of the operable portions. During installation and startup of the I&C systems for subsequent phases, adequate separation and isolation are maintained such that the operable portions of the systems are not adversely impacted. The following I&C systems/components are installed and tested in the SHINE facility control room (FCR) prior to initial (i.e., Phase 1) operations:

- Operator workstations, NDAS workstations, supervisor workstation, and the main control board as described in SHINE FSAR section 7.6;
- Cabling, conduit, and raceways for the process integrated control system (PICS) monitoring and control functions;
- Normal and uninterruptible electrical power supply systems (the normal electrical power supply system (NPSS) and uninterruptible electrical power supply system (UPSS) A and B);
- Nine TSV Reactivity Protection System (TRPS) cabinets (3 each for Divisions A, B, and C); and
- Three Engineered Safety Features Actuation System (ESFAS) cabinets (1 each for Divisions A, B, and C).

Except for the digital I&C hardware associated with TPS Trains B and C, all of the PICS I&C hardware (i.e., cabinets, power supplies, controllers, and programmable logic controllers) is installed prior to Phase 1. PICS monitoring includes inputs to PICS from field instruments. PICS monitoring and controls associated with equipment that is not yet installed or not yet operable to support Phase 1 are tested and placed in operation as required for subsequent phases. PICS controls include outputs to field equipment to perform process control functions. All the PICS related cabling, conduit, and raceways for monitoring and control functions will be installed prior to Phase 1.

Prior to initial (i.e., Phase 1) operations, the following vendor-provided control systems are made operable:

- Building automation system;
- Supercell control system;
- RLWI control system (except portions associated with selective removal);

- NDAS control system (NDAS units required for a given phase are connected to the NDAS control system and made operational to support the phase); and
- Integral controllers associated with:
  - Standby generator system (SGS);
  - FDWS reverse osmosis unit;
  - FNHS unit;
  - Facility heating water system (FHWS) boilers;
  - FCHS; and
  - PCHS chillers.

The IXP system's monitoring and alarms, control functions, and interlocks and permissives are made available when the system is made operational to support Phase 4.

The PICS equipment associated with the N2PS, radiological ventilation systems, RPCS, FNHS, and FCRS will be connected and tested as equipment is made operational to support a given phase.

The PICS software development and testing will be completed during each phase. During the phased approach to startup, each input to the PICS will be validated from the field to the cabinet as the field devices are installed and cabinet side leads terminated. Site acceptance testing is completed for the full set of equipment applicable to each phase prior to entering the phase.

All nine TRPS cabinets installed in the FCR prior to Phase 1 are brought into operation as follows:

- For Phase 1, Divisions A, B, and C TRPS cabinets associated with IUs 1 and 2 are made operational. The PICS hardware, monitoring, and controls for TPS Train A are installed to serve IUs 1 and 2.
- For Phase 2, Divisions A, B, and C TRPS cabinets associated with IUs 3, 4, and 5 are made operational. The PICS hardware, monitoring, and controls for TPS Train B are installed to serve IUs 3, 4, and 5.
- For Phase 3, Divisions A, B, and C TRPS cabinets associated with IUs 6, 7, and 8 are made operational. The PICS hardware, monitoring, and controls for TPS Train C are installed to serve IUs 6, 7, and 8.

Manual TPS isolation capability from both the facility master operating permissive and the manual push button are also phased such that only the installed TPS trains are isolated.

For each IU, associated NFDS and the RVZ1e IU cell radiation monitors are brought online in the corresponding phases.

The PICS monitoring and alarms, control functions, and interlocks and permissives associated with each IU will function as described in SHINE FSAR section 7.3.1.1 as the associated equipment is made operable to support an individual IU in a given phase.

All the ESFAS cabinets in the FCR are installed prior to Phase 1. Affected safety function modules (SFMs) of the HIPS platform that implement ESFAS are modified to accommodate the phased approach to startup. This HIPS SFM modification allows disabling of an individual input that is not required for a given phase. The disabling of individual inputs is required in Phases 1, 2, and 3 related to ESFAS equipment that is not yet operable. Individual inputs for each safety actuation not required to be operable in a given phase are disabled across all divisions. Information for inputs that are disabled is transmitted to the PICS and displayed to the operator as described in SHINE FSAR section 7.6.3. The disabled inputs are restored to operable status prior to entering the TS mode of applicability for the given input.

The safety functions associated with Supercell Area 10 (IXP Area) Isolation, VTS Safety Actuation, TPS Train B Isolation, TPS Train C Isolation, TPS Process Vent Actuation, IU Cell Nitrogen Purge, RCA Isolation, and IXP Alignment Actuation, as described in SHINE FSAR section 7.5.3.1, have inputs disabled and safety functions not utilized during the phased approach to startup, as described in SHINE Supplement tables 7.5-1, “Monitored Variable Inputs Disabled During Phases of Startup Operations,” and 7.5-2, “Safety Functions Not Utilized During Phases of Startup Operations.”

The functionality of disabling inputs is tested as part of the pre-factory acceptance test and the factory acceptance test, as described in SHINE FSAR section 7.4.5.4.7, “Independent Testing.” All of the inputs for ESFAS and TRPS are tested as part of the site acceptance test prior to Phase 1. Upon successful completion of the site acceptance test, TRPS cabinets associated with Phases 2, 3, and 4 are removed from operation and the ESFAS inputs associated with Phases 2, 3, and 4 are disabled. Prior to enabling the inputs to ESFAS for a given subsequent phase, the maintenance workstation is used to configure the inputs such that it does not affect equipment in operation. These ESFAS inputs are then enabled, verified, and the setpoint adjusted to the design value prior to being declared for applicable phased operations.

The manual push buttons identified in SHINE FSAR section 7.5.3.6 will only actuate safety functions utilized in a given phase.

During Phase 1, the following local PICS control stations are functional and available for operation:

- Target solution preparation;
- Radioactive liquid waste immobilization;
- Supercell A;
- Supercell B;
- Supercell C; and
- TPS Train A.

During Phase 2, in addition to the above local PICS control stations, the TPS Train B control station is functional and available for operation.

During Phase 3, the eighth and final local PICS control station, the TPS Train C control station, is functional and available for operation.
During the phased approach to startup, indication is provided to the operator for components that have been disabled and for components that have not been field terminated.

Safety-related process radiation monitors required for Phase 1 are installed prior to Phase 1. Safety-related process radiation monitors not required for Phase 1 are installed to support the phased operation of the IUs, TPS trains, and IXP system. The safety-related process radiation monitors are installed to the extent practicable given the extent of equipment installation. Radiation monitors required for the safe operation of the process equipment in each phase are fully tested and operable before that phase. Radiation monitors associated with individual IUs and TPS trains are installed for the phase associated with that IU or TPS train. SHINE Supplement table 7.7-1, "Safety-Related Process Radiation Monitor Phasing," provides a list of the safety-related process radiation monitors and the phase in which they will be operable to support operation.

All nonsafety-related process radiation monitoring and nonsafety-related radiation monitoring systems are installed prior to Phase 1.

7.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 7 using the guidance and acceptance criteria from chapter 7, "Instrumentation and Control Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Based on the information provided in SHINE Supplement chapter 7, the NRC staff finds that:

- The TRPS for each IU cell that is in operation in a given phase is capable of independently performing all the safety functions identified in SHINE FSAR section 7.4.3.1. Since all 3 divisions of the TPRS are operable for the applicable IU cell, the operable TRPS will continue to meet all relevant SHINE design criteria.

- In each phase, the ESFAS is capable of performing all safety functions identified in SHINE FSAR section 7.5.3.1 for the systems that are operable in that phase. Monitored variable inputs to the ESFAS that are disabled in Phases 1, 2, and 3 do not adversely impact the performance of any safety function required for operable systems. Since all 3 divisions of the ESFAS are operable, ESFAS will continue to meet all relevant SHINE design criteria for the operable systems.

- For the IU cells that are not in service during Phases 1 and 2, nitrogen purge signals that are transmitted from the TRPS to the ESFAS for nitrogen purge actuation are not disabled. Since these ESFAS input signals are not asserted by TRPS for IU cells not in operation, the nitrogen purge actuation capabilities for the IU cells that are in service are not impacted. Therefore, disabling/enabling these ESFAS input signals is not necessary for the phased approach to startup.

- The status of the disabled ESFAS inputs is transmitted to the PICS and displayed to the operator consistent with human factors design criteria described in SHINE FSAR section 7.6.2.2.7.

- Except for the TPS Trains B and C local control stations, all the PICS local control stations are functional to support Phase 1. The TPS Train B local control station is made functional for Phase 2 to support IU cells 3, 4, and 5 operations and the TPS Train C local control station is made functional for Phase 3 to support IU cells 6, 7, and 8 operations.

- The functionality of disabling inputs to ESFAS SFMs is tested as part of the pre-factory acceptance test and the factory acceptance test, as described in SHINE FSAR section 7.4.5.4.7. All of the inputs for ESFAS and TRPS are tested as part of the site acceptance test, as described in SHINE FSAR section 7.4.5.4.2.6, prior to Phase 1. Upon successful completion of the site acceptance test, TRPS cabinets associated with Phases 2, 3, and 4 are removed from operation, and the ESFAS inputs associated with Phases 2, 3, and 4 are disabled.

- Prior to enabling the inputs to ESFAS for subsequent phases, the maintenance workstation is used to configure the inputs such that they do not affect equipment in operation. Each input is then enabled, verified, and the setpoint adjusted to the design value prior to process equipment operation.

- All required safety-related process radiation monitors are made functional for each phase of operation and provide inputs to TRPS and ESFAS for IU cell safety actuation and isolation functions.

Based on the above technical evaluation, the NRC staff finds that during the phased approach to startup the SHINE I&C systems, as described in SHINE FSAR chapter 7, will continue to meet all applicable SHINE design criteria and are capable of performing the required safety functions during each phase such that the uncompleted items of construction can be completed without impacting the operating systems.

7.3 Human Factors Engineering

The SHINE design criteria are provided in SHINE FSAR section 3.1, “Design Criteria,” table 3.1-3, “SHINE Design Criteria.” The following design criterion is applicable to the human factors engineering (HFE) review:

> Criterion 6, “Control room”
>
> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

The NRC staff evaluates whether the SHINE facility meets the HFE-related aspects of SHINE Design Criterion 6 in section 7.4.9 of this SER. The staff also evaluates in section 7.4.9 of this SER whether the SHINE facility provides HFE support for administrative controls within the specific context of the operator role in safety at the facility. As part of its review of the SHINE Supplement, the staff determined that it was necessary to ascertain whether these evaluations remain valid in light of the proposed phased approach to startup.

Although NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2, do not contain guidance and acceptance criteria related to HFE with respect to a phased approach to startup, the NRC staff notes that SHINE’s proposed phased approach to startup involving, in part, the sequential installation of additional, independent IUs after previously installed IUs have already begun operation is conceptually similar to installing additional small modular reactor units at an operating power reactor facility. Therefore, the staff determined that it was appropriate to draw upon a similar set of considerations from the following guidance documents to inform its HFE review of the SHINE Supplement:

- NUREG/CR-7126, section 6, which identifies potential human-performance issues to consider in regulatory reviews. One of the issues identified for consideration is the potential for ongoing construction activities to distract facility operators.

- NUREG/CR-7202, which supplements NUREG/CR-7126 by identifying specific questions for use by reviewers. This guidance discusses that, in the absence of additional guidance, the NRC staff can use information about potential human-performance issues to support safety evaluations. It provides that for the human-performance issue of "impact of adding new units while other units are operating," the NUREG-0711 elements impacted are "Human-System Interface Design" and "Procedure Development." The guidance suggests that issues within these two elements be considered using the following questions:

  - For the Human-System Interface (HSI) Design element:
    - Will any changes to HSIs be needed during the time period when new units are added to the plant?
    - How will a new unit's HSIs be added to an existing workstation that is being used to monitor and control current units?
    - How will new workstations that support the operation of new units be introduced in a manner that does not distract or disrupt the monitoring and control of existing units?

  - For the Procedure Development element:
    - How will the installation of new units impact procedures? Will special procedures be used during this time?

The NRC staff applied its technical judgement to adapt these considerations to its evaluation of the HFE implications of SHINE's proposed phased approach to startup. The evaluation of each applicable area is detailed in the following sections.

7.3.1 Changes to Human-System Interfaces

The NRC staff considered whether any changes to HSIs would be needed during SHINE's proposed phased approach to startup, whether HSIs would be added to existing workstations that would already be in use, and whether the HFE evaluation previously conducted by the staff in section 7.4.9 of this SER remains valid.

SHINE Supplement chapter 3 states that the design of SSCs described in SHINE FSAR chapter 3 is not affected by the phased approach to startup and that the design criteria and systems and components descriptions provided in SHINE FSAR sections 3.1 and 3.5, respectively, are applied to the phased approach to startup. The staff noted that the design criteria of SHINE FSAR section 3.1 include Criterion 6 for the control room.

SHINE Supplement chapter 7 states that the descriptions of the main control board, operator workstation, supervisor workstation, maintenance workstation, and other control room interface equipment provided in SHINE FSAR subsections 7.6.1.1 through 7.6.1.5, respectively, are not affected by the phased approach to startup. SHINE Supplement chapter 7 also states that during the phased approach to startup, I&C systems required for the safe operation of the process equipment in each phase are fully tested and operable. The PICS monitoring and controls associated with equipment that is not yet installed, or not yet operable, is tested and placed in operation as required for a given phase. Each input to the PICS is validated as field devices are installed, with acceptance testing being completed for the equipment applicable to each phase prior to releasing the phase to operations. Additionally, the NDAS control system control stations are installed and operational prior to initial (i.e., Phase 1) operations, with the NDAS units being connected to the NDAS control system as they are installed to support the operation of a given phase.

SHINE Supplement section 7.4, “Target Solution Vessel Reactivity Protection System,” states that the TRPS description provided in SHINE FSAR section 7.4.1 is not affected by the phased approach to startup and that each IU is supported by an IU-specific instance of the TRPS. SHINE Supplement section 7.4 also states that the description of human factors provided in SHINE FSAR subsection 7.4.3.7 is not affected by the phased approach to startup, with the exception of the implementation of the manual TPS Isolation push button. Manual TPS Isolation from both the facility master operating permissive and the manual push button are only tied to instances of TRPS for the installed TPS trains during each phase; the same actuation push button is provided to the operator to initiate the manual TPS isolation, and only equipment applicable to the particular phase is actuated when the button is depressed.

SHINE Supplement section 7.5, “Engineered Safety Features Actuation System,” states that the ESFAS description provided in SHINE FSAR subsection 7.5.1 remains accurate during the phased approach to startup relative to the capabilities of the ESFAS. During phased startup, inputs to the ESFAS for equipment that is not required to be operable are disabled and are restored and verified to be operable prior to entering the TS mode of applicability associated with the given input. SHINE Supplement section 7.5 also states that the manual push buttons identified in SHINE FSAR subsection 7.5.3.6 will only actuate safety functions utilized in a given phase.

The NRC staff conducted an audit on August 25, 2022, to clarify and confirm the information described above. The observations from this audit are documented in an audit report (ML22287A185). During the audit discussion, SHINE clarified how it will be ensured that operators maintain a current understanding of system configuration and expected response during successive stages of the phased approach to startup. SHINE indicated that the initial licensed operator training program will be based upon the complete facility with all equipment installed, with a subsequent set of training occurring after the licensing examination that will cover current facility status. SHINE also indicated that a combination of configuration control, turnovers, just-in-time-training, and cycle training will be utilized to address the needs of operators that are already licensed at the facility.

The NRC staff finds that the applicant has described the changes to HSIs that will be needed during the phased approach to startup. The changes do not involve the physical installation of new HSIs during successive phases; rather, existing HSIs that have already been installed will be modified during facility operations. The HSIs needed to support the equipment associated with a given phase will be placed in service and tested in conjunction with completing successive phases. This is supported by operator training to assist operators in maintaining an awareness of facility status. Based on its review, the staff concludes that the modification of existing HSIs will be adequately managed and that the HFE evaluation previously conducted by the staff in section 7.4.9 of this SER remains valid.

7.3.2 Management of Distractions

The NRC staff considered whether HSIs associated with new facility equipment will be introduced in a manner that does not distract or disrupt the monitoring and control of existing facility equipment and whether the related HFE evaluation previously conducted by the staff in section 7.4.9 of this SER remains valid. SHINE Supplement chapter 7 states that control consoles and displays associated with equipment to be installed in later phases will have the capability to have their displays secured or their signals removed to avoid distracting the operators. SHINE Supplement chapter 7 also states that the description of the design basis provided in SHINE FSAR subsection 7.6.3 is not affected by the phased approach to startup. The staff noted that this is inclusive of SHINE FSAR subsection 7.6.3.3, which addresses the application of HFE principles. SHINE further stated that indication will be provided to the operator for components that have been disabled and for components that have not been field terminated.

The NRC staff conducted an audit on August 25, 2022, to clarify and confirm the information described above. The observations from this audit are documented in an audit report (ML22287A185). During the audit discussion, SHINE clarified how displays associated with the equipment that has not yet been installed will be managed to avoid creating operator distractions. SHINE indicated that the PICS separates displays in a manner that allows operators to remove power from certain displays to minimize distractions, with power being left off until startup testing is required. SHINE also clarified how indications will be provided via the PICS for components that are disabled or disconnected. SHINE indicated that displayed indications associated with systems that are not installed will be identified graphically. SHINE also indicated that an operator aid will be available that describes, on a progressive basis throughout the phased approach to startup, what indications will be in a status where a parameter value is displayed but has not yet been tested to verify its accuracy.

The NRC staff finds that the applicant has described how the HSIs associated with new facility equipment will be introduced in a manner that does not distract or disrupt the monitoring and control of existing facility equipment. Displays that are not needed during a given phase will remain off and, where displays that are turned on contain indications for components that are not yet fully installed, those indications will be annotated accordingly. This is also supported by the use of an operator aid to address indications that may display unreliable values based on the current state of installation and testing activities. Based on its review, the staff concludes that operator distractions and disruptions will be adequately managed and that the HFE evaluation previously conducted by the staff in section 7.4.9 of this SER remains valid.

7.3.3 Procedure Changes

The NRC staff considered whether the installation of new facility equipment will impact procedures used during SHINE's proposed phased approach to startup and whether the related HFE evaluation previously conducted by the staff in section 7.4.9 of this SER remains valid. SHINE Supplement chapter 12 states that the conduct of operations described in SHINE FSAR chapter 12 is not affected by the phased approach to startup and that the organizational and programmatic descriptions provided in SHINE FSAR chapter 12 will be implemented to support initial (i.e., Phase 1) operations. The staff noted that SHINE FSAR chapter 12 includes the

SHINE procedure management program and, furthermore, that procedure change control is a component of that program.

SHINE Supplement chapters 13a2 and 13b, "Radioisotope Production Facility Accident Analysis," describe that new or different accident scenarios that were identified as part of the phased approach to startup resulted in several new specific administrative controls being credited. The NRC staff noted that the HFE-related management measures used to support the reliability of SHINE's specific administrative controls continue to generally consist of training and procedures. Based upon this, the staff further considered whether the reliability of the new specific administrative controls would be adequately supported by these management measures.

The NRC staff conducted an audit on August 25, 2022, to clarify and confirm the information described above. The observations from this audit are documented in an audit report (ML22287A185). During the audit discussion, SHINE clarified how it would be ensured that crane operators are trained to implement crane-related administrative controls. SHINE indicated that crane operators will consist of either maintenance or operations personnel and that their qualification program will include coverage of specific administrative controls. In its response to NRC staff Request for Confirmatory Information (RCI) HFE-1 (ML22263A027), SHINE confirmed that crane operators will consist of either operations or maintenance personnel and, furthermore, that their training and qualification process will include coverage of both the specific administrative controls and procedures that are associated with crane-related lifting and rigging operations.

The NRC staff finds that the applicant has described how the installation of new facility equipment will impact procedures used during the phased approach to startup. The procedure management program includes measures to address procedure changes. Administrative controls that are credited are supported by HFE-related management measures in the areas of training and procedures, including those associated with crane operations. Based on its review, the staff concludes that the evaluation of the applicant's procedure management program's support for the implementation of administrative controls previously conducted by the staff in section 7.4.9 of this SER remains valid.

7.3.4 Conclusions

The NRC staff finds that the applicant described the changes to HSIs that will be needed during the proposed phased approach to startup and demonstrated that the changes will not adversely impact the monitoring and control of existing facility equipment. Therefore, the staff concludes that the requirement of 10 CFR 50.34(b) for an operating license application to include a description and analysis of the SSCs of the facility and the evaluations required to show that safety functions will be accomplished is still met within the context of the HFE-related aspects of SHINE Design Criterion 6 under the phased approach to startup.

The NRC staff finds that the applicant demonstrated that impacts to facility procedures due to the completion of uncompleted items of construction during the phased approach to startup will be adequately addressed. Therefore, the staff concludes that the requirement of 10 CFR 50.57(a)(3) for reasonable assurance that activities authorized by the operating license will not endanger the health and safety of the public and is supported by the application of HFE measures within the context of administrative controls under the phased approach to startup.

7.4 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's I&C systems as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 7, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the I&C systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's I&C systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

8.0 ELECTRICAL POWER SYSTEMS

Section 8, “Electrical Power Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE electrical power systems, as presented in SHINE Supplement chapter 8a2, “Irradiation Facility Electrical Power Systems,” and chapter 8b, “Radioisotope Production Facility Electrical Power Systems.”

8a Irradiation Facility Electrical Power Systems

Section 8a, “Irradiation Facility Electrical Power Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the final design of the SHINE IF electrical power systems as affected by the proposed phased approach to startup, as presented in SHINE Supplement chapter 8a2.

8a.1 Summary of the Supplement to the Application

SHINE Supplement chapter 8a2 provides SHINE’s proposed phased approach to startup related to the SHINE IF electrical power systems.

SHINE Supplement section 8a2.1, “Normal Electrical Power Supply System,” states that the description of the NPSS in SHINE FSAR section 8a2.1 is not affected by the phased approach to startup and that the NPSS is installed in full to support initial (i.e., Phase 1) operations. Sufficient isolation exists between operable and not yet installed or not yet operable equipment to ensure that not yet installed or not yet operable equipment loads do not impact the NPSS. The NPSS will continue to satisfy the codes and standards described in SHINE FSAR subsections 8a2.1.1, 8a2.1.3, 8a2.1.4, and 8a2.1.5. All raceway and cable routing is installed in full to support Phase 1.

SHINE Supplement section 8a2.2, “Emergency Electrical Power Systems,” states that the description of the emergency electrical power systems in SHINE FSAR section 8a2.2 is not affected by the phased approach to startup. All the emergency electrical power systems are installed in full to support initial (i.e., Phase 1) operations, including the UPSS, the nonsafety-related SGS, and nonsafety-related local power supplies and unit batteries. Sufficient isolation exists between operable and not yet installed or not yet operable equipment to ensure that not yet installed or not yet operable equipment loads do not impact the UPSS. SHINE FSAR subsections 8a2.2.1, 8a2.2.2, 8a2.2.3, 8a2.2.7, and 8a2.2.8 are not impacted by isolating loads that are not yet installed or not yet operable. The UPSS will continue to satisfy the codes and standards described in SHINE FSAR subsections 8a2.2.2 and 8a2.2.3.

8a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 8a2 using the guidance and acceptance criteria from section 8a2, “Aqueous Homogeneous Reactor Electrical Power Systems,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

With respect to the IF electrical power systems, all systems, i.e., the NPSS and the emergency electrical power systems, will be installed prior to initial (i.e., Phase 1) operations. Therefore, the IF electrical power systems are not affected by the phased approach to startup and they will continue to meet all applicable portions of the codes and standards described in SHINE FSAR chapter 8. SHINE uses the guidance in sections 6.1.2.1, 6.1.2.2, and 6.1.2.3 of IEEE Standard 384-2008, “Standard Criteria for Independence of Class 1E Equipment and Circuits,” for the isolation of electrical systems, as described in SHINE FSAR subsection 8a2.1.1. SHINE’s conformance with the applicable portions of IEEE Standard 384-2008 provides reasonable assurance that equipment not yet operable or not yet installed during the phased approach to startup will be appropriately isolated from the NPSS and the emergency electrical power systems.

Based on the above, the NRC staff finds that the IF electrical power systems described in SHINE FSAR chapter 8 are not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER chapter 8, “Electrical Power Systems,” is applicable to the phased approach to startup without further supplementation.

8a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE’s IF electrical power systems as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 8a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the IF electrical power systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE’s IF electrical power systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

8b Radioisotopes Production Facility Electrical Power Systems

SHINE Supplement chapter 8b states that the SHINE facility has one common normal electrical power system and one common emergency electrical power system. Therefore, the summary of the supplement to the application, technical evaluation, and review findings provided in section 8a of this appendix to the SER are applicable to both the IF and the RPF.

9.0 AUXILIARY SYSTEMS

Section 9, "Auxiliary Systems," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the final design of the SHINE auxiliary systems, as presented in SHINE Supplement chapter 9a2, "Irradiation Facility Auxiliary Systems," and chapter 9b, "Radioisotope Production Facility Auxiliary Systems."

9a Irradiation Facility Auxiliary Systems

Section 9a, "Irradiation Facility Auxiliary Systems," of this appendix to the SER provides the NRC staff's evaluation of the final design of the SHINE IF auxiliary systems as affected by the proposed phased approach to startup, as presented in SHINE Supplement chapter 9a2.

9a.1 Summary of the Supplement to the Application

SHINE Supplement section 1.1 states that the phased approach to startup was developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where remaining equipment installation is occurring during different phases to minimize impacts on the operating portions of the facility. Each IU has a dedicated IU cell, TOGS cell, and primary cooling room. This design results in an installation area for the nonoperating IUs that is physically separate from the operating IU units. The IU cells and primary cooling rooms are designed to allow access for maintenance or other operational needs while adjacent IUs are operating, including ICBS design, sufficient to minimize dose rates consistent with the ALARA principles at the facility.

The phased approach to startup is divided into four phases. Phase 1 brings the Mo-99 production capability online and Phases 2 and 3 increase this capability. During Phase 1, the equipment necessary to support the operation of IUs 1 and 2 are functional and available for operation. During Phase 2, the equipment necessary to support the operation of IUs 1 through 5 are functional and available for operation. During Phase 3, the equipment necessary to support the operation of all IUs (i.e., IUs 1 through 8) are functional and available for operation. Phase 4 adds iodine and xenon production capability. The SHINE Supplement describes the sequence in which the IUs will become operational during the phased approach to startup and the configuration of the radiological and non-radiological ventilation systems during different phases of startup, including the design features employed to isolate the ventilation systems that are supporting the operation of the active IUs and the Mo-99 production facility from other areas of the facility where uncompleted items of construction are being completed.

9a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 9a2 using the guidance and acceptance criteria from section 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

In its evaluation, the NRC staff reviewed the pertinent information associated with the proposed phased approach to startup and the system isolations necessary for safe operation of the facility during the various phases and the completion of uncompleted items of construction as described in SHINE Supplement chapter 9a2.

The radiological ventilation (RV) system descriptions provided in SHINE FSAR subsection 9a2.1.1 are not affected by the phased approach to startup, with the exception of the following:

- The ventilation system zone designations identified in SHINE FSAR figure 9a2.1-1 are not applicable for certain areas of the facility because they do not contain operational equipment during certain phases. Prior to Phase 1, IU-specific instances of RVZ1r and RVZ1e for IUs 1 and 2 are operational. The ICBS cover plugs for cooling rooms, TOGS cells, and IU cells are also installed. Once the cover plugs are installed, the IU cells, the TOGS cells, and RVZ1r for IUs 1 and 2 become part of ventilation zone 1. A similar sequencing for becoming a part of ventilation zone 1 is follow prior to Phase 2 for IUs 3, 4, and 5 and prior to Phase 3 for IUs 6, 7, and 8.

- RV interfaces with TPS Train A are operational for Phase 1, with TPS Train B and TPS Train C isolated during Phase 1. RV interfaces with TPS Train A and TPS Train B are operational for Phase 2, with TPS Train C isolated during Phase 2. RV interfaces with TPS Train A, TPS Train B, and TPS Train C are operational for Phase 3. RV interfaces with the IXP system are isolated during Phase 1 through Phase 3.

- The non-operating IUs during Phases 2 and 3 are part of ventilation zone 2 and become part of ventilation zone 1 for subsequent phases after their installation is completed and their ICBS cover plugs are installed.

The SHINE Supplement further states that IU-specific instances of RV systems are installed to support the phased approach to startup and that RV system interface points are isolated as needed to support the phased approach to startup for each RV system.

<u>Radiological Ventilation Zone 1</u>

Since there are no common components or connections between the IU-specific instances of RVZ1r or between RVZ1r and other RV systems, there is no need to isolate RVZ1r for the IU-specific instances that are not yet operational during the phased approach to startup.

The RVZ1e system interfaces with IU-specific instances of the PCLS within the IU cells (i.e., the PCLS expansion tank exhaust). The IU-specific portions of the RVZ1e system within the cooling rooms and the IU cells are installed to support the phased approach to startup in the same sequence as RVZ1r units. The RVZ1e system interface points for the IUs that are not yet operational are isolated outside of the cooling rooms and the IU cells by a manual isolation valve and a blind flange or cap to support the phased approach to startup.

The RVZ1 interfaces with the train-specific instances of the TPS process exhaust are isolated to support the phased approach to startup. The RVZ1 interface with TPS Train A is operational with the interfaces with TPS Train B and TPS Train C isolated during Phase 1. The isolations of the appropriate TPS trains in Phase 1 and Phase 2 are achieved by a manual isolation valve and a blind flange or cap.

The RVZ1 system interfaces with the IXP system exhaust. During Phase 1 through Phase 3, the RVZ1 system interface points with the IXP hot cell are isolated to support the phased approach to startup via two bubble-tight dampers. The RVZ1 system also interfaces with the IXP system processes cryotrap. During Phase 1 through Phase 3, the RVZ1 system interface point with the IXP system processes cryotrap is isolated via a manual isolation valve and a blind flange or cap. Prior to Phase 4, all RVZ1 interfaces with the IXP system exhaust become operational.

Radiological Ventilation Zone 2

The RVZ2 system interfaces with the train-specific instances of the TPS nitrogen exhaust are isolated to support the phased approach to startup. RVZ2 interfaces with TPS Train A and TPS Train B are open during Phase 2, with TPS Train C remaining isolated. TPS Train C will be operational during Phase 3. All isolations during Phase 1 and Phase 2 are achieved via a manual isolation valve and a blind flange or cap.

The RVZ2 system interfaces with the IXP system to supply air for tanks ventilated by the PVVS. During Phase 1 through Phase 3, the RVZ2 system interface point with the IXP system is isolated to support the phased approach to startup via a manual isolation valve and a blind flange or cap.

The RVZ2r interfaces with the IXP hot cell to supply air. During Phase 1 through Phase 3, the RVZ2r interface points with the IXP hot cell are isolated to support the phased approach to startup via two bubble-tight dampers.

Radiological Ventilation Zone 3

The phased approach to startup has no impact on the radiological ventilation zone 3 description provided in SHINE FSAR subsection 9a2.1.1.

Conclusion Regarding the Radiological Ventilation System

Based on the radiological ventilation system phased approach to startup descriptions in SHINE Supplement section 9a2.1.1, “Radiologically Controlled Area Ventilation System,” the main ventilation units located in the mezzanine levels of ventilation zones 2 and 4 will be installed and operational prior to initial (i.e., Phase 1) operations. They are the RVZ2 supply subsystem air handling units (AHUs) located in ventilation zone 4 and the Radiological Ventilation Zones 1 and 2 exhaust subsystems filter trains (RVZ1e and RVZ2e, respectively) located in ventilation zone 2. The AHUs and the filter trains will be installed prior to Phase 1, complete with the system automatic isolation provisions (bubble tight dampers and tornado dampers) with the adjacent radiological and non-radiological ventilation zones, as designed for the facility operation, as these isolations are required regardless of the number of IUs in operation.

The NRC staff determined that the ventilation systems are described in sufficient detail to describe the interim configuration of the ventilation systems in each of Phases 1, 2, 3, and 4, including the isolations provided to the uncompleted items of construction during the different phases. The isolation features and the locations of the portions of the ventilation systems that would not be required in each of Phases 1, 2, 3, and 4 are also described in sufficient detail. At the conclusion of Phase 4, the ventilation systems will be in full conformance with the SHINE FSAR.

The NRC staff reviewed the radiological ventilation systems information in SHINE Supplement table 7.5-1, table 7.5-2, and table 7.7-1 and determined that it is consistent with the description of the radiological controlled area ventilation in SHINE Supplement section 9a2.1.1.

Based on the passive and active isolation features described in the SHINE Supplement, the NRC staff finds that the operation of the SHINE facility ventilation systems during the different phases of the phased approach to startup is similar to the description provided in the SHINE FSAR in terms of the equipment required for responding to mitigate potential accidents/events analyzed in SHINE FSAR chapter 13.

Based on the above, the NRC staff concludes that the conclusions reached in SER section 9a regarding the ventilation systems are not affected by the proposed phased approach to startup. In addition, based on the above, the staff has reasonable assurance that the ventilation systems can operate safely during all four phases and remain unimpacted by the completion of uncompleted items of construction during the four phases.

Non-Radiological Ventilation and Support Systems

The non-radiological area ventilation system, the FCHS, the FHWS, handling and storage of target solution, fire protection systems and programs, communication systems, possession and use of byproduct, source, and SNM, and the NDAS service cell are not affected by the phased approach to startup. The NRC staff evaluated these systems and programs and concludes that the conclusions reached in SER section 9a regarding these systems and programs are not affected by the proposed phased approach to startup. In addition, based on the above, the staff has reasonable assurance that these systems and programs can operate safely during all four phases and remain unimpacted by the completion of uncompleted items of construction during the four phases.

Cover Gas Control in Closed Primary Coolant Systems

SHINE Supplement section 9a2.6, “Cover Gas Control in Closed Primary Coolant Systems,” states that the PCLS is the closed loop cooling system that provides cooling to the TSV. Cover gas control for the PCLS is described in section 5a2.2 of the SHINE FSAR. The NRC staff evaluated the PCLS in section 5a.2 of this appendix to the SER. The staff evaluated the PCLS and finds that the design of the PCLS is IU-specific and that the conclusions reached in SER section 5a.4.2.7, “Primary Closed Loop Cooling System Conclusion,” are not affected by the proposed phased approach to startup.

Tritium Purification System

SHINE Supplement section 9a2.7.1, “Tritium Purification System,” states that the TPS has three independent trains (i.e., Trains A, B, and C) that support the operation of the NDAS in specific IUs. TPS Train A supports IUs 1 and 2, TPS Train B supports IUs 3, 4, and 5, and TPS Train C supports IUs 6, 7, and 8. In Phase 1, IUs 1 and 2 and the associated TPS Train A are operational. In Phase 2, IUs 3, 4, and 5 and the associated TPS Train B are also operational. In Phase 3, the remaining IUs 6, 7, and 8 and the associated TPS Train C are operational.

SHINE Supplement section 9a2.7.1 also states that each TPS train is designed to operate independently from the other TPS trains and contains its own instances of the isotope separation system, TPS-NDAS interface lines, secondary enclosure cleanup (SEC), vacuum/impurity treatment subsystem, NDAS SEC, and TPS glovebox. Each TPS train has its own tritium confinement boundary and is not impacted by the installation and testing of the other trains. The interface points of uncompleted trains are isolated by manual valves, blind flanges, or caps, so that the installation of the new trains does not impact the operating trains.

Additionally, SHINE Supplement section 9a2.7.1 states that the process exhaust to facility ventilation RVZ1e connections to TPS trains are isolated with manual valves and blind flanges or caps. The liquid nitrogen exhaust to facility ventilation RVZ2e connections to TPS trains are isolated with manual valves and blind flanges or caps. The pneumatic equipment gas line connections to TPS trains are isolated with manual valves. The liquid nitrogen supply connections to TPS trains are isolated with manual valves. The deuterium supply connections to TPS trains are isolated with manual valves. The inert flush gas connections to TPS trains are isolated with manual valves.

With respect to the TPS, SHINE Supplement section 13a2 identifies a new accident sequence and an increase in the likelihood of an existing scenario related to the phased approach to startup. The new sequence is damage to an installed TPS train during the installation of a new TPS train. The modified sequence with an increased likelihood is a heavy load drop on the TPS. These are discussed in chapter 13 of this appendix to the SER.

Based on its review, the NRC staff finds that each TPS train is capable of operating independently of the other TPS trains and that uncompleted items of construction related to TPS trains can be completed without impacting operating systems. The staff also finds that the isolation of systems that interface with the operating TPS trains is adequate to allow the completion of uncompleted items of construction during the phased approach to startup. Therefore, the staff concludes that the conclusions reached in SER section 9a regarding the TPS are not affected by the proposed phased approach to startup and that the staff has reasonable assurance that the TPS can operate safely during all four phases and remain unimpacted by the completion of uncompleted items of construction during the four phases.

9a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's IF auxiliary systems as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 9a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the IF auxiliary systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF auxiliary systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

9b Radioisotope Production Facility Auxiliary Systems

Section 9b, "Radioisotope Production Facility Auxiliary Systems," of this appendix to the SER provides the NRC staff evaluation of the final design of the SHINE RPF auxiliary systems as affected by the proposed phased approach to startup, as presented in SHINE Supplement chapter 9b.

9b.1 Summary of the Supplement to the Application

SHINE Supplement section 9b.1, "Heating, Ventilation, and Air Conditioning Systems," states that the HVAC systems for the main production facility are common to the IF and RPF. The phased approach to startup of the main production facility HVAC systems is described in section 9a2.1 of the SHINE Supplement.

SHINE Supplement section 9b.2.1, "Target Solution Lifecycle," states that the target solution lifecycle description provided in section 9b.2.1 of the SHINE FSAR is not affected by the phased approach to startup, except that target solution is not delivered to the IXP system during Phase 1 through Phase 3. The IXP system is not installed, process connections to IXP are isolated, and the IXP hot cell is isolated during Phase 1 through Phase 3, as described in section 4b.2 and section 4b.3 of the SHINE Supplement.

SHINE Supplement section 9b.2.2, "Receipt and Storage of Unirradiated SNM," states that the description of receipt and storage of unirradiated SNM provided in subsection 9b.2.2 of the SHINE FSAR is not affected by the phased approach to startup.

SHINE Supplement section 9b.2.3, "Target Solution Preparation," states that the target solution preparation description provided in subsection 9b.2.3 of the SHINE FSAR is not affected by the phased approach to startup.

SHINE Supplement section 9b.2.4, "Target Solution Staging System," states that the TSSS description provided in subsection 9b.2.4 of the SHINE FSAR is not affected by the phased approach to startup.

SHINE Supplement section 9b.2.5, "Vacuum Transfer System," states that the VTS description provided in subsection 9b.2.5 of the SHINE FSAR is not affected by the phased approach to startup operations and that the VTS is available for operation in Phase 1. During Phase 1 and Phase 2, interfacing VTS connections to IU-specific instances of IU systems and components (i.e., TSV, TSV dump tank, and TOGS) are isolated as described in section 4a2.1 of the SHINE Supplement (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1 and interfaces with IUs 6 through 8 are isolated during Phase 2). During Phase 1 through Phase 3, interfacing VTS connections to the IXP system are isolated as described in section 4b.3 of the SHINE Supplement. Isolating the interfaces to individual IU systems and the IXP system does not affect the capability of the VTS to perform its functions for other system interfaces.

SHINE Supplement section 9b.2.6, “Radioactive Liquid Waste Storage,” states that the RLWS system description provided in subsection 9b.2.6 of the SHINE FSAR is not affected by the phased approach to startup.

SHINE Supplement section 9b.2.7, “Radioactive Liquid Waste Immobilization,” states that the RLWI system description in subsection 9b.2.7 of the SHINE FSAR is not affected by the phased approach to startup, except that the adsorption columns to remove select isotopes (e.g., Sr-90, Cs-137) are not available during Phase 1 and Phase 2. Additional description of RLWI operations during the phased approach to startup is provided in section 9b.7.3 of the SHINE Supplement.

SHINE Supplement section 9b.2.8, “Solid Waste Packaging and Shipment,” states that the solid radioactive waste packaging (SRWP) system description provided in subsection 9b.2.8 of the SHINE FSAR is not affected by the phased approach to startup, except that the MATB is not available during Phase 1 and Phase 2. Solid wastes generated during Phase 1 and Phase 2 are stored in the RCA within the main production facility prior to shipment off site to a designated disposal site. Additional description of SRWP operations during the phased approach to startup is provided in subsection 9b.7.5 of the SHINE Supplement.

SHINE Supplement section 9b.2.9, “Criticality Control,” states that inadvertent criticality is prevented in RPF systems involved in the processing of fissile materials through the application of the nuclear criticality safety program, described in section 6b.3 of the SHINE Supplement.

SHINE Supplement section 9b.3, “Fire Protection Systems and Programs,” states that the fire protection system and program for the SHINE facility are common to the IF and RPF. As described in section 9a2.3 of the SHINE FSAR, the fire protection program and facility fire protection systems are implemented in full to support initial (i.e., Phase 1) operations.

SHINE Supplement section 9b.4, “Communications Systems,” states that the communication systems for the SHINE facility are common to the IF and RPF. As described in section 9a2.4 of the SHINE FSAR, the facility data and communication system is installed in full to support initial (i.e., Phase 1) operations.

SHINE Supplement section 9b.5, “Possession and Use of Byproduct, Source, and Special Nuclear Material,” states that the possession and use of byproduct, source, and SNM described in section 9b.5 of the SHINE FSAR is not affected by the phased approach to startup, except that the IXP system is not operational until Phase 4. During Phase 1 through Phase 3, radioactive material is not present in the IXP system, iodine-131 and xenon-133 is not produced or shipped, and the quality control and analytical testing laboratories does not process iodine-131 and xenon-133 samples for analysis. Quantities of materials described in section 9b.5 of the SHINE FSAR remain bounding for operations during Phase 1 through Phase 4.

SHINE Supplement sections 9b.6.1, “Process Vessel Vent System,” and 9b.6.2, “Nitrogen Purge System,” discuss the impact of the phased approach to startup on SHINE FSAR section 9b.6, “Cover Gas Control in the Radioisotope Production Facility,” specifically SHINE FSAR sections 9b.6.1, “Process Vessel Vent System,” and 9b.6.2, “Nitrogen Purge System.” The PVVS collects and treats the off-gases from process vessels in the SHINE facility. The PVVS collects off-gases from each RPF tank containing irradiated solutions, from the VTS vacuum pump discharge, and periodically from the TOGS. The treatment part of the PVVS consists of acid absorbers, carbon filters, HEPA filters, condensers, reheaters, carbon beds, and blowers. N2PS provides a backup supply of sweep gas (nitrogen) to IUs and all tanks normally supplied by PVVS during a loss of normal sweep gas or a loss of normal power. The off-gas resulting from the nitrogen purge is treated by the same passive filtration equipment of the PVVS discussed above before discharging to the stack.

SHINE Supplement section 9b.7.1, "Molybdenum Isotope Product Packaging System," states that the MIPS description provided in SHINE FSAR subsection 9b.7.1 is not affected by the phased approach to startup, except that the IXP is not available during Phase 1 through Phase 3. During Phase 1 through Phase 3, MIPS is isolated from the IXP as described in SHINE Supplement section 4b.3. SHINE Supplement section 4b.3 is discussed in section 9a2 of this appendix to the SER.

SHINE Supplement section 9b.7.2, "Material Handling System," states that the material handling system (MHS) description provided in SHINE FSAR subsection 9b.7.2 is not affected by the phased approach to startup. The SHINE FSAR implements the material handling program in accordance with NUREG-0612, which is applicable during the phased approach to startup. The IF and RPF overhead cranes will be installed prior to initial (i.e., Phase 1) operations.

SHINE Supplement section 9b.7.3, "Radioactive Liquid Waste Immobilization System," states that the RLWI solidification equipment is available in Phase 1. Therefore, the RLWI equipment is available to receive and solidify blended liquid waste from the RLWS. SHINE also indicated that the RLWI description provided in SHINE FSAR subsection 9b.7.3 is not affected by the phased approach to startup, except that the selective removal process is not available during Phases 1 and 2 and its interfacing connections are isolated with a valve and a blind flange or cap.

SHINE Supplement section 9b.7.4, "Radioactive Liquid Waste Storage System," states that the RLWS description provided in SHINE FSAR subsection 9b.7.4 is not affected by the phased approach to startup, except that the IXP system is not available during Phase 1 through Phase 3. SHINE Supplement figure 6b.3-1, "Radioactive Liquid Waste System Overview," provides an overview of RLWS connections applicable to Phases 1, 2, and 3, which is consistent with SHINE FSAR figure 6b.2-2 without IXP system connection. During Phase 1 through Phase 3, interfacing RLWS connections to the IXP system are isolated with a manual valve and a blind flange or cap. SHINE Supplement chapter 4b indicates that the RLWS does not collect liquid wastes from the IXP system, as described in SHINE FSAR subsection 4b.1.3.7.2, during Phase 1 through Phase 3, and waste from the IXP system will not be generated in Phases 1 through 3.

SHINE Supplement section 9b.7.5, "Solid Radioactive Waste Packaging System," states that the SRWP system is not affected by the phased approach to startup, except that the MATB is not available during Phase 1 and Phase 2. The MATB will not be used for interim storage of wastes for decay until it is operational for Phase 3. Solidified waste generated during Phase 1 and Phase 2 are stored in the subgrade bore holes in the RPF. As indicated in SHINE Supplement section 9b.2.8, solid wastes generated during Phase 1 and Phase 2 are stored in the RCA within the main production facility prior to shipment off site to a designated disposal site. Solid wastes are characterized and staged for shipment in the main production facility in accordance with the radioactive waste management program.

SHINE Supplement section 9b.7.6, "Radioactive Drain System," states that the RDS description in SHINE FSAR subsection 9b.7.6 is not affected by the phased approach to startup, except that the IXP system is not available during Phase 1 through Phase 3. During Phase 1 through

Phase 3, the IXP hot cell is not operational. As indicated in SHINE Supplement section 4b.1, the supercell confinement boundary is isolated from the IXP hot cell and the IXP hot cell drain to RDS is plugged during Phase 1 through Phase 3.

SHINE Supplement section 9b.7.7, “Facility Potable Water System,” states that the FPWS is not affected by the phased approach to startup.

SHINE Supplement section 9b.7.8, “Facility Nitrogen Handling System,” indicates that the FNHS is not affected by the phased approach to startup and will be available for initial (i.e., Phase 1) operations. SHINE described the isolation of the interfaces to important individual IU systems, TPS trains, and the IXP system as not affecting the capability of the FNHS to perform its functions for other system interfaces.

SHINE Supplement Section 9b.7.9, “Facility Sanitary Drain System,” indicates that the facility sanitary drain system (FSDS) is not affected by the phased approach to startup. The system is nonsafety-related and functions normally during the phased approach to startup.

SHINE Supplement section 9b.7.10, “Facility Chemical Reagent System,” states that the FCRS is not affected by the phased approach to startup and that the FCRS is available for initial (i.e., Phase 1) operations.

9b.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 9b using the guidance and acceptance criteria from section 9b, “Radioisotope Production Facility Auxiliary Systems,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

In its evaluation, the NRC staff reviewed the pertinent information associated with the proposed phased approach to startup and the system isolations necessary for safe operation of the facility during the various phases and the completion of uncompleted items of construction as described in SHINE Supplement chapter 9b.

Heating, Ventilation, and Air Conditioning Systems

The HVAC system is common to both the IF and RPF. The NRC staff evaluated the HVAC system in section 9a.4.1 of this appendix to the SER.

Handling and Storage of Target Material

SHINE Supplement section 9b.2 describes the impacts of the phased approach to startup to systems used in the handling and storage of target material. SHINE Supplement section 9b.2.1, “Target Solution Lifecycle,” states, in part, that the IXP system is not installed, IXP connections are isolated, and the IXP hotcell is isolated during Phase 1 through Phase 3. The NRC staff evaluated and found acceptable the isolations to the IXP system in section 4b.2 of this appendix to the SER.

SHINE Supplement section 9b.2 also states that the receipt and storage of unirradiated SNM, target solution preparation, target solution staging system, and criticality control are not impacted by the phased approach to startup. The NRC staff reviewed SHINE Supplement sections 9b.2.2, 9b.2.3, 9b.2.4, and 9b.2.9 and did not identify any potential safety impacts to these systems and processes as a result of the phased approach to startup.

SHINE Supplement section 9b.2.5 states that the VTS is not affected by the phased approach to startup. During Phase 1, the VTS interfaces to IUs 3 through 8 and IU system components will be isolated as described in SHINE Supplement section 4b.3. The NRC staff evaluated and found acceptable the isolations of the VTS in section 4a.2 of this appendix to the SER.

The NRC staff evaluates the impact of the phased approach to startup to the RLWI system and the SRWP system below. SHINE Supplement section 1.1 states, in part, that the full capability of the RLWI system and waste staging is included in Phase 3. In its evaluation below, the staff finds that the RLWI system and the SRWP system are available for Phase 1 and Phase 2 and are not affected by the phased approach to startup.

Process Vessel Vent System

The PVVS description provided in SHINE FSAR subsection 9b.6.1 is not affected by the phased approach to startup because the PVVS is available for operation in Phase 1. However, the isolation of PVVS connections to non-operating IU cells and the IXP system is required during the phased approach to startup, as described in SHINE Supplement sections 4a2.1 and 4b.3.

During Phase 1 and Phase 2, interfacing PVVS connections to IU-specific instances of IU systems (i.e., TOGS) are isolated within the IU cell (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1 and interfaces with IUs 6 through 8 are isolated during Phase 2). The isolation is achieved by means of a locked closed isolation valve in the PVVS line that exits non-operating IU units.

During Phase 1 through Phase 3, interfacing PVVS connections to the IXP system are isolated with a manual isolation valve and a blind flange.

The NRC staff finds that the isolation provisions provided in the PVVS lines for the phased approach to startup are adequately described and acceptable, and that the isolations will not impact the capability of PVVS to perform its functions for other system interfaces during the completion of uncompleted items of construction.

Nitrogen Purge System

The N2PS description provided in SHINE FSAR subsection 9b.6.2 is not affected by the phased approach to startup, because the N2PS is available for operation in Phase 1. However, the isolation of N2PS connections to non-operating IU cells and the IXP system is required during the phased approach to startup as described in SHINE Supplement sections 4a2.1 and 4b.3.

During Phase 1 and Phase 2, interfacing N2PS connections to IU-specific instances of IU systems and components (i.e., TSV, TSV dump tank, and TOGS) are isolated within the IU cell (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1 and interfaces with IUs 6 through 8 are isolated during Phase 2). The isolation is achieved by means of one isolation valve and a blind flange or cap.

During Phase 1 through Phase 3, interfacing N2PS connections to the IXP system are isolated with a manual isolation valve and a blind flange. The RVZ2 air to the IXP elute hold tank, also served by N2PS supply, is isolated with a manual valve and blind flange or cap.

The NRC staff finds that the isolation provisions provided in the N2PS lines for the phased approach to startup are adequately described and acceptable, and that the isolations will not impact the capability of N2PS to perform its functions for other system interfaces during the completion of uncompleted items of construction.

Molybdenum Isotope Product Packing System

SHINE Supplement section 9b.7.1 states that the MIPS is not affected by the phased approach to startup, with the exception that the IXP system is not available during Phase 1 through Phase 3 and that the MIPS is isolated from the IXP system during these phases. The NRC staff evaluated and found acceptable the isolations to the IXP system in section 4b.2 of this appendix to the SER.

Material Handling System

The MHS includes overhead cranes and hoists that are used to move or manipulate radioactive material in the RCA. The MHS design is evaluated for loads associated with two overhead bridge cranes, one servicing the IF area and one servicing the RPF area. The IF overhead crane is a 40-ton, double girder, bridge style crane designed to span the width and travel the length of the IF. The RPF overhead crane is a 15-ton, double girder, bridge style crane designed for the handling of shield cover plugs and equipment within the RPF.

For the IF overhead crane, the use of a single-failure-proof crane with rigging and procedures that implement the guidance of NUREG-0612 ensure that the potential for a heavy load drop during construction is small. As described in SHINE FSAR section 9b.7.2, the RPF overhead crane is a non-single-failure-proof crane that employs the use of mechanical stops, electrical-interlocks, and predetermined safe load paths to minimize the movement of loads in proximity to redundant or dual safe shutdown equipment. For cranes operating in the vicinity of safety-related SSCs, SHINE has applied guidance from section 5.1.1 of NUREG-0612.

Areas of concern are the RLWI shielded enclosure or supercell during the phased approach to startup because these systems will not be complete during Phase 1 and Phase 2 and, therefore, ongoing work may be in process. SHINE FSAR section 13b.1.2.3 discusses potential accidents involving heavy load handling near the RLWI shielded enclosure or supercell during the phased approach to startup to account for the increased likelihood of the initiating event because of the on-going completion of uncompleted items of construction. A crane failure or operator error resulting in a heavy load drop on the RLWI shielded enclosure or supercell would cause damage to the affected structure and internal equipment. To prevent a heavy load drop on the RLWI shielded enclosure or supercell, crane operation procedures include safe load paths to avoid the enclosure and supercell and require suspension of supercell and RLWI activities during a heavy lift.

While SHINE Supplement section 9b.7.2 indicates that the MHS description provided in SHINE FSAR section 9b.7.2 is not affected by the phased approach to startup, it was unclear to the NRC staff whether NUREG-0612 controls will be applied during the phased approach to startup. During an audit on May 24, 2022, SHINE verified that the SHINE FSAR section 9b.7.2 crane program, including safe load paths, will be implemented for Phase 1 and that NUREG-0612 safety features will be applied throughout the phased approach to startup. The observations from this audit are documented in an audit report (ML22287A185).

SHINE Supplement section 13b.1.2.3 describes SHINE's modification of its evaluation related to heavy load drop onto the RLWI shielded enclosure or supercell during the phased approach to startup to account for an increased likelihood of the initiating event because of the on-going completion of uncompleted items of construction. SHINE indicated that this increase is small in comparison to the total planned lifts during normal operations and does not result in an increase in the likelihood index for the initiating event.

Because MHS controls and safety features defined in SHINE FSAR section 9b.7.2 and NUREG-0612 will be applied, potential accident conditions with the use of the IF and RPF cranes are minimized. Based on the above, the NRC staff finds that the conclusions reached in SER section 9b.4.7.2 are not affected by the proposed phased approach to startup.

Radioactive Liquid Waste Immobilization System

The RLWI system solidifies blended liquid waste to a form suitable for shipping and disposal. The RLWI system removes selected isotopes, as needed, from the blended liquid waste and then immobilizes the wastes for ultimate disposal. The immobilization feed tank, liquid waste drum fill pumps, and valves are in a shielded enclosure. Selective isotope removal and waste drum filling and mixing are also performed within the shielded enclosure.

The RLWI selective removal process is described in SHINE FSAR subsection 4b.1.3.8.2. Using the selective removal process, wastes can be recirculated in the RLWI system through a set of adsorption columns to remove isotopes that impact dose and classification of the waste package. As a result of the unavailability of this process, waste solidified during Phase 1 and Phase 2 may have higher dose rates and higher waste classifications than wastes solidified during Phase 3 and Phase 4. During Phase 1 and Phase 2, liquid waste is stored in the subgrade RLWS tanks prior to transfer to the RLWI to maximize the decay time and to limit the volume of solidified waste requiring disposal. Estimated waste streams during the phased approach to startup are described in SHINE Supplement section 11.2.

Because the RLWI is available to support initial (i.e., Phase 1) operations, with the exception of the selective removal process, which is isolated during Phase 1 and Phase 2, the RLWI is available to solidify blended liquid waste. SHINE will also maximize the decay time and limit the volume of solidified waste requiring disposal during Phase 1 and Phase 2 when the MATB is unavailable. Based on the above, the NRC staff finds that the conclusions reached in SER section 9b.4.7.3 are not affected by the proposed phased approach to startup.

Radioactive Liquid Waste Storage System

The RLWS system collects, stores, blends, conditions, and stages liquid wastes upstream of the RLWI system for solidification. The RLWS is a set of below grade tanks used to provide storage for radioactive liquid wastes prior to immobilization. Liquid wastes from other processes are collected separately.

Liquid wastes from the isotope production processes may contain SNM. These liquids are drained from the hot cells to the first favorable geometry uranium waste tank in the RLWS system. Once the liquid waste is verified to be below administrative limits, it is transferred to the second uranium waste tank where it is sampled again prior to being sent to the liquid waste blending tanks for additional storage time. Target solution batches are disposed of through the RLWS system. Once a batch is designated for disposal, it is transferred to the RLWS system to be blended with other wastes.

Because the RLWS is available to support initial (i.e., Phase 1) operations, with the exception of the IXP, which is isolated during Phase 1 through Phase 3, the RLWS is available to receive liquid waste. Based on the above, the NRC staff finds that the conclusions reached in SER section 9b.4.7.4 are not affected by the proposed phased approach to startup.

Solid Radioactive Waste Packaging System

The SRWP system consists of equipment designed and specified to collect, segregate, process (i.e., encapsulate), and stage for shipment solid radioactive waste from systems throughout the IF and RPF without limiting the normal operation or availability of the facilities. Solid waste may include dry active waste, spent ion exchange resin, and filters and filtration media. The SRWP system also inventories materials entering and exiting the facility structure storage bore holes as the supercell imports and exports them. Solid radioactive waste is collected in segregated containers. Containers may be sorted for potentially non-contaminated waste. Contaminated waste is sealed, labeled, and transported to the MATB for characterization, documentation, and staging for shipment.

SHINE Supplement section 9b.7.5 indicates that there is adequate bore hole storage space for waste streams that may require encapsulation processing until the MATB is available during Phase 3.

Because the SRWP is available to handle solid waste, with the exception of the MATB, which is not available during Phase 1 and Phase 2, the NRC staff finds that the conclusions reached in SER section 9b.4.7.5 are not affected by the proposed phased approach to startup.

Radioactive Drain System

The RDS is comprised of drip pans, piping, and collection tanks. The collection tanks are normally maintained empty and are equipped with instrumentation to alert personnel of an abnormal condition. The RDS operates by gravity drain, where overflows and leakage flow through installed piping drains directly to the RDS hold tanks.

Based on the RDS being functional and isolated from the collection of non-operational IXP process liquids or the overpressure protection for the IXP during Phase 1 through Phase 3, the RDS retains the ability to perform its function and the NRC staff finds that the conclusions reached in SER section 9b.4.7.6 are not affected by the proposed phased approach to startup.

Facility Potable Water System

The potable water supply to the SHINE facility is connected to the City of Janesville water supply. The FPWS ends at the backflow prevention device interfacing with both the FDWS and the FHWS. Because the FPWS interfaces contain backflow preventors to prevent inadvertent contamination from interfacing systems, the NRC staff finds that the conclusions reached in SER section 9b.4.7.7 are not affected by the proposed phased approach to startup.

Facility Nitrogen Handling System

The FNHS is designed to supply liquid and compressed gaseous nitrogen to systems inside the RCA. As described in SHINE FSAR section 9b.7.8, the FNHS is not relied upon to prevent accidents that could cause undue risk to the health and safety of the workers or the public or to control or mitigate the consequences of such accidents. SHINE Supplement section 9b.7.8 summarizes the isolated interfaces for the FNHS as follows:

- During Phase 1 and Phase 2, interfacing FNHS connections to IU-specific instances of IU systems (i.e., TOGS) are isolated outside the IU cell as described in SHINE Supplement section 4a2.1 (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1 and interfaces with IUs 6 through 8 are isolated during Phase 2).

- During Phase 1 and Phase 2, interfacing FNHS connections to TPS trains are isolated as described in SHINE Supplement section 9a2.7 (i.e., interfaces with TPS Train B and Train C are isolated during Phase 1 and interfaces with TPS Train C are isolated during Phase 2).

- During Phase 1 through Phase 3, interfacing FNHS connections to the IXP system are isolated as described in SHINE Supplement section 4b.3.

Based on the availability of the FNHS for initial (i.e., Phase 1) operations and the isolation from the phase-dependent interfacing systems, the NRC staff finds that the FNHS retains the ability to support its function and is not affected by the proposed phased approach to startup.

<u>Facility Sanitary Drain System</u>

The FSDS collects domestic sanitary waste and wastewater outside the RCA and discharges it to a city sewer main. SHINE FSAR section 9b.7.9 states that the FSDS removes domestic sanitary waste and wastewater from the areas of the main production facility (outside the RCA), the storage building, and the resource building; and discharges sanitary waste and wastewater to the City of Janesville public sewer main. Because the FSDS interfaces only with systems outside the RCA and contains backflow preventors to prevent inadvertent contamination with interfacing systems, the NRC staff finds that the conclusions reached in SER section 9b.4.7.9 are not affected by the proposed phased approach to startup.

<u>Facility Chemical Reagent System</u>

The FCRS provides storage and equipment for non-radioactive chemical reagents used in the SHINE processes. The SHINE Supplement describes that in Phase 1 and Phase 2, interfacing FCRS connections to IU-specific systems (i.e., TOGS) are isolated as described in SHINE Supplement section 4a2.1 (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1 and interfaces with IUs 6 through 8 are isolated during Phase 2). During Phase 1 through Phase 3, interfacing FCRS connections to the IXP system are isolated. Isolating the interfaces to individual IUs and the IXP system does not affect the capability of the FCRS to perform its functions for other system interfaces.

Additionally, FCRS reagents transported in portable containers are not connected to process tie-in locations until the respective equipment is installed.

Based on the availability of the FCRS for initial (i.e., Phase 1) operations and the isolation from the phase-dependent interfacing systems, the NRC staff finds that the FCRS retains the ability to support its function and is not impacted by the proposed phased approach to startup.

9b.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's RPF auxiliary systems as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 9b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the design of the RPF auxiliary systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's RPF auxiliary systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

10.0 EXPERIMENTAL FACILITIES

Section 10, “Experimental Facilities,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the SHINE experimental facilities, as presented in SHINE Supplement chapter 10, “Experimental Facilities.”

SHINE Supplement chapter 10 states that the SHINE facility does not contain experimental facilities as described in NUREG-1537 and the ISG augmenting NUREG-1537.

The NRC staff evaluated the sufficiency of SHINE’s description of experimental facilities using the guidance and acceptance criteria from chapter 10, “Experimental Facilities and Utilization,” of NUREG-1537, Parts 1 and 2, and Chapter 10, “Experimental Facilities,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR chapter 10 is not affected by the phased approach to startup. Therefore, the staff evaluation provided in SER Chapter 10, “Experimental Facilities,” is applicable to the phased approach to startup without further supplementation.

11.0 RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

Section 11, “Radiation Protection Program and Waste Management,” of this appendix to the SER provides the NRC staff evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE radiation protection program and waste management, as presented in SHINE Supplement Chapter 11, “Radiation Protection Program and Waste Management.”

11.1 Summary of the Supplement to the Application

The SHINE Supplement provides information on the areas in which workers are expected to be during the proposed phased approach to startup. The radiation sources previously described in the SHINE FSAR are applicable and bounding for the dose analysis that would be used for the phased approach to startup.

During Phase 1 with IU cells 1 and 2 operating, a worker could be in the adjacent IU and TOGS cell 3. During Phase 2 with IU cells 1 through 5 operating, a worker could be in the adjacent IU and TOGS cell 6. In addition, the applicant provided information on the IXP hot cell dose rates for Phase 1 through Phase 3. During Phase 3 and Phase 4 for the IU and TOGS cells and during Phase 4 for the IXP hot cell, the occupational doses are expected to match the information in SHINE FSAR figure 11.1-1 for normal operations.

For radioactive waste controls, the MATB will not be used for interim storage of waste until it is operational for Phase 3. Any solidified waste generated during Phase 1 and Phase 2 will be stored in bore holes as discussed in SHINE FSAR chapter 9b.

Radioactive waste streams expected to be produced during the phased approach to startup are provided in SHINE Supplement table 11.2-1, “Estimated As-Generated Annual Waste Stream Summary During Phased Startup Operations.” The radioactive waste streams expected to be disposed of during the phased approach to startup are provided in SHINE Supplement table 11.2-2, “Estimated As-Disposed Annual Waste Stream Summary During Phased Startup Operations.”

Releases of radioactive wastes are not affected by the phased approach to startup, except that the RLWI selective removal process is not available during Phase 1 and Phase 2, and the IXP system is not available during Phase 1 through Phase 3. The phased approach to startup entails that waste solidified during Phase 1 and Phase 2 may have higher dose rates and higher waste classifications than waste solidified during Phase 3 and Phase 4. During Phase 1 and Phase 2, liquid waste is stored in the subgrade RLWS tanks prior to transfer to the RLWI in order to maximize the decay time and to limit the volume of solidified waste requiring disposal.

11.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 11 using the guidance and acceptance criteria from chapter 11, “Radiation Protection Program and Waste Management,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

In its evaluation, the NRC staff determined the impacts of radiation exposures on workers that would work in non-operational cells adjacent to operational cells. The staff reviewed dose rates specified by the applicant and confirmed those results from the calculation files available to the staff during the audit conducted on May 26, 2022. The observations from this audit are documented in an audit report (ML22287A185). In its response to NRC staff RCI 11-1 (ML22213A049), the applicant confirmed the following information:

- The average dose rate in an empty IU cell adjacent to an operating IU cell is approximately 15 millirem per hour (mrem/hr) below the normal light water pool height and less than 5 mrem/hr above the light water pool height. The dose rate in the empty IU cell is approximately 60 mrem/hr at the height of the TSV near the south wall.

- The maximum dose rate in an adjacent TOGS cell is expected to be approximately 60 mrem/hr.

- The maximum dose rate in an adjacent primary cooling room is expected to be approximately 5 mrem/hr.

- During installation of the IXP system components, the adjacent cell can be operating, and the dose rate is expected to be approximately 5 mrem/hr.

- Radiation protection surveys and ALARA work planning practices will be implemented to maintain occupational doses ALARA.

Based on the above, the NRC staff finds that SHINE has an appropriate level of understanding of those areas that could be a concern for occupational exposures during the phased approach to startup. SHINE confirmed varying dose rates for these areas and acknowledged the use of radiation protection and ALARA work planning before entering these areas. Given this information and the commitments made in the SHINE FSAR, the staff has reasonable assurance that the SHINE facility will meet the ALARA guidelines in accordance with 10 CFR 20.1101, “Radiation protection programs,” paragraph (b).

The NRC staff review of the expected waste streams both produced and disposed of during the phased approach to startup determined that the information in SHINE Supplement tables 11.2-1 and 11.2-2 is consistent with the information provided in SHINE FSAR table 11.2-1, as demonstrated by the fact that, as more IUs come online, the waste generation and disposal rates approach the values provided in SHINE FSAR table 11.2-1. The information in SHINE Supplement tables 11.2-1 and 11.2-2 identifies the amounts of radioactive material that is expected and supports the conclusions established in the FSAR to show that exposures and releases of radioactive material are bounded by the FSAR analysis. SHINE Supplement section 11.2.3, “Release of Radioactive Waste,” states that during Phase 1 and Phase 2, the solidified waste generated may have higher dose rates and waste classifications than would be observed in Phase 3 and Phase 4 because there is no RLWI selective removal process available. As a result, SHINE plans to maximize decay times using the below grade RLWS tanks prior to transfer to the RLWI.

Given that the MATB will not be used for the interim storage of waste until it is operational for Phase 3, SHINE stated that the use of the subgrade bore holes in the RPF will ensure that dose rates within the RPF remain ALARA. SHINE’s proposed radiation protection and ALARA programs will ensure that doses will be ALARA around these storage areas. The NRC staff find this to be acceptable because the bore holes are intended to be used for interim storage prior to disposals or movement into the MATB.

SHINE FSAR chapter 11 is not affected by the proposed phased approach to startup except for those areas discussed above. The applicant will continue to implement the Radiation Protection Program, the ALARA Program, the Radiation Monitoring and Surveying Program, and Radiation Exposure Control and Dosimetry, Contamination Control, Environmental Monitoring, and Radioactive Waste Management programs consistent with the information described in the SHINE FSAR. The applicant confirmed the expected dose rates and waste storage options at the facility during the completion of uncompleted items of construction. Based on the above, the staff finds that the SHINE Supplement appropriately addresses those areas where the phased approach to startup could be of concern for the issues of the radiation protection program and waste management.

11.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's radiation protection program and waste management as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 11, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the radiation protection program and waste management and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 19, 10 CFR Part 20, 10 CFR Part 50, 10 CFR Part 61, 10 CFR Part 71, 40 CFR, Chapter I, and 49 CFR, Chapter I and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's radiation protection program and waste management as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

12.0 CONDUCT OF OPERATIONS

Section 12, “Conduct of Operations,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the SHINE conduct of operations, as presented in SHINE Supplement chapter 12, “Conduct of Operations.”

SHINE Supplement chapter 12 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE’s description of the conduct of operations using the guidance and acceptance criteria from chapter 12, “Conduct of Operations,” of NUREG-1537, Parts 1 and 2, and chapter 12, “Conduct of Operations,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR chapter 12 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER chapter 12, “Conduct of Operations,” is applicable to the phased approach to startup without further supplementation.

13.0 ACCIDENT ANALYSES

Section 13, “Accident Analyses,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the SHINE accident analyses, as presented in SHINE Supplement chapter 13a2, “Irradiation Facility Accident Analysis,” and chapter 13b, “Radioisotope Production Facility Accident Analysis.”

13.1 Irradiation Facility and Radioisotope Production Facility Accident Analyses

Section 13.1, “Irradiation Facility and Radioisotope Production Facility Accident Analyses,” of this appendix to the SER provides the NRC staff’s evaluation of the SHINE IF and RPF accident analyses as affected by the proposed phased approach to startup, as presented in SHINE Supplement chapter 13a2 and chapter 13b.

13.2 Summary of the Supplement to the Application

The proposed phased approach to startup was developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where the completion of uncompleted items of construction would be occurring during operation to minimize the impacts on the operating portions of the facility. The phased approach to startup is divided into four phases. Phase 1 brings the Mo-99 production capability online and Phases 2 and 3 increase this capability. Phase 4 adds iodine and xenon production capability.

SHINE used its SSA methodology described in SHINE FSAR chapter 13 to evaluate whether any new or different hazards are introduced by the phased approach to startup. Additional details on the safety analysis evaluation specific to the phased approach to startup are provided in SHINE Supplement chapter 13a2 and chapter 13b. The results of this evaluation are that the phased approach to startup does not result in new accident categories, but does result in the following new accident sequences within the IF:

- Improper target solution routing to an uninstalled IU cell.
- Damage to an installed TPS train during the installation of another TPS train.
- Damage to a PVVS to TOGS interface line during installation of the SCAS.

The results of the safety analysis evaluation specific to the phased approach to startup increased the likelihood of the following accident sequences within the IF:

- Heavy load drop on the TPS.
- Heavy load drop on an in-service IU or TOGS cell.
- Fire in the IF general area.

Within the RPF, the phased approach to startup does not result in new accident categories, but does result in the following new accident sequences:

- Improper target solution routing to the IXP cell prior to Phase 4.
- Backflow of target solution to the IXP cell prior to Phase 4 operations.

The results of the safety analysis evaluation specific to the phased approach to startup increased the likelihood of the following accident sequences within the RPF:

- Heavy load drop onto the RLWI shielded enclosure or supercell.
- Fire in the RPF general area.

13.3 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 13a2 and chapter 13b using the guidance and acceptance criteria from section 13a2, "Aqueous Homogeneous Reactor Accident Analyses," and section 13b, "Radioisotope Production Facility Accident Analyses," of the ISG augmenting NUREG-1537, Parts 1 and 2.

The SHINE IU systems are designed and operated at the unit level. The SHINE design criteria for each IU system, both general and system-specific, are met during all phases for the IU systems in operation. During each phase, the equipment necessary to support the operation of IU systems is functional and available for operation. As such, the ESFs required to mitigate the DBAs are not affected by the phased approach to startup. Additionally, support systems and auxiliary systems are installed prior to initial (i.e., Phase 1) operations. Support systems and process line interfaces with the IUs are isolated as needed to support the phased approach to startup.

Isolations at interface points with uninstalled systems are described throughout the SHINE Supplement and generally consist of one or more valves and blind flanges or caps. The blind flanges and caps described are not credited controls and are not necessary to meet SHINE design criteria for the systems. As system installation progresses in preparation for the operation of the next phase, the blind flanges and caps are removed and the appropriate process connections are made. Confinement boundaries for operating systems are not impacted by installation activities. During Phase 1, the primary confinement boundaries for the operable IUs 1 and 2 are operable. During Phase 2, the primary confinement boundaries for the operable IUs 1 through 5 are operable. The primary confinement boundaries for all 8 IUs are operable during Phase 3 and Phase 4. For the primary confinement boundaries for IUs that are not operable in Phase 1 and Phase 2, system isolations are in place to prevent the release of radiological or chemical hazards into the uninstalled IUs. For Phase 1, only Train A of the TPS is installed and supports the operation of IUs 1 and 2. For Phase 2, Trains A and B of the TPS are installed, with Train A supporting the IUs installed for Phase 1 (i.e., IUs 1 and 2) and Train B supporting the IUs installed for Phase 2 (i.e., IUs 3 through 5). For Phase 3 and Phase 4 operations, the IUs and TPS are installed in full.

Within the IF, the following isolation points are provided inside IU cells 3 through 8 during Phase 1 and inside IU cells 6 through 8 during Phase 2:

- The VTS line to fill the TSV includes two isolation valves.
- The VTS line to the TSV dump tank includes one isolation valve inside the IU cell and an additional isolation valve outside of the IU cell.
- The VTS line to the TOGS vacuum tank includes two isolation valves.
- The PVVS line that exits the IU cell includes one locked closed isolation valve.

The following isolation points are provided outside IU cells 3 through 8 or TOGS cells 3 through 8 during Phase 1 and outside IU cells 6 through 8 or TOGS cells 6 through 8 during Phase 2:

- RPCS supply and return lines.
- FNHS supply lines include one isolation valve.
- FCRS supply lines include one isolation valve.
- N2PS purge lines include one isolation valve and a blind flange or cap.
- RVZ1 exhaust lines.

Mishandling or Malfunction of Target Solution

SHINE Supplement section 13a2.1.4, “Mishandling or Malfunction of Target Solution,” identifies and evaluates the additional mishandling and malfunction of target solution scenario of improper target solution routing to an uninstalled IU cell. The initiating event in this scenario is a failure of the VTS lower lift tank target solution valve. In the uncontrolled sequence, failure of the valve would cause leakage of target solution into an uninstalled IU cell. This scenario is prevented by the dump tank drain isolation valve, which is installed prior to initial (i.e., Phase 1) operations and is maintained disconnected from power until the phase in which the associated IU is operable. Since this scenario has preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in section 13a.4.4 of this SER are not affected by the phased approach to startup.

System Interaction Events

SHINE Supplement section 13a2.1.11, “System Interaction Events,” identifies and evaluates the additional system interaction event of damage to a PVVS to TOGS interface line during installation of the SCAS during the phased approach to startup. The accident scenario of fire in the IF general area leading to damage of cooling room equipment was also modified and evaluated for an increased initiating event likelihood during the phased approach to startup. Errors during installation of SCAS equipment in a non-operable IU cell during Phase 1 or Phase 2 may result in damage to the PVVS to TOGS interface line that extends into the IU cell. Damage to this line could create a preferred flow path for PVVS gas to bypass process tanks, leading to deflagration and radiological dose. This scenario is prevented through the application of a new passive engineered control of a physical barrier installed over vulnerable portions of the PVVS to TOGS interface line and a specific administrative control to limit crane hoist speed during SCAS installation. The accident sequence of a fire in the IF general area leading to damage of cooling room equipment resulting in a complete loss of PCLS cooling in one or more IU cells or TOGS cells is modified during the phased approach to startup to account for an increased likelihood of the initiating event as a result of on-going completion of uncompleted items of construction. Radiological release due to this scenario is prevented by the credited controls currently in place. Since these events have preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in SER section 13a.4.11 are not affected by the phased approach to startup.

Facility-Specific Events

SHINE Supplement section 13a2.1.12, "Facility-Specific Events," identifies and evaluates the additional facility-specific event of damage to an operating TPS train during the installation of another TPS train. The accident scenarios of a heavy load drop onto an open in-service IU cell or TOGS cell and a heavy load drop onto TPS equipment were also modified and evaluated for an increased initiating event likelihood during the phased approach to operations. Errors during installation of TPS Trains B or C during Phase 1 or Phase 2 operations, respectively, may result in damage to an operating TPS train. In the uncontrolled scenario, mechanical damage to an installed TPS train could lead to a release of tritium and radiological dose to workers and the public. The physical distance separating the TPS train installation locations reduces the likelihood of the initiating event. This scenario is prevented through the application of a new specific administrative control for operators to install physical barriers (e.g., roping or stanchions) around installed TPS trains to limit access to areas where mechanical damage to an installed TPS train is possible. The accident sequence of a heavy load drop onto an in-service IU cell or TOGS cell and a heavy load drop onto TPS equipment is modified during the phased approach to startup to account for an increased likelihood of the initiating event as a result of on-going completion of uncompleted items of construction. These scenarios are prevented by a credited control currently in place (i.e., the single-failure-proof crane in the IF). Since these events have preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in section 13a.4.12 of this SER are not affected by the phased approach to startup.

Radioisotope Production Facility Critical Equipment Malfunction

SHINE Supplement section 13b.1.2.3, "RPF Critical Equipment Malfunction," identifies and evaluates two additional RPF critical equipment malfunction scenarios of a target solution leak into the IXP cell. The initiating event in this first scenario is the failure of a locked closed valve between the MEPS and the IXP system, located in the MEPS cell. In the uncontrolled scenario, failure of the valve could cause leakage of target solution into the IXP cell, resulting in dose consequences to workers and the public. This scenario is prevented by a second locked closed manual valve between the MEPS and the IXP system, located in the IXP cell. The initiating event in the second RPF critical equipment malfunction scenario is the backflow of target solution from the TSSS to the IXP due to failure of a TSSS tank isolation valve. In the uncontrolled sequence, failure of the TSSS tank isolation valve during molybdenum extraction causes a backflow of target solution into the IXP cell through the MEPS drain line, resulting in dose consequences to workers and the public. This scenario is prevented by the locked closed isolation valve between the MEPS and the IXP system, located inside the IXP cell, as well as the cap on the pipe entering the IXP cell. The accident sequence of a heavy load drop onto the RLWI shielded enclosure or supercell was also modified and evaluated for an increased initiating event likelihood during the phased approach to operations. This increase was small in comparison to the total planned lifts during normal operations and did not result in an increase in the likelihood index for the initiating event. This scenario is prevented by the credited controls currently in place, including the application of applicable guidance from NUREG-0612 for control of heavy loads in the SHINE facility. Since these scenarios have preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in section 13a.4.6 of this SER are not affected by the phased approach to startup.

Radioisotope Production Facility Fire

SHINE Supplement section 13b.1.2.5, "RPF Fire," identifies and evaluates an increase in the initiating event likelihood for a fire in the RPF general area during the phased approach to startup, which resulted in an increase in the likelihood index for the initiating event. The new specific administrative control of suspension of radiological material processing in the adjacent cell during hot work was applied in addition to the existing RPF fire controls. Since this scenario has preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in SER section 13b.4.8 are not affected by the phased approach to startup.

13.4 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's IF and RPF accident analyses as affected by the proposed phased approach to startup, as described in SHINE Supplement chapter 13a2 and chapter 13b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

(1) SHINE described the IF and RPF accident analyses and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF and RPF accident analyses as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

13.5 SHINE Safety Analysis

13.5.1 Summary of the Supplement to the Application

SHINE identified that the proposed phased approach to startup has impacts on the SHINE SSA. These impacts and the evaluations of the impacts are summarized in the SHINE Supplement, including chapter 13, and a supplement to the SSA Summary (hereafter, the SSA Supplement), as amended. The evaluations include the identification of new accidents or revisions to accident evaluations in the SHINE FSAR and SSA and new safety-related controls to ensure that the new and revised accidents will not exceed the SHINE safety criteria as specified in SHINE FSAR section 3.1. SHINE's approach is to provide a supplement to the SSA Summary (i.e., the SSA Supplement) that addresses the impacts due to the phased approach to startup that is intended to address the facility, including operations and the impacts of the completion of uncompleted items of construction for all the phases prior to the phase (i.e., Phase 4) in which the facility is complete and fully operational in accordance with the SHINE FSAR. This SSA Supplement is a separate part of the SSA Summary that is to be removed when the final phase of the SHINE facility is complete and in operation.

13.5.2 Technical Evaluation

The purpose of the NRC staff's review regarding the phased approach to startup is to confirm that, with the SSA Supplement, the SSA and SHINE's safety program are adequate to ensure the health and safety of the public and workers during the phased approach to startup. The staff's review does this by evaluating the SSA Supplement to confirm:

- Consistency with the SHINE FSAR as modified by the SHINE Supplement for the phased approach to startup,
- The SSA Supplement demonstrates that impacts from the phased approach to startup have been identified and evaluated and that appropriate safety-related controls and reliability management measures have been identified and will be put in place to prevent or mitigate accident sequences so as to not exceed the SHINE safety criteria as specified in SHINE FSAR section 3.1,
- Implementation of the SSA method in the SSA Supplement, and
- SHINE's approach to phased startup adequately implements SHINE's commitments regarding the SSA.

The NRC staff reviewed the SSA Supplement pursuant to the ISG augmenting NUREG-1537, Parts 1 and 2, which endorses the use of integrated safety analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, but also allows for alternatives with adequate justification. For its review, the staff reviewed the SSA Supplement and the SHINE Supplement. The staff also referred to relevant sections of the SHINE FSAR and SSA to support its review of the supplements. As part of this review, the staff conducted an audit and issued an audit report for the phased approach to startup (ML22287A185).

As described in SHINE Supplement section 1.1, the phased approach to startup is divided into four phases. Phase 1 brings the Mo-99 production capability online and Phases 2 and 3 increase this capability. Phase 4 adds iodine and xenon production capability, at which point all systems and processes will be in place in accordance with the descriptions in the SHINE FSAR and operating license application.

13.5.3 Consistency with Final Safety Analysis Report, Phased Startup Impacts, and Safety-Related Controls

The NRC staff compared the information in the SHINE Supplement to that in the SHINE FSAR to understand the differences in the systems and operations and to identify differences in the facility and systems' configurations that could impact the safety analysis. Particularly, the staff sought to identify where differences could introduce new accident sequences or result in changes in consequences or likelihoods of analyzed accident sequences. The staff also looked to identify where new safety-related controls might be needed or where already identified safety-related controls may need to perform their functions differently or need different reliability management measures.

Through its review, the NRC staff identified configuration differences and activities that the staff considered as having the potential for accident sequences of increased consequences (e.g., leak of materials through connections to yet-to-be-installed systems or system components), introducing new accident sequences, or increasing likelihoods of accident sequences, including due to human error (e.g., errors in performing activities associated with the completion of uncompleted items of construction affecting already installed and operating facility systems). The staff also considered that the amount of licensed material being processed in earlier phases will be less (i.e., fewer IUs in operation), which means that the consequences for some accidents will be less than that analyzed in the SSA because the material available for release will be less as compared to full facility operation.

Based on the information in the SHINE Supplement, the NRC staff identified components and personnel actions that would seem to be needed and relied on to prevent or mitigate accidents during the different phases. The staff reviewed systems descriptions in the SHINE FSAR to determine if and how these components had been described. The staff also audited the SSA Summary to determine if and how these components and personnel actions had been identified and evaluated as safety-related controls. Additionally, the staff considered whether differences in configuration would affect those components identified as safety-related controls in terms of their safety function (e.g., continuous isolation vs. isolation upon demand). The staff further considered that components that are not relied on as safety-related controls for the full facility could be needed as safety-related controls during one or more phases prior to the final phase where the facility is complete and fully operational. Certain operations, such as those to be done in the MATB, would be done in a different location within the radiological controlled area. Thus, in its review, the staff determined whether the operations, including safety-related controls, would be conducted in the same manner and how the operations being in a different location may impact other facility operations. Additionally, as part of the phased approach to startup, uncompleted items of construction will be completed while installed systems are operating.

The NRC staff then reviewed SHINE Supplement chapter 13 and the SSA Supplement to determine whether the applicant's accident analysis adequately addresses the potential impacts that the staff identified from its review. The applicant identified that the phased approach to startup introduced a limited number of new accident sequences. The applicant also identified that the phased approach to startup affected a few of the accident sequences in the SSA in a way that increased likelihoods or consequences. For those accident sequences where the likelihoods or consequences were reduced, the applicant did not perform a new evaluation. The staff considered whether there may be additional accident sequences, either new or affected sequences (with higher likelihoods or greater consequences), from the completion of uncompleted items of construction (e.g., heavy load drops), potential human error-induced events, and differences in operations arising from systems being not yet installed during certain phases. Based on this review and evaluation of the descriptions of the differences between the facility and facility systems during the earlier phases of startup versus the final phase regarding the considerations identified above, the staff finds that the applicant has identified and evaluated the appropriate accident sequences for the phased approach to startup.

To ensure that the new and modified accident sequences do not exceed the SHINE safety criteria as described in SHINE FSAR section 3.1, the applicant identified new engineered and administrative safety-related controls. In its review of the SHINE Supplement, the NRC staff determined that a number of valves are relied on for isolation of connections to uninstalled systems. SHINE Supplement chapter 13 and the SSA Supplement only identify a few of these valves as new safety-related controls. Therefore, the staff reviewed the system descriptions in the SHINE FSAR and the SSA Summary to determine whether these documents already identify the remaining valves discussed in the SHINE Supplement as part of the facility's systems' designs and as safety-related controls. For any valves not described in the SHINE FSAR and SSA Summary as part of the systems' designs and safety-related controls, the staff used the information in the SHINE FSAR and SHINE Supplement to evaluate whether the SSA Supplement and SHINE Supplement chapter 13 should identify them as safety-related controls.

Based on this review, the NRC staff determined that some of these valves are already part of the systems' designs and are already identified as safety-related controls in the SSA Summary. Also, some safety-related controls in the SSA Summary involve multiple SSCs (e.g., controls identified for confinement functions). Valves that are added to or included among the SSCs identified to be part of such safety-related controls and that are used for isolation during the phased approach to startup would then be part of that safety-related control. Also, some of the valves need not be safety-related controls because the nature of the accident that they would prevent is captured already by accidents evaluated in the SSA without the need to rely on these valves. Thus, the staff finds that the applicant appropriately identified those valves that should be new safety-related controls.

The NRC staff also considered the reliability management measures for the new safety-related controls and for those safety-related controls (including those controls that are valves) that are identified in the SSA Summary and that are also relied on in the SSA Supplement. The staff reviewed whether the reliability management measures are appropriate for the type and nature of the control and how the control performs the required function. In this review, the staff confirmed that measures identified for engineered controls are appropriate for engineered controls and that measures identified for administrative controls are appropriate for administrative controls. The staff also identified that the measures are consistent with the nature of the control. The staff's review included consideration of differences in how the control performs its function and the potential differences in the nature of the accidents they control (whether prevention or mitigation) for the earlier phases of startup versus the final phase (e.g., valves that perform continuous isolation versus isolation on demand). The staff considered that these differences have potential implications for the reliability management measures that would be necessary for these controls. In its review, the staff determined that the applicant adequately accounted for these considerations. The staff also determined that the identified reliability management measures do not include items that are in fact administrative safety-related controls.

Based on its review of the SHINE FSAR and the SSA Summary, as modified by the SHINE Supplement and the SSA Supplement, the NRC staff finds that the SSA Supplement is consistent with the SHINE FSAR, as modified by the SHINE Supplement, for the phased approach to startup. The staff also finds that the SSA Supplement demonstrates that the applicant has adequately identified and evaluated the impacts from the phased approach to startup and has identified appropriate safety-related controls and reliability management measures to prevent or mitigate accident sequences. Therefore, the staff has reasonable assurance that operations of the SHINE facility will not exceed the SHINE safety criteria, thus ensuring the health and safety of the public and workers.

13.5.4 SHINE Safety Analysis Method Implementation

The applicant used the same SSA methods for the analysis of the phased approach to startup as for the SSA for the operating license application, which is summarized in SHINE FSAR section 13a2. Thus, the NRC staff's review of the SSA Supplement included confirmation that the SSA methods were implemented appropriately in the SSA Supplement. The staff considered the accident sequence evaluations in the SSA Supplement. The staff also considered the identification and evaluation of safety-related controls and the identification of reliability management measures in the SSA Supplement. These considerations include the failure frequency and failure probability indices that the applicant assigned to the safety-related controls. Based on this review, the staff determined that the evaluations in the SSA Supplement are consistent with the applicant's SSA method and, therefore, the staff finds that the applicant appropriately implemented its SSA method for evaluating the phased approach to startup.

13.5.5 SHINE Safety Analysis Implementation

The SSA needs to be maintained to ensure that it reflects the as-built and as-operated facility, including as it is described in the SHINE FSAR, and that the SSA demonstrates that the facility ensures the health and safety of the public and workers. Management of the SSA also ensures that the necessary safety-related controls and their reliability management measures are identified and maintained, with appropriate controls exercised over changes to them, particularly for those safety-related controls that are not captured in TSs.

SHINE's approach in support of the phased approach to startup is to append a supplement to the SSA (i.e., the SSA Supplement), which will be removed when the facility is in Phase 4. However, the NRC staff notes that the management of the SSA, including SHINE's configuration management program in TS 5.5.4 and the SHINE nuclear safety program in TS 5.5.1, applies to the as-built facility and as facility operations progress from phase to phase. This includes following SHINE's change control program and ensuring that the SSA, with the SSA Supplement, reflect the as-built and as-operated facility, including the impacts of any ongoing completion of uncompleted items of construction in each phase. Thus, SHINE will need to perform the activities and evaluations at each phase to maintain the SSA.

The SSA Supplement is part of the SSA Summary. Thus, with the SSA Supplement including accident sequences that are similar to those in the SSA Summary, the NRC staff considers it important that the sequences in the SSA Supplement be adequately distinguishable from those similar sequences in the SSA Summary. Otherwise, the same accident sequence will have two different, concurrent analyses that indicate different consequences or frequencies for the same initiating events or include new safety-related controls in order to not exceed the SHINE safety criteria. This would seem to be inconsistent with the commitment to maintain the SSA Summary and the purpose of that commitment. In its review, the staff identified that accident sequences in the SSA Supplement that are similar to sequences in the SSA Summary have descriptions that distinguish them from each other such that it is sufficiently clear that they are different accident sequences. Based on the applicant's modifications and explanations, the staff finds the applicant's approach to the SSA for evaluating the phased approach to startup to be acceptable and consistent with the purpose of the SSA.

13.5.6 Conclusion

Based on its review of the SHINE FSAR, as modified by the SHINE Supplement; the SSA, as modified by the SSA Supplement; the TSs; and SHINE's commitments captured in the SHINE FSAR and TSs, the NRC staff finds that:

- The SSA Supplement is consistent with the SHINE FSAR, as modified by the SHINE Supplement for the phased approach to startup;
- The SSA Supplement demonstrates that the applicant has adequately identified and evaluated the potential safety impacts from the phased approach to startup and has identified appropriate safety-related controls and reliability management measures to prevent or mitigate accident sequences;
- The applicant appropriately implemented its SSA method in evaluating the phased approach to startup, and the staff finds this SSA method acceptable; and
- The applicant's approach to the SSA for evaluating the phased approach to startup is consistent with its commitments regarding the SSA and with the purpose of the SSA.

Therefore, based on these findings, the NRC staff has reasonable assurance that operations of the SHINE facility will not exceed the SHINE safety criteria and that SHINE's SSA, with the SSA Supplement, and SHINE's safety program will be adequate for ensuring the health and safety of the public and workers during the phased approach to startup in accordance with 10 CFR 50.34(b)(2) and 10 CFR 50.57(a)(3).

14.0 TECHNICAL SPECIFICATIONS

Section 14, “Technical Specifications,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the TSs of the SHINE facility, as presented in the SHINE Supplement chapter 14, “Technical Specifications.”

SHINE Supplement chapter 14 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE’s TSs using the guidance and acceptance criteria from chapter 14, “Technical Specifications,” of NUREG-1537, Parts 1 and 2, and chapter 14, “Technical Specifications,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR chapter 14 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER chapter 14, “Technical Specifications,” is applicable to the phased approach to startup without further supplementation.

15.0 FINANCIAL QUALIFICATIONS

Section 15, “Financial Qualifications,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the financial qualifications of SHINE, as presented in SHINE Supplement chapter 15, “Financial Qualifications.”

SHINE Supplement chapter 15 states that the information provided in the SHINE FSAR is not materially affected by the phased approach to startup. SHINE stated that the decommissioning cost estimate for the facility remains bounding for the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE’s financial qualifications using the guidance and acceptance criteria from chapter 15, “Financial Qualifications,” of NUREG-1537, Parts 1 and 2, and chapter 15, “Financial Qualifications,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR chapter 15 is not materially affected by the phased approach to startup and that the decommissioning cost estimate remains bounding for the facility with the phased approach to startup. Therefore, the staff technical evaluation provided in SER chapter 15, “Financial Qualifications,” is applicable to the phased approach to startup without further supplementation.

16.0 OTHER LICENSE CONSIDERATIONS

Section 16, “Other License Considerations,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the issue of other license considerations, as presented in SHINE Supplement chapter 16, “Other License Considerations.”

SHINE Supplement chapter 16 states that the SHINE facility utilizes new components and systems and, therefore, discussions regarding used components and systems are not applicable to the SHINE facility. SHINE also stated that the facility does not contain equipment or facilities associated with direct medical administration of radioisotopes or other radiation-based therapies and, therefore, discussions regarding medical use of the SHINE facility are not applicable.

The NRC staff evaluated the sufficiency of SHINE’s discussion regarding other license conditions using the guidance and acceptance criteria from chapter 16, “Other License Considerations,” of NUREG-1537, Parts 1 and 2, and chapter 16, “Other License Considerations,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR chapter 16 is not affected by the phased approach to startup. Therefore, the staff evaluation provided in SER chapter 16, “Other License Considerations,” is applicable to the phased approach to startup without further supplementation.

17.0 DECOMMISSIONING AND POSSESSION-ONLY LICENSE AMENDMENTS

Section 17, “Decommissioning and Possession-Only License Amendments,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the issue of decommissioning and possession-only license amendments, as presented in SHINE Supplement chapter 17, “Decommissioning and Possession-Only License Amendments.”

SHINE Supplement chapter 17 states that a decommissioning report is provided in SHINE FSAR section 15.3, “Financial Ability to Decommission the SHINE Facility.” SHINE also stated that a possession-only license is not applicable to the SHINE facility.

The NRC staff evaluated the sufficiency of SHINE’s discussion regarding decommissioning and possession-only license amendments using the guidance and acceptance criteria from chapter 17, “Decommissioning and Possession-only License Amendments,” of NUREG-1537, Parts 1 and 2, and Chapter 17, “Decommissioning and Possession-only License Amendments,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 17 is not affected by the phased approach to startup. Therefore, the staff evaluation provided in SER chapter 17, “Decommissioning and Possession-only License Amendments,” is applicable to the phased approach to startup without further supplementation.

18.0 HIGHLY ENRICHED TO LOW ENRICHED URANIUM CONVERSIONS

Section 18, “Highly Enriched to Low Enriched Uranium Conversions,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the issue of highly enriched to low-enriched uranium conversions, as presented in SHINE Supplement chapter 18, “Highly Enriched to Low Enriched Uranium Conversion.”

SHINE Supplement chapter 18 states that the SHINE facility is a new facility that uses low enriched uranium and, therefore, discussions of highly enriched to low enriched uranium conversions are not applicable.

The NRC staff evaluated the sufficiency of SHINE’s discussion regarding highly enriched to low enriched uranium conversions using the guidance and acceptance criteria from chapter 18, “Highly Enriched to Low-Enriched Uranium Conversions,” of NUREG-1537, Parts 1 and 2, and chapter 18, “Highly Enriched to Low-Enriched Uranium Conversions,” of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR chapter 18 is not affected by the phased approach to startup. Therefore, the staff evaluation provided in SER chapter 18, “Highly Enriched to Low Enriched Uranium Conversion,” is applicable to the phased approach to startup without further supplementation.

APPENDIX B
REFERENCES

CHAPTER 1

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- Letter 2019-SMT-0015 from SHINE Medical Technologies, "SHINE Medical Technologies, Inc. Application for Order Approving Indirect Transfer of Control of Construction Permit Response to Request for Additional Information," dated March 8, 2019 (ML19071A059), Enclosure 2, "Response to Request for Additional Information" (ML19071A056).

- U.S. Nuclear Regulatory Commission, "Commission Memorandum and Order CLI-99-06," dated March 5, 1999 (ML16195A533).

- Letter 2018-SMT-0083 from SHINE Medical Technologies, "Request for Confirmation of the 10 CFR Part 140 Financial Protection Requirements for the SHINE Facility," dated August 27, 2018 (ML18239A219).

Chapters 16, 17, and 18

- Letter 2019-STM-0054 from SHINE Medical Technologies, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143).

- Letter 2022-SMT-0077 from SHINE Technologies, "SHINE Technologies, LLC Application for an Operating License Supplement No. 30," dated August 31, 2022 (ML22249A148).

- U.S. Nuclear Regulatory Commission, NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," dated February 1996 (ML042430048).

- U.S. Nuclear Regulatory Commission, "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ML12156A075).

Appendix A

- Letter 2021-SMT-0027 from SHINE Medical Technologies, "SHINE Medical Technologies, LLC Overview of Phased Approach to Initial Facility Operations," dated February 26, 2021 (ML21057A340).

- Letter 2022-SMT-0019 from SHINE Technologies, "SHINE Technologies, LLC Application for an Operating License Supplement No. 15 Submittal of the Phased Startup Operations Application Supplement," dated January 27, 2022 (ML22027A353).

- Letter 2022-SMT-0058 from SHINE Technologies, "SHINE Technologies, LLC Application for an Operating License Response to Request for Additional Information," dated May 23, 2022 (ML22143A814).

- Letter 2022-SMT-0081 from SHINE Technologies, "SHINE Technologies, LLC Application for an Operating License Response to Request for Confirmatory Information," dated August 1, 2022 (ML22213A049).

- Letter 2022-SMT-0077 from SHINE Technologies, "SHINE Technologies, LLC Application for an Operating License Supplement No. 30," dated August 31, 2022 (ML22249A148).

- Letter 2022-SMT-0100 from SHINE Technologies, "SHINE Technologies, LLC Application for an Operating License Response to Request for Confirmatory Information," dated September 19, 2022 (ML22263A027).

- Letter 2022-SMT-0098 from SHINE Technologies, "SHINE Technologies, LLC Application for an Operating License Response to Request for Additional Information," dated September 20, 2022 (ML22263A344).

- Letter 2022-SMT-0101 from SHINE Technologies, "SHINE Technologies, LLC Application for an Operating License Supplement No. 31 Revision to the Phased Startup Operations Application Supplement," dated September 28, 2022 (ML22271A962).

- U.S. Nuclear Regulatory Commission, NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," dated February 1996 (ML042430055).

- U.S. Nuclear Regulatory Commission, NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," dated February 1996 (ML042430048).

- U.S. Nuclear Regulatory Commission, "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ML12156A069).

- U.S. Nuclear Regulatory Commission, "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ML12156A075).

- U.S. Nuclear Regulatory Commission, NUREG-0711, Revision 3, "Human Factors Engineering Program Review Model," dated November 2012.

- U.S. Nuclear Regulatory Commission, NUREG/CR-7126, "Human-Performance Issues Related to the Design and Operation of Small Modular Reactors," dated June 2012.

- U.S. Nuclear Regulatory Commission, NUREG/CR-7202, “NRC Reviewer Aid for Evaluating the Human-Performance Aspects Related to the Design and Operation of Small Modular Reactors,” dated June 2015.
- U.S. Nuclear Regulatory Commission, NUREG-0612, “Control of Heavy Loads at Nuclear Power Plants – Resolution of Generic Technical Activity A-36,” dated July 1980.
- U.S. Nuclear Regulatory Commission, NUREG-1520, Revision 2, “Standard Review Plan for Fuel Cycle Facilities License Applications,” dated June 2015 (ML15176A258).
- Letter 2022-SMT-0019 from SHINE Technologies, “SHINE Technologies, LLC Application for an Operating License Supplement No. 15 Submittal of the Phased Startup Operations Application Supplement,” dated January 27, 2022 (ML22027A353).
- U.S. Nuclear Regulatory Commission, Letter from Holly D. Cruz to Dr. Gregory Piefer, “SHINE Medical Technologies, LLC - Request for Additional Information Related to the Office of The General Counsel Review of the Phased Startup Operations Application Supplement (EPID NO. L-2022-NEW-0004),” dated August 25, 2022 (ML22105A110).
- U.S. Nuclear Regulatory Commission, NRC Inspection Manual, Inspection Procedure 69022, “Inspections of Operational Readiness During Construction of Non-Power Production and Utilization Facilities,” dated October 9, 2019 (ML19193A110).
- Letter 2022-SMT-0098 from SHINE Technologies, “SHINE Technologies, LLC Application for an Operating License Response to Request for Additional Information,” dated September 20, 2022 (ML22263A344).
- Letter SMT-2013-012 from SHINE Medical Technologies, “Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit,” dated March 26, 2013 (ML13088A192).
- Letter SMT-2013-023 from SHINE Medical Technologies, “Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit,” dated May 31, 2013 (ML13172A361).
- Letter SMT-2013-033 from SHINE Medical Technologies, “Submittal of the SHINE Medical Technologies, Inc. Preliminary Emergency Plan,” dated September 25, 2013 (ML13269A378).
- *Federal Register* (79 *FR* 62329), “Action: Final Rule,” dated October 17, 2014.
- U.S. Nuclear Regulatory Commission, Construction Permit No. CPMIF-001 for the SHINE facility, dated February 26, 2016 (ML16041A471).
- Letter 2022-SMT-0101 from SHINE Technologies, “SHINE Technologies, LLC Application for an Operating License Supplement No. 31 Revision to the Phased Startup Operations Application Supplement,” dated September 28, 2022 (ML22271A962), Enclosure 3, “Phased Startup Operations Application Supplement (Public Version)” (ML22271A966).

- U.S. Nuclear Regulatory Commission, letter from Holly D. Cruz to Dr. Gregory Piefer, “SHINE Technologies, LLC Regulatory Report on the Audit of Phased Startup Operations Application Supplement (EPID NO. L-2022-NEW-0004), dated February 1, 2023 (ML22287A185).

- Letter 2022-SMT-0100 from SHINE Technologies, “SHINE Technologies, LLC Application for an Operating License Response to Request for Confirmatory Information,” dated September 19, 2022 (ML22263A027).

- Institute of Electrical and Electronics Engineers, “IEEE Standard Criteria for Independence of Class 1E Equipment and Circuits,” IEEE std 384-2008, December 2008.

- Letter 2022-SMT-0081 from SHINE Technologies, “SHINE Technologies, LLC Application for an Operating License Response to Request for Confirmatory Information,” dated August 1, 2022 (ML22213A049). Response to NRC staff RCI 11-1.

APPENDIX C
SAFETY EVALUATION REPORT
PRINCIPAL CONTRIBUTORS

Name	Chapter	Area of Expertise
Adam Rau	5	Cooling Systems
Amitava Ghosh	2	External Hazards
Amy Beasten	12	Operator Training
Andrew Prinaris	3	Seismic
Beth Reed	12	Physical Security
Brandon Ayersman	All	General Counsel
Brian Green	7	Human Factors
Bryce Lehman	3	Meteorological and Water
Charles Moulton	9	Fire Protection
Charles Teal Jr.	12	Physical Security
David Heeszel	2	Geology, Seismology
Dan Warner	12	Cybersecurity
Dinesh Taneja	7	Instrumentation and Controls
Duane Hardesty	3, 7, 14	Design Criteria, Instrumentation and Controls, Technical Specifications
Duane White	12	Materials Security
Edward Robinson Jr.	12	Emergency Planning
Elijah Dickson	13	Accident Analysis
Frankie Vega	12	Quality Assurance
Gerard Jackson	12	Materials Security
Glenn Tuttle	12	Material Control and Accounting
Gordon Curran Jr.	5, 9	Cooling Systems, Auxiliary Systems
Holly Cruz	All	Project Management
Ian Tseng	3, 4, 9	Mechanical Engineering
James Hammelman	13	Chemical Safety
Jason White	2	Meteorology
Jay Robinson	9	Fire Protection
Jeremy Munson	6	Criticality Safety
Jeremy Wachutka	All	General Counsel
Jesse Seymour	7	Human Factors Engineering
Jorge Cintron-Rivera	8	Electrical Power Systems
Joseph Staudenmeier	4, 9	Neutronics, Thermal Hydraulics
Juan Lopez	3	Structural Engineering
Kenneth See	2	Geography, Demography
Kevin Quinlan	3	Meteorology
Kevin Roche	12	Startup Plan
Michael Balazik	All	Project Management
Michael Salay	4	Neutronics, Thermal Hydraulics

Name	Chapter	Area of Expertise
Mike Call	13	Accident Analysis
Molly-Kate Gavello	All	Project Management
Naeem Iqbal	9	Fire Protection
Mike Call	13	Safety Analysis
Nageswara Karipineni	6, 9	Engineered Safety Features, Auxiliary Systems
Nathanael Hudson	4	Neutronics, Biological Shielding
Norbert Carte	7	Instrumentation and Controls
Raju Patel	12	Quality Assurance
Rossnyev Alvarado	7	Instrumentation and Controls
Sheila Ray	8	Electrical Power Systems
Steven Lynch	1, 12	Project Management
Trent Wertz	15	Financial Qualifications
Tarek Zaki	4, 13	Neutronics, Thermal Hydraulics, Project Management
Weijun Wang	2	Geotechnical Engineering
William Schuster IV	12	Physical Security
Yawar Faraz	4	Fuel Cycle Facilities
Zachary Gran	11	Radiation Protection
Zuhan Xi	2	Geotechnical Engineering

APPENDIX D
REPORT BY THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

December 15, 2022

The Honorable Christopher T. Hanson
Chair
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: REPORT ON THE SAFETY ASPECTS OF THE SHINE MEDICAL TECHNOLOGIES, LLC, OPERATING LICENSE APPLICATION REVIEW

Dear Chair Hanson:

During the 701st meeting of the Advisory Committee on Reactor Safeguards (ACRS), November 29 – December 2, 2022, we completed our review of the SHINE Technologies, LLC (SHINE or the applicant), operating license (OL) application for its Medical Isotope Production Facility and the staff's associated Safety Evaluation Report (SER) with no open items.

During our review, we had the benefit of interactions with representatives of the Nuclear Regulatory Commission staff and the applicant. This included a visit to the SHINE construction site in Janesville, Wisconsin, in August 2022. We also benefited from the documents referenced. Appendix I lists the chronology of Full Committee and Subcommittee meetings on this topic. Appendix II contains the list of our memoranda on SER chapter reviews. This letter report fulfills the ACRS review requirement in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards."

CONCLUSION AND RECOMMENDATION

1. The staff SER provides a comprehensive review of important safety aspects of the design and operation of the SHINE facility.

2. The OL for the SHINE Medical Isotope Production Facility should be issued.

BACKGROUND

When operational, the SHINE Medical Isotope Production Facility will provide a domestic, reliable supply of molybdenum-99 (Mo-99) for medical applications. Not utilizing highly enriched uranium for medical isotope production supports U.S. national security interests and nuclear non-proliferation policy objectives.

Facility Description

SHINE submitted an OL application for the SHINE Medical Isotope Production Facility to produce Mo-99 in accordance with the requirements contained in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," on July 17, 2019. The facility would be licensed as a non-power utilization and production facility (NPUF), as defined in 10 CFR 50.2, "Definitions." Issuance of the OL would authorize SHINE to operate this facility for 30 years. The facility includes an irradiation facility and a radioisotope production facility. The irradiation facility consists of eight subcritical operating assemblies (or irradiation units). The radioisotope production facility consists of hot cell structures for the processing of the irradiated solution.

The Mo-99 production process begins in an irradiation unit where accelerator-driven deuterons bombard tritium gas to create a fusion reaction, producing neutrons. This neutron flux is enhanced by a neutron multiplier and induces fission in the low-enriched uranyl sulfate target solution, creating Mo-99 as a byproduct. The Mo-99 is extracted and purified in the radioisotope production facility.

Construction Permit Application

During the 628th meeting of the ACRS, October 7 - 10, 2015, we reviewed the construction permit (CP) application for the SHINE Medical Isotope Production Facility. After completing our review, we recommended the CP for this facility be approved. The SHINE CP was issued on February 29, 2016, and construction commenced in September 2019.

During the OL review, the applicant proposed a "phased approach" that allows operation of some irradiation units while the remaining units were being installed. The staff determined that this approach did not pose an impact to safety. We concur.

Operating License Review Approach

We conducted our review of the Final Safety Analysis Report (FSAR) and draft SER with no open items on a chapter-by-chapter basis. Individual members were assigned chapters or topics for detailed technical review. The entire SHINE Subcommittee participated in chapter briefings with the staff and applicant. The cognizant member summarized findings in a memorandum reflecting subsequent Full Committee deliberation. This approach provided a comprehensive, in-depth review of the SHINE submittal. The overall process significantly reduced the number of presentations required of the staff and applicant for our review.

Our review identified a number of items not thoroughly addressed in the initial FSAR and SER. Concerns relative to the OL were resolved during subsequent meetings. Beyond that, the Appendix II memoranda expand upon several other noteworthy points, including:

- The importance of human factors and actions in the conduct of operations of an irradiation and radioisotope production facility
- Coordination with local community resources to respond to low-frequency hazards (e.g., fire, chemical, and aircraft impact)

- Broadening of cyber security assessments to all critical digital assets required for mission critical system operation

DISCUSSION

The staff review followed NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Parts 1 and 2, supplemented by guidance in the associated Interim Staff Guidance document. In our review of this first-of-a-kind facility, we identified the following three noteworthy attributes that characterize the innovativeness of the design and the completeness of this application.

SHINE Safety Characteristics

The SHINE facility incorporates several important safety features. The low power density irradiation units are designed to automatically shut down the irradiation process and place the target solution into a safe stable passively cooled condition without immediate operator actions. Criticality during the dissolving and filling processes is largely precluded by the engineering design. Additionally, critically safe vessels or double contingency controls are used for fissile solutions in the production facility.

SHINE Safety Analysis Approach

Using common hazard evaluation methods, such as Hazard and Operability Analysis and Failure Modes and Effects Analysis, the SHINE Safety Analysis (SSA) methodology provides a systematic approach to identify, evaluate, and group credible accident sequences. Both internal and external events were considered. Results were ranked using a risk matrix. Design Basis Accidents (DBAs) were identified as those events with maximum consequences for each accident sequence grouping. The DBAs were used to identify those structures, systems, and components (SSCs) and procedural controls required to prevent unacceptable consequences. As a result, these SSCs are categorized as safety-related.

SHINE hazard analysis documents were not provided on the docket but were made available to us. These documents are thorough, well structured, and reflect an in-depth, systematic approach for the selection of DBAs used in accident analyses. The applicant did not rely on pre-conceived notions or tabulated lists to identify DBAs, satisfying our generic concern about licensing basis event identification.

SHINE used the concept of maximum hypothetical accident (MHA) to demonstrate compliance with acceptable limits for both radiological and chemical consequences. SHINE's evaluation indicates that the MHA is a large break in the top of the Target Solution Vessel Off-gas System which allows all radioactive gases to escape into the confinement. Consequences of exposure to facility staff and the public were evaluated to be within regulatory acceptance criteria. The DBA analysis identified that the limiting accident not involving the irradiation facility is a tritium purification system failure; this accident results in consequences similar to those of the MHA (and within the acceptance criteria).

Our review also explored the adequacy of assumed sensor response times to mitigate accident sequences because they affect the margins for proposed setpoints. In response to our questions and an audit completed by the staff, the applicant revised the FSAR to explicitly list these response times. Subsequently, the staff completed independent evaluations of the associated margins. The additional input from SHINE and the staff addressed our concerns.

<u>Technical Specifications Justifications</u>

SHINE's proposed Technical Specifications (TSs) address relevant safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation (LCOs), and surveillance requirements (SRs). The staff assessed these TSs as well as design features that affect SSC function, availability, or reliability, and administrative controls to ensure their required availability.

The processes associated with SHINE isotope production include several interrelated irradiation and chemical processes that must be controlled by TSs. A key example of this is the prevention of uranyl peroxide precipitation. Uranyl peroxide can form and precipitate from the target solution if the concentration exceeds the temperature dependent solubility limit. The equilibrium uranyl peroxide concentration and precipitation limit are functions of temperature (power), uranium concentration, pH, and catalyst concentration.

The applicant provided extensive details related to the basis for the TSs for each of the LCOs and the SRs related to uranyl peroxide precipitation. We find the bases for these LCOs and SRs to be extremely detailed and easy to follow.

<u>SUMMARY</u>

The staff SER provides a comprehensive review of important safety aspects of the design and operation of the SHINE facility. The OL for the SHINE Medical Isotope Production Facility should be issued.

Sincerely,

Signed by Rempe, Joy on 12/15/22

Joy L. Rempe
Chairman ACRS

APPENDICES:
Appendix I: Chronology of the ACRS Review of the SHINE, LLC, Operating License Application

Appendix II: Lead Member Memoranda on SER Chapters with no Open Items, SHINE Medical Technologies, LLC, Operating License Application

REFERENCES

1. SHINE Medical Technologies, LLC, “Application for an Operating License,” July 17, 2019 (ML19211C143).

2. SHINE Medical Technologies, LLC, “General and Financial Information,” Enclosure 2, July 17, 2019 (ML19211C089).

3. SHINE Medical Technologies, LLC, “Overview of Phased Approach to Initial Facility Operations,” February 26, 2021 (ML21057A340).

4. SHINE Medical Technologies, LLC, “Final Safety Analysis Report, Application for an Operating License, Supplement No. 30,” August 31, 2022 (ML22249A148).

5. SHINE Technologies, LLC, “Application for an Operating License Supplement No. 15, Submittal of the Phased Startup Operations Application Supplement,” January 27, 2022 (ML22027A353).

6. SHINE Technologies, LLC, “Application for an Operating License Supplement No. 31, Revision to the Phased Startup Operations Application Supplement,” September 28, 2022 (ML22271A962).

7. United States Nuclear Regulatory Commission, Safety Evaluation Report for SHINE Technologies, LLC, Operating License Application, November 29, 2022 (ML22314A132).

8. Advisory Committee on Reactor Safeguards, “Report on the Safety Aspects of the Construction Permit Application for SHINE Medical Technologies, Inc. Medical Isotope Production Facility,” October 15, 2015 (ML15286A426).

9. NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 28, 1996 (ML042430055).

10. NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 29, 1996 (ML042430048).

11. “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ML12156A069).

12. “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ML12156A075).

APPENDIX I

Chronology of the ACRS Review of the SHINE Medical Technologies, LLC, Operating License Application

The following table lists ACRS interactions on the SHINE Operating Licensing Application Review

Subcommittee (SC)/Full Committee (FC) Meetings	Date	Subject	Transcript ML#
Non-power production or utilization facility (NPUF) Subcommittee (SC)	October 22, 2020	NPUF Subcommittee Review Approach	ML20339A634
NPUF SC	November 4, 2020	Overview of SHINE Medical Isotope Production Facility	ML20345A277
NPUF SC	January 12, 2021	NPUF Subcommittee Review Approach	ML21055A548
NPUF SC	February 16, 2022	Overview of SHINE Medical Isotope Production Facility and Phased Approach	ML22060A150
NPUF SC	March 17, 2022	Chapters 1, 2, 4, 5, & 6	ML22095A053
694th ACRS FULL COMMITTEE (FC)	April 6-8, 2022	Review of memorandums for Chapters 2, 4, 5, & 6	N/A[1]
SHINE SC (previously the NPUF SC)	May 6, 2022	Chapters 3, 8, 9 & 11	ML22158A263
SHINE SC	May 17-18, 2022	Chapter 6, Section 6b.3, Chapter 12, Section 12.7, Chapter 12, Section 12.13 & Chapter 13	ML22172A022 ML22172A025
696th ACRS FC	June 1, 2022	Review of memorandums for Chapters 1, 2, 4, 5, & 6	N/A
SHINE SC	June 21, 2022	Review of technical issues identified in memorandums for Chapters 4, 8, 9, 11, 12.7, 12.13, & 13	ML22193A110
SHINE SC	July 19-20, 2022	Chapter 3, Section 3.1 (Design Criteria), Chapter 7 (Instrumentation and Control Systems), Chapter 9, Section 9a.3 (Fire Protection), Chapter 12, Section 7.9 (Human Factors Engineering), Chapter 12, Section 12.10 (Operator Training/Requalification) & Chapter 12, Section 12.11 (Startup Plan)	ML22243A210 ML22243A217

[1] Transcription does not exist. Committee deliberations are reflected in the associated review memorandum. See Appendix II of this letter report.

698th ACRS FC	September 7, 2022	Review of memorandums for Chapter 3, Section 3.1 (Design Criteria), Chapter 9, Section 9a.3 (Fire Protection), Chapter 12, Section 7.9 (Human Factors Engineering), Chapter 12, Section 12.10 (Operator Training/Requalification) & Chapter 12, Section 12.11 (Startup Plan)	ML22278A065
698th ACRS FC	September 9, 2022	Chapter 14, Technical Specifications, Cybersecurity, & Programmable Lifecycle Overview.	ML22278A068
SHINE SC	October 21, 2022	Chapter 7, Section 7.4.3 (Process Integrated Systems) & Phased Startup Operations	ML22334A138
SHINE SC	November 15, 2022	Review of memorandums for Chapters 7, 14, Cybersecurity, & Programmable Lifecycle Overview and discussion of Draft Final Letter Report.	N/A
701st ACRS FC	November 29 – December 2, 2022	Report on the Safety Aspects of the SHINE Medical Technologies, LLC, Operating License Application Review	ML22348A105

<u>**APPENDIX II**</u>

Lead Member Memoranda on SER Chapters with no Open Items
SHINE Medical Technologies, LLC, Operating License Application

Subject	Date	ADAMS Accession Number
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 2, “Site Characteristics”	April 29, 2022	ML22111A049
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 3, “Design of Structures, Systems, & Components”	September 26, 2022	ML22258A308
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 4, “Facility Description”	April 27, 2022	ML22111A143
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 5, “Cooling Systems”	April 27, 2022	ML22111A169
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 6, “Engineered Safety Features”	May 4, 2022	ML22111A177
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 6, “Engineered Safety Features,” Section 6B.3, “Criticality Safety”	July 8, 2022	ML22175A188
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 7, “Instrumentation and Control Systems”	November 16, 2022	ML22319A217
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 7, “Instruments & Control Systems,” Section 7.4.9, “Human Factors Engineering”	September 26, 2022	ML22258A305
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 8, “Electrical Power Systems”	July 12, 2022	ML22175A192
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 9, “Auxiliary Systems”	July 11, 2022	ML22164A915
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 9, “Auxiliary Systems,” Section 9A.2.3, “Fire Protection Systems & Programs”	September 23, 2022	ML22258A307

Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 11, "Radiation Protection Program and Waste Management"	July 12, 2022	ML22164A913
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 12, "Conduct of Operations (Operator Training and Requalification, and Startup Plan)"	September 27, 2022	ML22258A310
Input for ACRS Review of SHINE Operating License Application – Safety Evaluation Report for Chapter 12, "Conduct of Operations," Section 12.4.14, "Cybersecurity"	November 17, 2022	ML22321A191
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 12, "Conduct of Operations," Section 12.7, "Emergency Plan"	July 11, 2022	ML22164A914
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 12, "Conduct of Operations," Section 12.13, "Material Control and Accountability"	July 8, 2022	ML22164A917
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 13, "Accident Analysis"	July 8, 2022	ML22175A182
Input for ACRS Review of SHINE Operating License Application – Software Life Cycle	November 16, 2022	ML22321A210
Input for ACRS Review of SHINE Operating License Application – Safety Evaluation Report for Chapter 14, "Technical Specifications"	November 17, 2022	ML22321A139

December 15, 2022

SUBJECT: REPORT ON THE SAFETY ASPECTS OF THE SHINE MEDICAL TECHNOLOGIES, LLC, OPERATING LICENSE APPLICATION REVIEW

Accession No: ML22342A144 **Publicly Available (Y/N):** Y **Sensitive (Y/N):** N
If Sensitive, which category?
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