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U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Safety Evaluation Report

Northwest Medical Isotopes, LLC Construction Permit Application for a Radioisotope Production Facility

Docket Number 50-609

Office of Nuclear Reactor Regulation

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ABSTRACT

This safety evaluation report (SER) documents the results of the safety review conducted by the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) on the Northwest Medical Isotopes, LLC (NWMI or the applicant) application to obtain a construction permit for a production facility (NWMI production facility or facility) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," to be constructed in Columbia, Missouri. Subject to 10 CFR Part 50, the proposed production facility would receive irradiated special nuclear material (SNM), and process the SNM to produce the medical radioisotope molybdenum-99. The production facility would be part of a larger facility, which the staff refers to as the radioisotope production facility (RPF), and which would also include target fabrication activities conducted under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." Although the staff reviewed NWMI's entire application, including information related to the 10 CFR Part 70 activities, to understand the interfaces between the 10 CFR Part 50 and 10 CFR Part 70 portions of the RPF, the staff findings in this SER are limited to those required for licensing a production facility under 10 CFR Part 50.

This SER presents the results of the staff's review of the NWMI construction permit application as updated on September 8, 2017, and as supplemented by the applicant's responses to requests for additional information (RAIs).

The staff's environmental review of the NWMI construction permit application is documented in NUREG-2209, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility."

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 November 6, 2017. Appendix D, "Report by the Advisory Committee on Reactor Safeguards," to this SER includes a copy of the report by the ACRS on the NWMI construction permit application.

Based upon the review documented in the SER, the staff finds that the preliminary design and analysis of the NWMI production facility, including the principal design criteria; design bases; information relative to materials of construction, general arrangement, and approximate dimensions; and preliminary analysis and evaluation of the design and performance of structures, systems, and components (SSCs) of the facility, as described in the NWMI preliminary safety analysis report, as supplemented by responses to RAIs: (1) provides reasonable assurance that the final design will conform to the design basis; (2) includes an adequate margin of safety; (3) demonstrates that SSCs adequately provide for the prevention of accidents and the mitigation of consequences of accidents; and (4) meets applicable regulatory requirements as well as applicable NRC guidance. Therefore, the staff recommends that the Commission make the necessary findings with respect to the safety of the construction permit in accordance with 10 CFR 50.35, "Issuance of construction permits"; 50.40, "Common standards"; and 50.50, "Issuance of licenses and construction permits."

The Commission issued its Memorandum and Order, CLI-18-06, documenting its final decision on the mandatory hearing held on January 23, 2018. The Commission's final decision authorized the issuance of the construction permit for the NWMI medical radioisotope

production facility, contingent upon the inclusion of a revised safety permit condition. In May 2018, the staff updated the permit condition in Section 2.4.5 and Appendix A.1 of this SER to reflect the Commission's final decision. The staff also reformatted the permit condition related to the criticality accident alarm system in Section 6.4.5 of this SER for clarity.

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ABBREVIATIONS AND ACRONYMS

10 CFR	Title 10 of the Code of Federal Regulations
ac	acre
ACI	American Concrete Institute
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
AISC	American Institute of Steel Construction
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANECF	average neutron energy causing fission
ANS	American Nuclear Society
ANSI	American National Standards Institute
AOA	area of applicability
ASCE	American Society of Civil Engineers
ASTM	American Society for Testing and Materials
BMS	building management system
Bq	becquerel
CAAS	criticality accident alarm system
CAM	continuous air monitor
cc	cubic centimeter
CF2	carbon fluoride
CGA	Compressed Gas Association
C-I	Category I
C-II	Category II
CIP	construction inspection program
cm	centimeter
cm2	square centimeter
COO	Chief Operating Officer
CSE	criticality safety evaluation
DAAP	diamyl-amyl phosphonate
DAC	derived air concentration
DBE	design-basis event
DBEQ	design-basis earthquake
DCP	double contingency principle
DOE	Department of Energy

dpm	disintegration per minute
EAL	emergency action level
EIS	environmental impact statement
EOI	end of irradiation
EPA	U.S. Environmental Protection Agency
EPZ	emergency planning zone
ERP	emergency response plan
ESC	emergency support center
ESF	engineered safety feature
FEMA	Federal Emergency Management Agency
FOCD	foreign ownership, control, or domination
FPC	facility process control
FPS	fire protection system
FQ	financial qualification
FR	Federal Register
FSAR	final safety analysis report
ft	foot
G-M	Geiger-Mueller
H/X	hydrogen-to-fissile
H2O2	hydrogen peroxide
HAZOP	hazards and operability
HEGA	high-efficiency gas adsorption
HEPA	high-efficiency particulate air
HIC	high-integrity container
HMI	human-machine interface
HNO3	nitric acid
hp	horsepower
HVAC	heating, ventilation, and air conditioning
Hz	hertz
I&C	instrumentation and control
IBC	International Building Code
IEEE	Institute of Electrical and Electronics Engineers
IHECSBE	International Handbook of Evaluated Criticality Safety Benchmark Experiments
IMC	NRC Inspection Manual Chapter
IROFS	items relied on for safety

IRU	iodine removal unit
ISA	integrated safety analysis
ISG	Interim Staff Guidance
IX	ion exchange
keff	effective neutron multiplication factor
km	kilometer
kW	kilowatt
LCO	limiting condition for operation
LEU	low-enriched uranium
LFL	lower flammability limit
LOOP	loss of offsite power
LWR	light-water reactor
m	meter
M&TE	measuring and test equipment
MC&A	material control and accounting
MCNP	Monte Carlo N-Particle computer code
MHA	maximum hypothetical accident
mi	mile
min	minute
Mo	molybdenum
Mo-99	molybdenum-99
MoS	margin of subcriticality
mph	miles per hour
mrem	millirem
mSv	millisievert
MU	University of Missouri
MURR	University of Missouri – Columbia Research Reactor
NaOH	sodium hydroxide
NCS	nuclear criticality safety
NCSP	nuclear criticality safety program
NEP	normal electrical power
NFPA	National Fire Protection Association
NIOSH	National Institute of Occupational Safety and Health
NMSZ	New Madrid Seismic Zone
NOx	nitric oxide
NRC	U.S. Nuclear Regulatory Commission
NS	non-seismic

NWMI	Northwest Medical Isotopes, LLC
OL	operating license
OSL	optically-stimulated luminescence
OSTR	Oregon State University TRIGA Reactor
OSU	Oregon State University
OTS	offgas treatment system
P&ID	piping and instrumentation diagrams
PAG	protective action guide
PGA	peak ground acceleration
PHA	preliminary hazard analysis
PLC	programmable logic controller
PMP	probable maximum precipitation
PSAR	preliminary safety analysis report
psi	pounds per square inch
PUREX	plutonium-uranium extraction
QA	quality assurance
QAPP	Quality Assurance Program Plan
QL	quality level
QRA	quantitative risk analysis
R&D	research and development
RAI	request for additional information
RAM	radiation area monitor
RAM	radioactive material (SER Appendix A only)
RASCAL	Radiological Assessment System for Consequence Analysis
REMP	radiological environmental monitoring program
RG	NRC Regulatory Guide
RPF	radioisotope production facility
RPM	Radiation Protection Manager
RPP	Radiation Protection Program
RSAC	Radiological Safety Analysis Code
RSC	radiation safety committee
RWP	radiation work permit
SDG	standby diesel generator
SEP	standby electrical power
SER	safety evaluation report
SH&L	safety, health, and licensing

SNM	special nuclear material
SR	safety-related
SSCs	structures, systems, and components
SSE	safe shutdown earthquake
TBD	to be determined
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeter
TNT	trinitrotoluene
TSs	technical specifications
U	uranium
U.S.C.	United States Code
U-235	uranium-235
U-238	uranium-238
UH3	uranium trihydride
UPS	uninterruptable power supply
USGS	U.S. Geological Survey
USL	upper subcritical limit
W	watt
wt%	weight percent
yr	year

1 THE FACILITY

The tests were performed at a special facility for testing the thermal hydraulic integral effect. Transducers were installed to check accurately the dynamic pressure data. The experimental tests proceeded to reach a steady state condition and then the break was simulated with data logging. During the test, the major thermal-hydraulic parameters, such as dynamic and static pressures, local temperatures, and flow rates, were obtained in the course of an abrupt break of the steam generator steam line using the double rupture disk assembly. Also, the reproducibility of the test was checked by doing additional test cases observing the characteristics of the dynamic pressure during the tests. Details are shown in the following subsections.

1.1 Introduction

This SER documents the results of the safety review conducted by the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) on the NWMI application to obtain a construction permit for a production facility (NWMI production facility or facility) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," to be constructed in Columbia, Missouri.

By letter dated February 5, 2015 (Reference 1), NWMI submitted Part One of a two-part application for a construction permit, which, if granted, would allow NWMI to construct a medical isotope production facility in Columbia, Missouri. The staff acknowledged receipt of Part One of NWMI's two-part application for a construction permit under 10 CFR Part 50 in a notice published in the *Federal Register* (FR) on April 21, 2015 (80 FR 22227). An exemption from certain requirements of 10 CFR Part 2, Section 101 (10 CFR 2.101), "Filing of application," paragraph (a)(5) was granted by the Commission and published in the FR on October 24, 2013 (78 FR 63501), in response to a letter from NWMI dated August 9, 2013 (Reference 4). The exemption allowed NWMI to submit its construction permit application in two parts. Specifically, the exemption allowed NWMI to submit a portion of its application for a construction permit up to 6 months prior to the remainder of the application regardless of whether an environmental impact statement or a supplement to an environmental impact statement is prepared during the review of its application. In accordance with 10 CFR 2.101(a)(5), NWMI submitted the following in Part One of its construction permit application:

- Description and safety assessment of the site required by 10 CFR 50.34, "Contents of applications; technical information," paragraph (a)(1).

- Environmental report required by 10 CFR 50.30, "Filing of application; oath or affirmation," paragraph (f).

- Filing fee information required by 10 CFR 50.30(e) and 10 CFR 170.21, "Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses."

- General information required by 10 CFR 50.33, "Contents of applications; general information."

- Agreement limiting access to classified information required by 10 CFR 50.37, "Agreement limiting access to Classified Information."

The staff conducted a docketing acceptance review of NWMI's partial application and, by letter dated June 1, 2015 (Reference 6), determined that Part One of NWMI's application for a construction permit was complete and acceptable for docketing. The application was assigned Docket No. 50-609. A notice of docketing Part One of NWMI's application was published in the FR on June 8, 2015 (80 FR 32418).

The staff performed an environmental review of the NWMI construction permit application and this review and its conclusions are documented in an environmental impact statement, published as NUREG-2209, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility," in May 2017 (Reference 22).

By letter dated July 20, 2015 (Reference 2), NWMI submitted the second and final part of its two-part application (Reference 3) for a 10 CFR Part 50 construction permit. Part Two of the application provided the remainder of the preliminary safety analysis report (PSAR) required by 10 CFR 50.34(a).

By letter dated December 24, 2015 (Reference 7), the staff informed NWMI that Part Two of its construction permit application for a production facility, as supplemented, contained the balance of the PSAR required by 10 CFR 50.34(a), was submitted in accordance with the requirements of 10 CFR 2.101(a)(5), and was placed, in its entirety, under Docket No. 50-609. This letter acknowledged NWMI's request for a construction permit for the proposed production facility. A notice of docketing was published in the FR on January 4, 2016 (81 FR 101). A notice of a 60-day opportunity to request a hearing and petition for leave to intervene was published in the FR on May 24, 2016 (81 FR 32793). No petitions were filed in response to the notice.

The safety review of the application for a construction permit for the 10 CFR Part 50 production facility is based on information in the application, as revised, and on the applicant's responses to requests for additional information (RAIs). Unless otherwise stated, this SER evaluates the information contained in Revision 3 of NWMI's PSAR, dated September 8, 2017 (Reference 60), as supplemented by responses to RAIs dated September 18, 2017 and September 28, 2017 (References 63 and 64, respectively).

1.1.1 Scope of Safety Review

The NWMI application discusses a proposed radioisotope production facility (RPF). The application describes performing various processes within the RPF. The following processes described in the application fall within the definition of "production facility," under 10 CFR 50.2, "Definitions": (a) irradiated low-enriched uranium (LEU) target receipt (from a network of U.S. research reactors); (b) irradiated LEU target disassembly and dissolution; (c) molybdenum-99 (Mo-99) recovery and purification; (d) uranium recovery and recycle; (e) waste management; and (f) associated laboratory and support area activities. Therefore, these processes are subject to the licensing requirements of 10 CFR Part 50. The staff refers to these processes as the production facility processes and the RPF area within which they are described to occur as "the production facility."

The NWMI application also describes performing a process that does not fall within the 10 CFR Part 50 definition of production facility. Specifically, NWMI PSAR Section 4.1.3.1.1, "Target Fabrication Process Overview," describes a target fabrication process consisting generally of receiving fresh LEU in metal form from a U.S. Department of Energy (DOE) supplier; fabricating LEU target material using uranyl nitrate, which consists of a combination of

fresh LEU, recovered recycled LEU (referred to as "recovered scrap LEU" in NWMI PSAR Section 4.1.3.1.1, Revision 0), and LEU recovered from the processing of irradiated targets; assembling, loading, and fabricating targets; and packaging the targets for shipment to a network of U.S. research reactors. NWMI PSAR Sections 4.1.3.1.2, "Target Fabrication Physical Location," and 4.1.4.4, "Target Fabrication Area," explain that the target fabrication process will be performed in a separate area within the RPF called the target fabrication area.

NWMI PSAR Section 1.1, "Introduction," states that target fabrication will be licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," which will be "applied for under a separate license application submittal." As of October 25, 2017, the NRC has not yet received a 10 CFR Part 70 application from NWMI regarding the target fabrication process described in NWMI's 10 CFR Part 50 construction permit application.

Although the staff reviewed the entire application, including NWMI's descriptions related to 10 CFR Part 70 activities associated with target fabrication (e.g., possession and processing of enriched uranium and scrap recovery), the staff's review was limited to understanding the interface between the production facility processes and the target fabrication process in order to determine whether NWMI satisfies the requirements for the potential issuance of a construction permit for a 10 CFR Part 50 production facility. To the extent that the production facility and the target fabrication area share structures and systems (e.g., vessel cooling, ventilation, radioactive waste control, and instrumentation and control), these shared items were only evaluated to support the staff's conclusions regarding the issuance of a construction permit for NWMI's 10 CFR Part 50 production facility.

Consequently, the staff findings in this SER are limited to those required for licensing a production facility under 10 CFR Part 50.

1.1.2 Areas of Review

The review of the NWMI construction permit application consisted of two concurrent reviews: a safety review and an environmental review. The safety review was based on information in the application, as supplemented or revised by NWMI's responses to RAIs. The staff reviewed the NWMI application against applicable regulatory requirements in 10 CFR Part 50, using appropriate regulatory guidance and standards, as discussed below, to assess the sufficiency of the preliminary design of the NWMI production facility. As part of this review, the staff evaluated descriptions and discussions of the facility's structures, systems, and components (SSCs), with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI production facility was evaluated to ensure the sufficiency of principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions, to provide reasonable assurance that the final design will conform to the design bases. The preliminary items relied on for safety (IROFS) for the NWMI production facility were also evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents. The staff reviewed NWMI's analysis of the performance of the SSCs of the preliminary design of the production facility, with the objective of assessing the risk to public health and safety resulting from operation of the NWMI production facility.

In accordance with Section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. [United States Code] § 4332(2)(C)) and implementing NRC regulations in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory

Functions," the staff prepared a final environmental impact statement (EIS) based on its independent assessment of the information provided by NWMI and information developed independently by the staff. The staff conducted an independent evaluation of the application and conducted a systematic, interdisciplinary review of the potential impacts of the proposed action on the quality of the human environment and reasonable alternatives to NWMI's proposal. Before development of the Draft EIS, the staff published a notice of intent to prepare an EIS and invited the public to provide information relevant to the environmental review at a scoping meeting held on December 8, 2015, in Columbia, Missouri. The staff also provided opportunities for governmental and general public participation during the public comment period and meeting on December 6, 2016, in Columbia, Missouri, on the Draft EIS, and used publicly available guidance in the development of its Final EIS. The Final EIS, published as NUREG-2209, addressed comments received and meets the requirements of 10 CFR Part 51.

1.1.3 Regulatory Basis and Acceptance Criteria

The staff reviewed the NWMI application against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design of the NWMI production facility in support of the issuance of a construction permit. The staff evaluated the sufficiency of the facility's preliminary design, as described in the Revision 3 of the PSAR, based on NWMI's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases and allow adequate margin for safety.

In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued if the NRC makes the following findings:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production

facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and 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 (Reference 9). The staff's review in Chapter 2 of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

Although a construction permit, if issued, would authorize NWMI to proceed with construction of the NWMI production facility, the staff's evaluation of the preliminary design and analysis of the NWMI production facility does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur only after the staff completes an evaluation of the final design of the NWMI production facility, as described in the FSAR submitted as part of an NWMI operating license (OL) application.

In addition to the findings listed in 10 CFR 50.35, a construction permit application must also provide sufficient information to allow the Commission to make the following determinations in accordance with 10 CFR 50.40, "Common standards," and 50.50, "Issuance of licenses and construction permits":

(1) There is reasonable assurance: (i) that the construction of the facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations.

(2) The applicant is technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

(3) The applicant is financially qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

(4) The issuance of a permit for the construction of the facility would not be inimical to the common defense and security or to the health and safety of the public.

(5) After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of the construction permit, subject to the conditions for protection of the environment set forth therein, is in accordance with Subpart A of 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

(6) The application meets the standards and requirements of the Atomic Energy Act (AEA) and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made.

While the NWMI construction permit application for a production facility is evaluated against all applicable regulatory requirements, the staff's evaluation of NWMI's preliminary design and analysis was based primarily on the following regulatory requirements:

- 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,” paragraph (f).
- 10 CFR 50.34, “Contents of applications; technical information,” paragraph (a), “Preliminary safety analysis report.”
- 10 CFR 50.35, “Issuance of construction permits.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR 50.42, “Additional standard for class 103 licenses.”
- 10 CFR 50.50, “Issuance of licenses and construction permits.”
- 10 CFR 50.55, “Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.”
- 10 CFR 50.58, “Hearings and report of the Advisory Committee on Reactor Safeguards.”
- 10 CFR Part 50, Appendix C, “A Guide for the Financial Data and Related Information Required to Establish Financial Qualifications for Construction Permits and Combined Licenses.”
- 10 CFR Part 50, Appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities.”
- 10 CFR 20.1201, “Occupational dose limits for adults.”
- 10 CFR 20.1301, “Dose limits for individual members of the public.”
- 10 CFR 70.61, “Performance requirements” and 10 CFR 70.62, “Safety program and integrated safety analysis” (referenced in the “Final Interim Staff Guidance [ISG] 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” (Reference 11), as an acceptable way to demonstrate compliance with 10 CFR Part 50 for radioisotope production facilities).

As required by 10 CFR 50.34(a)(3)(i), NWMI must describe the principal design criteria for its proposed production facility in the PSAR. NWMI has addressed the following principal design criteria for its proposed production facility consistent with 10 CFR 70.64, “Requirements for new facilities or new processes at existing facilities” (referenced in the ISG Augmenting NUREG-1537 as an acceptable way to demonstrate compliance with 10 CFR Part 50 for radioisotope production facilities), which were reviewed by the staff:

- Quality standards and records – Design is being developed and implemented in accordance with management measures to provide adequate assurance that IROFS

will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

- Natural phenomena hazards – Design will provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

- Fire protection – Design will provide for adequate protection against fires and explosions.

- Environmental and dynamic effects – Design will provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

- Chemical protection – Design will provide 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.

- Emergency capability – Design will provide for emergency capability to maintain control of: (i) licensed material and hazardous chemicals produced from licensed material, (ii) evacuation of on-site personnel, and (iii) on-site emergency facilities and services that facilitate the use of available off-site services.

- Utility services – Design will provide for continued operation of essential utility services.

- Inspection, testing, and maintenance – Design of IROFS will provide for adequate inspection, testing, and maintenance to ensure their availability and reliability to perform their function when needed.

- Criticality control – Design will provide for criticality control, including adherence to the double-contingency principle.

- Instrumentation and controls – Design will provide for inclusion of instrumentation and control (I&C) systems to monitor and control the behavior of IROFS.

- Facility and system design and facility layout will be based on defense-in-depth practices – Design will incorporate, to the extent practicable: (i) preference for the selection of engineered controls over administrative controls to increase overall system reliability, and (ii) features that enhance safety by reducing challenges to IROFS.

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors and

fuel cycle facilities. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with 10 CFR regulatory requirements, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).

- 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 (Reference 9).

- "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 (Reference 10).

- "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 (Reference 11).

- NUREG-1520, Revision 1, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," dated May 2010 (Reference 24).

- NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," dated October 1983 (Reference 79).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, subpart H, does not mean that the performance requirements in subpart H are required for a radioisotope production facility license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, the 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, and NRC office instructions) in the review of NWMI's application. 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 NWMI application.

1.1.4 Review Procedures

The staff's review of NWMI's application was informed by the staff's ISG Augmenting NUREG-1537, NUREG-1537, as well as other relevant guidance cited therein, cited in the application, or used based on the staff's technical judgment. In particular, NWMI's 10 CFR Part 50 construction permit application only seeks authorization to construct the proposed NWMI production facility. Therefore, the level of detail needed in the application and the staff's corresponding SER is different than that needed for an OL application and corresponding SER. For the purposes of issuing a construction permit, the NWMI production facility may be adequately described at a functional or conceptual level in the PSAR. As such, NWMI has deferred providing some design and analysis details until the submission of its FSAR with its OL application.

The objective of the staff's evaluation was to assess the sufficiency of information contained in the NWMI application for the issuance of a 10 CFR Part 50 construction permit, in accordance with the requirements of 10 CFR Part 50. An in-depth evaluation of the NWMI design will be performed following the docketing of an NWMI application for an OL and its accompanying FSAR.

1.1.5 Resolving Technical Issues

For those technical areas that require additional information supported by research and development (e.g., a maturation of facility design), the staff has several options:

(1) The staff may determine that such technical issues must be resolved prior to the issuance of a construction permit.

(2) The staff may determine that such information may be left until the submission of the FSAR.

(3) The staff may require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit.

Technical issues that fall within the scope of the first option require additional information be provided in order to establish principal design criteria and/or design bases so that the staff may have confidence that the final facility design will conform to the design basis. The staff resolves such technical issues through RAIs.

In the second and third options, the staff may also issue RAIs to resolve identified technical issues. These types of technical issues include those that require a design maturity beyond what is required by 10 CFR 50.34(a) to issue a construction permit. Although determining what constitutes a preliminary versus a final design may be somewhat subjective, according to 10 CFR 50.34, a preliminary design must only include principal design criteria, the design bases, and general facility arrangement and approximate dimensions. This information should be sufficient to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. The staff may issue RAIs if it determines that doing so is necessary for the applicant to acknowledge certain technical deficiencies that could impact final design. Appropriate responses to these RAIs include commitments to resolving these deficiencies either in the FSAR or before the completion of construction.

During its review of the NWMI construction permit application, the NRC staff determined that additional information was required for it to complete its review and prepare this SER. Therefore, the staff prepared and issued RAIs dated March 28, 2016, September 29, 2016, January 25, 2017, March 29, 2017, and September 21, 2017 (References 12, 13, 14, 15, and 61, respectively). NWMI provided RAI responses in letters dated April 25, 2016, November 28, 2016, March 6, 2017, April 28, 2017 (2), September 18, 2017, and September 28, 2017 (References 16, 17, 18, 19, 20, 63, and 64, respectively).

Additionally, SER Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," contains a listing of those elements of design, analysis, and administration identified as requiring additional research and development or correction by the applicant. The staff determined that resolution of these items is not necessary for the issuance of a construction permit, but that the applicant should ensure that these items are fully addressed in the FSAR supporting an NWMI OL application. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of an NWMI OL application.

1.1.6 Ongoing Research and Development

The provisions of 10 CFR 50.34(a)(8) allow for ongoing research and development to confirm the adequacy of the design of SSCs to resolve safety questions prior to the completion of construction. In accordance with 10 CFR 50.34(a)(8), and as described in NWMI PSAR Section 1.3.4, "Experimental Facilities and Capabilities," NWMI states the following:

> The RPF does not include experimental SSCs that require research and development (R&D) to:
>
> - Confirm adequacy of the facility design
> - Identify and describe the R&D program that will [be] completed to resolve any safety questions associated with such SSCs
> - Schedule the R&D program to show that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility.
>
> NWMI has and will continue to perform testing to validate the acceptable operating conditions for material and target solution compatibility at MURR [the University of Missouri – Columbia Research Reactor] and the DOE national laboratories prior to completion of RPF construction. Selected materials will be examined following irradiation testing at fluence levels expected in the operation of the target solution vessel for a 30-year lifetime. The testing will include specific work involving irradiation in a corrosive environment to examine the effects on the properties of selected raw materials and welded samples in an as-received and as-fabricated state. This work will be completed no later than December 31, 2017.

In accordance with 10 CFR 50.34(a)(8), and as described in NWMI's response to RAI 13.1-2 (Reference 31), there are ongoing research and development activities related to the safety of

the uranium purification technology proposed to be used at the NWMI production facility. These include the following activities:

(1) Laboratory resin tests are being completed to determine the interactions between the solutions and resin as a function of temperature. The results from these tests will help define the hazard and accident controls if needed.

(2) Confirm the feasibility of a pressure relief system for a uranium ion exchange system or the need for a design change or separation technology change.

(3) Tests are being performed to evaluate the release of diamylamylphosphonate from the ion exchange column media during operation.

As described in Appendix A to this SER, the staff is tracking these activities and will verify their resolution prior to the completion of construction.

1.1.7 Advisory Committee on Reactor Safeguards Review

To support the Advisory Committee on Reactor Safeguards (ACRS) in providing an independent review and report to the Commission regarding the NWMI construction permit application, the staff presented the results of its safety evaluation to the ACRS Northwest Medical Isotopes Subcommittee at five meetings on June 19, July 11, August 22, August 23, and September 21, 2017. The staff presented the results of its NWMI construction permit application review to the ACRS Full Committee on November 2, 2017. The ACRS issued a letter on November 6, 2017, which has been included as Appendix D, "Report by the Advisory Committee on Reactor Safeguards," of this SER, fulfilling the requirement of 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards," that the ACRS review and report on construction permit applications for a facility of a type described in 10 CFR 50.22.

The ACRS letter to the Commission recommended that a construction permit be issued to NWMI. During the ACRS Northwest Medical Isotopes Subcommittee meetings, NWMI identified elements of design, analysis, and administration that require additional information to address the comments of the ACRS Northwest Medical Isotopes Subcommittee members. NWMI listed these items in its letters dated September 18, 2017 (Reference 63) and September 28, 2107 (Reference 65). The staff determined that the resolution of these items is not necessary for the issuance of a construction permit, but that the applicant expects that these items are addressed in the FSAR supporting an NWMI OL application. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of an NWMI OL application. These items are listed in Appendix A.4, "Regulatory Commitments Identified Through Meeting with the Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee," of this SER.

1.1.8 Application Availability

Publicly-available documents related to the NWMI construction permit application may be obtained online in the Agencywide Documents Access and Management System (ADAMS) Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents," and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

For the convenience of the reader, the ADAMS accession numbers for publicly-available documents are provided in a table in Appendix B, "References," of this SER.

The current version (Revision 3) of the NWMI PSAR submitted September 8, 2017, is publicly available in ADAMS under Accession No. ML17257A019 (Reference 60). Other public documents and correspondence related to this application may be found by searching for NWMI Docket Number, 50-609, or project number, PROJ803, in ADAMS. Portions of the application or 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."

1.1.9 NRC Staff Contact Information

The project manager for this SER was Michael Balazik, Project Manager, Division of Licensing Projects, U.S. Nuclear Regulatory Commission. Mr. Balazik may be contacted regarding this SER at 301-415-2856 or by e-mail at Michael.Balazik@nrc.gov. Appendix C, "Principal Contributors," to this SER provides a listing of principal contributors, including their areas of technical expertise and chapters of authorship.

1.2 Summary and Conclusions on Principal Safety Considerations

The staff evaluated the descriptions and discussions of the proposed NWMI production facility, as described in the NWMI application, as supplemented by the applicant. Based on its review, the staff makes the following findings:

(1) Applicable standards and requirements of the AEA and Commission regulations have been met.

(2) The acceptance criteria in or referenced in NUREG-1537 or the ISG Augmenting NUREG-1537, have been satisfied for a preliminary design supporting a construction permit application.

(3) Required notifications to other agencies or bodies related to this licensing action have been duly made.

(4) The design of the facility includes adequate margins of safety and there is reasonable assurance that the final design will conform to the design basis.

(5) There is reasonable assurance that the production facility can be constructed in conformity with the permit, the provisions of the AEA, and the Commission's regulations.

(6) NWMI identified credible accidents based on the preliminary design and designed IROFS to provide for the prevention of accidents or the mitigation of consequences of accidents. The staff has evaluated the accident analyses presented by NWMI in the PSAR and determined that NWMI identified appropriate preliminary controls to demonstrate, with reasonable assurance, that the performance objectives contained in 10 CFR 70.61 for the production facility can be met.

(7) Releases of radioactive materials and wastes from the facility are not expected to result in concentrations outside the limits specified by 10 CFR Part 20, Subpart D,

"Radiation Dose Limits for Individual Members of the Public," and are as low as is reasonably achievable.

(8) The financial information, technical analyses and programs, and organization as described in the application demonstrate that NWMI is financially and technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

(9) The preliminary emergency plan provides reasonable assurance that NWMI will be prepared to assess and respond to emergency events.

(10) The application presents information at a level of detail that is appropriate for general familiarization and understanding of the proposed facility.

(11) The application describes the relationship of specific facility design features to the major processes that will be ongoing at the facility. This description includes the building locations of major process components and drawings illustrating the layout of the buildings and structures within the controlled area boundary that are used for the description.

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

(13) Issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public.

Therefore, the staff finds that, subject to certain conditions, the preliminary design and analysis of the NWMI production facility, as described in the NWMI PSAR, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Appendix A to this SER identifies certain permit conditions that the staff recommends the Commission include, if the construction permit is issued.

Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR.

Based on these findings as documented in this SER, and subject to the conditions identified in Appendix A of this SER, the staff recommends that the Commission make the following conclusions for the issuance of a construction permit for the production facility in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) Safety features or components that require R&D have been described by NWMI and an R&D program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(5) There is reasonable assurance: (i) that the construction of the NWMI facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations.

(6) NWMI is technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

(7) NWMI is financially qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

(8) The issuance of a permit for the construction of the facility would not be inimical to the common defense and security or to the health and safety of the public.

(9) After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of the construction permit, subject to the conditions for protection of the environment set forth therein, is in accordance with Subpart A, "National Environmental Policy Act—Regulations Implementing Section 102(2)," of 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

(10) The application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications to other agencies or bodies have been duly made.

1.3 General Description

The staff evaluated the sufficiency of the general description of the NWMI production facility, as presented in NWMI PSAR 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, control and electrical systems; coolant and other auxiliary systems; radioactive waste management provisions; radiation protection; the general arrangement of major structures and equipment; safety features of special interest; and novel facility design considerations using the guidance and acceptance criteria from Section 1.3, "General Description," of NUREG-1537, Parts 1 and 2.

NWMI is a limited liability company that was established in 2010 to ensure a domestic, secure, and reliable supply of Mo-99 for medical application. NWMI was formed under the laws of the state of Oregon and NWMI's corporate headquarters is located in Corvallis, Oregon. NWMI

intends to construct and operate a production facility to recover and purify Mo-99 in Columbia, Missouri, at Discovery Ridge Research Park (Discovery Ridge), an emerging research park development owned and managed by the University of Missouri (MU) System. The proposed 3-hectare (ha) (7.4-acre) site is situated within Discovery Ridge, north of Discovery Ridge Drive. Discovery Ridge is located in the City of Columbia, Boone County, Missouri.

The NWMI application describes an RPF within which will be performing the following 10 CFR Part 50 production facility processes:

- Irradiated LEU target receipt (from a network of U.S. research reactors);
- irradiated LEU target disassembly and dissolution;
- Mo-99 recovery and purification;
- uranium recovery and recycle;
- waste management; and
- associated laboratory and support area activities.

The NWMI application also describes a target fabrication process consisting generally of receiving fresh LEU in metal form from a DOE supplier; fabricating LEU target material using uranyl nitrate, which consists of a combination of fresh LEU, recovered recycled LEU (referred to as "recovered scrap LEU" in NWMI PSAR Section 4.1.3.1.1, Revision 0), and LEU recovered from the processing of irradiated targets; assembling, loading, and fabricating targets; and packaging the targets for shipment to a network of U.S. research reactors. PSAR Sections 4.1.3.1.2 and 4.1.4.4 explain that the target fabrication process will be performed in a separate area within the RPF called the target fabrication area and NWMI PSAR Section 1.1, Revision 3, states that this process will be licensed under 10 CFR Part 70, which will be "applied for under a separate license application submittal."

As described in subsequent SER chapters, the design of the NWMI production facility includes engineered safety features to mitigate design-basis events or accidents, control and protection systems, equipment and processes related to handling and storage of byproduct material and special nuclear material, and fire protection systems. NWMI has a radioactive waste management program and a radiation protection program. Therefore, the staff concludes that the general description of the NWMI production facility, as described in NWMI PSAR Section 1.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit under 10 CFR Part 50.

1.4 Shared Facilities and Equipment

The staff evaluated the sufficiency of the evaluation of shared facilities and equipment, as presented in NWMI PSAR 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. The acceptance criteria state that the production facility should be designed to accommodate all uses or malfunctions of the shared facilities without degradation of the production facility.

Consistent with the review procedures of NUREG-1537, Part 2, Section 1.4, the staff confirmed that all facilities or equipment shared by the NWMI production facility are discussed in the PSAR. As stated in NWMI PSAR Section 1.4, "The NWMI RPF does not share any systems or equipment with facilities not covered by this Construction Permit Application." However, the NWMI RPF building does include both a production facility and a target fabrication area, which,

while functionally separate, share common systems such as ventilation, cooling water, and waste processing systems. These shared facilities and equipment are described in the PSAR and are solely dedicated for use by the RPF.

The staff finds that there are no existing facilities or equipment that will be shared by the NWMI RPF and that the NWMI production facility represents new construction on previously undeveloped property. The interface between the NWMI production facility and the target fabrication area, including common systems shared between them, is analyzed in other chapters in the PSAR. Therefore, the staff concludes that the shared facilities and equipment, as described in NWMI PSAR Section 1.4, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit under 10 CFR Part 50.

1.5 Comparison with Similar Facilities

The staff evaluated the sufficiency of the comparison of the NWMI production facility with other similar facilities, as presented in NWMI PSAR 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.

Section 1.5 of the NWMI PSAR states that the production facility is a conventional design, similar to the design used in other nuclear processing facilities that utilize hot cells. NWMI stated that it has developed extraction and purification chemistries, is designing and plans to construct a facility to extract and purify Mo-99, and intends to sell Mo-99 assuring a reliable, securable, and domestic supply of this medical isotope. In addition, NWMI will recover and recycle the LEU. The process equipment is typical of that used in a DOE nuclear facility, with geometrically favorable tanks, ion exchange columns, centrifugal contactors, evaporators, and batch solidification systems.

The dissolution of irradiated target material will use a standard hot nitric acid process. The offgas treatment unit operations are well known and commercially available. The molybdenum recovery and purification system selectively adsorbs molybdenum from the irradiated target solution. The molybdenum purification process is very similar to the Cintichem process developed in the 1950s and 1960s by Union Carbide. Cintichem, Inc. used the process until 1990 when the facility ceased operation as a means of purifying Mo-99 for use as a medical isotope.

The proposed uranium recovery process is a modification of a widely-used uranium separation and purification process known as plutonium-uranium extraction (PUREX). The PUREX process was developed in the late 1940s and uses tributyl phosphate to selectively remove uranium from a nitric acid solution typically containing a host of fission products and other actinide contaminants. The NWMI process uses similar chemistry but, instead of a solvent process, the active agent is attached to a solid substrate.

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

Based on its review, the staff finds 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 findings:

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

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

(3) NWMI is using test data and operational experience from facilities with similar components in designing the production facility components, as practicable.

Therefore, the staff concludes that the comparisons with similar facilities, as described in NWMI PSAR Section 1.5, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit under 10 CFR Part 50.

1.6 Summary of Operations

The staff evaluated the sufficiency of the NWMI summary of operations, as presented in NWMI PSAR 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. Consistent with the review procedures of NUREG-1537, Part 2, Section 1.6, the staff verified that proposed operations of the NWMI production facility had been summarized.

NWMI listed the operations to be performed in the NWMI RPF, as follows:

- Receiving LEU from the DOE.
- Producing LEU target materials and fabrication of targets under 10 CFR Part 70.
- Packaging and shipping LEU targets to the U.S. research or test reactor network for irradiation.
- Receiving irradiated LEU targets for dissolution, recovery, and purification of Mo-99.
- Recovering and recycling LEU to minimize radioactive, mixed, and hazardous waste generation.
- Treating/packaging wastes generated by RPF process steps to enable transport to a disposal site.

Based on its review, the staff finds that the level of detail provided on the summary of operations satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 1.6. The proposed operations of the NWMI production facility are consistent with the relevant assumptions in later chapters of the PSAR, in which any safety implications of the proposed operations are evaluated.

Therefore, the staff concludes that the summary of operations, as described in NWMI PSAR Section 1.6, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit under 10 CFR Part 50.

1.7 Compliance with the Nuclear Waste Policy Act of 1982

The Nuclear Waste Policy Act of 1982 (42 U.S.C. § 10101) (Reference 23) provides that the U.S. government is responsible for the permanent disposal of high-level radioactive waste and spent nuclear fuel, but the cost of disposal should be the responsibility of the generators and owners of such waste and spent fuel. The staff evaluated the sufficiency of NWMI's compliance with the Nuclear Waste Policy Act, as presented in NWMI PSAR 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.

As stated in NWMI PSAR Section 1.7, "The RPF does not produce either high-level nuclear wastes or spent nuclear fuel. Therefore, the Nuclear Waste Policy Act of 1982 is not applicable to the RPF." As described in NWMI PSAR Chapter 11.0, "Radiation Protection and Waste Management," NWMI has identified commercial disposition pathways for all of its radioactive waste.

As described in the American Medical Isotopes Production Act (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 considered to be low-level radioactive waste if it is acceptable under federal requirements for disposal as low-level radioactive waste. Since NWMI will be removing radioactive material resulting from the production of medical radioisotopes, the staff has determined that the NWMI facility will produce low-level radioactive waste and will not produce high-level nuclear wastes. As discussed in Chapter 11.0, "Radiation Protection Program and Waste Management," of this SER, NWMI plans to follow applicable NRC, DOE, and U.S. Department of Transportation regulations for disposal of its radioactive waste. Additionally, NWMI has identified licensed commercial disposal sites that can take receipt and dispose of the facility's solid radioactive waste. The staff finds that NWMI's plans for handling radioactive waste demonstrate appropriate consideration of regulatory requirements for the types of waste at the facility. Further evaluation of NWMI's plans for handling radioactive waste may reasonably be left for consideration during the review of NWMI's FSAR.

As defined in 10 CFR 72.3, "Definitions," spent nuclear fuel or spent fuel means "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 the NWMI process does not involve a power reactor or reprocessing of spent fuel, the staff has determined that the NWMI production facility will not produce spent nuclear fuel.

Therefore, since NWMI will not be producing spent nuclear fuel or high-level nuclear wastes, the staff confirms that the Nuclear Waste Policy Act is not applicable to this facility.

The staff notes that a provision of the American Medical Isotopes Production Act of 2012 (42 U.S.C. § 2065(c)(3)(A)(ii)) states that DOE would take title to, and be responsible for, the final disposition of radioactive waste created by the irradiation, processing, or purification of uranium leased from DOE for medical radioisotope production, if it determines that the producer

(e.g., NWMI) does not have access to a disposal path. For example, if a disposal pathway for NWMI's Greater-Than-Class C Low-Level Radioactive Waste did not exist, DOE would be responsible for its disposal.

Chapter 11.0 of the NWMI PSAR describes NWMI's proposed radioactive waste management program, radioactive waste controls, and release of radioactive waste.

Therefore, the staff concludes that NWMI's description of the applicability of the Nuclear Waste Policy Act in Section 1.7 of the NWMI PSAR is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit for a production facility under 10 CFR Part 50.

1.8 Facility Modifications and History

The staff evaluated the sufficiency of NWMI's descriptions of facility modifications and history, as presented in NWMI PSAR 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.

As stated in NWMI PSAR Section 1.8, "There are no existing facilities at the proposed NWMI Discovery Ridge site, thus, no facilities modifications have occurred. This section is not applicable to the NWMI RPF."

The staff has determined that there are no existing facilities, there have been no modifications, and there is no history to report on the NWMI production facility. Therefore, this section is not applicable to this facility.

Therefore, the staff concludes that NWMI's description of facility modifications and history in NWMI PSAR Section 1.8 is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit for a production facility under 10 CFR Part 50.

2 SITE CHARACTERISTICS

The principal purpose of this chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) is to describe why the site selected is suitable for constructing and operating the proposed NWMI production facility.

This chapter of the NWMI construction permit SER describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the NWMI production facility site characteristics as presented in Chapter 2.0, "Site Characteristics," of the NWMI preliminary safety analysis report (PSAR), Revision 3, and contained in responses to requests for additional information (RAIs). As explained in this SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

2.1 Areas of Review

NWMI PSAR Sections 2.1 through 2.6 provide the bases for the site selection and describe the applicable site characteristics, including geography, demography, meteorology, hydrology, geology, seismology, and interaction with nearby installations and facilities.

The staff reviewed NWMI PSAR Sections 2.1 through 2.6 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the site selection for the NWMI facility for the purposes of issuance of a construction permit under 10 CFR Part 50. As part of this review, the staff reviewed and evaluated descriptions and discussions of NWMI's bases for the site selection.

Areas of review for this section included the following:

- The geography and demography descriptions of the site area and facility location used to assess the acceptability of the NWMI site.

- The description of locations and routes where potential external hazards or hazardous materials are present or may reasonably be expected to be present during the projected lifetime of the NWMI site.

- The description of averages and extremes of climatic conditions and regional meteorological phenomena that could affect the safe design and siting of the NWMI site.

The description of the NWMI site and safety-related elevations, structures, and systems from the standpoint of hydrologic considerations including the topographic map showing the proposed changes to grading and to natural drainage features.

2.2 Summary of Application

The proposed 3.0 hectares (ha) (7.4 acre [ac]) site is situated in Boone County, Missouri, within the University of Missouri (MU) Discovery Ridge Research Park (Discovery Ridge) in Columbia, Missouri. The site is north of Discovery Ridge Drive. The site is situated in central Missouri approximately 201 kilometers (km) (125 miles [mi]) east of Kansas City and 201 km (125 mi) west of St. Louis. The site is 7.2 km (4.5 mi) south of United States (U.S.) Interstate Highway 70 and just to the north of U.S. Highway 63. The Missouri River is 15.3 km (9.5 mi) to the west of the site. The site is located 5.6 km (3.5 mi) to the southeast of the main MU campus. Figure 2-1 below shows the relative location of the City of Columbia, Missouri with respect to Kansas City, Missouri and St. Louis, Missouri. While the topography of Boone County ranges from highly dissected hills to flat floodplains and nearly flat uplands, the NWMI facility site is primarily characterized by relatively flat surfaces at an elevation of 231 meters (m) (758 feet [ft]).

The combined resident and transient population within an 8 km (5 mi) band from the site is estimated at 68,766 persons in 2010 and 105,004 persons in 2050. The total resident population estimated for 2010 is 205 people at a distance from 0 to 1 km (0 to 0.6 mi) from the proposed site, and 1,862 people at a distance of 1 to 2 km (0.6 to 1.2 mi) from the site.

There are several major industrial and transportation facilities located within 8 km (5 mi) of the NWMI site. As shown or described in NWMI PSAR Tables 2-5, 2-12, 2-13, 2-14, and 2-15; Figures 2-4 and 2-29; and Section 2.2.2.1, “Airports,” these include industrial facilities, pipelines, combustible fuel storage facilities, railroads, major highways, waterways, airports, heliports, and a hospital. There are no military bases within 8 km (5 mi) of the site.

NWMI PSAR Section 2.2.2, “Air Traffic,” identifies air traffic and heliports located within 10 mi (16 km) of the NWMI facility (distance from the center of the NWMI site to the nearest edge of the airway). NWMI also describes its analysis of aircraft hazards associated with these airways, including approach and holding patterns near its proposed facility.

NWMI PSAR Section 2.2.3, “Analysis of Potential Accidents at Facilities,” describes the analysis of postulated accidents and possible effects that could occur at the NWMI facility, including explosions, flammable vapor clouds, toxic chemicals, and fires.

NWMI PSAR Section 2.3, “Meteorology,” describes the general and local climate, including historical averages and extremes of climatic conditions and regional metrological phenomena. The NWMI facility location places it in the Humid Continental-Warm Summer climatic zone. This type of climate has a characteristic long, warm summer with moderate relative humidity. The winters are cool to cold and mark a period of lower precipitation than during the remainder of the year. Because of its geographical location far inland, the region is subject to significant seasonal and daily temperature variations. Air masses moving over the state during the year include cold continental polar air from Canada, warm and humid maritime tropical air from the Gulf of Mexico and the Caribbean Sea, and dry eastward flowing air masses from the Rocky Mountains located to the west. Prolonged periods of extreme hot or cold temperatures are unusual. In addition, the applicant also discusses the potential meteorological effects to the

NWMI facility and discusses 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.

NWMI PSAR Section 2.4, “Hydrology,” identifies the NWMI facility site surface water, groundwater aquifers, and floods. NWMI PSAR Section 2.4.3, “Floods,” identifies the effects of potential floods on the proposed NWMI facility site. The site is located outside of the 500-year flood plain. The nearest Federal Emergency Management Agency (FEMA) flood zone A is located along Gans Creek located to the southeast of the site. The elevation of this zone is 242 m (795 ft). The NWMI facility site elevation is 248 m (815 ft). There are no water impoundments or dams upstream of the NWMI facility site on Gans Creek that could affect the facility. There are also two ponds located near the NWMI facility site within Discovery Ridge. These ponds include the 7.9 ha (19.6 ac) common grounds storm water management pond located to the northwest of the site. The top of the dam for this pond is 246 m (807 ft), with the spillway at 245 m (804 ft). The second, smaller pond, covers approximately 4 ha (10 ac), and is located to the northeast of the site. The elevation of the dam is approximately 244 m (801 ft). Failure of either of these two ponds would not likely affect the NWMI facility site because the elevation of the dams is lower than the elevation of the NWMI facility site.

Figure 2-1 City of Columbia

NWMI PSAR Section 2.5, “Geology, Seismology, and Geotechnical Engineering,” provides a summary description of geomorphic provinces and their tectonic development, and the glacial history responsible for surface topography features found today in the state of Missouri. These descriptions are based on a review of relevant, readily available published reports and maps and, where available, records and unpublished reports from federal and state agencies. Information on the site characteristics has been acquired from those sources and from site-specific investigations, including geotechnical field studies. NWMI PSAR Section 2.5.1, “Regional Geology,” states the three geomorphic provinces of the state of Missouri, which are Interior Plains Province, Interior Highland Province, and Atlantic Plains Province, including discussion on the

glacial history. The NWMI facility site is located in Boone County north of the Missouri River within the Interior Plains Province. The Interior Plains Province is characterized by moderately dissected, glacial, flat to rolling plains that gently slope towards Missouri and Mississippi River valleys. Drainage is dendritic, and current geomorphic processes are floral erosion, transport and deposition, and minor mass wasting.

Precambrian metamorphic and igneous rocks now form the basement of the Interior Plains Province. The overlying sedimentary rocks are mostly composed of limestone, sandstone and shale. Several areas of Boone County contain numerous, well developed, and documented cave and sinkhole formations.

NWMI PSAR Section 2.5.2, "Site Geology," describes the geology within 8 km (5 mi) of the NWMI facility site. Specifically, this section describes the stratigraphy of the geologic units that underline the proposed site. The section also states that highly plastic clays that exhibit volumetric change with variations in moisture content are commonly encountered near the ground surface.

NWMI PSAR Section 2.5.3, "On-site Soil Types," describes the geotechnical studies, including borings that were performed to provide preliminary geotechnical recommendations concerning earthwork and the design and construction of foundations.

NWMI PSAR Section 2.5.4, "Seismicity," describes the regional geology associated with the faults and provides the listing of historical earthquakes in a large area of the state, with magnitudes larger than 3.0. As described in NWMI PSAR Section 2.5.5, "Maximum Earthquake Potential," if an earthquake occurred along the New Madrid Seismic Zone (NMSZ) within the next 50 years, Boone County could expect a 25- to 40-percent chance of a magnitude 6.0 or greater earthquake occurring. There is also a 7- to 10-percent chance of a magnitude 7.5 to 8.0 earthquake occurring within the same time period.

NWMI PSAR Section 2.5.5 identifies the maximum expected earthquake intensity at the NWMI facility site, and concludes that a postulated 7.6 magnitude earthquake with an epicenter at the NMSZ, approximately 300 mi (483 km) (away, would severely impact the site area. NWMI PSAR Table 2-42, "Projected Earthquake Hazards for Boone County," establishes the intensity as VII (very strong) for the NWMI facility site.

NWMI PSAR Section 2.5.6, "Vibratory Ground Motion," describes the development of the ground spectrum and maximum ground acceleration utilizing methodologies in various industry codes and standards.

NWMI PSAR Section 2.5.7, "Surface Faulting," identifies potential faults within 8 km (5 mi) of the NWMI facility site and identifies Fox Hollow Fault, which is approximately 5.6 km (3.5 mi) southeast of the site, as a significant but inactive and shallow normal fault.

NWMI PSAR Section 2.5.8, "Liquefaction Potential," identifies the types of underlying soils, ground water levels, and liquefaction potential, and concludes that additional geotechnical analyses are to be conducted to determine the liquefaction potential of the soils at the NWMI facility site.

2.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 2.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the bases and the information provided by NWMI for the selection of the NWMI site for the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI facility site. However, the staff evaluated the NWMI facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and 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 (Reference 9). The staff's review in this chapter of this SER 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 issuance of the construction permit for the production facility will not be inimical to public health and safety. The staff also evaluated structures, components, equipment, and systems 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.

2.3.1 Applicable Regulatory Requirements

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

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a)(1)(i).
- 10 CFR Part 20, "Standards for Protection against Radiation."

2.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- 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 (Reference 9).
- "Final Interim Staff Guidance [ISG] 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 (Reference 10).
- "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 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility," as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of items relied on for safety (IROFS), and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements," when referring to 10 CFR Part 70,

Subpart H, does not mean that the performance requirements in Subpart H are required for a radioisotope production facility license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineer standards, American National Standards Institute/American Nuclear Society standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

2.4 Review Procedures, Technical Evaluation, and Evaluation Findings

NWMI PSAR Chapter 2.0 discusses site characteristics including the geographical, geological, seismological, hydrological, and meteorological characteristics of the site and the vicinity in conjunction with present and projected population distributions, industrial facilities and land use, and site activities and controls. The staff's review of the NWMI site considers the site characteristics; design and analyses of SSCs; radiation protection and waste management programs; and accident analyses.

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 2.0, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of NWMI's site characteristics for the issuance of a construction permit, in accordance with 10 CFR 50.35. The sufficiency of the NWMI facility site characteristics is determined by ensuring the site descriptions meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 2.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the technical evaluation is described in this SER Section 2.5, "Summary and Conclusions."

2.4.1 Geography and Demography

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding geography and demography, as described in NWMI PSAR Section 2.1, "Geography and Demography," for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.1, "Geography and Demography," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 2.1, "Geography and Demography," the staff compared and verified the NWMI facility's site characteristics geography and demography with the bases for the site selection, as presented in NWMI PSAR Section 2.1.

NUREG-1537, Part 1, Section 2.1, states, in part, that the applicant should provide the descriptions of the site area and facility location to assess the acceptability of the site. The applicant should provide the following information: (1) specification of the location with respect to latitude and longitude, political subdivisions, and prominent natural and manmade features of the area; (2) site area map to determine the distance from the facility to the boundary lines of the exclusion area, including consideration of the location, distance, and orientation of plant structures with respect to highways, railroads, and waterways that traverse or lie adjacent to the

exclusion area; and (3) a description of population distributions that address population in the site vicinity, including transient populations.

NUREG-1537, Part 1, Section 2.3.2, "Site Meteorology," states that sufficient information should be provided "for the dispersion analyses of airborne releases from the facility." Also, NUREG-1537, Part 2, Section 2.1, states that the staff should determine sufficient information is provided to conclude that "land use in the area of the facility is sufficiently stable or well enough planned that likely potential radiological risks to the public can be analyzed and evaluated with reasonable confidence." NUREG-1537, Part 2, Section 2.1, states that the PSAR should contain sufficient demographic information to allow accurate assessments of the potential radiological impact on the public resulting from the siting and operation of the proposed facility. In NWMI PSAR Section 2.1.2.1, "Resident Population," the applicant provided the distance to the nearest residences in all 16 compass directions for use in its assessments of potential radiological impact on the public resulting from the siting and operation of the proposed facility.

The staff reviewed the information provided in NWMI PSAR Section 2.1 and finds that this section of the PSAR forms the basis for evaluations (e.g., dose calculations) performed in other chapters. The distance-direction relationships specified in the PSAR to area boundaries, roads, railways, waterways, and other significant features of the area were independently verified using a third-party-supplied map.

Based on its review, the staff finds that the level of detail provided on the NWMI facility's geography and demography satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.1, allowing the staff to find that: (1) the information is sufficiently detailed to provide an accurate description of the geography surrounding the facility; (2) 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 proposed facility; and (3) there is reasonable assurance that no geographic or demographic features render the site unsuitable for operation of the proposed facility.

Therefore, the staff concludes that the proposed facility's geography and demography, as described in NWMI PSAR Section 2.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35.

2.4.2 Nearby Industrial, Transportation, and Military Facilities

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding nearby industrial, transportation, and military facilities, as described in NWMI PSAR Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," of NUREG-1537, Parts 1 and 2, and Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

NUREG-1537, Part 2, does not specifically provide acceptance criteria for evaluating the aircraft accident probability posed by airports and airways. As such, to assess aircraft impact at the proposed NWMI facility, the applicant followed the guidance contained in: (1) NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [light-water reactor] Edition," Section 3.5.1.6, "Aircraft Hazards" (Reference 26), which states, in part, that accidents "with a probability of occurrence greater than an order of

magnitude of 10^{-7} per year should be considered in the design of the plant," and (2) DOE-STD-3014-2006, "Accident Analysis for Aircraft Crash into Hazardous Facilities" (Reference 27).

Consistent with the review procedures in NUREG-1537, Part 2, Section 2.2, the staff confirmed that any hazards to the NWMI facility posed by normal operation and potential malfunctions and accidents at the nearby manmade stationary facilities and those related to transportation have been described and analyzed to the extent necessary to evaluate the potential radiological risks to the facility staff, the public, and the environment.

NUREG-1537, Part 1, Section 2.2, states, in part, that "the applicant should establish whether the effects of potential accidents in the vicinity of the [facility] from present and projected industrial, transportation, and military installations and operations should be used in the safety analyses and should establish the … facility design parameters related to accidents selected. The applicant should consider all facilities and activities within 8 kilometers of the [facility]. Facilities and activities at greater distances should be included as appropriate to their significance of accident impact on the facility."

In NWMI PSAR Section 2.2.1, "Location and Routes," the applicant provides maps showing locations and distances of nearby industrial facilities, pipelines, waterways, highways, railroads, fuel storage facilities, airports, and airways from the NWMI facility site. The staff confirmed that any hazards to the facility posed by normal operation and potential malfunctions and accidents at nearby manmade stationary facilities and those related to transportation have been described and analyzed to the extent necessary to evaluate the potential radiological risks to the facility staff, the public, and the environment.

NUREG-1537, Part 1, Section 2.2.2, "Air Traffic," states that factors such as frequency and type of aircraft movement, flight patterns, local meteorology, and topography should be considered for (1) sites located with 8 km (5 mi) of an existing or projected commercial or military airport, and (2) sites located between 8 km (5 mi) and 16 km (10 mi) from an existing or projected commercial or military airport with more than approximately 200 d^2 (where d is the distance in kilometers from the airport to the site) commercial or military aircraft movements per year.

In NWMI PSAR Section 2.2.2, the applicant describes the air traffic, including airports and airways approach and holding patterns near the proposed NWMI facility site, and the evaluation and results of its analyses of the aircraft hazards associated with this air traffic. There are three airports and three helicopter ports located within 16 km (10 mi) of the site. Because the three heliports are closer than 8 km (5 mi) to the NWMI facility site, the frequency of an aircraft crashing into the site was evaluated further using the methodology in NUREG-0800, Subsection 3.5.1.6 (Reference 26). The crash frequencies that were used by the applicant were derived from the guidance in DOE-STD-3014-2006, "Accident Analysis for Aircraft Crash into Hazardous Facilities" (Reference 27). Based on the results of the analyses, the applicant determined that the crash impact frequencies from the heliports are lower than the thresholds set in NUREG-0800. Since the crash frequencies are within an order of magnitude of 10^{-7} occurrences per year, no additional analysis is needed.

The calculated crash impact probabilities from other aircraft is slightly higher than an order of magnitude of 10^{-7} per year. Since the frequency of aircraft accidents exceeds the criteria for further evaluation as stated in Section 3.5.1.6 of NUREG-0800, the applicant stated that the general aviation crash will be evaluated as part of the integrated safety analysis (ISA) external event analysis and included in the operating license (OL) application. The staff concludes that

the analyses of aircraft impacts that exceed the criteria can reasonably be left for further evaluation in the OL application based on the final design of the facility. Analyses at that time should reasonably be able to determine consequences and potential design changes that may be needed to demonstrate compliance with regulatory requirements.

As a result of several deficiencies identified during Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee meetings, the staff performed an independent confirmatory analysis of NWMI's aircraft impact frequencies. These deficiencies in NWMI's analysis include inconsistent flight operations, incorrect crash rates for specific aircraft, inconsistent non-airport crash frequency, transposition errors in crash impact probabilities, and incorrect runway bearings for the Columbia Regional airport. SER Table 2-1 presents a summary of the aircraft impact frequencies that were calculated by the staff and compares those impact frequencies to the frequencies calculated by NWMI using the non-airport crash frequencies in NWMI PSAR Table 2-19, "Effective Area Input Values and Calculated Effective Plant Area," and the Columbia Regional airport operations crash impact probabilities in NWMI PSAR Table 2-20, "Crash Impact Probabilities."

Table 2-1 Comparison of Aircraft Impact Frequency

Type of Aircraft	Impact Frequency (yr^{-1})	
	NWMI	**NRC Staff**
General aviation	1.78E-07	3.22E-07
Commercial air carrier	1.61E-11	2.55E-10
Air taxis	3.27E-11	4.38E-09
Military large	1.66E-08	2.60E-08
Helicopter	9.7E-07	5.1E-07
Airways	1.0E-06	1.1E-06
Total	2.2E-06	1.9E-06

The impact frequencies calculated by the staff are generally larger than the frequencies calculated by NWMI for flight operations at the Columbia Regional airport. However, the staff calculated helicopter impact frequency is smaller compared to NWMI's helicopter impact frequency. The total aircraft impact frequency calculated by the staff is of the same order of magnitude as that calculated by NWMI. Since the staff's independent calculations also support a total impact frequency greater than an order of magnitude of 10^{-7} per year, the staff finds that the applicant should evaluate the impact of a general aviation crash as part of the ISA in the OL application as stated in NWMI PSAR Section 2.2.2 and prescribed in Section 3.5.1.6 of NUREG-0800. The staff will further review the aircraft impact analysis in the FSAR as part of the OL application to ensure that these deficiencies are corrected.

In NWMI PSAR Section 2.2.3, the applicant identifies and describes its analysis of potential accidents to be considered design-basis events and the potential effects of those accidents on the facility, in terms of design parameters (e.g., overpressure, missile energies) or physical phenomena (e.g., impact, flammable or toxic clouds). Design-basis events, internal and external to the NWMI facility, are defined by NWMI using NUREG-1520 as those accidents that have a probability of radiological release to the public on the order of magnitude of 10^{-7} per year, or greater, with the potential consequences serious enough to affect the safety of the facility. The following accident categories were considered in selecting design-basis events: explosions, flammable vapor clouds (delayed ignition), toxic chemicals, and fires. Since the

applicant applied methodologies for analyzing design-basis events consistent with NUREG-1520, the staff finds the applicant's preliminary calculation of the effects of potential accidents involving hazardous materials or activities on site and in the vicinity of the NWMI facility site acceptable. The staff will verify these calculations during the review of an OL.

Based on its review, the staff finds that: (1) the level of detail and analyses provided in NWMI PSAR Section 2.2 demonstrate an adequate design basis and satisfy the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.2, and (2) the applicant discusses all nearby manmade facilities and activities that could pose a hazard to its operations of the production facility. There is reasonable assurance that normal operations of such facilities would not affect the NWMI facility's operations. In addition, the analyses in NWMI PSAR Chapter 13.0, "Accident Analysis," of potential malfunctions or accidents at nearby manmade facilities and consideration of normal activities at those facilities show that safe shutdown would not be prevented, and no undue radiological risk to the public, the environment, or the operating staff is predicted. The potential consequences of these events at nearby facilities are considered or bounded by applicable accidents analyzed in Chapter 13.0 of the NWMI PSAR.

Therefore, the staff concludes that the applicant's description of operations and potential accidents at nearby manmade facilities and activities (i.e., industrial, transportation, and military) is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35.

2.4.3 Meteorology

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding meteorology, as described in NWMI PSAR Section 2.3, for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.3, "Meteorology," of NUREG-1537, Part 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 2.3, the staff verified that sufficient documented and referenced historical information is provided for the necessary analyses of meteorological effects at the proposed site. The staff determined that data provided address both short-term conditions applicable to accidental releases of radioactive material and long-term averages applicable to releases during normal operation. The staff also verified that the predicted frequencies of recurrence and intensities of severe weather conditions are documented. The staff evaluated wind and tornados in Section 3.4.2, "Meteorological Damage," of this SER.

NUREG-1537, Part 1, Section 2.3, "Meteorology," states, in part, that "the applicant should describe the meteorology of the site and its surrounding areas. Sufficient data on average and extreme conditions should be included to permit an independent evaluation by the reviewer."

NWMI PSAR Section 2.3.1, "General and Local Climate," provides a general and local climate analysis, with respect to historical and annual frequencies of severe weather for the proposed site, including the following:

- Identification of region with climate representative of the project site.
- Regional data sources
- Identification and selection for analysis of weather monitoring stations located within the site climate region
- Extreme weather

- Wind
- Tornadoes
- Humidity
- Maximum probable snowpack and precipitation
- Temperature

NWMI PSAR Section 2.3.1.2, "Precipitation," states the probable maximum precipitation (PMP) rate for the proposed site is 3.14 inches per hour. The staff examined the potential impact to the facility as a result of pond overflow during a PMP event. The staff used an independent elevation map of the site and determined that potential overflow of the ponds would not impact the facility. NWMI states in PSAR Section 3.3.1.1.1, "Flooding from Precipitation Events," that the site will be graded to direct the storm water from localized downpours with a rainfall intensity for the 100-year storm for a 1-hour duration around and away from the facility. The staff will evaluate the final grading of the site and the potential impact of precipitation to the facility at the final design stage (i.e., submission of an OL application). NWMI committed to accounting for precipitation and flooding in the grading of its site. The staff finds this to be an acceptable response to support the issuance of a construction permit. Following receipt of NWMI's final design (i.e., submission of an OL application), staff will confirm that this issue has been resolved. The staff is tracking this issue in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER.

In NWMI PSAR Section 2.3.2, "Site Meteorology," the applicant provides its local climate analysis for the dispersion conditions in the vicinity of the proposed site. The applicant provides the meteorological information to be used in NWMI PSAR Chapters 11.0, "Radiation Protection and Waste Management," and 13.0 for both long-term and short-term dispersion calculations. The applicant also provides several alternative sources of meteorological information and plans for access to meteorological information during the proposed license period.

Based on its review, the staff finds that the level of detail and analyses provided in NWMI PSAR Section 2.3 demonstrate an adequate design basis and satisfy the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.3, allowing the staff to find that: (1) the meteorological history and projections for the proposed site have been prepared in an acceptable form, (2) these projections have been factored into the choice of facility location and design sufficiently to provide assurance that no weather-related event is likely to cause damage to the facility during its lifetime that could release uncontrolled radioactive material to the unrestricted area, (3) the meteorological information is sufficient for analyses applicable to and commensurate with the risks of the dispersion of airborne releases of radioactive material in the unrestricted environment at the proposed site, and (4) the methods and assumptions are applied to releases from both normal operations and postulated accidents at the facility.

Therefore, the staff concludes that the applicant's description of general, local, and site meteorology is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35.

2.4.4 Hydrology

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding hydrology, as described in NWMI PSAR Section 2.4, for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.4, "Hydrology," of NUREG-1537, Part 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 2.4, the staff verified that the proposed site was selected with due consideration of potential hydrologic events and consequences, including any that could be initiated by either local or distant seismic disturbances. In addition, the staff confirmed that the design bases were incorporated into the facility design to address predicted hydrologic events and radioactive contamination of ground or surface waters.

NUREG-1537, Part 1, Section 2.4, "Hydrology," states, in part, that:

> The applicant should give sufficient information to allow an independent hydrologic engineering review to be made of all hydrologically related design bases, performance requirements, and bases for operation of structures, systems, and components important to safety. Sufficient information should also be given about the water table, groundwater, and surface water features at the [facility] site to support analyses and evaluations in Chapters 11 and 13 of consequences of uncontrolled release of radioactive material from pool leakage or failure, neutron activation of soils in the vicinity of the [facility], or deposition and migration of airborne radioactive material released to the unrestricted area.

In NWMI PSAR Section 2.4, the applicant provides a detailed description of hydrological characteristics for its proposed site, including watersheds, floods, and potential dam failures.

NUREG-1537, Part 1, Chapter 2 states, in part, that "the applicant should discuss and describe the …hydrological… characteristics of the site and vicinity in conjunction with present and projected population distributions, industrial facilities and land use, and site activities and controls."

The NWMI facility site is located outside of the 500-year flood plain. The nearest FEMA flood zone A is located along Gans Creek located to the southeast of the site. The elevation of this zone is 242 m (795 ft). The NWMI facility site elevation is 248 m (815 ft). There are no water impoundments or dams upstream of the NWMI facility site on Gans Creek that could affect the facility. There are also two ponds located near the NWMI facility site within Discovery Ridge. These ponds include the 7.9 ha (19.6 ac) common grounds stormwater management pond located to the northwest of the site. The top of the dam for this pond is 246 m (807 ft), with the spillway at 245 m (804 ft). The second, smaller pond, covers approximately 4 ha (10 ac), and is located to the northeast of the site. The elevation of the dam is approximately 244 m (801 ft). Failure of either of these two ponds would not likely affect the NWMI facility site because the elevation of the dams is lower than the elevation of the NWMI facility site.

Based on its review, the staff finds that the level of detail and analyses provided in NWMI PSAR Section 2.4 demonstrate an adequate design basis and satisfy the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.4, which allows the staff to find that: (1) the applicant considered hydrologic events in selecting the facility site and the site is not located where catastrophic hydrologic events are credible; (2) the applicant considered anticipated hydrologic events in developing the design bases for the facility, to mitigate or avoid significant damage so that safe operation and shutdown of the facility would not be precluded by a hydrologic event; (3) the applicant selected combinations of site characteristics and facility design bases to provide reasonable assurance that an uncontrolled release of radioactive material in the event

of a credible hydrologic occurrence would be bounded by accidents analyzed in PSAR Chapter 13.0; and (4) the facility design bases give reasonable assurance that contamination of ground and surface waters at the site from inadvertent radioactive releases would not exceed the applicable limits of 10 CFR Part 20.

Therefore, the staff concludes that the applicant's description of general, local, and site hydrology is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35.

2.4.5 Geology, Seismology, and Geotechnical Engineering

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding geology, seismology, and geotechnical engineering, as described in NWMI PSAR Section 2.5, for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.5, "Geology, Seismology, and Geotechnical Engineering," of NUREG 1537, Part 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 2.5, "Geology, Seismology, and Geotechnical Engineering," the staff confirmed that the information presented in the PSAR 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 site are considered in the design bases of structures, systems, and other facility features discussed in NWMI PSAR Chapter 3.0, "Design of Structures, Systems, and Components."

NUREG-1537, Part 1, Section 2.5 states, in part, that the applicant should detail the seismic and geologic characteristics of the proposed 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 NWMI PSAR Section 2.5, the applicant provides 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. As identified in NWMI PSAR Section 2.5.4, the most significant seismological feature in Missouri is the NMSZ, which is made up of reactivated faults. The NMSZ is the most seismically active region in the U.S. east of the Rocky Mountains and is located approximately 483 km (300 mi) southeast of the proposed NWMI facility site.

NUREG-1537, Part 1, Section 2.5.2, "Site Geology," states, in part, that "The applicant should discuss in detail the structural geology at the facility site and should pay particular attention to specific structural units of significance to the site such as folds, faults, synclines, anticlines, domes, and basins."

NUREG-1537, Part 1, Sections 2.5.3, "Seismicity," 2.5.4, "Maximum Earthquake Potential," 2.5.5, "Vibratory Ground Motion," 2.5.6, "Surface Faulting," and 2.5.7, "Liquefaction Potential," states, in part, that, "The applicant should list all historically reported earthquakes….of modified Mercalli intensity of greater than IV or magnitude (Richter) greater than 3.0…[in the list]...the applicant should evaluate the largest earthquake that could occur…and isoseismal maps for the earthquakes should be presented… the applicant should assess the ground motion at the site from the maximum potential earthquakes…and the applicant should establish the vibratory

ground motion design spectrum … [and] the applicant should discuss soil structure … [and] prepare an appropriate state-of-the-art analysis of the potential for liquefaction at the site."

NUREG-1537, Part 2, Section 2.5 further states that, "The reviewer should confirm that the information presented has been obtained from sources of adequate credibility and is consistent with other available data, such as data from the USGS or in the [FSAR] of a nearby nuclear power plant."

NWMI PSAR Section 2.5.1.3, "Local Topography and Soils of Boone County," states that several areas of the county contain well-developed cave and sinkhole formations. NWMI PSAR Section 2.5.2.3, "Mississippian Age Osagean Series Burlington Formation (Mo)," references a report by Terracon Consultants, Inc. (Reference 62) that states that "No caves or sinkholes are known to exist … within approximately 1 mi of [the NWMI facility site]. However, several areas of known karst activity are present…." The PSAR states that no sinkholes have occurred at the NWMI facility site since the Terracon report was issued in 2011. The most recent sinkhole formed in May 2014 at East Creek Road, approximately 0.45 km (0.73 mi) to the southwest of the NWMI facility site. The applicant also states that a site-specific investigation of the site will be conducted to ensure that the area does not have the potential for sinkhole formations. If the investigation does identify the potential for sinkholes, the design would incorporate one of the following alternatives: (1) excavate site both vertically and horizontally to remove the potential and backfill with structural fill, or (2) install piers to bedrock to support the structure if a sinkhole was to occur. If one of these alternatives needs to be implemented, it will be determined after the geotechnical investigation is complete, incorporated in the final NWMI facility design, and presented in the FSAR as part of an OL application.

NWMI PSAR Section 2.5.2.1, "Quaternary Age Holocene Series," states, in part, that "[h]ighly plastic clays that exhibit volume change with variations in moisture are commonly encountered near the ground surface (Terracon 2011)." Additionally, the applicant states in that a site specific geotechnical investigation of the NWMI facility site will be conducted to identify the site specific soil characteristics. If highly plastic clays are identified at the site, the design will include excavation of the clays and backfill with structural fill. The structural details will be developed in the final NWMI facility design and presented in the FSAR submitted as part of an OL application.

NWMI PSAR Section 2.5.3, states that "Soils with moisture levels above their measured plastic limits may be prone to rutting and can develop unstable subgrade conditions during general construction operations (Terracon 2011). Moderate to high plasticity clays were observed at the site. Such soils are commonly referred to as 'expansive' or 'swelling' soils…. Footings, floor slabs, and pavements supported on expansive soils often shift upward or downward causing possible distortion, cracking, or structural damage."

Consistent NUREG-1537, Part 1, Section 2.5.3, NWMI PSAR Section 2.5.4 presents a listing of recorded earthquakes with a magnitude equal to or larger than 3.0 in NWMI PSAR Table 2-41, "Recorded Missouri Earthquake History," with the last listed earthquake, with magnitude 3.0, occurred in 2016.

NWMI PSAR Section 2.5.6, states that the seismic design parameters for the proposed project are discussed in terms of the 2012 International Building Code (IBC) and associated standards. Since NUREG-1537, Part 1, Section 3.4, "Seismic Damage," as supplemented by the ISG Augmenting NUREG 1537, Part 1, Chapter 3, "Design of Structures, Systems, and Components," states that the seismic design of a radioisotope production facility should, at a

minimum, be consistent with local building codes and other applicable standards, the staff finds NWMI's use of the 2012 IBC acceptable.

NUREG-1537, Part 2, Section 2.5, states that the information on potential seismic effect should be in a form suitable for developing design basis in Chapter 3 for SSCs, and that the information presented should be "obtained from sources of adequate credibility and is consistent with other available data, such as data from the USGS or in the [FSAR] of a nearby nuclear power plant."

NWMI has committed to using the NRC Regulatory Guide (RG) 1.60, "Design Response Spectra for Seismic Design of Nuclear Power Plants" for the final seismic design adjusted to reflect the ground acceleration response of 0.2 g. The nearby University of Missouri – Columbia Research Reactor and Callaway Energy Center, used the same seismic design. The staff developed a general seismic design response spectrum incorporating site amplification factors for the proposed NWMI facility site to confirm the seismic design. Within the 1 to 10 hertz (Hz) range of the design response spectrum, the staff found the seismic response acceptable for issuance of a construction permit. This frequency range tends to impact large facility structures, components, and equipment. The staff identified a potential high-frequency (e.g., greater than 10 Hz) impact to electrical relays, piping, and instrumentation. A major factor affecting the high frequency response will be excavation depth of the site. The applicant also stated that additional information on the seismic requirements and evaluations of the NWMI facility and associated IROFS will be provided in the OL application. If an OL application is submitted, the staff will review the seismic design for both the structure and for IROFS components in order to determine whether regulatory requirements have been met. The staff concludes that these analyses on the seismic design can reasonably be left for further evaluation in the OL application when the final design is completed and IROFS components have been identified. The staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 2.5.5, states that Boone County would be severely impacted by a 7.6 magnitude earthquake with the epicenter on or near the New Madrid Seismic Zone, with an estimated intensity of VII at the site, as shown on NWMI PSAR Table 2 42. The applicant states in the PSAR that the estimated maximum ground acceleration at the NWMI facility site will meet the RG 1.60 free-field response spectrum, anchored to a peak ground acceleration (PGA) of 0.2 g, and states that, as mentioned in Chapter 3.0, the seismic design of the facility and associated IROFS will ensure the functionality and integrity of SSCs required to prevent radiological releases below the performance requirements of 10 CFR 70.61, and noted that additional information on seismic requirements and evaluations of the NWMI facility and associated IROFS will be provided in the FSAR submitted as part of an OL application. The NRC staff finds that it is acceptable for the applicant to defer the identification of specific IROFS until the OL application since NWMI has described classifications and performance requirements for the SSCs, including IROFS, at its facility in NWMI PSAR Section 3.5, "Systems and Components."

NUREG-1537, Part 1, Section 2.5.5, states that the applicant should assess the ground motion at the site from the maximum potential earthquakes associated with each tectonic province and should consider any site amplification effects. Using the results, the applicant should establish the vibratory ground motion design spectrum. The applicant states in the PSAR that that the design spectrum and estimated maximum acceleration at the NWMI facility site will meet the RG 1.60 spectrum anchored at a PGA of 0.2 g for building structural analysis and design.

The applicant stated in NWMI PSAR Section 2.5.6 that the seismic soil classification for the NWMI facility site is Class C.

NUREG-1537, Part 1, Section 2.5.7, pertains to the evaluation of soil structure, and states, in part, that, "If the foundation materials at the site adjacent to and under safety-related structures are saturated soils or soils that have a potential for becoming saturated, the applicant should prepare an appropriate state-of-the-art analysis of the potential for liquefaction at the site. The applicant should also determine the method of analysis on the basis of actual site conditions, the properties of the … facilities, and the earthquake and seismic design requirements for the protection of the public."

NUREG-1537, Part 2, Section 2.5, instructs the staff to confirm that the information on the geologic features and the potential seismic activity at the site have been provided in sufficient detail and in a form to be integrated acceptably into design bases for structures, systems, and operating characteristics of the facility.

NWMI PSAR Section 2.5.8 provides information based on preliminary investigations of the NWMI facility site by Terracon, and concludes that the available data are insufficient and contradictory and that the liquefaction potential cannot be conclusively determined. It also states that additional geotechnical analysis will be conducted at the site to determine the liquefaction potential of the soils on site. The applicant states that additional information on geotechnical investigations and analyses of the site will be conducted and submitted as part of the OL application. The staff determined that the completion of the evaluation can reasonably be left for further evaluation in the OL application since the depth of soil over the bedrock is thin enough that the applicant could remove or modify the soil layer in order to address liquefaction potential if needed. The final design of the NWMI facility will need to include the actual soil characteristics of the site. The staff is tracking this issue in Appendix A of this SER.

Based on its review, the staff finds that the level of detail and analyses provided in NWMI PSAR Section 2.5 demonstrate an adequate design basis and satisfy the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.5, allowing the staff to find that: (1) the information on the geologic features and the potential seismic activity at the site has been provided in sufficient detail and in a form to be integrated acceptably into the design bases for structures, systems, and operating characteristics of the facility; (2) the information in the PSAR indicates that damaging seismic activity at the proposed site during its projected lifetime is very unlikely and that, if seismic activity were to occur, any radiological consequences are bounded or analyzed in PSAR Chapter 13; and (3) the PSAR 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 site unsuitable for the proposed facility.

Because NWMI must conduct additional geotechnical surveys to further investigate sinkhole potential, liquefaction, and soil characteristics, which could impact the final design bases of the facility, the staff recommends that the construction permit include the following condition:

Prior to the beginning of construction, NWMI shall (a) complete a geotechnical investigation to identify any potential voids that may adversely impact stability of subsurface materials and foundation, soil and rock characteristics, and liquefaction potential at the site and (b) submit the results of this investigation, including any design changes made to the facility based on the findings of the investigation, in a report to the NRC. This condition terminates once NWMI submits the results of the geotechnical investigation in either this report or as part of its final safety analysis report, whichever occurs first.

Therefore, the staff concludes that the applicant's description of geology, seismology, and geotechnical engineering characteristics is sufficient and meets the applicable regulatory

requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical information required to complete the safety analysis can reasonably be left for consideration, and will be provided in, the FSAR.

2.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI facility's site characteristics, as described in Chapter 2.0 of the NWMI PSAR, and finds that the NWMI facility site characteristics: (1) provide reasonable assurance that the final design will conform to the design basis, and (2) meet all applicable regulatory requirements and NUREG-1537 acceptance criteria. Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the production facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that, taking into consideration the site criteria contained in 10 CFR Part 100, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

3 DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

The purpose of the Northwest Medical Isotopes, LLC (NWMI or the applicant) production facility's structures, systems, and components (SSCs) is to ensure the safety of the facility and the protection of the public and workers. The material presented in this chapter of the NWMI preliminary safety analysis report (PSAR) should discuss the safety and protective functions and related design features of the SSCs that help provide protection against uncontrolled releases of radioactive material and chemical related exposures. The bases for the design criteria for some of the SSCs discussed in this chapter may be developed in other chapters of the PSAR.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility's SSCs as presented in Revision 3 of Chapter 3.0, "Design of Structures, Systems, and Components," of the NWMI PSAR. As explained in SER Section 1.1.1, "Scope of Safety Review," the NWMI construction permit application generally refers to the building that will house all activities, including SSCs related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility," or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

3.1 Areas of Review

NWMI PSAR Chapter 3.0 identifies and describes the design criteria for the SSCs for the NWMI production facility. The information presented emphasizes safety and protective functions, items relied on for safety (IROFS) used by NWMI to demonstrate compliance with 10 CFR Part 50 requirements for a production facility, and related design features that help provide defense-in-depth against releases of radioactive material and chemical exposures to workers and the public. The bases for the design criteria for some of the SSCs discussed in this chapter are developed in other chapters of the PSAR and are cross-referenced, when appropriate.

The staff reviewed NWMI PSAR Chapter 3.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design criteria of the NWMI production facility SSCs for the purposes of issuance of a construction permit under 10 CFR Part 50. As part of this review, the staff evaluated descriptions and discussions of the NWMI production facility SSCs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI production facility SSCs was evaluated to ensure the design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions are sufficient to provide reasonable

assurance that the final design will conform to the design basis. In addition, the staff reviewed NWMI's identification of credible events and IROFS that demonstrate reasonable assurance that the performance requirements of 10 CFR 70.61, "Performance requirements," can be met for the NWMI production facility.

Areas of review for this chapter included the NWMI production facility SSCs. Within these review areas, the staff assessed the capability of the SSCs to ensure safe facility operation, safe facility shutdown and continued safe conditions, response to anticipated transients, response to potential accidents analyzed in PSAR Chapter 13.0, "Accident Analysis," and control of radioactive material described in PSAR Chapter 11.0, "Radiation Protection Program and Waste Management."

3.2 Summary of Application

NWMI PSAR Chapter 3.0 describes the design bases of SSCs for the NWMI production facility established to ensure production facility safety and protection of the public and workers.

NWMI PSAR Section 3.1, "Design Criteria," describes the design criteria applied to the NWMI production facility and SSCs within the production facility. The PSAR states that the principal design criteria for a production facility establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs. The SSC systems associated with the NWMI production facility are identified. The IROFS for the facility that are discussed in NWMI PSAR Section 3.1 are further evaluated in NWMI PSAR Chapter 6.0, "Engineered Safety Features," and Chapter 13.0.

NWMI PSAR Section 3.2, "Meteorological Damage," includes a discussion of NWMI production facility meteorological accidents with radiological or chemical consequences, which was derived from an NWMI evaluation of natural phenomena and manmade events on engineered safety features and IROFS. This section also discusses the criteria used to design the NWMI production facility to withstand wind, tornado, snow, ice, and water damage. The combinations of the meteorological loads with other loads (i.e., dead loads and earthquake loads) for the structural analysis are provided in NWMI PSAR Section 3.4, "Seismic Damage."

NWMI PSAR Section 3.2.8, "External Hazards," discusses NWMI's evaluation of external events including aircraft impacts, external explosions, and external fires.

NWMI PSAR Section 3.3, "Water Damage," identifies the requirements and guidance for the water damage design of the NWMI production facility SSCs. The applicant used NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," and American Society of Civil Engineers (ASCE) 7, Chapter 5, which provide guidance on flood protection of nuclear SSCs. Updates and development of technical specifications (TSs) associated with the design of the NWMI production facility SSCs for water damage will be provided in Chapter 14.0 of the operating license (OL) application.

NWMI PSAR Sections 3.4.1, "Seismic Input," and 3.4.2, "Seismic Qualification of Subsystems and Equipment," provides information on design response spectra, soil-structure interactions and dynamic soil pressures, seismic input and analysis, equivalent-static analyses, dynamic analyses, and seismic qualification of subsystems and equipment.

NWMI PSAR Section 3.4.3, "Seismic Instrumentation," discusses the instrumentation that will be used to record accelerations during a seismic event. The purpose of the instrumentation is to

(1) permit a comparison of measured responses of structures and selected components with predetermined results of analyses that predict when damage might occur, (2) permit facility operators to understand the possible extent of damage within the facility immediately following an earthquake, and (3) permit determination of when a safe-shutdown earthquake event has occurred that would require emptying of the process tank(s) for inspection, as specified in National Fire Protection Association (NFPA) 59A, "Standard for the Production, Storage, and Handling of Liquefied Natural Gas," Section 4.1.3.6(c).

NWMI PSAR Section 3.5, "Systems and Components," states that certain systems and components of the NWMI production facility are considered safety-related because they perform safety functions during normal operations or are required to prevent or mitigate the consequences of abnormal operational transients or accidents. This PSAR section also defines the safety classifications for the NWMI production facility. This section also summarizes the design basis for design, construction, and operating characteristics of safety-related SSCs of the NWMI production facility. The NWMI production facility systems and components are also classified by three seismic categories (i.e., Seismic Category I, Seismic Category II, and non-safety-related SSCs) as defined in Section 3.5.1.3.2, "Seismic Classification for Structures, Systems, and Components," of the NWMI PSAR and three quality levels (i.e., QL-1, QL-2, and QL-3) as defined in Section 3.5.1.3.1, "Quality Group Classifications for Structures, Systems, and Components," of the NWMI PSAR.

NWMI evaluated the general design criteria from 10 CFR 70.64, "Requirements for new facilities or new processes at existing facilities," and 10 CFR Part 50, Appendix A (General Design Criteria 60 through 64) consistent with the "Final Interim Staff Guidance [ISG] 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," (Reference 11) to inform the production facility design basis. This evaluation is presented in NWMI PSAR Table 3-22, "Design Criteria Requirements." NWMI PSAR Section 3.5.2, "Radioisotope Production Facility," states that these general design criteria provide a rational basis from which to initiate the production facility design but are not mandatory. Since the general design criteria were derived from 10 CFR Part 70 and Appendix A of 10 CFR Part 50, which are not regulatory requirements for a production facility licensed under 10 CFR Part 50, NWMI states in PSAR Section 3.5.2 that there are some cases where conformance to a particular criterion is not directly measurable. For each of the criteria, a specific assessment of the NWMI production facility design is made, and a list of references is included to identify where detailed design information pertinent to each criterion is treated. The accident sequences in PSAR Chapter 13.0 define the credible events as determined by NWMI for the production facility. NWMI states that the safety-related parameter limits ensure that the associated design basis is met for the events presented in Chapter 13.0.

Additionally, the following NWMI PSAR tables list facility systems and provide references to guidance, codes, and standards.

- Table 3-2, "Summary of Items Relied on for Safety Identified by Accident Analyses"
- Table 3-3, "Relevant U.S. Nuclear Regulatory Commission Guidance"
- Table 3-4, "Other Federal Regulations, Guidelines, and Standards"
- Table 3-5, "Local Government Documents"
- Table 3-6, "Discovery Ridge/University of Missouri Requirements"
- Table 3-7, "Design Codes and Standards"

3.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 3.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design criteria for the NWMI production facility SSCs for the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) Based on the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI facility site. However, the staff evaluated the NWMI facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and 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 (Reference 9). The staff's review in this SER chapter evaluated the design criteria, meteorological damage, water damage, seismic damage and systems and components to ensure that issuance of the construction permit for the production facility will not be inimical to public health and safety.

3.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of NWMI's SSC design criteria are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."

- 10 CFR 50.40, "Common standards."

3.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with NRC regulations, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).

- 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 (Reference 9).

- "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 (Reference 10).

- "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 (Reference 11).

- NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," dated June 2015 (Reference 24).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility," as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a radioisotope production facility license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

3.4 Review Procedures, Technical Evaluation, and Evaluation Findings

NWMI PSAR Chapter 3.0 describes the design bases of SSCs for the NWMI production facility established to ensure facility safety and the protection of the public. The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 3.0. The purpose of the review was to assess the sufficiency of the preliminary design and performance of the NWMI production facility's SSC design criteria for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). Sufficiency of the preliminary design criteria for the NWMI production facility's SSCs is determined by ensuring the design meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in SER Section 3.3, "Regulatory Basis and Acceptance Criteria." The staff also evaluated the potential impacts of events that may cause radiological or chemical exposures exceeding the thresholds in 10 CFR 70.61, from the 10 CFR Part 70 target fabrication activities, on the 10 CFR Part 50 production facility. A summary of the technical evaluation is described in SER Section 3.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility's SSCs may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility's SSCs based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of the NWMI production facility's SSCs does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the NWMI production facility's SSCs as described in the FSAR submitted as part of NWMI's OL application.

3.4.1 Design Criteria

The staff evaluated the sufficiency of the design criteria, as described in NWMI PSAR Section 3.1 using the guidance and acceptance criteria from Section 3.1, "Design Criteria," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 3.1, the staff compared the specified design criteria with the proposed normal operation of the NWMI production facility, response to anticipated transients, and consequences of accident conditions applicable to the appropriate SSCs assumed to function in NWMI PSAR Section 3.1 and other relevant chapters of the PSAR.

Section 3.1 of NUREG-1537, Part 2, states that for a production facility the design criteria should be specified for each SSC that is assumed in the PSAR to perform an operational or safety function. Additionally, design criteria should include references to applicable up-to-date

standards, guides, and codes. The design criteria for SSCs should be stipulated as outlined below:

- Design for the complete range of normal facility operating conditions.
- Design to cope with anticipated transients and potential accidents.
- Design with redundancy to protect against unsafe conditions in case of single failures of facility protective and safety systems.
- Design to facilitate inspection, testing, and maintenance.
- Design to limit the likelihood and consequences of fires, explosions, and other potential manmade conditions.
- Design with quality standards commensurate with the safety function and potential risks.
- Design to withstand or mitigate wind, water, and seismic damage to reactor systems and structures.
- Design includes analysis of function, reliability, and maintainability of systems and components.

In addition, NUREG-1537, Part 2 also states that the applicant should identify the SSCs by function(s), modes of operation, location, type(s) of actuation, relative importance in the control of radioactive material and radiation, applicable design criteria, and the chapter and section in the PSAR where these design criteria are applied to the specific SSC.

NWMI PSAR Tables 3-3, 3-4, 3-5, 3-6, and 3-7, present the design inputs that were used in the development of the design. The PSAR notes in Section 3.1.7, "Codes and Standards," that codes and standards are used as guidance for the design of the facility SSCs. The technical evaluation performed by the staff assumed that the production facility will be constructed consistent with the design inputs in PSAR Section 3.1. The staff expects that NWMI will document changes to design inputs following its quality assurance (QA) program as shown in NWMI PSAR Chapter 12.0, "Conduct of Operations." The staff will examine the detailed final design and design inputs as part of an OL application review.

NWMI PSAR Section 3.0 states that the NWMI production facility and system design are based on defense-in-depth practices. Defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. PSAR Section 3.1 also provides sufficient information to guide the staff to the appropriate section of the PSAR where the design criteria for specific SSCs are discussed in detail including a crosswalk. Additionally, PSAR Section 3.1 outlines the standards, guides, and codes that were used as design inputs for the NWMI production facility.

Based on its review, the staff finds that the level of detail provided in NWMI PSAR Section 3.1 demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.1, allowing the staff to find that: (1) the design criteria are based on applicable standards, guides, codes, and criteria and provide reasonable assurance that the facility SSCs can be built and will function as designed and as required by the PSAR; and (2) the design criteria provide reasonable assurance that the public will be protected from radiological risks from operation. As noted above, NWMI should keep the staff informed of changes to design inputs that impact the construction of the facility to support the NRC's construction inspection program of the facility.

Therefore, the staff concludes that the design criteria of the NWMI production facility's SSCs are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information, based on the final design, that is required to complete the safety analysis can reasonably be left for later consideration. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR submitted as part of the OL application.

3.4.2 Meteorological Damage

The staff evaluated the sufficiency of the NWMI production facility's preliminary design features to cope with wind or other meteorological damage, as described in NWMI PSAR Section 3.2, for the issuance of a construction permit using the guidance and acceptance criteria from Section 3.2, "Meteorological Damage," of NUREG-1537, Part 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 3.2, the staff considered the description of the site meteorology to ensure that all SSCs that could suffer meteorological damage are considered, as presented in NWMI PSAR Section 3.2 and other relevant chapters of the PSAR. 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 retain function throughout the predicted meteorological conditions. The staff also reviewed (a) design load definitions; (b) design load combinations for the SSCs; (c) the detailed determination of applicable design loads, including the wind loadings and tornado wind loadings; (d) tornado generated missile impact effects; and (e) rain, snow, and ice loadings for SSCs from Section 3.4.2 of the NWMI PSAR, for the adequacy and completeness of content and compliance with regulatory requirements and guidance in accordance with the review procedures and acceptance criteria of NUREG-1537, Part 2, Section 3.2. The applicant has specifically considered and described the approach to comply with NUREG-1537, Part 1, Section 2.3.1, "General and Local Climate," as discussed in NWMI PSAR Section 3.2.5.2, "Snow Load," Section 3.2.5.2.1, "Normal Snow Load," and Section 3.2.5.3, "Atmospheric Ice Loads."

NWMI PSAR Section 3.2.3.1.3, "Live Loads," and Table 3-13, "Floor Live Loads," state that some of the loads that may affect the global structural response and the local structural element designs are "To Be Determined" (TBD). The applicant further states that a conservative load value is assumed in the preliminary design for all unknown loads and these are marked as "Hold." All "Holds" are removed as the design matures, and no final design is issued with any remaining "Holds." NWMI states that all TBD loads will be provided in the FSAR as part of the OL application.

NWMI PSAR Section 3.2.4.2 states that the regulatory basis used for the tornado winds and generated missile characteristics used in the design is Regulatory Guide (RG) 1.76, Revision 1, "Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants," for Region 1. The tornado load criteria will be updated by using tornado loading in accordance with 10^{-5} annual probability of exceedance in the OL application which is consistent with NUREG-1520, Part 3, Appendix D, "Natural Phenomena Hazards."

Based on its review, the staff finds that the level of detail provided on meteorological damage for the preliminary design demonstrates an adequate design basis and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.2, allowing the staff to find that: (1) the design criteria and designs provide reasonable assurance that SSCs would continue to perform their safety functions as specified in the PSAR under potential meteorological damage conditions; and (2) the design criteria and designs use local building codes, standards, or other applicable criteria to ensure that significant meteorological damage at the production facility site is minimized.

Therefore, the staff concludes that the NWMI production facility design features for coping with meteorological damage are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis, based on the final design, can reasonably be left for later consideration. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR submitted as part of the OL application.

3.4.3 Water Damage

The staff evaluated the sufficiency of the NWMI production facility's preliminary design features to cope with predicted hydrological conditions, as described in NWMI PSAR Section 3.3, for the issuance of a construction permit using the guidance and acceptance criteria from Section 3.3, "Water Damage," of NUREG-1537, Part 2.

Consistent with the review procedures of Section 3.3 of NUREG-1537, Part 2, the staff considered the site description to ensure that all SSCs with the potential for hydrological (water) damage, including the damage due to a potential inadvertent fire protection system (FPS) discharge, are considered in this PSAR section. For any such SSC, the staff reviewed the design bases to verify that consequences are addressed and described in detail in appropriate chapters of the NWMI PSAR.

NWMI PSAR Section 3.3.1.1.1, "Flooding from Precipitation Events," describes the flood protection measures for the NWMI production facility's SSCs and states the following:

> The site will be graded to direct the storm-water from localized downpours with a rainfall intensity for the 100-year storm for a 1-hr duration around and away from the RPF. Thus, no flooding from local downpours is expected based on standard industrial design. Rainwater that falls on the waste management truck ramp and accumulates in the trench drain has low to no consequence for radiological, chemical, and criticality hazards.
>
> Situated on a ridge, the RPF will be located above the 500-year flood plain according to the flood insurance rate map for Boone County, Missouri, Panel 295…. The site is

above the elevation of the nearest bodies of water (two small ponds and a lake), and no dams are located upstream on the local streams. This data conservatively provides a $2x10^{-3}$ year return frequency flood, which can be considered an unlikely event according to performance criteria. However, the site is located at an elevation of 248.4 m (815 ft), and the 500-year flood plain starts at an elevation of 231.6 m (760 ft), or 16.8 m (55 ft) below the site. Since the site, located only 6.1 m (20 ft) below the nearest high point on a ridge (relative to the local topography), is well above the beginning of the 500-year flood plain, and is considered a dry site, the probable maximum flood from regional flooding is considered highly unlikely, without further evaluation.

NWMI PSAR Section 3.3.1 also states that, per NUREG-1520, Section 3.2.3.4(1)(c), and ASCE 7, Chapter 5, flood loads will be based on the water level of the 100-year flood (one percent probability of exceedance per year). NWMI has determined the NWMI production facility to be above both the 100-year and the 500-year flood plain. Chapter 2.0, Section 2.5.3, "On-site Soil Types," of the NWMI PSAR, provides additional detail related to flood protection measures.

NWMI PSAR Section 3.3.1.1, "Flood Protection Measures for Structures, Systems, and Components," and Section 3.3.1.2, "Flood Protection from External Sources," state that the flood loads on the SSCs are considered highly unlikely based on the elevation above the 100-year and 500-year flood plain and are not considered in the design loads. Section 3.3.1.2 further states that the SSCs located below grade will be protected using the hardened protection approach, where systems and components are enclosed in a robust reinforced concrete structure. Water stops at expansion and construction joints will be installed and waterproofing of the NWMI production facility will be provided to protect external surfaces from exposure to water. The level of waterproofing to be used will be contained in the OL application.

NUREG-1537, Part 1, Section 3.3, "Water Damage," states, in part, that "the applicant should specifically describe … (2) the impact on systems resulting from instrumentation and control electrical or mechanical malfunction due to water, and (3) the impact on equipment, such as fans, motors, and valves, resulting from degradation of the electromechanical function due to water." NUREG-1537, Part 2, Section 3.3, states, in part, that "The design criteria and designs should provide reasonable assurance that structures, systems, and components would continue to perform required safety functions under water damage conditions. For the design the applicant should use local building codes, as applicable, to help ensure that the water damage to structures, systems, and components at the [NWMI] production facility site … would not cause or allow uncontrolled release of radioactive material."

NWMI PSAR Section 3.3 discusses water damage and Section 3.3.1.3, "Compartment Flooding from Fire Protection Discharge," and Section 3.3.1.4.1, "Potential Failure of Fire Protection Piping," deal with flooding due to malfunction of the FPS. The applicant stated, in part, that sensitive systems and components, whether electrical, optical, mechanical or chemical, are typically protected within the enclosure designed for the anticipated adverse environmental conditions resulting from these types of inadvertent water discharges. These critical components will be installed within appropriate severe-environment rated enclosures consistent with relevant industry standards (e.g., NFPA, etc.). The applicant also stated that the final comprehensive NWMI production facility design will include any design elements, and sensitive equipment protection measures that will be included in the FSAR as part of the OL application. The applicant also stated that the OL application will include the identification of or commitments to codes, standards, and other referenced documents that make up the design bases. The

flood protection measures described by the applicant are designed to guard against flooding from the rupture of an on-site fire protection tank if the final design determines that feature is necessary.

Per NWMI PSAR Section 3.3.1.4, "Compartment Flooding from Postulated Component Failures," Section 3.3.1.5, "Permanent Dewatering System," and Section 3.3.1.6, "Structural Design for Flooding," the flood water depth due to a rupture of water containing components and its consequences will be included in the FSAR as part of the NWMI OL application. The applicant stated that there is no impact of flood water on structural systems, and no dewatering system is required.

Based on its review, the staff finds that the level of detail provided on hydrological damage demonstrates an adequate design basis and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.3 because the applicant's design should allow for SSCs to continue to perform their safety functions based on the use of applicable codes and standards including local building codes. This allows the staff to find that the design criteria and preliminary design would protect against potential hydrological (water) damage and would provide reasonable assurance that the NWMI production facility's SSCs would continue to perform their required safety functions, would not cause unsafe production facility operation, would not prevent safe shutdown of the production facility, and would not cause or allow uncontrolled releases of radioactive material or chemical exposures.

Therefore, the staff concludes that the NWMI production facility design features for coping with hydrological damage are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis, based on the final design, can reasonably be left for later consideration. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will confirm that the final design conforms to this design basis during its review of the NWMI FSAR submitted as part of the OL application.

3.4.4 Seismic Damage

The staff evaluated the sufficiency of the NWMI production facility's preliminary design features in the case of a seismic event, as described in NWMI PSAR Section 3.4, for the issuance of a construction permit using the guidance and acceptance criteria from Section 3.4, "Seismic Damage," of NUREG-1537, Part 2.

Consistent with the review procedures of Section 3.4 of NUREG-1537, Part 2, the staff considered the site description and historical data to ensure that the appropriate seismic inputs have been considered. For any SSC damage, the staff considered the extent to which a seismic event would impair the safety function of the SSCs for the NWMI production facility. NWMI PSAR in Section 3.4 discusses the seismic inputs, soil-structure interaction, methods of seismic analysis, seismic qualification of subsystems and equipment, and seismic instrumentation. The PSAR section discusses NWMI's use of the methodology from RG 1.60, "Design Response Spectra for Seismic Design of Nuclear Power Plants," as the basis for the NWMI production facility seismic design.

NUREG-1537, Part 1, Section 3.4, "Seismic Damage," states, in part, that "the applicant should specify and describe the SSCs that are required to maintain the necessary safety function if a seismic event should occur." The NWMI production facility seismic design should provide

reasonable assurance that the NWMI production facility could be shut down and maintained in a safe condition. To verify that seismic design functions are met, the applicant should give the bases for TSs necessary to ensure operability, testing, and inspection of associated systems, including instrumentation and control portions, as applicable.

NUREG-1537, Part 2, Section 3.4, "Seismic Damage," states that the review should include the designs and design bases of SSCs that are required to maintain function in case of a seismic event at the NWMI production facility site. The finding required is that the NWMI production facility design should provide reasonable assurance that it can be shut down and maintained in a safe condition.

NUREG-1537, Part 2, Section 2.5, "Geology, Seismology, and Geotechnical Engineering," states, in part, that the information has been obtained from sources of adequate credibility and is consistent with other available data, such as data from the USGS or in the FSAR of a nearby nuclear power plant.

In NWMI PSAR Section 3.4, the applicant stated that the safe shutdown earthquake (SSE) design basis is the RG 1.60 ground response spectrum anchored at 0.2 g peak ground acceleration, as was adopted by the University of Missouri – Columbia Research Reactor and Callaway Nuclear Plant, which are both in the proximity of the NWMI production facility site. The regulatory guide is not indexed to any specific soil type and is sufficiently broad to cover all soil types. The composition of soil in which the NWMI production facility is embedded will be included in the soil-structure-interaction analyses as part of the building response analysis for the FSAR based on the final design. Structural damping will follow the recommendations of RG 1.61, "Damping Values for Seismic Design of Nuclear Power Plants." Response spectra corresponding to the recommended damping values of RG 1.61 will be used to derive seismic loads. The staff expects that the applicant will analyze the final design of NWMI production facility structure with respect to the SSE and determine the impacts of high frequency (i.e., greater than 10 Hertz) ground accelerations on components that are determined to be IROFS. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. This item is being tracked in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER.

NWMI PSAR Section 3.4.1.2, "Method of Analysis," discusses methods of seismic analysis and the spatial combination of three directional earthquake response effects. The applicant states in NWMI PSAR Section 3.4.1.2.1, "Equivalent-Static Analysis," that the design of IROFS will consider seismic loads in all three directions using a combination of square-root-of-the-sum-of-squared or 100/40/40 methodologies per RG 1.92, "Combining Modal Responses and Spatial Components in Seismic Response Analysis." The 100/40/40 methodology will be used in the development of the final NWMI production facility design and in the FSAR as part of the OL application.

NWMI PSAR Section 3.4.2 discusses seismic qualification methodologies. NWMI PSAR Section 3.4.2.1, "Qualification by Analysis," discusses qualification by analysis, and NWMI PSAR Section 3.4.2.2, "Qualification by Testing," discusses qualification by testing. In NWMI PSAR Section 3.4.2.2 the applicant also states that it will define specific acceptable qualification methods in the procurement package to demonstrate seismic qualification. Seismic qualification of IROFS will include three options: (1) calculations and verification that the main structural components of the SSCs can withstand the seismic loads derived from the in-structure floor response spectra at the damping value derived from RG 1.61, (2) reference to available shake

table testing that demonstrates the seismic capacity of the SSCs or of multiple similar items, and (3) demonstration of the seismic capacity through the performance of the type of SSCs in actual earthquakes.

NWMI PSAR Section 3.4.1.2.2, "Dynamic and Static Analysis," discusses the dynamic and static seismic analyses and in-structure floor response spectra generation of the NWMI production facility. Dynamic analyses are used for the evaluation of NWMI production facility structural components. A static analysis will be completed by the applicant during the final design stage using a combination of static load computations to ensure that SSCs remain in place and intact. Additionally, the applicant will consider a combination of existing shake table test data and existing earthquake experience to ensure that the equipment functions following an earthquake event. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will examine the analyses as part of the review of the final design when the FSAR is submitted as part of the OL application.

NWMI PSAR Section 3.4.2.2 discusses qualification of subsystems and equipment by testing. The applicant also stated that the capacity of the standard support system for overhead fixtures mounted above IROFS will be checked to ensure that they will withstand the seismic loads derived from the floor response spectra. The applicant also stated that the seismic analysis will include a check to ensure that pounding or sway impact will not occur between fixtures, (e.g., there is a sufficient rattle space). NWMI states that it will provide more detail in the NWMI FSAR included in the OL application based on the development of the final design. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will examine the analyses as part of the review of the final design when the FSAR is submitted as part of the OL application.

NWMI PSAR Section 3.4.3 provides a description of seismic monitoring instrumentation for the NWMI production facility. It also includes a discussion of types of seismic design categories for instrumentation which the applicant states will be in accordance with ASCE 7, Chapter 11. The applicant stated that the seismic instrumentation is not an IROFS, it provides no safety function, and therefore it is not a safety-related system. However, the applicant also stated that the seismic recorders need to be designed to withstand any credible level of shaking to ensure that the ground motion would be recorded in the event of an earthquake.

Based on its review, the staff finds that the level of detail provided on seismic damage demonstrates an adequate design basis and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.4. This allows the staff to find that: (1) the design criteria and design should provide reasonable assurance that SSCs would continue to perform their required safety functions during and following a seismic event and (2) the design to protect against seismic damage provides reasonable assurance that the consequences of credible seismic events will be considered to adequately protect public health and safety.

Therefore, the staff concludes that the NWMI production facility design features for coping with seismic damage are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR Part 50. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR submitted as part of the OL application.

3.4.5 Systems and Components

The staff evaluated the sufficiency of the NWMI production facility's preliminary design features for systems and components, as described in NWMI PSAR Section 3.5, for the issuance of a construction permit using the guidance and acceptance criteria from Section 3.5, "Systems and Components," of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria of NUREG-1537, Part 2, Section 3.5, the staff verified that the design bases for the SSCs that are required to ensure safe operation of the NWMI production facility are described in NWMI PSAR Section 3.5 or other PSAR sections in sufficient detail.

Further, consistent with the guidance in the ISG Augmenting NUREG-1537, Part 2, Section 3.5, while compliance with 10 CFR 70.64 is not required for a 10 CFR Part 50 production facility, if the applicant can adequately address the baseline design criteria in 10 CFR 70.64, the application would be found to be acceptable by the staff. Therefore, since the NWMI PSAR evaluates the production facility against the baseline design criteria of 10 CFR 70.64, the staff used additional guidance from NUREG-1520, Section 3.4.3.2, "Integrated Safety Analysis Summary and Documentation," in the review of how the design of the production facility addresses each baseline design criterion.

In NWMI PSAR Section 3.5.1.3, "Nuclear Safety Classifications for Structures, Systems, and Components," NWMI has defined terms related to SSCs as follows:

> Safety-related: is a classification applied to items relied on to remain functional during or following a postulated DBE [design-basis event] to ensure the:
>
> - Integrity of the facility infrastructure
> - Capability to shut down the facility and maintain it in a safe shutdown condition
> - Capability to prevent or mitigate the consequences of postulated accidents identified through accident analyses that could result in potential offsite and worker exposures comparable to the applicable guideline exposures set forth in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61 (d)
> - Operation of the facility without undue risk to the health and safety of workers, the public, and the environment to meet 10 CFR [Part] 20 normal release or exposure limits for radiation doses and applicable limits for chemical exposures
>
> Safety-related IROFS: SSCs identified through accident analyses are required to meet the performance requirements of 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d) ([see PSAR] Table 3-2)
>
> Safety-related Non-IROFS: SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of workers, the public, and environment, and includes SSCs to meet 10 CFR [Part] 20 normal release or exposure limits
>
> Non-safety-related: SSCs related to the production and delivery of products or services that are not in the above safety classifications

NWMI PSAR Section 3.5 is divided into two sections. Section 3.5.1, "General Design Basis Information," discusses SSCs and the criteria used to determine if SSCs are considered safety-related or non-safety-related. Additionally, SSCs were classified by three seismic categories (i.e., Seismic C-I, Seismic C-II, and non-seismic) and three quality levels (i.e., QA Level 1, QA Level 2, and QA Level 3). Safety-related IROFS are classified QA Level 1 and Seismic C-I. At a minimum, safety-related non-IROFS are classified as QA Level 2 and Seismic C-II, and non-safety-related SSCs are classified as QA Level 3 and non-seismic. QA Level 1 SSCs are controlled to the full measure of the NWMI QA plan. NWMI PSAR Section 3.5.2 lists systems that are part of the NWMI production facility. Specifically, SSCs required to operate during and/or after design-basis accidents or a design-basis earthquake are discussed in this section or in the system's PSAR section and include relevant requirements, standards, and documentation.

NWMI developed these specific definitions in order to show how the results of the integrated safety analysis and the development of IROFS allow for the designation of QA levels and seismic design criteria. The definitions are acceptable to the staff based on (a) the use of safety-related definitions that include the QA and seismic categories that have been derived for IROFS and non-IROFS; and (b) the designation of all IROFS to be QA Level 1 and Seismic Category I. The definitions and QA requirements are consistent with the NWMI QA program plan which is evaluated in Chapter 12.0 of this SER.

Further evaluations of the identification of safety-related SSCs, including IROFS can be found in Chapter 13 of this SER. A discussion of the development of TSs from IROFS can be found in Chapter 14, "Technical Specifications," of this SER.

Based on its review, the staff finds that the level of detail provided on systems and components demonstrates an adequate design basis and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.5 and NUREG-1520 (for review of Baseline Design Criteria). This allows the staff to find that: (1) the design criteria included consideration of the conditions required of the SSCs to ensure safe facility operation, including response to transient and potential accident conditions analyzed in the PSAR and (2) the design of the SSCs addressed the baseline design criteria of 10 CFR 70.64.

Therefore, the staff concludes that the NWMI production facility design features for systems and components are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR Part 50. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR submitted as part of the OL application.

3.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility's SSC design criteria, as described in Chapter 3.0 of the NWMI PSAR and finds that the preliminary design criteria of NWMI's SSCs, including the principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provide reasonable assurance that the final design will conform to the design basis, and (2) meet applicable regulatory requirements and acceptance criteria in NUREG-1537 and the ISG Augmenting NUREG-1537.

Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the production facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that, taking into consideration the site criteria contained in 10 CFR Part 100, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(4) NWMI is technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

4 RADIOISOTOPE PRODUCTION FACILITY DESCRIPTION

The facility description addresses the principal features, operating characteristics, and parameters of the proposed Northwest Medical Isotopes, LLC (NWMI or the applicant) production facility. The primary functions of the facility are to disassemble and dissolve targets; recover and purify molybdenum-99 (Mo-99); and package Mo-99.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility as presented in Chapter 4.0, "Radioisotope Production Facility Description," of the NWMI preliminary safety analysis report (PSAR), Revision 3. As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility," or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

4.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 4.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of the NWMI facility systems for the purposes of issuance of a construction permit under 10 CFR Part 50. As part of this review, the staff evaluated descriptions and discussions of the NWMI facility, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI facility was evaluated to ensure the principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions, are sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items, which are determined to be probable subjects of technical specifications (TSs) for the facility, with special attention given to those items which may significantly influence the final design. The staff documented its review of NWMI's probable subjects of TSs for the facility in Chapter 14, "Technical Specifications," of this SER.

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

4.2 Summary of Application

NWMI PSAR Chapter 4.0 contains a summary description of the production facility where NWMI plans to disassemble and dissolve irradiated low enriched uranium (LEU) targets, recover and purify Mo-99, and package Mo-99. Chapter 4.0 describes the design of the facility and the processes employed within it, and includes the principal safety considerations that were factored into the facility design, construction, and expected operation. It also describes the facility's biological shield, the radioisotope extraction system, and SNM processing and storage. The NWMI production facility includes the irradiated target receipt bay, hot cells, waste management facilities, a laboratory, and utilities.

4.3 Regulatory Basis and Acceptance Criteria

The staff reviewed the NWMI PSAR Chapter 4.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility for the issuance of a construction permit under 10 CFR Part 50. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described and identified by NWMI, and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI facility. However, the staff evaluated NWMI's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 9). The staff's review in this chapter of the SER evaluated the facility and process description, the facility biological shield,

the radioisotope extraction system, and processing and storage to issuance of the construction permit for the production facility will not be inimical to public health and safety.

4.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility are as follows:

- 10 CFR 50.23, "Construction permits."
- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.35, "Issuance of construction permits."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.45, "Standards for construction permits, operating licenses, and combined licenses."
- 10 CFR Part 20, "Standards for Protection against Radiation."

4.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- 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 (Reference 9).
- "Final Interim Staff Guidance [ISG] 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 (Reference 10).
- "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 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility," as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence 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 a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements," when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a radioisotope production facility license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, and American National Standards Institute/American Nuclear Society (ANSI/ANS) standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

4.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 4.0 to assess the sufficiency of the preliminary design and performance of NWMI's production facility for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance of NWMI's production facility is demonstrated by following applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 4.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of this technical evaluation is described in SER Section 4.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of NWMI's production facility does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of NWMI's production facility, as described in the FSAR, submitted as part of NWMI's operating license (OL) application.

4.4.1 Facility and Process Description

The staff evaluated the sufficiency of NWMI's facility and process description of its facility, as described in NWMI PSAR Section 4.1, "Facility and Process Description," for the issuance of a construction permit 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 NWMI PSAR Section 4.1 is descriptive in nature and requires no technical analysis. The information in this section provides background for the descriptions of the facility provided in later sections and chapters of the application. The staff reviewed the information in this section to ensure a general understanding of the facility and consistency with other sections of the application.

NWMI PSAR Section 4.1 contains a summary description of the facility. Consistent with Section 4b.1 of the ISG Augmenting NUREG-1537, Part 2, this section includes the principal safety considerations that were factored into the facility design, construction, and operation. The design bases and functions of the systems and components are presented in sufficient detail to allow a clear understanding 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 staff and the public. Drawings and diagrams are provided to allow a clear and general understanding of the physical facility features and of the processes involved. The primary function of the facility is to extract, purify, package, and ship medical radioisotopes. The primary fission product barrier in the facility consists of vessels and associated piping, which contain the irradiated SNM and fission products (in solid, liquid, or gaseous form) during the separation process.

NWMI PSAR Section 4.1, provides a summary of the maximum amount of SNM and the physical and chemical forms of SNM used in the process.

NWMI PSAR Section 4.1 contains a summary description of the raw materials, byproducts, wastes, and finished products of the facility. 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.

NWMI PSAR Section 4.1 contains a general description of the design basis and implementation of any criticality safety features of the facility for establishing and maintaining a nuclear criticality safety program. The staff evaluation of the criticality safety program is discussed in Section 6.4.5, "Nuclear Criticality Safety," of this SER.

NWMI PSAR Section 4.1 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 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, "Accident Analysis," of this SER.

NWMI PSAR Section 4.1 contains a description of the design basis and implementation of any hazardous chemical safety features of the facility for establishing and maintaining a hazardous chemical safety program. The staff evaluation of the chemical safety program is discussed in Section 13.4.9, "Analyses of Accidents with Chemical Hazards," of this SER.

Based on its review of NWMI PSAR Section 4.1, the staff finds that the level of detail is sufficient to provide a general understanding of the production facility and the isotope production process.

Therefore, the staff concludes that the summary description of the NWMI production facility and processes, as described in NWMI PSAR Section 4.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

4.4.2 Radioisotope Production Facility Biological Shield

The staff evaluated the sufficiency of NWMI's facility biological shield, as described in NWMI PSAR Section 4.2, "Radioisotope Production Facility Biological Shield," for the issuance of a construction permit using the guidance and acceptance criteria from Section 4b.2, "Processing Facility Biological Shield,'' of the ISG Augmenting NUREG-1537, Parts 1 and 2, which refers to Section 4.4, "Biological Shield," of NUREG-1537, Parts 1 and 2.

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

NWMI PSAR Section 4.2 states that the facility biological shield will provide an integrated system of features that protect workers from the high-dose radiation generated during the radioisotope processing to recover Mo-99. The primary function of the biological shield will be to reduce the radiation dose rates and accumulated doses in occupied areas to not exceed the limits of 10 CFR Part 20 and the guidelines of the facility ALARA (as low as is reasonably achievable) program. The shielding and its components will withstand seismic and other concurrent loads, while maintaining containment and shielding during a design basis event.

NWMI PSAR Section 4.2.2, "Shielding Design," describes the shield design, which includes a description of the shielding materials of construction, nuclear properties of shielding materials, the structural integrity of shielding design, and construction of the facility biological shield. The shield design also describes the functional design of the biological shield, showing entry and exit facilities for products, wastes, process equipment, and operating staff.

NWMI PSAR Section 4.2.2.3, "Design of Penetrations," states that the penetrations provided for ventilation, piping, shield plugs, personnel entryways, and viewports in biological shield structures will reduce the shielding effectiveness. The magnitude of the reduced effectiveness will depend on geometry, material composition, and source characteristics. NWMI PSAR Section 4.2.2.3 also states that each penetration in a shield will be evaluated in the final design for its impact on the effectiveness of the shield in which it is located. Penetrations are designed with offsets and steps to prevent direct streaming of radiation through the penetration.

NWMI PSAR Section 4.2.5, "Ventilation System for the Biological Shield Structure," states that the ventilation around the biological shield structure will be Zone II/III supply and the Zone I exhaust. The biological shielding will be subjected to ambient temperature conditions. The Zone I exhaust will provide ventilation of the hot cell and confinement of the hot cell atmosphere, and maintain the hot cell at negative pressure. The supply air will maintain the temperature for personnel comfort. The process off-gas treatment system will provide confinement of the chemical vapors from the process equipment within the hot cell and treat the radioactive

off-gases through retention, adsorption, and filtration. NWMI PSAR Section 9.1.2, "System Description," states that supply air will be conditioned.

Based on its review of NWMI PSAR Section 4.2, the staff finds that the level of detail provided on the biological shield demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 4.4 allowing the staff to make the following findings: (1) there is reasonable assurance that the shield designs will limit exposures from the facility sources of radiation so as not to exceed the limits of 10 CFR Part 20 and the guidelines of the facility ALARA program; (2) there is reasonable assurance that the shield can be successfully installed with no radiation streaming or other leakage that would exceed the limits of 10 CFR Part 20 and the guidelines of the facility ALARA program; and (3) facility components are sufficiently shielded to avoid significant radiation-related degradation or malfunction.

Therefore, the staff concludes that the preliminary design of the NWMI facility biological shield, as described in NWMI PSAR Section 4.2, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis (e.g., evaluation of penetrations in the shield) can reasonably be left for later consideration in the FSAR since the biological shield's design bases reduce radiation dose rates and accumulated doses to within regulatory requirements following ALARA guidelines.

4.4.3 Radioisotope Extraction System

The staff evaluated the sufficiency of NWMI's facility radioisotope extraction system, as described in NWMI PSAR Section 4.3, "Radioisotope Extraction System," for the issuance of a construction permit 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 staff considered whether the information provided a clear understanding of the processes and verified that the information presented in this section is consistent with the information in other sections and chapters of the PSAR (e.g., accident analyses presented in Chapter 13.0, engineered safety features presented in Chapter 6.0, and probable subjects of technical specifications presented in Chapter 14.0).

NWMI PSAR Section 4.3 describes the radioisotope extraction process from the time irradiated targets enter the facility through the Mo-99 product shipment. The radioisotope extraction process includes the following major systems: (a) irradiated target receipt and disassembly (irradiated target receipt subsystem), (b) irradiated target receipt and disassembly (target disassembly subsystem), (c) target dissolution, and (d) molybdenum recovery and purification.

The staff notes that NWMI PSAR Section 4.3 provides a complete description, including diagrams and drawings, in sufficient detail to give a clear understanding of the extraction and purification process and how the process can be performed within regulatory limits.

Based on its review, the staff finds that the level of detail provided on the NWMI production facility's radioisotope extraction process, as described in NWMI PSAR Section 4.3, demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 4b.3, allowing the staff to make the following findings: (1) NWMI PSAR Section 4.3 provides a detailed account of

the SNM in process in the NWMI production facility, along with any included fission-product radioactivity, and gives a clear understanding that these operations can be conducted safely in this facility; (2) the processing of irradiated targets is described in sufficient detail to provide confidence that the SNM and byproduct material can be controlled throughout the production facility processes so that the health and safety of the public and workers will be protected; (3) the criticality control measures provided throughout the radioisotope extraction process are consistent with the double-contingency principle[1] and provide suitable defense-in-depth for the production facility processes; and (4) engineered safety features have been developed to provide safe margins for all safety-related process variables.

Therefore, the staff concludes that the preliminary design of the NWMI facility radioisotope extraction system, as described in NWMI PSAR Section 4.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis (e.g., additional criticality control analysis) can reasonably be left for later consideration in the FSAR since the design bases provide for the control of all radioisotope extraction processes and protection of workers and the public. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

4.4.4 Special Nuclear Material Processing and Storage

NWMI PSAR Section 4.4, "Special Nuclear Material Processing and Storage," describes the processing components and procedures involved in handling, processing, and storing SNM beyond the radioisotope extraction process. NWMI PSAR Section 4.4.1, "Processing of Irradiated Special Nuclear Material," describes the processing of irradiated LEU, which comprises the uranium recovery and recycle system. The product of the uranium recovery and recycle system will be recycled LEU with doses low enough to be directly handled without shielding. NWMI PSAR Section 4.4.2, "Processing of Unirradiated Special Nuclear Material," describes the processing of the fresh and recycled LEU, which comprises the target fabrication system. As noted above in Section 4.0, the staff only reviewed the NWMI target fabrication area to understand the interface between and impact on the NWMI production facility from the target fabrication area. The staff's findings and conclusions in the SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

4.4.4.1 *Processing of Irradiated Special Nuclear Material*

The staff evaluated the sufficiency of the NWMI facility irradiated SNM processing and storage, as described in NWMI PSAR Section 4.4.1, for the issuance of a construction permit 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 staff considered whether the information provided a clear understanding of the processes and verified that the information presented in this section is consistent with the

[1] The double-contingency principle is defined in 10 CFR 70.4, "Definitions," to mean "that process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible." ANSI/ANS-8.1-1983, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors" (Reference 30), further provides that "[p]roper application of the double contingency principle provides assurance that no single error or loss of a control will lead to the possibility of a criticality accident."

information in other sections and chapters of the PSAR (e.g., accident analyses presented in Chapter 13.0, engineered safety features presented in Chapter 6.0, and probable subjects of technical specifications presented in Chapter 14.0).

NWMI PSAR Section 4.4.1 provides a clear description of the process systems and components to allow a good understanding that the facility can be operated within regulatory limits. The processing components are compatible with the process material 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.

The uranium recovery and recycle system description in NWMI PSAR Section 4.4 provides information regarding the SNM processing time cycle, process, process equipment, SNM and radioactive inventories, and the hazardous chemicals used in the system of the NWMI production facility. NWMI PSAR Figure 4-72, "Uranium Recovery and Recycle Process Functions," provides an overview of the uranium recovery and recycle process. Uranium-bearing raffinate from the Mo-99 recovery and purification system is processed by the uranium recovery and recycle system.

The SNM processing time cycle identifies the functions for lag storage for feed storage and product solutions described in NWMI PSAR Section 4.3.1, "Extraction Time Cycle." The process description (NWMI PSAR Section 4.4.1.1, "Process Description") provides a detailed account of the SNM in process during normal operations and provides the basis for equipment design.

The arrangement and design of the processing equipment, including normal operating conditions, are described in NWMI PSAR Section 4.4.1.2, "Process Equipment Arrangement," and NWMI PSAR Section 4.4.1.3, "Process Equipment Design." These sections describe the equipment in sufficient detail to provide reasonable assurance that the SNM and byproduct material can be controlled throughout the process in the NWMI production facility.

The description of SNM in terms of physical and chemical form, volume in process, required criticality control features, and radioactive inventory in process is provided in NWMI PSAR Section 4.4.1.4, "Special Nuclear Material Description," and NWMI PSAR Section 4.4.1.5, "Radiological Hazards." The hazardous chemicals that are used or may evolve during the process, along with the provisions to protect workers and the public from exposure, are described in NWMI PSAR Section 4.4.1.6, "Chemical Hazards." NWMI PSAR Table 4-46, "Molybdenum Recovery and Purification System In-Process Special Nuclear Material Inventory,"[2] specifies the stream, chemical form, concentration, and SNM mass.

A discussion of criticality control features is also contained in NWMI PSAR Section 4.4.1.4, including passive design and active engineered features supporting the adherence to the double-contingency principle. This section applies the criticality control features that are discussed in NWMI PSAR Chapter 6.0, "Engineered Safety Features," Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility." NWMI states that the criticality control features for this subsystem will include passive design and active engineered features.

Additionally, NWMI states that the passive design features will include geometric constraints of the floor, process equipment, workstations, and ventilation system. The active engineered

[2] This table contains security-related information and has been withheld from public disclosure in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding."

features will include a requirement for continuous ventilation. The staff will review these passive and engineered design features in greater detail in NWMI's OL application.

NWMI PSAR Section 4.4.1.6 provides a summary of the maximum amounts of chemicals used in the process and the associated chemical hazards. This section also identifies any required chemical protection provisions that are designed into the process systems and components. The chemical reagents for uranium recovery and recycle are listed in NWMI PSAR Table 4-54, "Uranium Recovery and Recycle Chemical Inventory." In addition to the chemical reagents, off-gases will include nitric oxide, nitrogen dioxide, and nitric acid fumes.

NWMI states that it will have chemical inventory controls, including separation of chemicals based on the potential for exothermic reactions. These controls, in addition to procedures controlling the processing of irradiated SNM, will include measures to prevent accidents. The staff will review these controls when they are made available in NWMI's OL application.

Based on its review, the staff finds that the level of detail provided on NWMI's processing of irradiated SNM in its production facility, as described in NWMI PSAR Section 4.4.1 and the included tables and figures, demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 4b.4.1 allowing the staff to make the following findings for the NWMI production facility: (1) the process descriptions in Section 4.4.1 of the PSAR provide a detailed account of the SNM in process in the NWMI production facility, along with fission-product radioactivity, and gives a clear understanding that these operations can be conducted safely in the facility; (2) the production facility processing facilities and apparatus have been described in sufficient detail to provide reasonable assurance that the SNM and byproduct material can be controlled throughout the process so that the health and safety of the public and workers will be protected; and (3) the criticality control measures provided are consistent with the double-contingency principal, and provide suitable defense-in-depth for the contained processes.

Therefore, the staff concludes that the preliminary description of the processing of irradiated SNM, as described in NWMI PSAR Section 4.4.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis (e.g., additional information on passive and engineered design features and chemical inventory controls) can reasonably be left for later consideration in the FSAR since the facility's design bases support the control of SNM and byproduct material throughout the production facility processes so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

4.4.4.2 *Processing of Unirradiated Special Nuclear Material*

Section 4.4.2 of the NWMI PSAR describes the target fabrication system and process. Targets are fabricated from fresh LEU metal and recycled uranyl nitrate. As described in Section 4.4.2 of the NWMI PSAR, "The system begins with the receipt of LEU from the DOE [U.S. Department of Energy] supplier, and ends with packaging new targets for shipment to the irradiation facilities." The fabrication of targets is similar to processes at fuel-cycle facilities that manufacture fuel, which are licensed under 10 CFR Part 70. Although the staff reviewed the entire application, including NWMI's descriptions related to the target fabrication process, the staff review was only to determine whether the NWMI production facility satisfied the requirements for the issuance of a 10 CFR Part 50 construction permit. Since the information

provided in Section 4.4.2 of the NWMI PSAR does not impact the construction of the NWMI production facility, the staff has made no findings or conclusions on this section of the NWMI PSAR.

4.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of NWMI's facility, as described in NWMI PSAR Chapter 4.0, and finds that the preliminary design of NWMI's facility, including the principal design criteria, design bases, and information relative to materials of construction and general arrangements, provides reasonable assurance that the final design will conform to the design basis and meets all applicable regulatory requirements and acceptance criteria in or referenced in the applicable guidance, including the ISG Augmenting NUREG-1537.

Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the production facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis and which can reasonable be left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that: (i) the construction of the NWMI production facility will not endanger the health and safety of the public, and (ii) construction activities can be conducted in compliance with the Commission's regulations.

(4) The issuance of a permit for the construction of the production facility would not be inimical to the common defense and security or to the health and safety of the public.

5 COOLANT SYSTEMS

The principal purpose of cooling systems in the NWMI production facility is to safely remove decay heat from the radioisotope extraction process vessels and dissipate it to the environment under normal and accident conditions. Cooling systems, including auxiliary and subsystems, should be shown to safely remove and transfer heat to the environment from all significant heat sources identified in the Northwest Medical Isotopes, LLC (NWMI or the applicant) preliminary safety analysis report (PSAR). The design of the cooling systems is based on interdependent parameters, including thermal power level at the target irradiation site, transport and handling times after the end of irradiation (EOI) prior to receipt at the NWMI facility, type and form of special nuclear material (SNM), neutronic physics, and radiation shielding.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility cooling systems as presented in Chapter 5.0, "Coolant Systems," of the NWMI PSAR, Revision 3, as supplemented by the applicant's responses to requests for additional information (RAIs). As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility," or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

5.1 Areas of Review

NWMI PSAR Chapter 5.0 describes the cooling systems used to control the temperature of process solutions in the NWMI production facility. Portions of the cooling systems (i.e., one of the secondary coolant loops and the portion of the process chilled water loop, which serves that secondary coolant loop), which are also discussed in NWMI PSAR Chapter 5.0, are located in the NWMI target fabrication area. Such equipment in the target fabrication area is outside the scope of the staff's review in this SER, which is limited to the NWMI production facility, and is discussed in this SER with regard to its relationship to the cooling systems in the NWMI production facility.

The staff reviewed NWMI PSAR Chapter 5.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design of the NWMI production facility's cooling systems. As part of this review, the staff evaluated descriptions and discussions of the NWMI production facility's cooling systems, with special attention to design and operating characteristics, unusual or novel design features, thermal characterization of process vessels, and principal safety considerations. The

preliminary design of the NWMI production facility's cooling systems was evaluated to ensure the sufficiency of principal design criteria, design bases, and information relative to maximum temperature and pressure to provide reasonable assurance that the final design will conform to the design bases. The staff also considered the preliminary analysis and evaluation of the design and performance of the SSCs of the NWMI production facility's cooling systems with the objective of assessing the risk to public health and safety resulting from operation of the facility. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items, which are determined to be probable subjects of technical specifications (TSs) for the facility, with special attention given to those items which may significantly influence the final design. The staff documented its review of NWMI's probable subjects of TSs for the facility in Chapter 14, "Technical Specifications," of this SER. NWMI did not identify any specific probable subjects of TSs for SSCs of the NWMI production facility's cooling systems.

Because the NWMI production facility cooling systems do not influence operation of any reactor primary core cooling system, the NWMI production facility cooling systems are, according to NUREG-1537, Part 1 "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," characterized as auxiliary cooling systems, rather than primary or secondary cooling systems. However, the PSAR refers to the NWMI production facility's and target fabrication area's large geometry and criticality-safe geometry cooling loops (which are, in turn, cooled by a process chilled water loop) as secondary coolant loops, and therefore this terminology is also used in this chapter of the SER to describe these cooling loops.

Areas of review for this chapter included the irradiated target design basis (i.e., the amount of heat produced by the irradiated targets), vessels considered for thermal characterization, heat load and thermal flux, maximum vessel temperature and pressure estimates, potential impact of overcooling process solutions, and potential impact on the gas management system. Within these review areas, the staff assessed the following capabilities of the NWMI production facility's cooling systems:

- The capability of the secondary coolant loops to remove decay heat during normal operation and possible accident conditions, and transfer such heat to the process chilled water system.

- The capability of the process chilled water system to provide controlled heat dissipation to the environment.

- The capability of the NWMI production facility's cooling systems to limit maximum temperature and pressure within the facility's vessels to prevent failure of process apparatus.

- The capability of the NWMI production facility's vessel configurations to prevent inadvertent criticality due to overcooling of process solutions.

- The capability of a failure of the NWMI production facility's cooling systems to impact the dose consequences of an inadvertent release of noble gases.

5.2 Summary of Application

As described in NWMI PSAR Chapter 5.0, chilled water is used as the cooling fluid to control the temperature of process solutions in the NWMI production facility. The summary provided below describes the cooling systems that are used at the NWMI production facility, which are categorized as auxiliary cooling systems according to NUREG-1537, Part 1 and the "Final Interim Staff Guidance [ISG] 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."

In NWMI PSAR Section 5.1, "Summary Description," NWMI states that chilled water is used as the cooling fluid to the NWMI production facility process vessels. A central process chilled-water loop is used to cool (1) one large geometry secondary loop in the hot cell, (2) one criticality-safe geometry secondary loop in the hot cell, and (3) one criticality-safe geometry secondary loop in the target fabrication area. The central process chilled-water loop relies on air-cooled chillers to maintain chilled water to various process equipment at no greater than 50 degrees Fahrenheit (10 degrees Celsius) during normal operation. The central process chilled-water loop cools the three secondary loops through plate-and-frame heat exchangers. Several NWMI production facility process demands require cooling at less than the freezing point of water. These demands are met with water-cooled refrigerant chiller units, cooled by the secondary chilled water loops.

5.2.1 Irradiated Target Design Basis

NWMI's irradiated target basis refers to the thermal load generated by irradiated targets. In NWMI PSAR Section 5.1.1, "Irradiated Target Basis," NWMI considers this thermal load in its evaluation of the cooling needed for NWMI production facility process vessels. NWMI PSAR Section 5.1.1 states that thermal characteristics of irradiated targets entering the NWMI production facility are based on preliminary calculations for targets irradiated at the Oregon State University TRIGA Reactor (OSTR). The OSTR preliminary calculations were extrapolated to estimate the heat load of a target irradiated at the University of Missouri – Columbia Research Reactor (MURR). The OSTR calculations resulted in an average power per OSTR target of approximately four times lower than the average power per MURR target. The MURR operation is based on irradiating 8 targets per week while the OSTR operation is based on irradiating 30 targets per week. Based on the combination of the number of targets, the reactor source, and the decay time for receipt of targets, the weekly heat load from radionuclide decay is estimated to be three times higher from MURR targets at 8 hours after EOI than compared to OSTR targets at 48 hours after EOI. Therefore, the MURR targets are used as the upper bound for evaluating the cooling requirements in the NWMI facility. These preliminary calculations are supported by the following NWMI PSAR figures:

- Figure 5-1, "Individual Irradiated Target Heat Generation"
- Figure 5-2, "Weekly Irradiated Target Receipt Heat Generation"

5.2.2 Vessels Considered for Thermal Characterization

NWMI PSAR Section 5.1.2, "Vessels Considered for Thermal Characterization," states that thermal characteristics of selected NWMI production facility process vessels are based on an evaluation in NWMI-2015-CALC-022, "Maximum Vessel Heat Load, Temperature, and Pressure Estimates." The evaluation did not include every process vessel; however, the selected vessels were considered sufficient to span the range of potential heat generation rates anticipated to be

contained in process vessels. The evaluation included vessels that contain water-cooling jackets, vessels not projected to require cooling, and vessels used for transfer of solid material in air that are not influenced by the cooling water system, but are included in the evaluation to provide a more complete description of the vessel thermal characteristics and to indicate that some vessels will exist with relatively high surface temperatures during NWMI facility operation. The vessels selected for evaluation are shown in NWMI PSAR Table 5-1, "Vessels Selected to Describe Radioisotope Production Facility Thermal Characteristics."

5.2.3 Heat Load and Thermal Flux

NWMI PSAR Section 5.1.3, "Heat Load and Thermal Flux," states that the volumetric heat load contained by NWMI production facility process vessels varies throughout the system as radioisotopes decay, selected radioisotopes are separated, and solution compositions are adjusted by NWMI production facility operations. Thermal flux at the containment apparatus walls for process vessels is conservatively estimated by assuming only radial heat transfer, no radial temperature gradient, and neglecting heat loss from solution evaporation. The estimated volumetric heat load and radial thermal flux at the containment apparatus wall for several process vessels selected for evaluation indicate the range of conditions experienced as process solution is transferred through the NWMI production facility process equipment. These are shown in the following NWMI PSAR tables:

- Table 5-2, "Heat Load and Thermal Flux for Selected Water-Cooled Vessels"
- Table 5-3, "Heat Load and Thermal Flux for Selected Vessels without Water Cooling"

5.2.4 Maximum Vessel Temperature and Pressure Estimates

PSAR Section 5.1.4 states that an estimate of maximum vessel temperature and pressure is based on an overall heat transfer coefficient for a tank on legs containing water with an ambient air temperature of 35 °C (95 °F). Vessel temperatures are estimated assuming no water-cooling system is active. Vessel pressures are estimated assuming each vessel is unvented and based on the vapor pressure of water at the estimated vessel temperature. The estimated maximum vessel temperature and pressure are shown in the following PSAR tables:

- Table 5-4, "Estimate of Maximum Temperature and Pressure in Water-Cooled Vessels"
- Table 5-5, "Estimate of Maximum Temperature and Pressure in Vessels without Water Cooling"

The maximum temperature and pressure that could be observed in process vessels without cooling system operation is listed in PSAR Table 5-4 for the molybdenum system feed tanks.

5.2.5 Potential Impact of Overcooling Process Solutions

NWMI PSAR Section 5.1.5, "Potential Impact of Overcooling Process Solutions," states that overcooling of uranium-bearing process solutions has the potential to precipitate uranyl nitrate hexahydrate as a solid which effectively increases the uranium concentration contained by a process vessel and creates the potential for a nuclear criticality. Criticality evaluations are described in the following three documents:

- NWMI-2015-CALC-002, "Irradiated Target Low-Enriched Uranium Material Dissolution"
- NWMI-2015-CALC-005, "Target Fabrication Tanks, Wet Processes, and Storage"
- NWMI-2015-CALC-006, "Tank Hot Cell"

The results indicate that precipitation of uranyl nitrate hexahydrate as a solid, results in conditions that remain below an upper subcritical limit of 0.94 for the configurations evaluated.

5.2.6 Potential Impact on Gas Management System

NWMI PSAR Section 5.1.6, "Potential Impact on Gas Management System," states that the primary gas management system cooled section controls the decay time provided for noble gases (isotopes of krypton and xenon) by holdup in the dissolver offgas system.

5.3 Regulatory Basis and Acceptance Criteria

As previously stated and described in NWMI PSAR Chapter 5.0, chilled water is used as the cooling fluid to control the temperature of process solutions in the NWMI production facility. The NWMI production facility is at a separate site, independent from the reactors used to irradiate the targets. Therefore, the regulatory basis and acceptance criteria provided below apply to the NWMI production facility.

The staff reviewed NWMI PSAR Chapter 5.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility's cooling systems for the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of its facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described and identified by NWMI, and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the

guidance in NUREG-1537, Parts 1 and 2 (References 8 and 9), and the ISG Augmenting NUREG-1537, Parts 1 and 2 (References 10 and 11).

5.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility's cooling systems are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.40, "Common standards."
- 10 CFR Part 20, "Standards for Protection against Radiation."

5.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- 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 (Reference 9).
- "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 (Reference 10).
- "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 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility," as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of items relied on for safety (IROFS), and establishment of management measures are acceptable ways

of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements," when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a radioisotope production facility license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

5.4 Review Procedures, Technical Evaluation, and Evaluation Findings

As described in NWMI PSAR Section 5.1, cooling water systems are used to control the temperature of process solutions in the NWMI production facility from process activities and the heat load resulting from radioactive decay of the fission product inventory. An air-cooled central process chilled water loop cools three secondary loops in the hot cell and target fabrication areas through plate-and-frame heat exchangers. Water-cooled refrigerant chiller packages are used to cool selected NWMI production facility processes to less than the freezing point of water. As stated in Section 5.1, "Areas of Review," of this SER, the NWMI production facility cooling systems are not primary or secondary cooling systems, and the technical evaluation of the cooling systems focuses on the thermal characteristics of irradiated targets and process vessels and whether an adequate analysis has been provided to justify auxiliary cooling during the course of any part of the production process.

The staff evaluated the technical information presented in NWMI PSAR Chapter 5.0, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of the NWMI production facility's cooling systems for the issuance of a construction permit, in accordance with 10 CFR Part 50. Additionally, the staff reviewed portions of the PSAR that describe vessels with and without water-cooling jackets and solid transfer containers without cooling jackets that may require cooling from chilled water. The staff also reviewed portions of the PSAR that describe the chilled water system. Sufficiency of the preliminary design and performance of the NWMI production facility's cooling systems is determined by ensuring that the design and performance meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 5.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the staff's technical evaluation is described in SER Section 5.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility's cooling systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility's cooling systems based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate

margin for safety. As such, the staff's evaluation of the preliminary design of the NWMI production facility's cooling systems does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the NWMI production facility's cooling systems as described in the FSAR submitted as part of NWMI's operating license (OL) application.

5.4.1 Summary Description

The staff evaluated the sufficiency of NWMI's summary description of its production facility's cooling systems, as described in NWMI PSAR Section 5.1, for the issuance of a construction permit using the guidance and acceptance criteria from Section 5.1, "Summary Description," of NUREG-1537, Parts 1 and 2, and Section 5b, "Radioisotope Production Facility Cooling Systems," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

As stated, in part, in Section 5.1 of NUREG-1537, Part 2, the summary description of reactor cooling systems should include the type of primary coolant, type of primary coolant system, type of coolant flow in the primary and secondary cooling systems and the method of heat disposal to the environment, capability to provide sufficient heat removal for continuous operation at full licensed reactor power, and any special or facility-unique features. As stated, in part, in Section 5b of the ISG Augmenting NUREG-1537, Part 2, the applicant should provide a complete description of the design and operation of any required auxiliary cooling system.

NWMI PSAR Section 5.1 provides descriptions of the cooling water systems used to control the temperature of process solutions in the NWMI facility. As stated in NWMI PSAR Section 5.1, "… the RPF cooling system does not influence operation of a reactor primary core cooling system."

Based on its review, the staff finds that because the NWMI facility cooling system is independent of any reactor cooling system, Section 5.1 of NUREG-1537, Part 2, does not apply to the NWMI production facility. The staff also finds that NWMI described the design and operation of the process vessel cooling systems in its facility, including the capability of these systems to provide sufficient heat removal for the process vessels, consistent with Section 5b of the ISG Augmenting NUREG-1537, Part 2. Therefore, based on the information provided in NWMI PSAR Section 5.1, the staff concludes that the summary description of the NWMI production facility's cooling systems contains enough information for an overall understanding of the functions and relationships of the cooling systems to the preliminary design of the NWMI production facility, and satisfies the applicable acceptance criteria of NUREG-1537 and the ISG Augmenting NUREG-1537 for the issuance of a construction permit in accordance with 10 CFR Part 50.

5.4.2 Irradiated Target Design Basis

The staff evaluated the sufficiency of the analysis supporting the preliminary design of the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.1 by reviewing the irradiated target processing capacity of the NWMI production facility, the operating power of the targets during irradiation in the off-site reactors, and the decay time allowed after the EOI in the off-site reactor before the separation process progresses using the guidance and acceptance criteria from Section 5b of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 5b, the staff compared the thermal characteristics of irradiated targets entering the NWMI production facility with the cooling system design basis, as presented in NWMI PSAR Chapter 5.0.

The ISG Augmenting NUREG-1537, Part 1, Section 5b states, in part, that "License applications for radioisotope production facilities should present an analysis of the thermal characteristics of the anticipated process that considers … [t]he operating power of the SNM during irradiation in the reactor [and] [t]he decay time allowed after the [EOI] in the reactor before the separation process progresses." As described in NWMI PSAR Section 5.1.1, the thermal characteristics of irradiated targets entering the NWMI production facility depend on the source reactor and decay time prior to receipt.

The applicant states that the heat load is based on preliminary calculations for targets irradiated at OSTR based on the OSTR operating power of 980 kilowatts thermal irradiating a target for a specified time period. The preliminary calculations resulted in an average power per target based on actinide and fission products produced during irradiation of a fresh uranium target containing a limited set of assumed impurities. The applicant extrapolated these preliminary calculations to estimate the heat load of a target irradiated at MURR. Assuming a similar irradiation time period, the extrapolation produces an average MURR target power of approximately four times higher per target.

The applicant states that due to the location of the NWMI production facility relative to the MURR and OSTR sites, the minimum decay time for receipt of targets after the EOI is estimated to be 8 hours for a MURR target and 48 hours for an OSTR target. Further, the applicant states that the combination of reactor source and minimum decay time produces estimated target heat loads of less than 200 watts (W) for a MURR irradiated target and less than 20 W for an OSTR irradiated target. In RAI 5.1-1 (Reference 13), the staff asked the applicant to provide additional detail on the 8-hour decay time allowed after the EOI of MURR targets including how the handling and transportation times have been determined and to demonstrate why the 8-hour decay time is conservative for evaluating the need for chilled water cooling.

In response to RAI 5.1-1 (Reference 31) and in PSAR Section 5.1.1, the applicant states that several material-handling steps must occur after the EOI within the reactor before a cask containing irradiated targets can be transported to the NWMI production facility. Examples include transfer of targets into the cask, removal of the loaded cask from the reactor pool, assembly of the cask lid, removal of water from the cask, drying the cask, performing the cask leak-check procedure, and cask decontamination and verification. The applicant states that at-reactor handling procedures are projected to require significantly longer than 8 hours for an individual cask. In addition, the applicant states that independent of the actual cask handling time required, the clock time for EOI of a target batch becomes a data point recorded on transfer papers, and a cask will not be unloaded until the minimum decay time after EOI used in safety evaluations has elapsed.

The applicant states that the number of irradiated targets received by the NWMI production facility in a single week varies with the source reactor. The MURR operation is based on irradiating 8 targets per week, while the OSTR operation is based on irradiating 30 targets per week. The combination of source reactor and number of targets per week results in an approximately equal total weekly heat load from radionuclide decay from either reactor as a function of decay time. However, the shorter decay time for MURR targets (8 hours) versus OSTR targets (48 hours) results in a higher weekly total heat load for MURR targets than OSTR targets. The applicant, therefore, concludes that the MURR operation would be used as a design basis upper bound for irradiated target receipt at the NWMI production facility. NWMI

PSAR Section 4.1.2.1, “Process Design Basis,” states that, “The RPF is designed to have a nominal operational processing capability of one batch per week of up to 12 targets from University of Missouri Research Reactor (MURR)….” The nominal operational processing capability of 12 targets per week from MURR, as stated in NWMI PSAR Section 4.1.2.1, is greater than the 8 targets per week from MURR as stated in NWMI PSAR Section 5.1.1 for evaluating the need for auxiliary cooling and, therefore, in RAI 5.1-2 (Reference 13), the staff asked the applicant about this inconsistency.

In response to RAI 5.1-2 (Reference 31) and in PSAR Section 5.1.1, the applicant states that the target load per week described in PSAR Section 5.1.1 will be changed to 12 MURR targets per week in the FSAR included in its OL application. The applicant further states that the modification will include an update of NWMI-2015-CALC-022 with a more detailed analysis and revision of PSAR Section 5.1.1, Figure 5-2. The applicant states that the inconsistency identified is not expected to affect the thermal analysis in subsequent sections of NWMI PSAR Chapter 5.0 because the thermal load is characterized by radial heat transfer in a vessel and the uranium concentration of solutions held within vessels throughout the NWMI production facility. Additionally, the applicant states that increasing the number of targets processed during a given week increases the total liquid volume contained in geometrically favorable vessels (or liquid level height), but does not change the uranium concentration or radial thermal flux. The staff is tracking this issue in Appendix A, “Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments,” of this SER.

The staff finds that with the information in the NWMI PSAR and its response to RAIs 5.1-1 and 5.1-2, discussed above, the applicant addressed the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 5b, by presenting an adequate analysis of the thermal characteristics of its anticipated process, and demonstrates an adequate design basis for a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI’s FSAR.

Although the preliminary calculations did not consider recycled uranium, a broader set of impurities, potential activation products, and MURR-specific radionuclide and thermal characteristics, based on its review, the staff finds that the description of the irradiated target basis contains a sufficient level of detail for an overall understanding of the functions and relationships of the NWMI production facility cooling system to the preliminary design of the NWMI production facility and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 5b, allowing the staff to make the following findings: (1) the irradiated target basis is adequate to determine the need for auxiliary cooling, (2) the preliminary calculations of irradiated target heat load based on OSTR operation and extrapolated to MURR operation are reasonable and sufficient, (3) the decay time design basis for MURR and OSTR irradiated targets is sufficient, and (4) the number of irradiated targets received by the NWMI production facility in a single week is sufficient for use in determining the need for auxiliary cooling.

Therefore, the staff concludes that the preliminary irradiated target basis for the NWMI production facility’s chilled water system, as described in NWMI PSAR Section 5.1.1 and supplemented by the applicant’s responses to RAIs, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided in the FSAR. The staff will confirm that all aspects of the final design conform to the design basis during the evaluation of NWMI’s FSAR.

5.4.3 Vessels Considered for Thermal Characterization

The staff evaluated the sufficiency of the analysis supporting the preliminary design of the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.2 by reviewing the design basis for vessel thermal characterization and the types of vessels selected for evaluation using the guidance and acceptance criteria from Section 5b of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 5b, the staff compared the thermal characteristics of process vessels within the NWMI production facility with the cooling system design basis, as presented in NWMI PSAR Chapter 5.0.

The ISG Augmenting NUREG-1537, Part 1, Section 5b states, in part, that "License applications for radioisotope production facilities should present an analysis of the thermal characteristics of the anticipated process that considers … [t]he volumetric heat load and the resultant thermal flux at heat transfer surfaces of the process containment apparatus throughout the process." As described in NWMI PSAR Section 5.1.2, a number of vessels were selected to describe the thermal characteristics; however, not every vessel was selected. The applicant states that the selected vessels were considered sufficient to span the range of potential heat generation rates anticipated to be contained in the process vessels.

The applicant selected three groups of vessels for thermal characterization including vessels that include water-cooling jackets, vessels not projected to require cooling, and vessels used for transfer or storage of solid material in air not influenced by the cooling water system. Uncooled vessels were included in the evaluation to provide a complete description of the vessel thermal characteristics. The applicant also states that the detailed design of the dissolver basket has not been completed; however, the thermal characterization calculations included calculations for the dissolver basket at the beginning and end of the dissolver cycle based on preliminary information. These calculations indicate that the dissolver basket has the potential to achieve relatively high equilibrium temperatures, but NWMI stated that the dissolver basket is not currently anticipated to be a completely enclosed vessel with the potential to build pressure on heating. The staff finds that these preliminary calculations are sufficient because they provide approximate values of dissolver basket temperatures that could be reached. The staff finds that the applicant's selected vessels are sufficient because these vessels are representative of the major process of the production facility.

Based on its review, the staff finds that the description of NWMI's selection of vessels for thermal characterization contains a sufficient level of detail for an overall understanding of the functions and relationships of the NWMI production facility cooling system to the preliminary design of the NWMI production facility and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 5b, allowing the staff to find that the vessels selected adequately represent the range of temperatures and pressures anticipated throughout the NWMI production facility.

Therefore, the staff concludes that the preliminary vessel thermal characterization design basis for the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.2, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. The staff will review the vessel thermal characterization design basis again during its review of the OL application. The staff will confirm that all aspects of the final design conform to the design basis during the evaluation of NWMI's FSAR.

5.4.4 Heat Load and Thermal Flux

The staff evaluated the sufficiency of the analysis supporting the preliminary design of the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.3 by reviewing the design basis for the volumetric heat load contained by process vessels using the guidance and acceptance criteria from Section 5b of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 5b, the staff compared the heat load and thermal flux within the NWMI production facility process vessels with the cooling system design basis, as presented in NWMI PSAR Chapter 5.0.

The ISG Augmenting NUREG-1537, Part 1, Section 5b states, in part, that "License applications for radioisotope production facilities should present an analysis of the thermal characteristics of the anticipated process that considers … [t]he volumetric heat load and the resultant thermal flux at heat transfer surfaces of the process containment apparatus throughout the process." As described in NWMI PSAR Section 5.1.3, the volumetric heat load contained by process vessels varies throughout the system as radioisotopes decay, selected radioisotopes are separated, and solution compositions are adjusted by the unit operations. The applicant states that the heat flux at the vessel boundary is estimated based on a simple steady-state heat balance considering only radial heat flow while neglecting axial heat flow and heat losses associated with evaporation of the liquid phase.

NWMI did not calculate the radial thermal flux for the dissolver at the start of the dissolution cycle in the PSAR, because NWMI did not consider its simplified evaluation methodology to be applicable. The staff finds that this calculation is not necessary for the issuance of a construction permit because it will not significantly alter the construction of the facility.

The applicant states that the heat load of process solutions prior to separating uranium from other radionuclides is characterized by the solution uranium concentration where the uranium concentration is estimated based on planned operating conditions and goal compositions during operation. Heat load in subsequent processes is estimated on a per-unit, uranium mass basis to approximate the impact of radionuclide separations. The applicant also states that three radionuclide decay times are used to describe the NWMI production facility thermal characteristics including: (1) a decay time of 8 hours after EOI for process solutions in the dissolver, molybdenum system feed tanks, and solution transferred into the impure uranium collection tanks, (2) a decay time of 3 weeks after EOI for process solutions at the end of the impure uranium collection tank storage period, solution in ion exchange feed tank one, solution transferred into the uranium decay tanks, and waste entering the high-dose waste concentrate collection tank, and (3) a decay time of 16 weeks after EOI for process solutions at the end of the storage period in the uranium decay tanks. The applicant states that the heat load in the high-dose waste vessels is based on accumulating waste from 16 weeks of operation even though current plans are based on accumulating waste for only 4 weeks.

Based on its review, the staff finds that the NWMI heat load and thermal flux analysis contains a sufficient level of detail for an overall understanding of the functions and relationships of the NWMI production facility cooling system to the preliminary design of the NWMI production facility and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 5b, allowing the staff to make the following findings: (1) the design basis for calculating heat load and thermal flux is adequate to determine the need for auxiliary cooling, (2) the three radionuclide decay times used to describe the NWMI production facility thermal

characteristics are sufficiently conservative to determine the need for auxiliary cooling, and (3) the 16 weeks of accumulating waste in the high-dose waste vessel is sufficiently conservative relative to the planned 4-week accumulation time period to bound the expected waste vessel heat load.

Therefore, the staff concludes that the preliminary vessel heat load and thermal flux design basis for the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. The staff will review the vessel heat load and thermal flux design basis again during its review of the OL application. The staff will confirm that all aspects of the final design conform to the design basis during the evaluation of NWMI's FSAR.

5.4.5 Maximum Vessel Temperature and Pressure Estimates

The staff evaluated the sufficiency of the analysis supporting the preliminary design of the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.4 by reviewing the design basis for the process vessel temperature and pressure calculations using the guidance and acceptance criteria from Section 5b of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 5b, the staff compared the maximum temperature and pressure within the NWMI production facility process vessels with the cooling system design basis, as presented in NWMI PSAR Chapter 5.0.

The ISG Augmenting NUREG-1537, Part 1, Section 5b states, in part, that "License applications for radioisotope production facilities should present an analysis of the thermal characteristics of the anticipated process that considers … [c]alculations of the resultant maximum temperature of material in process with the objective of determining the need for auxiliary cooling to maintain the temperature and pressure within the processing components at safe levels to prevent the failure of the process apparatus or the containment system." As described in NWMI PSAR Section 5.1.4, vessel temperatures are estimated assuming no water-cooling system is active and pressures are estimated assuming each vessel is unvented.

The applicant states that the preliminary temperature estimates assume that radial temperature variations within the generating heat material are not significant and that this assumption is questionable for containers of heat-generating solids. The applicant also states that the vapor pressure of water at the estimated vessel temperature is used to approximate the maximum pressure within the process vessels and that this method is conservative since the total vapor pressure of a solution is decreased by the addition of nitric acid or uranyl nitrate to the liquid phase. Based on this design basis, the maximum temperature and pressure that could be observed in NWMI production facility process vessels without operation of the coolant systems is listed in NWMI PSAR Table 5-4 for the molybdenum system feed tank. However, the design basis was not considered applicable to the dissolver tank at the beginning of the dissolver cycle because of the non-uniform distribution of heat-generating material. The staff finds that the calculation of maximum temperature and pressure for the dissolver tank at the beginning of the dissolver cycle is not necessary for the issuance of a construction permit, because it will not significantly alter the construction of the facility.

Based on its review, the staff finds that the description of the NWMI production facility's heat load and thermal flux design basis contains a sufficient level of detail for an overall understanding of the functions and relationships of the NWMI production facility cooling system to the preliminary design of the NWMI production facility and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 5b, allowing the staff to make the following findings: (1) the design basis for calculating maximum vessel temperature and pressure is adequate to determine the need for auxiliary cooling and (2) maximum temperature and pressure within the processing components are maintained at safe levels without the need for cooling.

Therefore, the staff concludes that the preliminary maximum temperature and pressure design basis for the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.4, is sufficient to meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. The staff will review the maximum temperature and pressure design basis again during its review of the OL application. The staff will confirm that all aspects of the final design conform to the design basis during the evaluation of NWMI's FSAR.

5.4.6 Potential Impact of Overcooling Process Solutions

The staff evaluated the sufficiency of the analysis supporting the preliminary design of the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.5, "Potential Impact of Overcooling Process Solutions," by reviewing the design basis for evaluating the impact of uranium precipitation upset conditions using the guidance and acceptance criteria from Section 5b of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 5b, the staff compared the uranium precipitation calculations with the cooling system design basis, as presented in NWMI PSAR Chapter 5.0.

The acceptance criteria in the ISG Augmenting NUREG-1537, Part 2, Section 5b, states, in part, that "adequate precautionary measures are in place to prevent detrimental changes to the physical or chemical characteristics of the SNM solution. As an example, precautions against exceeding the solubility limits of the SNM in solution due to overcooling should be in place." As described in NWMI PSAR Section 5.1.5, overcooling of uranium-bearing process solutions has the potential to precipitate uranyl nitrate hexahydrate as a solid that effectively increases the uranium concentration potentially resulting in a nuclear criticality.

The applicant states that the impact of uranium precipitation upset conditions on nuclear criticality was evaluated by interspersing selected tanks containing a specified uranium concentration among the vessels containing uranium at a conservative nominal process concentration. The results of adding this additional uranium to the NWMI production facility process vessels to simulate uranyl nitrate hexahydrate precipitation indicates that the precipitation upset conditions remain below the upper subcritical limit and pose no nuclear criticality hazard for the current NWMI production facility equipment configuration.

Based on its review, the staff finds that the description of the potential impact of overcooling process solutions contains a sufficient level of detail for an overall understanding of the functions and relationships of the NWMI production facility cooling system to the preliminary design of the NWMI production facility and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 5b, allowing the staff to make the following findings: (1) the design basis for calculating the potential impact of overcooling process solutions is adequate to

determine the potential threat of an inadvertent nuclear criticality, and (2) overcooling of process solutions does not pose a nuclear criticality hazard for the current NWMI production facility equipment configuration that could impact the occupational safety and protection of the public and environment.

Therefore, the staff concludes that the overcooling design basis for the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.5, is sufficient to meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. The staff will review the overcooling design basis again during its review of the OL application. The staff will specifically confirm these criticality calculations and that all aspects of the final design conform to the design basis during the evaluation of NWMI's FSAR.

5.4.7 Potential Impact on Gas Management System

The staff evaluated the sufficiency of the analysis supporting the preliminary design of the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.6, "Potential Impact on Gas Management System," by reviewing the design basis for evaluating the potential impact of coolant systems on the gas management system using the guidance and acceptance criteria from Section 5b of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 5b, the staff compared the bounding release of noble gases from the dissolver offgas system with the cooling system design basis, as presented in NWMI PSAR Chapter 5.0.

The acceptance criteria in the ISG Augmenting NUREG-1537, Part 2, Section 5b, states, in part, that "The acceptance criteria specified in NUREG-1537, Part 2, Section 5a2.7, may be used as they would apply to any required radioisotope processing cooling system." The acceptance criteria in the ISG Augmenting NUREG-1537, Part 2, Section 5a2.7, states, in part, that "The system should not cause radiation exposures or release of radioactivity to the environment that exceed the requirements of 10 CFR Part 20 and the facility's [as low as is reasonably achievable] ALARA program guidelines." As described in NWMI PSAR Section 5.1.6, coolant system operation has the potential to impact the performance of the gas management system cooled sections since the cooled sections of the gas management system control the decay time provided for noble gases by holdup in the dissolver offgas system. However, NWMI stated that based on its dose analyses in NWMI PSAR Chapter 13.0, "Accident Analysis," the dose consequences of bounding noble gas releases would be small, and consequently NWMI does not consider the cooling water system to be an IROFS based on the potential impact to the gas management systems.

Based on its review, the staff finds that the description of the NWMI production facility's potential impact on the gas management system contains a sufficient level of detail for an overall understanding of the functions and relationships of the cooling system to the preliminary design of the NWMI production facility and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 5b, allowing the staff to make the following findings: (1) the design basis for calculating the dose consequences from a bounding release of noble gases is adequate to determine the potential threat of an inadvertent discharge of noble gases, and (2) the coolant system is not an IROFS based on the impact of a coolant system failure on the gas management system.

Therefore, the staff concludes that the design basis for the NWMI production facility's chilled water system, as described in NWMI PSAR Section 5.1.6, is sufficient to meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. The staff will review the chilled water system's potential impact on the gas management system again during its review of the operating license application. The staff will confirm that all aspects of the final design conform to the design basis during the evaluation of NWMI's FSAR.

5.5 Summary and Conclusions

As described in NWMI PSAR Chapter 5.0, chilled water is used as the cooling fluid to control the temperature of process solutions in the NWMI production facility. The summary and conclusions provided below apply to the NWMI production facility's cooling systems.

The staff evaluated the descriptions and discussions of the NWMI production facility's cooling systems as described in NWMI PSAR Chapter 5.0 and supplemented by the applicant's responses to RAIs, and finds that the preliminary design of the cooling systems, including the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in or referenced in NUREG-1537 and the ISG Augmenting NUREG-1537. The staff further notes that the NWMI production facility is designed to operate with a minimal heat load during normal operation. This, coupled with the absence of long-lived fission product build-up, indicates that operation of the NWMI production facility would pose a minimal risk to the health and safety of the public.

Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the production facility cooling systems, including, but not limited to, the principal architectural and engineering criteria for the design, and has demonstrated that the cooling system is not an IROFS, and that the major features or components incorporated therein do not need to be functional for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis of the facility cooling systems and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that, taking into consideration the site criteria contained in 10 CFR Part 100, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(4) There is reasonable assurance: (i) that the construction of the NWMI facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations.

(5) The issuance of a permit for the construction of the facility would not be inimical to the common defense and security or to the health and safety of the public.

(6) The preliminary design of the production facility cooling systems provides reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 20 and that the health and safety of the public will not be endangered.

6 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 Northwest Medical Isotopes, LLC (NWMI or the applicant) proposed production facility. The ESFs associated with confinement of the process radionuclides and hazardous chemicals for the NWMI production facility are summarized in Table 6-1, "Summary of Confinement Engineered Safety Features," of the NWMI preliminary safety analysis report (PSAR).

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility ESFs, as presented in Chapter 6.0, "Engineered Safety Features," of the NWMI PSAR, Revision 3, as supplemented by the applicant's responses to staff request for additional information (RAI). As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

6.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 6.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of the NWMI production facility ESFs for the purposes of issuance of a construction permit. As part of this review, the staff evaluated descriptions and discussions of the NWMI production facility ESFs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of ESF systems was evaluated to ensure the sufficiency of principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications (TSs) for the facility, with special attention given to those items which may significantly influence the final design.

Areas of review for this section included a summary description of the NWMI production facility ESFs, as well as a description of the NWMI production facility confinement and nuclear criticality

safety analysis. Within these review areas, the staff assessed, in part, confinement system and components, functional requirements of confinement, management of the nuclear criticality safety program (NCSP), planned responses to criticality accidents, criticality-safety controls, nuclear criticality safety evaluations (CSEs), and the criticality accident alarm system (CAAS).

6.2 Summary of Application

NWMI PSAR Section 6.1, "Summary Description," briefly describes the SSCs that constitute the confinement and criticality safety ESFs in the NWMI production facility design and summarizes the postulated accidents that are mitigated. As described in greater detail in NWMI PSAR Chapter 13.0, "Accident Analysis," specific postulated accident scenarios indicate the need for the confinement ESF.

NWMI PSAR Section 6.2, "Detailed Descriptions," describes the confinement ESF SSCs that will be incorporated into the NWMI production facility's design. These also include the derived confinement items relied on for safety (IROFS) and the dissolver offgas systems. Details include: accidents mitigated, system components, functional requirements, design basis, and test requirements. Information related to the exhaust system, the effluent monitoring system, radioactive release monitoring system and the confinement system mitigation effects, which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR) as part of an NWMI operating license (OL) application.

According to NWMI, the confinement consists of passive and active features designed to mitigate the consequences of accidents and to keep the radiological and chemical exposures to the public, the facility staff, and the environment within acceptable values described in 10 CFR Part 20, "Standards for Protection against Radiation," and 10 CFR 70.61, "Performance requirements." NWMI PSAR Section 6.2 provides the details of design, initiation, and operation of confinement ESF SSCs that are provided to mitigate the design-basis accidents discussed in NWMI PSAR Section 6.1. Confinement of hazardous chemical spills will be provided by berms located within the NWMI production facility.

NWMI PSAR Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," describes NWMI's preliminary NCSP applicable to the design, construction, and operation of the NWMI production facility, including organization and administration, management measures, and technical practices related to nuclear criticality safety (NCS). Based on its commitments in NWMI PSAR Section 6.3, NWMI's NCSP will be consistent with the following American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, as modified by exceptions in Regulatory Guide (RG) 3.71, "Nuclear Criticality Safety Standards for Fuels and Material Facilities" (Reference 32):

- ANSI/ANS-8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors" (Reference 30),
- ANSI/ANS-8.3, "Criticality Accident Alarm System" (Reference 33),
- ANSI/ANS-8.7, "Nuclear Criticality Safety in the Storage of Fissile Materials" (Reference 34),
- ANSI/ANS-8.10, "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement" (Reference 35),

- ANSI/ANS-8.19, “Administrative Practices for Nuclear Criticality Safety” (Reference 36),

- ANSI/ANS-8.20, “Nuclear Criticality Safety Training” (Reference 37),

- ANSI/ANS-8.22, “Nuclear Criticality Safety Based on Limiting and Controlling Moderators” (Reference 38),

- ANSI/ANS-8.23, “Nuclear Criticality Accident Emergency Planning and Response” (Reference 39),

- ANSI/ANS-8.24, “Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations” (Reference 40), and

- ANSI/ANS-8.26, “Criticality Safety Engineer Training and Qualification Program” (Reference 41).

Commitments related to the design of the NWMI production facility and its SSCs are described in NWMI PSAR Section 6.3, to ensure that subcriticality will be maintained with an acceptable margin of safety under normal and credible abnormal conditions. These commitments include the establishment of engineered and administrative controls; adherence to the double contingency principle (DCP); the installation of a criticality monitoring system; performance of CSEs; the use of management measures such as training, assessments, procedures, postings, labeling, and configuration control; and emergency preparedness and response related to NCS.

6.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 6.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility ESF systems for the issuance of a construction permit under 10 CFR Part 50. In accordance with paragraph (a) of 10 CFR 50.35, “Issuance of construction permits,” a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final FSAR.

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9) and "Final Interim Staff Guidance [ISG] 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," (Reference 10) 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" (Reference 11). The staff's review in Chapter 2, "Site Characteristics," of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

6.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility ESFs are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.35, "Issuance of construction permits."
- 10 CFR 50.40, "Common standards."
- 10 CFR Part 20, "Standards for Protection against Radiation."

6.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors.

For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).

- 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 (Reference 9).

- "Final Interim Staff Guidance [ISG] 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 Homogenous Reactors," dated October 17, 2012 (Reference 10).

- "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 Homogenous Reactors," dated October 17, 2012 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. Taking into consideration the design and operational similarities between production facilities and fuel cycle facilities licensed under 10 CFR Part 70, applicable non-reactor guidance contained in NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24) has been incorporated into the Final ISG Augmenting NUREG-1537 for medical isotope production facilities. In the ISG Augmenting NUREG-1537, the staff determined that the use of certain methodologies as described in 10 CFR Part 70, including the performance requirements of 10 CFR 70.61, and NUREG-1520, are an acceptable way of demonstrating adequate safety for a medical isotope production facility.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, ANSI/ANS standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

6.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 6.0 to assess the sufficiency of the preliminary design and performance of the NWMI production facility ESFs for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance standards of the NWMI production facility ESFs is determined by ensuring that the design and performance standards meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 6.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the staff's technical evaluation is described in Section 6.5, "Summary and Conclusions," of this SER.

The staff's review also compared the NWMI PSAR Chapter 6.0 documented ESFs and IROFS to the NWMI PSAR Chapter 13.0 unmitigated accident analysis results, IROFS selected to mitigate the bounding accidents, and the success of the selected IROFS and ESFs in reducing the analyzed accident consequences.

For the purposes of issuing a construction permit, the preliminary design of the ESFs may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the ESFs based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. The staff's evaluation of the preliminary design of the ESFs does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the ESFs, as described in the FSAR submitted as part of the NWMI OL application.

6.4.1 Summary Description

The staff evaluated the sufficiency of NWMI's summary description of its production facility's ESFs, as described in NWMI PSAR Section 6.1, for the issuance of a construction permit using the guidance from Section 6.1, "Summary Description," of NUREG-1537, Parts 1 and 2.

In NWMI PSAR Section 6.1, NWMI briefly describes the IROFS that constitute the confinement ESFs in the facility design.

NWMI PSAR Section 6.2 and its subsections provide detailed descriptions of the safety features that are in place to mitigate the accidents identified in NWMI PSAR Chapter 13.0, Section 13.1.3, "Preliminary Hazards Analysis Results." The confinement ESF consists of the following IROFS:

- Hot cell shielding boundary (reduces direct radiation exposure),
- Hot cell confinement boundaries (confines fissile and high dose solids, liquids, and gases, in addition to controlling gaseous releases to the environment), and
- Administrative and passive design features to provide subcritical control of fissionable material.

Based on its review, the staff finds that the summary description of the NWMI production facility ESFs contains enough information for an overall understanding of the functions and relationships of the ESFs to the preliminary design of the facility.

Therefore, the staff concludes that the summary description of the NWMI production facility ESFs, as described in NWMI PSAR Section 6.1, is sufficient to meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

6.4.2 Confinement

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility's confinement and related systems as described in NWMI PSAR Section 6.2.1, "Confinement," for the issuance of a construction permit in part, by reviewing 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 abnormal operational conditions. The detailed functional requirements, design

bases, probable subjects of TSs, and testing requirements are not provided in the PSAR, and can reasonably be left for later consideration as these details are not anticipated to significantly impact construction, and will be supplied in the FSAR as part of the OL application. The staff's review of the facility ventilation system is described in further detail in SER Section 9.4.1, "Heating, Ventilation, and Air Conditioning Systems."

Consistent with the review procedures of NUREG-1537, Part 2, Section 6.2.1, "Confinement," the staff: (1) reviewed the accident scenarios analyzed in NWMI PSAR Chapter 13.0 and evaluated whether the confinement will sufficiently mitigate consequences; (2) reviewed design and functional bases against analyzed accidents; and (3) compared diffusion and dispersion of released airborne radionuclides. More specifically, the staff evaluated the following elements of the NWMI production facility's confinement:

- Design bases and functional description of the required mitigative features of the confinement ESF IROFS, derived from the accident scenarios. The accident scenarios are documented in NWMI PSAR Chapter 13.0 and was also the subject of several staff RAIs. NWMI responded to these RAIs with a commitment to revise and reanalyze the accident scenarios, with the final results to be documented in the FSAR. The preliminary accident scenarios presented in NWMI PSAR Chapter 13.0 documented that the confinement system would be credited to operate and would minimize the release of radiological material to the environment in the event of an accident and reduce the off-site radiological consequences to less than 10 CFR Part 20 release limits during normal and abnormal operations.

- Discussion and analyses, keyed to drawings, of how the structure provides the necessary confinement analyzed in NWMI PSAR Chapter 13.0, with cross reference to other NWMI PSAR sections for discussion of normal operations including Chapter 4.0, "Radioisotope Production Facility Description," and Chapter 11.0, "Radiation Protection and Waste Management."

- Discussion of the required limitations on release of confined effluents to the environment.

- Surveillance methods, test requirements, and test intervals are not included in the PSAR, but will be developed by NWMI during final design and documented in the FSAR TSs to ensure operability and availability of the confinement ESF IROFS.

NWMI PSAR Section 6.2.1 provides descriptions of the safety features that are in place to mitigate the accidents identified in Chapter 13.0, Section 13.1.3. The confinement ESF consists of the following general components and their respective functional requirements:

- Confinement system enclosure structures such as sealed flooring, diked areas, and catch basins to contain liquid or solid accidental releases. The staff finds that these structures are used to isolate and confine radioactive material in the event of an accident, thereby preventing the inadvertent spread of contamination.

- Ventilation ducting to provide and maintain negative air pressure in the hot cell and ventilation duct system. Exhaust stack with a radioactivity monitoring system to provide dispersion of radionuclides in normal and abnormal releases. The staff finds that the preliminary confinement system design relies upon several areas of increasing

negative pressure zones, intended to always draw from confinement areas of potentially less contamination to confinement areas of potentially increased contamination, prior to being exhausted out the stack.

- Bubble-tight isolation dampers to prevent the inadvertent spread of radiological material. The staff finds that the bubble-tight isolation dampers are arranged to isolate and confine radioactive material in the event of an accident, thereby preventing the inadvertent spread of contamination.

- Zone I exhaust filter trains that remove greater than 99.9 percent of any radiological particulates and remove greater than 90 percent of iodine from the process ventilation stream. The staff finds that the Zone I exhaust filter design efficiencies are greater than the filter efficiencies credited in the mitigated accident analyses documented in NWMI PSAR Chapter 13.0. Therefore, the NWMI PSAR Chapter 13.0 mitigated accident analyses are conservative by overestimating the dose consequence to the public.

- Two 100-percent-capacity exhaust fans for redundancy. The staff finds that the Zone I exhaust system design employs two trains of exhaust fans, so as not to be susceptible to single failures.

NWMI PSAR Section 6.2.1.7, "Derived Confinement Items Relied on for Safety," identifies specific SSCs that are designated as IROFS and will have associated TSs necessary to ensure operation in the production facility:

- Primary offgas relief system to mitigate target offgas system malfunctions, including loss of power during target dissolution operations (IROFS RS-09). The staff finds that the primary offgas system relies on vacuum pumps to maintain a vacuum from the irradiated target dissolver process vessels in order to capture the gaseous effluent from the irradiated target dissolution process vessels. The design uses a redundant pressure relief tank to contain the offgas in the event of an upset condition or loss of power. This redundancy will prevent any release of irradiated target offgas in the event of an accident.

- Active radiation monitoring and isolation of low-dose waste transfer to mitigate the potential spills of high-dose process liquids outside the hot cell shielding boundary (IROFS RS-10). The staff finds that continuous radiation monitoring of the low-dose waste transfer piping would prevent an accidental transfer of waste with a higher dose than desirable from the hot cell to the low-dose waste tank. The continuous radiation monitoring system must provide a low-dose permissive signal to allow movement of the piping isolation valves.

- Cask local ventilation during closure lid removal and docking preparations to mitigate irradiated target cladding failures during transportation, releasing gaseous radionuclides within the cask containment boundary (IROFS RS-13). The staff finds that the ventilation system is expected to provide worker protection in the event of an irradiated target cladding failure and uncontrolled release of radioactive material while the targets are inside the transfer cask and the cask lid is being removed as part of the cask unloading procedures.

- Cask docking port enabling sensor to mitigate the potential failure of the cask lift after removal of the shield plug with irradiated targets in the cask (IROFS RS-15). The staff finds that this system would protect the worker from a direct radiation exposure accident that could occur if the cask is not mated securely to the cask unloading port.

- Process vessel emergency purge system to mitigate hydrogen deflagration or detonation in a process vessel (IROFS FS-03). The staff finds that this is a redundant, passive backup system to provide nitrogen purge gas to prevent an explosive hydrogen gas buildup in the event that any irradiated target process system tanks or piping normal purge gas would malfunction.

- Irradiated target cask lifting fixture to mitigate a dislodged irradiated target shipping cask shield plug during target unloading activities (IROFS FS-04). The staff finds that the cask lifting fixture passively functions to prevent any cask tipping in the unlikely event of a seismic event during cask handling operations where the cask lid would not be installed on the cask.

- Exhaust stack height to mitigate process solutions spills and sprays and carbon fire (IROFS FS-05). The exhaust stack height is credited to disperse any release of radioactive material from the confinement system. The staff finds that Zone I exhaust stack height has been credited in the NWMI PSAR Chapter 13.0 mitigated accident analyses.

- Double wall piping to mitigate leaks in piping that passes between confinement enclosures (IROFS CS-09). The staff finds the use of double wall piping to be employed where process piping transfers radioactive material between confinement enclosures (hot cells) to be an effective method of preventing spills or sprays in the event of a single failure, and thereby preventing accidental release of radioactive materials outside of the designed confinement system. An additional safety feature of the double wall piping design is expected to provide passive gravity drain from the piping annulus to leak collection tanks.

- Backflow prevention devices and safe-geometry day tanks to mitigate the potential backflow of process material located inside a confinement boundary to a vessel located outside the confinement via connected process piping due to process upset (IROFS CS-18 and CS-18). The staff finds the use of back flow preventers to be installed on process lines entering confinement areas to be an effective method of preventing accidental exposure of workers to direct radiation hazard solutions in the event of a process upset within the confinement areas.

Based on its review, the staff finds that the level of detail provided on the confinement in the production facility is adequate and supports the preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 6.2.1, allowing the staff to find that: (1) the scenarios for potential accidents at the facility have been analyzed by the applicant. Mitigation of consequences by a confinement system has been proposed in the PSAR analyses for any accident that could lead to potential unacceptable radiological exposures to the public, the facility staff, or the environment. The preliminary designs and functional descriptions of the confinement ESF provide reasonable assurance that the consequences will be limited to the levels found acceptable in the accident analyses of NWMI PSAR Chapter 13.0; and (2) the radiological consequences from accidents to the public, the facility staff, and the environment

will be reduced by the proposed confinement ESF to values that do not exceed the applicable limits of 10 CFR Part 20 and are as far below the regulatory limits as is reasonably achievable.

Therefore, the staff concludes that the preliminary design of the NWMI production facility's confinement ESF is sufficient to meet applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided in the FSAR, because it will not significantly alter the construction of the facility. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

6.4.3 Containment

The staff evaluated the sufficiency of NWMI's treatment of containment in the production facility, as described in NWMI PSAR Section 6.2.2, "Containment," for the issuance of a construction permit using the guidance and acceptance criteria of Section 6.2.2, "Containment," of NUREG-1537, Parts 1 and 2. NWMI PSAR Section 6.2.2 states that the accident analysis has not identified a need for a containment system.

The staff's review of the NWMI PSAR Chapter 13.0 unmitigated and mitigated analyses of potential facility accidents confirmed that the credited operation of the confinement system (e.g., Zone I exhaust and filters) provides sufficient reduction of the bounding accident dose consequences so that the mitigated dose consequences to the public are less than the acceptable limits specified by 10 CFR 20.1301, "Dose limits for individual members of the public."

Based on its review, the staff finds that, because NWMI provides a confinement ESF to keep the potential risk to the public from accidents low, containment is not required for normal operation or accident mitigation. The safety analyses in NWMI PSAR Chapter 13.0 show that confinement provides sufficient mitigation for accidents and, therefore, that containment is not necessary.

6.4.4 Emergency Cooling System

The staff evaluated the sufficiency of NWMI's treatment of emergency cooling systems, as described in NWMI PSAR Section 6.2.3, "Emergency Cooling System," for the issuance of a construction permit using the guidance and acceptance criteria of Section 6.2.3, "Emergency Core Cooling System," of NUREG-1537, Parts 1 and 2. As stated in NWMI PSAR Section 6.2.3, "the current accident analysis described in Chapter 13.0 has not identified a need for an emergency cooling system as an engineered safety feature."

Based on its review of the accident analysis provided in NWMI PSAR Chapter 13.0, the staff finds that there are no accidents requiring emergency cooling and, therefore, that an emergency cooling system is not required to mitigate the consequences of an accident in the NWMI production facility.

6.4.5 Nuclear Criticality Safety

The staff evaluated the sufficiency of the NWMI production facility's NCS design criteria and methods, as described in NWMI PSAR Section 6.3, as supplemented by the applicant's responses to RAIs, computer code validation report, and a sampling of preliminary CSEs, for

the issuance of a construction permit 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, which is based on Chapter 5, "Nuclear Criticality Safety," of NUREG-1520 (Reference 24). Specifically, the pertinent portions of Section 6b.3 of this ISG were drawn from Section 5.4.3, "Regulatory Acceptance Criteria," of NUREG-1520.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 6b.3, the staff reviewed the applicant's NCSP, including its organization and administration, management measures, and technical practices, as well as a sampling of preliminary CSEs. For the purposes of issuing a construction permit, the staff determined that it was not necessary for NWMI's NCSP to meet all of the acceptance criteria provided in Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2. The staff's review of NWMI PSAR Section 6.3 evaluated the adequacy of pertinent commitments to the design of processes within the NWMI production facility.

Since the design and analyses of the NWMI production facility are in preliminary stages, the scope of the staff's evaluation focused on the NCS design criteria and methods that will be utilized to perform NCS analyses and design the facility so as to maintain subcriticality in fissile material processes within the facility. This section of the SER pertains to the analysis and design methods used to ensure that the facility will remain subcritical under normal and credible abnormal conditions by an acceptable margin of safety. As explained in Chapter 1, "The Facility," of this SER, the target fabrication process described in the PSAR will take place in an area separate from the production facility and, as described by NWMI, is not encompassed by the definition of a 10 CFR Part 50 production facility. Activities that are within the scope of this SER review and for which the staff makes 10 CFR Part 50 findings for the issuance of a construction permit consist of all processes within the facility associated with the handling and use of irradiated fissionable material, including irradiated target handling, disassembly, and dissolution, hot cell operations, Molybdenum-99 (Mo-99) recovery, solid and liquid waste processing, and auxiliary operations, such as offgas ventilation, from removal of irradiated targets from their shipping containers until purified material is reintroduced into the target fabrication line. During the course of reviewing NWMI's NCSP, the staff needed additional information to evaluate the adequacy of NWMI's principal design criteria and design bases, in accordance with the requirements of 10 CFR 50.34(a)(3). Therefore, in RAIs 6.3-10 through 6.3-16 (Reference 13), the staff requested that the applicant provide additional information to demonstrate how it satisfied the acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 6b.3. As discussed below, these RAIs covered the adequacy of the applicant's commitments and the implementation of those commitments in performing NCS evaluations and computer code validation.

The applicant committed to establishing an NCSP meeting the requirements as set forth in the ANSI/ANS standards listed in Section 6.2 above, as modified with the exceptions stated in NRC RG 3.71. NWMI PSAR Section 6.3 states that, for the purpose of design and construction, no deviations from these standards were identified. NWMI PSAR Section 6.3 enumerates roles and responsibilities for the NCSP and staff performing NCS duties. During design and construction, these responsibilities consist mainly of performing criticality analyses and establishing controls to ensure subcriticality under normal and credible abnormal conditions and satisfy the DCP, based on the preliminary design of the facility and any subsequent modifications to that design. Supporting tasks include development of program procedures, peer reviews of CSEs, training and qualification, and criticality code validation. NCS staff consists of an NCS manager, NCS representative, and qualified NCS engineers. NWMI stated that management and staff having NCS responsibilities will satisfy minimum initial qualifications

and will be subject to periodic requalification. The PSAR states that training and qualification of personnel with NCS responsibilities will be done in accordance with ANSI/ANS-8.26, which has been endorsed by the NRC in RG 3.71.

During design and construction, NCSP staff will perform periodic inspections and assessments to ensure that activities are in accordance with program and regulatory requirements. These assessments will be in accordance with written procedures and consistent with the requirements as set forth in ANSI/ANS-8.1 and 8.19. In addition, management assessments of the NCSP will be performed by the NCS manager and NCS staff. This will consist of periodic audits by senior applicant management independent of the NCS organization, as well as a triennial external audit to verify program effectiveness. This will be performed by a qualified senior NCS engineer external to the applicant's organization.

The PSAR states that NCS controls are established in reviewed and approved CSEs and implemented in criticality prevention specifications, operating procedures, and postings. This will be done consistent with the ANSI/ANS standards listed in SER Section 6.2 above, in particular ANSI/ANS-8.19. The applicant's described approach is in accordance with industry standards and best practices and is therefore acceptable to the staff. Design and process changes will be documented and reviewed by the NCS representative or an NCS Engineer to ensure that they are within the scope of the existing approved CSE, or else will be reviewed and approved under the applicant's change control process. The change process will be consistent with ANSI/ANS-8.19 and the requirements of 10 CFR 50.59, "Changes, tests, and experiments." All dimensions, nuclear properties, and other features relied on for criticality safety will be documented and verified prior to operation. While the PSAR is not requesting approval to operate the facility at the construction stage, design and configuration control is essential to ensure criticality safety all through the design and construction process. The applicant's commitments in that regard are in accordance with ANSI/ANS-8.19 and standard industry practice and are therefore acceptable to the staff. The staff is tracking these commitments in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER.

In NWMI PSAR Section 6.3, the applicant states that it will document the controlled parameters, limits, and controls in CSEs. Preliminary CSEs are listed in NWMI PSAR Section 6.3.1.1, "Preliminary Criticality Safety Evaluations," along with a list of controlled parameters (NWMI PSAR Table 6-5, "Controlled Nuclear Criticality Safety Parameters") and a description of the double contingency controls (NWMI PSAR Tables 6-6 through 6-13). There is also a detailed description of IROFS in NWMI PSAR Section 6.3.1.2, "Derived Nuclear Criticality Safety Items Relied on for Safety." The staff finds that the controlled parameters in PSAR Table 6-5 appear consistent with the typical control strategy for a nuclear processing facility. For the majority of the processes listed, criticality safety relies on a combination of mass, geometry and/or volume, and interaction control. Geometry is controlled in all but waste liquid processing, consistent with the industry-accepted and NUREG-1520 stated preference for reliance on passive geometry. Similarly, mass is controlled in all but hot cell uranium purification, providing two independent parameters that must fail before criticality is possible. Concentration is controlled in several liquid processing units through control of the fissile mass in solution. Specific criteria for how these parameters will be controlled and how they will be modeled in criticality analysis have been provided in an RAI response (Reference 64). Section 6b.3 of the ISG Augmenting NUREG-1537 specifies that the applicant should commit to technical practices for the control and modeling of controlled parameters. The staff considers these methods to be part of the design basis for the facility, and reviewed these commitments against the acceptance criteria in Section 6b.3 of the applicant's integrated safety analysis (ISA). The commitments were

consistent with this guidance, and therefore are acceptable to the staff. The staff also reviewed a representative CSE to verify proper implementation of controls, as discussed below.

The applicant also stated that it would follow the accepted preference of passive over active and engineered over administrative controls. The staff finds that the controls listed in the remainder of NWMI PSAR Chapter 6.0 appear to largely follow this preferred hierarchy of controls. However, a determination of the adequacy of the double contingency controls and IROFS cannot be done apart from a review of the underlying contingencies and accident sequences, which depend on the specific process, its controlled parameters, and spectrum of credible abnormal conditions. It therefore requires review of the CSEs that contain the safety analysis and basis for the controls. Because of this, the staff finds that detailed review of the adequacy of the double contingency controls and IROFS in NWMI PSAR Tables 6-6 through 6-13 and Section 6.3.1.2 can reasonably be left for later consideration, and will be provided, in the FSAR submitted as part of the OL application. During its construction permit review, the staff did not review all of the CSEs, but instead reviewed a representative CSE for the facility to confirm the correct implementation of NWMI's approach. To understand the basis for the double contingency controls in the PSAR and to verify that criticality safety is adequately incorporated into the preliminary design of the facility, the staff reviewed CSE NWMI-2015-CSE-008, "NWMI Preliminary Criticality Safety Evaluation: Hot Cell Uranium Purification," Revision A (Reference 48). Other CSEs listed pertain to the target fabrication area or auxiliary systems that support both target fabrication and the production facility.

NWMI-2015-CSE-008 describes the criticality safety basis for purification of the uranyl nitrate solution following Mo-99 extraction, and prior to reuse as feed material in the target fabrication area. The process equipment consists of favorable geometry collection tanks, ion exchange columns, thermosiphon evaporators, associated offgas and waste collection tanks, and piping. Favorable geometry is maintained throughout the process, with the spacing and arrangement of safe individual units also controlled. Optimum concentration and reflection up to full flooding of the hot cell is assumed in process tanks and piping, as determined by the applicant's parametric study in the supporting criticality calculation document, NWMI-2015-CRITCALC-006. The CSE states that the uranium in the purification process should not exceed a specified concentration under normal conditions, and that NWMI-2015-CRITCALC-006 analyzed the uranium concentration over a specified range. The staff performed confirmatory analysis, which showed that the optimum concentration for 20 weight percent (wt%) uranium-235 (U-235) uranyl nitrate in a 6-inch (15.24-centimeters [cm]) diameter column with 1-inch (2.54-cm) tight-fitting water reflection occurs around 575 grams of uranium per liter. Moreover, a single such column is still safely subcritical with a calculated effective neutron multiplication factor (k_{eff}) of approximately 0.67. The applicant's parametric study therefore includes the optimum concentration for an array of solution-bearing columns.

Given the substantial margin of subcriticality on individual units and 36-inch (91.44-cm) spacing between most process vessels, tank risers, and piping, the only scenarios leading to criticality are those involving a loss of geometry control, primarily through solution leaks or backflow to unfavorable geometry. In the event of a leak (Scenario C1 from the CSE), uranyl nitrate solution will spread out into a slab on the hot cell floor. The floor is epoxy-sealed and verified flat. Based on the total volume of process vessels available and surface area of the floor, the applicant determined that a catastrophic failure of all process vessels would cause solution to collect in a slab 1.73 cm (0.68 inch) deep. The applicant stated that the single parameter limit for slab depth is 3.76 cm (1.48 inch), indicating that there is a substantial safety margin. The staff did not have the calculations upon which this limit was based, but noted that this value is much less than the safe slab depth for uranyl nitrate. ANSI/ANS-8.1, which has been endorsed

in NRC RG 3.71 contains a single-parameter slab depth of 11.9 cm (4.68 inch) for uranyl nitrate enriched up to 10 wt% U-235. With an extrapolation to 20 wt% U-235, the slab depth is reduced somewhat but still will greatly exceed either the applicant's limit of 3.76 cm (1.48 inch) or the actual solution depth of 1.73 cm (0.68 inch). Reaching such a depth would require failure of all process vessels in the unit simultaneously. In addition, the model conservatively assumed that all process vessels remained full, despite having spilled their contents to the floor. The staff therefore concludes that the area will remain subcritical with a substantial margin even in the event of a catastrophic failure of all process vessels.

The other scenario of concern is backflow from favorable to unfavorable geometry equipment. Backflow into the unfavorable geometry offgas treatment system, steam condensate or cooling water return system, water and chemical reagent supply system, fresh resin supply system, or process gas system is considered in Scenarios C3 and C5 through C8. For each scenario, at least two engineered backflow prevention barriers are credited, such that at least two unlikely, independent, and concurrent failures must occur before concentrated solution can backflow to unfavorable geometry, consistent with the DCP. These barriers include passive overflows, air breaks, double block-and-bleed valves, and tank venting. For the steam and cooling water supply system, an intermediate cooling loop is employed, along with process monitoring to detect leaks in either the primary or secondary loop. For the water and chemical reagent supply systems, favorable geometry day tanks equipped with air breaks are used. For the process gas systems, the gas is maintained at a higher pressure than vented process vessels; in the event of loss of pressure, a passive over loop seal prevents backflow to the unfavorable geometry gas supply system. For the fresh resin supply system, a double block-and-bleed valve and paddle blank will be used to satisfy the DCP. While the proper valve alignment and paddle blank installation is considered administrative, the reliability of these measures is enhanced by requiring that the affected equipment be locked and that supervisors verify that the affected equipment is in the proper configuration. Together, these enhanced administrative controls are each sufficient to ensure that each contingency is at least "unlikely." The applicant justified the use of administrative controls by stating that the use of passive features, such as passive overflows or air breaks, is not practical because the operation requires the process vessels to be pressurized. The staff reviewed the various scenarios resulting in backflow from favorable to unfavorable geometry and concludes that the controls are sufficient to provide for double contingency protection against backflow and are consistent with the preference for passive controls wherever practical. Moreover, the strategy to prevent backflow is consistent with the typical industry practice for solution-processing facilities and is therefore acceptable to the staff. Based on its review of the Hot Cell Uranium Purification System CSE, the staff concludes that the control strategies for scenarios leading to criticality were consistent with industry best practices, were adequate to ensure subcriticality under normal and credible abnormal conditions (except as noted below for certain flooded cases impacted by a reduction in the Upper Subcritical Limit [USL]), and were in compliance with the DCP.

In addition to reviewing a representative CSE for hot cell uranium purification in the production facility, the staff also reviewed the applicant's validation methodology and results, as documented in its validation report, NWMI-2014-RPT-006, "MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections" (Reference 49). The applicant states in NWMI PSAR Section 6.3 that the validation will follow the requirements as set for in "shall statements" of ANSI/ANS-8.1 and ANSI/ANS-8.24, which include methods and practices related to criticality code validation that have been endorsed in NRC RG 3.71, and which are therefore acceptable to the staff. Specific commitments related to validation are included in NWMI PSAR Section 6.3.1.1. The staff reviewed these commitments and the Validation Report identified above. The MCNP 6.1 code, using the ENDF/B-VII.1 cross section library, is widely used and

accepted in the nuclear industry. NWMI PSAR Section 6.3.1.1 states that the design of the facility will be based on a minimum margin of subcriticality (MoS) of 0.05. This is combined with the bias and bias uncertainty determined in the validation study to determine an appropriate USL. The bias and uncertainty were determined by the applicant using a non-parametric method because the underlying condition of data normality was determined to not be satisfied. The statistical method NWMI used to determine bias and bias uncertainty is widely used and accepted in the nuclear industry and by the NRC (e.g., NUREG/CR-6361, "Criticality Benchmark Guide for Light-Water-Reactor Fuel in Transportation and Storage Packages," and NUREG/CR-6698, "Guide for Validation of Nuclear Criticality Safety Calculational Methodology" [References 50 and 51]). The USL and range of parameters for which the code is considered validated—referred to as the validated Area of Applicability (AOA)—must be adhered to when using criticality calculations in deriving the criticality safety basis of the facility, and are therefore part of the design basis of the facility.

The MCNP 6.1 code, ENDF/B-VII.1 cross section library, and statistical methods in the Validation Report, are widely accepted in the nuclear industry. Overall, the staff finds that the applicant's validation is consistent with industry practice, the aforementioned standards, and NRC regulations and guidance. The staff noted that use of the code to model systems at 20 wt% enrichment is somewhat unusual, and therefore examined the benchmark experiments to ensure that there were sufficient benchmarks similar to those conditions expected to be encountered in the facility to support the use of a minimum subcritical margin of 0.05. The applicant's benchmarks were all drawn from the industry-accepted, "International Handbook of Evaluated Criticality Safety Benchmark Experiments" (IHECSBE) (Reference 52). The IHECSBE is developed and maintained under the International Criticality Safety Benchmark Evaluation Project run out of Idaho National Laboratory. The experiments contained therein have been evaluated to be of benchmark quality for the validation of criticality safety calculational methods. Code bias and bias uncertainty in general vary depending on physical parameters such as the enrichment, moderator-to-uranium ratio, and neutron energy spectrum. In addition to these continuous parameters, bias and uncertainty may also vary with the inclusion of different moderating, reflecting, and neutron absorbing materials. Therefore, the applicant divided the selected IHECSBE benchmarks into several groups to determine if there was a statistically significant difference between them, and also to look for trends as a function of the various continuous parameters mentioned above. Based on the distribution of experiments as a function of the parameters and any trends observed, the applicant derived an AOA in the Validation Report, which was included in the NWMI PSAR as Table 6-4, "Area of Applicability Summary." The staff examined the trending analysis as discussed below.

The staff noted that the applicant divided the benchmarks into low, intermediate, and high enrichment categories, and determined a separate USL for each. For the purpose of trending the bias—consistent with the definitions used in the IHECSBE—low enrichment is less than 10 wt% U-235, intermediate enrichment is between 10 and 30 wt% U-235, and high enrichment is greater than 30 wt% U-235. The applicant divided the data into these three categories, and also performed a linear regression fit of the calculated k_{eff} as a function of enrichment to determine if there was a trend in the bias. The bias appeared to be very consistent across the three different enrichment ranges. While low and high enriched benchmarks were included to investigate any trends in the bias, only the results for the intermediate cases had an impact on the final USL, which included an 0.05 MoS. This is because only the lowest calculated k_{eff} value is used in determining the USL, and that occurs in the intermediate enrichment set of benchmarks.

In addition to enrichment, the applicant trended the calculated k_{eff} against the hydrogen-to-fissile (H/X) ratio and the neutron energy, characterized by the average neutron energy causing fission (ANECF). While there was a slight trend in bias as a function of ANECF, the trend was slight and adequately bounded by the USL. The other parameters exhibited no significant trend. The applicant further divided the data into different subgroups according to moderator type, reflector type, and chemical form. For each case, the applicant stated that there was no significant trend.

To evaluate this hypothesis, the staff performed its own statistical analysis of the different subgroups, as well as by two subgroupings not evaluated in the validation report (grouping by neutron absorber type and homogeneous vs. heterogeneous). First, the staff used the applicant's statistical methods to determine a USL for each subgroup as a function of the five different parameters (moderator, reflector, chemical form, neutron absorber, and homogeneity). For each subdivision of the benchmark data, the staff concluded that the USLs for almost every subgroup were very close and still bounded by the overall USL.

Next, the staff performed a more detailed analysis using the two-sample t-test for two subgroups or one-way analysis of variation for more than two subgroups. At the 95 percent confidence level, the applicant's null hypothesis—that there is no trend—was thus ruled out by the staff for some of the data. In particular, the tests demonstrated a significant difference for some subdivisions by reflector, chemical form, and homogeneity. The test for subdivision by neutron absorber (which was not performed by the applicant) demonstrated that there was a particularly significant difference. The staff examined any subsets of the data that exhibited a large negative bias to see if it was of concern, and finds that those subsets either were still adequately bounded by the overall USL or represented conditions that were no longer considered applicable to anticipated calculation needs for the current facility design.

The staff did not find the applicant's conclusion of no significant trend of k_{eff} against the H/X ratio to be fully supported and determined that there were some statistically significant differences as a function of reflector, chemical form, homogeneity, and neutron absorber type, these differences were bounded by the presence of a net positive bias in the benchmarks as a whole—which was conservatively ignored by the applicant—and by margin in the overall USL. In addition, the validation approach included many different systems in the analysis to look for trends, but many of the observed differences are considered irrelevant by the staff when compared to anticipated conditions supporting the current facility design as reflected in the AOA table.

Finally, the staff compared the AOA definition table, Table 13 of the Validation Report, and Table 6-4 of the NWMI PSAR, against the distribution of benchmarks with respect to the various continuous and discrete parameters mentioned above. The staff finds that the validated AOA was consistent with or conservatively bounded (i.e., was narrower than) the range of parameters covered by the evaluated benchmark experiments.

Verifying that design calculations fall within the validated AOA is done as part of each calculation document. The staff verified that results fell within the validated AOA in the calculation document supporting the CSE reviewed as discussed above, NWMI-2015-CRITCALC-006, Revision A, "Hot Cell Tank Pit" (Reference 54). This document contains a table comparing its criticality calculations to the AOA table in the Validation Report. All parameters were within bounds, except for calculations involving high values of H/X. These calculations represent highly overmoderated systems. The spectrum is essentially fully thermalized and no additional changes will occur for values beyond the range of the benchmarks considered in the validation. The thermal cross sections of all relevant nuclides

(mainly hydrogen, U-235, and uranium-238 [U-238]) are well-known and included in many validation benchmarks. The staff reviewed the applicant's AOA comparison and justification for extrapolating H/X and, based on the foregoing information, finds them to be acceptable. The applicant has stated in NWMI PSAR Section 6.3 that it would document any extrapolation beyond the AOA and justify whether additional margin is needed.

The staff also reviewed the basis for the applicant's MoS of 0.05. The applicant states that a value of 0.05 has been widely used in typical low-enriched uranium (LEU) processing facilities, which it identifies as uranium enriched to less than 20 wt% U-235. The enrichment to be used in the NWMI production facility is just slightly less than 20 wt% U-235. While this meets the definition of LEU in 10 CFR 50.2, "Definitions," NUREG-1520, Revision 2, Appendix B, "Justification for Minimum Margin of Subcriticality for Safety," refers to a typical fuel processing facility limited to about 5 wt% U-235 in stating that a MoS value of 0.05 "has generally been found acceptable for most typical low-enriched fuel cycle facilities without a detailed technical justification." NWMI's facility is not a typical fuel cycle facility in that it is processing irradiated special nuclear material (SNM) and proposes to use a higher uranium enrichment range than comparable fuel cycle facilities in the nuclear industry.

Therefore, a technical justification for the MoS, in light of the relative lack of critical benchmarks in the intermediate enrichment range, as well as the increased sensitivity of k_{eff} to system parameters as enrichment is increased, is needed. The applicant's justification that the neutron spectrum softens with increasing enrichment due to decreasing parasitic absorption on U-235 is overgeneralized. The applicant does not, for example, account for equipment dimensions being reduced for higher enrichments so as to stay within the validation USL. Thus, at higher enrichments there is typically greater neutron leakage from individual units, which can lead to a hardening of the neutron spectrum depending on boundary conditions. Therefore, a general conclusion about shifts in the neutron spectrum with increasing enrichment does not take into account all of the different variables that can vary from one system to another. Such spectral shifts are significant because the pertinent cross sections are less well-known as the neutron energy leaves the thermal range and enters the epithermal or intermediate energy (resonance) range, which could impact the MoS determined to be acceptable.

While there were few benchmarks around 20 wt% U-235, the staff noted that there were many around 10 wt% or 30 wt% U-235. In the staff's experience, the range in enrichment that may be considered applicable is fairly broad. Table 2.3 of NUREG/CR-6698 (Reference 51) indicates that for 20 wt% U-235 calculations, benchmarks from 5 to 35 wt% U-235 are considered applicable. Interpolation of the data over the range of 10 to 30 wt% U-235 indicates that the bias varies smoothly over this range and no deviations from a linear regression fit to the bias is in evidence (except for the added benchmarks discussed below). Nor would any sudden deviation be expected, because both the U-235 and U-238 cross sections are well-characterized and have been benchmarked throughout the validation and a change in enrichment is merely a change in the relative proportions of these well-benchmarked nuclides. Therefore, the staff finds neither any empirical evidence for, nor any theoretical reason to expect, any unusual deviation from a straight-line fit to the bias over this range. In addition, the analytical methods used to calculate k_{eff} for the facility were observed, as discussed above, to be consistent with standard industry practices, which ensure acceptable conservative margin. Moreover, the non-parametric statistical method used to determine the USL is considered to be conservative, as it is based on the lowest calculated k_{eff} for the benchmarks evaluated. For the NWMI production facility, most of the benchmarks analyzed had a slight net positive bias, which is conservatively ignored. Four benchmarks from the IEU-SOL-THERM-001 benchmark set calculated low, with an average negative bias of around 0.015. These four benchmarks were

conducted near the design enrichment of 20 wt% U-235, but otherwise had physical characteristics dissimilar to those of the NWMI production facility. These unusual characteristics included having uranyl sulfate in the fissile solution, being graphite-reflected, and containing borated polyethylene as a neutron absorber. Therefore, despite having the same enrichment, the staff does not consider these benchmarks to be highly applicable to the applicant's facility. The effect of these benchmarks is to skew the benchmark distribution such that the benchmarks do not pass the normality test, necessitating use of the conservative non-parametric method. The net effect is to reduce the USL by 0.0166. Whether these IEU-SOL-THERM-001 benchmarks are deemed to represent a real bias effect applicable to the applicant's facility or are spurious, the use of the non-parametric margin introduces added conservatism in determining the USL. Based on the applicant's use of conservative modeling practices, and its conservative validation methodology, the staff has reasonable assurance that a MoS of 0.05 is acceptable to ensure subcriticality of the applicant's proposed facility under normal and credible abnormal conditions.

The reduction in the final USL occurred when the additional benchmarks were incorporated into NWMI's Validation Report. The staff noted that some of the flooded cases in NWMI-2015-CRITCALC-006 had calculated k_{eff} values below the original USL but above the new USL. With the reduction in USL caused by the inclusion of the IEU-SOL-THERM-001 benchmarks, it is therefore possible that some calculations and design analysis for this or other areas will need to be redone. Therefore, in order to confirm that the applicant will integrate the revised USL in the criticality calculations and design analysis of the facility, the staff recommends that the construction permit include the following condition:

> Prior to the completion of construction, NWMI shall ensure that all nuclear processes are evaluated to be subcritical under all normal and credible abnormal conditions. This determination shall be done for each area as described in Section 6.3.1.1 of the NWMI PSAR prior to each area being completed, and shall be done consistent with the USL established in Revision 2 of NWMI's Validation Report. NWMI shall submit periodic reports to the NRC, at intervals not to exceed 6 months from the date of the construction permit, summarizing any changes or indicate no change to the criticality safety evaluations as a result of the revised USL. This condition terminates once NWMI submits its FSAR.

Besides the preventive controls to ensure subcriticality and to satisfy double contingency, the applicant also included in its design a CAAS, as stated in NWMI PSAR Section 6.3.1.1. NWMI PSAR Section 2.5, "Geology, Seismology, and Geotechnical Engineering," and NWMI PSAR Section 4.3.2.2.5, "Special Nuclear Material Description," states that the CAAS will be installed wherever SNM is handled, processed, or stored. The applicant states that the CAAS will be consistent with ANSI/ANS-8.3, as modified by NRC RG 3.71. The CAAS will be capable of detecting a criticality that produces an absorbed dose in soft tissue of 20 rad of combined neutron and gamma radiation at an unshielded distance of 2 meters in one minute, and that each area in which SNM is stored, handled, or used should be covered by two such detectors. The staff finds that these statements are consistent with the requirements of 10 CFR 70.24, "Criticality accident requirements," paragraph (a) and guidance in NRC RG 3.71, which endorses ANSI/ANS-8.3, and are therefore acceptable to the staff.

The applicant further states that the CAAS will consist of neutron and gamma radiation detectors, will account for intervening shielding and the minimum accident of concern, and will be designed to remain operational during design basis accidents (including providing for use of an uninterruptible power supply). The CAAS will be clearly audible in areas to be evacuated or

will provide alternative notification (e.g., strobing lights) to alert personnel to promptly evacuate. Operations will be rendered safe by shutdown and quarantine if CAAS coverage is lost and cannot be restored within a predetermined number of hours (to be determined on a case-by-case basis allowing for safe shutdown). If compensatory measures are to be used during CAAS outage, they will be included in the OL application. The staff finds that these statements are consistent with the standard industry practice as provided in ANSI/ANS-8.3 and with NRC guidance and are therefore acceptable to the staff.

The applicant states that the evaluation of CAAS coverage will be performed after the final design is complete but prior to startup. The applicant indicated that this analysis will be based on a one-dimensional deterministic, or point-kernel, method, considering the minimum accident of concern (defined as that leading to the threshold dose specified in 10 CFR 70.24(a), the aforementioned 20 rad/min at 2 meters) wherever practical. The point-kernel method is generally conservative in accounting for buildup and attenuation due to intervening shielding. Where this method cannot be practically employed, the applicant states that it will use three-dimensional Monte Carlo analysis. Both methods are widely used in the nuclear industry and are acceptable to the staff. However, the presence of permanently-installed shielding for the facility could interfere with the ability of detectors to detect the minimum accident of concern. If the evaluation is not completed prior to installation of permanent shielding or other structural materials, there is a potential that the final design may not satisfy the detector coverage requirements of 10 CFR 70.24(a), which can be satisfied by 10 CFR Part 50 facilities in lieu of those set forth in 10 CFR 50.68, “Criticality accident requirements.” Because the applicant must provide assurance that the CAAS design will have the capability to detect the minimum accident of concern given the installation of SSCs into the facility, the staff recommends that the construction permit include the following condition:

> Prior to the completion of construction, NWMI shall submit periodic reports to the NRC, at intervals not to exceed 6 months from the date of the construction permit, and these reports shall:
>
> (1) Provide the technical basis for the design of the CAAS or notify the NRC of no change.
>
> (2) Demonstrate detector coverage as defined in the requirements of 10 CFR 70.24(a).
>
> This condition terminates once NWMI submits its FSAR.

The installation of a CAAS implies a nontrivial risk of criticality. To protect workers and the public from the consequences of an inadvertent criticality, the applicant also describes its emergency preparedness and response activities in NWMI PSAR Section 6.3. These include the development of emergency procedures, coordination with offsite responders, training and evacuation drills, and provision for fixed and personnel dosimeters and radiation monitoring instrumentation. Emergency procedures will include specifying evacuation routes, making provision for medical treatment and decontamination of exposed individuals, and recovery. Specific requirements related to the impact of firefighting activities on criticality safety will be developed at the OL stage. The above provisions are consistent with the requirements of 10 CFR 70.24(b) and standard industry practice and NRC guidance, and are therefore acceptable to the staff. Additional provisions for responding to deviations involving NCS controls, including event investigation, external reporting, and corrective action, are also described. While emergency planning should be considered in the development of the final

design, the staff finds that it can reasonably be left for later consideration, and the final emergency plan will be provided, in the FSAR at the OL stage when the final design is complete. The staff's evaluation of NWMI's preliminary emergency plan is discussed in Chapter 12, "Conduct of Operations," Section 12.4.7, "Emergency Planning," of this SER.

Based on the foregoing review and proposed permit conditions provided in this section of the SER, the staff finds that there is reasonable assurance that (1) NWMI described an NCSP that will, if properly implemented, ensure that all NWMI production facility processes are subcritical under both normal and credible abnormal conditions, and will comply with the DCP; and (2) the NWMI production facility will have a CAAS and associated emergency procedures to protect workers and the public from the consequences of inadvertent criticality.

6.4.6 Probable Subjects of Technical Specifications

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of TSs for the NWMI production facility ESFs, with special attention given to those items which may significantly influence the final design.

NWMI PSAR Chapter 14.0, "Technical Specifications," states that the facility ISA process identified SSCs that are defined as IROFS. The importance of these SSCs will also be reflected in the TSs. Each IROFS will be examined and likely translated into a limiting condition for operation (LCO). This translation will involve identifying the most appropriate specification to ensure operability and a corresponding surveillance periodicity for the IROFS.

The PSAR also provided an outline for TSs that will be prepared during the development of the OL application. This outline includes actions, administrative controls, LCOs, limiting safety system settings, safety limits, and surveillance requirements.

In a response to RAI 14.0-1 (Reference 13), NWMI developed a table of potential items or variables that are expected topics of TSs. NWMI states in the response that this table will be included in Chapter 14.0 of the revised NWMI PSAR as Table 14-1 (Reference 56). The staff review of Revision 3 to NWMI PSAR Chapter 14.0 verified that the applicant's proposed resolution was incorporated into the PSAR.

For criticality control purposes, the applicant proposes the following items as potential topics of TSs:

- Uranium mass limits on batches, samples, and approved containers
- Spacing requirements on targets and containers with SNM
- Floor and sump designs
- Hot cell liquid confinement
- Process tanks size and spacing
- Evaporator condensate monitor
- Criticality monitoring system
- In-line uranium content monitoring

Based on the information provided in NWMI PSAR Chapter 14.0, as supplement by an RAI response (Reference 64), the staff finds that the applicant's identification and justification for the selection of those variables, conditions, or other items determined to be probable subjects of

TSs for criticality control is sufficient and meets the applicable regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. A detailed evaluation of TSs, including limiting conditions for operation and surveillance requirements, will be performed during the review of NWMI's OL application.

6.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility ESFs, including probable subjects of TSs, as described in NWMI PSAR Chapter 6.0, and finds that the preliminary design of the ESFs, including the principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in or referenced in the applicable guidance.

Based on these findings and subject to the conditions identified above, the staff makes the following conclusions for the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the NWMI production facility ESF systems, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis of the ESF systems, and which can be reasonably left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that: (i) safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(4) There is reasonable assurance: (i) that the construction of the NWMI production facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations.

(5) The issuance of a permit for the construction of the production facility would not be inimical to the common defense and security or to the health and safety of the public.

7 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 Northwest Medical Isotopes, LLC (NWMI or the applicant) production facility processes. I&C systems are also employed to avoid or mitigate accidents. Instruments are provided to monitor, indicate, control, and record such operating parameters as process system flowrate, pump actuation, heater actuation, pump motor speed, valve actuation, valve position, solution temperature, solution density, solution conductivity, vessel level, and radiation intensities in selected areas. I&C subsystems may also be designed to actuate engineered safety features (ESFs) upon the detection of abnormal conditions.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility I&C systems as presented in Chapter 7.0, "Instrumentation and Control Systems," of the NWMI preliminary safety analysis report (PSAR), Revision 3 (Reference 60) and supplemented by requests for additional information (RAIs). As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In the SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

7.1 Areas of Review

NWMI PSAR Chapter 7.0 describes the preliminary I&C configuration for the special nuclear material (SNM) preparation and handling processes, radioisotope extraction and purification processes, process utility systems, criticality accident alarm system (CAAS), and radiation monitoring systems.

The staff reviewed NWMI PSAR Chapter 7.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of the NWMI production facility's I&C systems. As part of this review, the staff evaluated the design criteria, design bases, system descriptions, and system performance analysis of the NWMI production facility's I&C systems, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI production facility's I&C systems was evaluated to ensure the sufficiency of principal design criteria, design bases, and information relative to general arrangement sufficient to provide reasonable assurance that the final design

will conform to the design basis. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items that are determined to be probable subjects of technical specifications (TSs) for the facility, with special attention given to those items that may significantly influence the final design. The staff documented its review of NWMI's probable subjects of TSs for I&C systems in Chapter 14, "Technical Specifications," of this SER.

Areas of review for this chapter included facility I&C process control system descriptions, ESFs actuation systems, control console and display instruments, and radiation monitoring systems. Within these review areas, the staff assessed the preliminary analysis of I&C systems needed to monitor key parameters and variables, maintain parameters and variables within prescribed operating ranges, alert operators when operating ranges are exceeded, assure safety limits are not exceeded, and initiate mitigating systems and components important to safety.

7.2 Summary of Application

NWMI PSAR Chapter 7.0 describes the preliminary design of the NWMI production facility I&C systems, including the process control systems, ESFs and alarm functions, control console and display information, and radiation monitoring systems. The applicant states that the RPF is at a separate site, independent from the reactors used to irradiate the targets and that the RPF does not have or need I&C subsystems to monitor reactor operating parameters (i.e., reactor control system) or to place the reactor in a subcritical shutdown condition (i.e., reactor protection system), as described in Section 7.3, "Reactor Control System," and Section 7.4, "Reactor Protection System," of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (Reference 8), and Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9), that are necessary to maintain reactor facility conditions within the range of design conditions. Therefore, the preliminary design of the NWMI production facility I&C systems does not include any features related to reactors.

The NWMI facility process control (FPC) system is the overall production process controller that monitors and controls the process instrumented functions within the facility and monitors safety-related components within the facility. The building management system (BMS) monitors the facility ventilation system and monitors and controls the mechanical utility systems. ESF systems are designed to automatically operate on actuation of an alarm setpoint reached for a specific monitoring instrument or device using hard-wired analog controls and interlocks. For redundancy, this automatic operation is in addition to the FPC system or BMS ability to actuate ESFs as needed. The ESF parameters and alarm functions are integrated into and monitored at the FPC system or BMS to support manual operation of the ESF systems. The fire protection system has a dedicated central alarm panel that reports the status of fire protection equipment to the central alarm station and the facility control room. The preliminary concept for the facility I&C system configuration is supported by NWMI PSAR Figure 7-1, "Radioisotope Production Facility Instrumentation and Control System Configuration."

7.2.1 Design of Instrumentation and Control Systems

The NWMI production facility I&C basic components include the FPC system, ESF actuation systems, control console and display instruments, and BMS. The FPC system is a digital control system that controls and monitors the target fabrication system, molybdenum recovery and purification system, uranium recovery and recycle system, process utility and support

systems, and waste handling activities. The primary control location of the FPC system is in the control room. The control room FPC system operates with a synchronized, redundant, hot standby system with identical programmable logic controller (PLC) software systems. Items relied on for safety (IROFS) (i.e., ESF safety functions) are activated by hard-wired interlocks. The operator has direct visualization of critical values and the ability to allow, perform, or modify a task or event through a static display, an alarm and event annunciator display panel, and human-machine interfaces (HMIs). The BMS is a subsystem of the FPC system and monitors the facility ventilation system.

The applicable design criteria and guidelines that apply to the NWMI production facility I&C systems are summarized in the following NWMI PSAR tables:

- Table 7-1, “Instrumentation and Control System Design Criteria”
- Table 7-2, “Instrumentation and Control Criteria Crosswalk with Design Basis Applicability and Function Means.”

7.2.2 Process Control Systems

The process control system includes both hard-wired interlocks and computer logic to automatically actuate ESF functions when a parameter approaches or is outside its setting. In addition to interlocks, the facility also implements a permissive philosophy that allows HMI operations to be enabled once the control room has confirmed the prerequisite conditions have been completed. Permissives differ from interlocks in that a permissive requires manual approval for an activity to occur. Interlocks are engineered features while permissives are administrative features.

The FPC system will administer process control for the uranium recovery and recycle system, target receipt and disassembly system, target dissolution system, molybdenum recovery and purification system, waste handling system, and the CAAS.

The uranium recovery and recycle system processes raffinate from the molybdenum recovery and purification system for recycle to the target fabrication system. Normal uranium recovery and recycle system process functions are performed remotely using the FPC system in the control room. Control parameters include, in part, flowrate, pump actuation, pump motor speed, density, level, temperature, and valve actuation. Monitored parameters include, in part, density, differential pressure, flowrate, level, pressure, temperature, valve position, and analyzer uranium concentration. Hard-wired safety interlocks are provided to reroute condensate in the event of high uranium concentration in the condensate tanks. The description of the uranium recovery and recycle system is summarized in the following NWMI PSAR tables:

- Table 7-3, “Uranium Recovery and Recycle Control and Monitoring Parameters”
- Table 7-4, “Uranium Recycle and Recovery System Interlocks and Permissive Signals”

The target receipt and disassembly system includes the delivery and receipt of irradiated target casks from offsite, transfer of irradiated targets into the hot cell, disassembly of irradiated targets, and retrieval and transfer of irradiated target material for processing. Normal target receipt and disassembly system process functions are performed remotely using the FPC system HMI in the truck bay, cask preparation airlock, and the operating gallery (i.e., local control station). Redundant control functions are provided in the control room. Permissive signals required to start disassembly operations include an operable hot cell ventilation system,

functional and operational fission gas capture hood, proper positioning of the irradiated target material collection container, and an open waste drum transfer port.

The target dissolution system receives low-enriched uranium target material from the target receipt and disassembly system and dissolves the solid uranium and molybdenum target material in hot nitric acid. The concentrated uranyl nitrate solution is transferred to the molybdenum recovery and purification system. Normal target dissolution system process functions are performed by operators using remote in-cell cranes and manipulators and remotely using the FPC system HMI in the operating gallery. Redundant control functions are provided in the control room. Control parameters include, in part, dissolver agitator actuation and speed, flowrate, pump actuation, pump motor speed, temperature, and valve actuation. Monitored parameters include, in part, dissolver agitator speed, flowrate, flowrate totalizer, level, pressure, radiation, temperature, and valve position. Hard-wired safety interlocks are provided to capture dissolved gases in the event of high pressure in the pressure relief tank. The description of the target dissolution system is summarized in the following NWMI PSAR tables:

- Table 7-7, “Target Dissolution System Control and Monitoring Parameters”
- Table 7-8, “Target Dissolution System Interlocks and Permissive Signals”

The molybdenum recovery and purification system receives impure, concentrated molybdenum/uranium solution from the target dissolution system that is processed through ion exchange units to achieve the desired purified molybdenum product. The functions of product transfer and packaging in the molybdenum recovery and purification process are performed by operators using remote in-cell manipulators and remotely using the FPC system HMI in the operating gallery. Redundant control functions are provided in the control room. Control parameters include, in part, temperature, valve actuation, pump status, and capping unit actuation. Monitored parameters include, in part, density, flowrate, level, pressure, radiation, temperature, molybdenum weight, and valve position. The description of the molybdenum recovery and purification system is summarized in the following NWMI PSAR tables:

- Table 7-9, “Molybdenum Recovery and Purification System Control and Monitoring Parameters”
- Table 7-10, “Molybdenum Recovery and Purification System Interlocks and Permissive Signals”

The waste handling system consists of storage tanks for accumulating high-dose and low-dose waste liquids and adjusting the waste composition, and equipment that handles and encapsulates solid waste. Liquid waste is mixed with an adsorbent material. Solid waste is placed in a waste drum and encapsulated with a cement material to fill voids. All normal operating functions for low-dose liquid solidification are controlled locally using HMIs in the low-dose waste room. All normal operating functions for the high-dose liquid waste solidification, high-dose waste decay, spent resin dewatering, and solid waste handling hot cell operations are controlled and/or monitored from the low-dose waste room. Liquid waste collection and low-dose liquid waste evaporation operations are controlled from the facility control room. Control parameters include, in part, valve position, flowrate, pump actuation, pump motor speed, temperature, and grout mixer actuation. Monitored parameters include, in part, density, differential pressure, flowrate, flowrate totalizer, level, pressure, radiation,

temperature, and valve position. The description of the waste handling system is summarized in the following NWMI PSAR tables:

- Table 7-11, “Waste Handling System Control and Monitoring Parameters”
- Table 7-12, “Waste Handling System Interlocks and Permissive Signals”

The CAAS provides continuous monitoring indication, and recording of neutron or gamma radiation levels in areas where personnel may be present and wherever an accidental criticality event could result from facility operational processes. The CAAS is a vendor package with an integrated control system. Two detectors are provided in each area needing coverage. The CAAS control HMI is located in the control room and provides local alarms at the detector locations and at the CAAS HMI. The FPC system provides alarm and status monitoring in the control room. Uninterruptible power supplies provide emergency power to the CAAS during a loss-of-offsite power. Further discussion of the CAAS is found in Chapter 6, “Engineered Safety Features,” of this SER.

7.2.3 Engineered Safety Features Actuation Systems

The ESFs are active or passive features designed to mitigate the consequences of accidents and to keep radiological exposures to workers, the public, and the environment within acceptable values. The ESF systems have hard-wired controls that operate independently from the FPC systems. However, the ESFs are integrated into the FPC systems as a common point of HMI, monitoring, and alarming at the control room and local HMI workstations. ESFs that are required to be actuated by the I&C system and monitoring systems credited in the safety analysis are summarized in NWMI PSAR Table 7-13, “Engineered Safety Feature Actuation or Monitoring Systems.”

7.2.4 Control Console and Display Instruments

The control room contains overall process controls, monitoring, alarms, and acknowledgement and consists of a control console with two or three operator interface stations or HMIs and a master PLC or distributed controller. The control system is supported by a data highway of sensing instrument signals gathered by an Ethernet interface. The control room also contains dedicated controllers and HMI stations for the facility crane, closed-circuit television system, CAAS, and radiation monitoring systems.

7.2.5 Radiation Monitoring Systems

The radiation monitoring systems provide the facility control room personnel with a continuous record and indication of radiation levels at selected locations where radioactive materials may be present, stored, handled, or inadvertently introduced. The radiation monitoring systems include continuous air monitors located in work areas where there is a potential for airborne radioactivity; continuous exhaust stack monitoring for noble gases, particulates, and iodine; radiation area monitors located in areas where personnel may be present and where radiation levels could become significant; process control instruments to analyze for uranium concentrations; personnel monitoring including count rate meters, hand/foot monitors, and portal monitors; and passive dosimeters for all personnel entering restricted areas. When radiation levels exceed predetermined levels, visual and audible alarms actuate in the control room and at selected detector locations.

7.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 7.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility's I&C systems for the issuance of a construction permit under 10 CFR Part 50. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety evaluation, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9) and "Final Interim Staff Guidance [ISG] 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," (Reference 10) 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" (Reference 11). The staff's review in Chapter 2, "Site Characteristics," of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

7.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility's I&C systems are as follows:

> 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."

7.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).

- 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 (Reference 9).

- "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 (Reference 10).

- "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 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and

prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society standards) has been used in the staff's review of the PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

7.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff evaluated the technical information presented in NWMI PSAR Chapter 7.0, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of the NWMI production facility's I&C systems for the issuance of a construction permit, in accordance with 10 CFR Part 50. Sufficiency of the preliminary design and performance of the NWMI production facility's I&C systems is determined by ensuring the design and performance meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 7.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the staff's technical evaluation is described in SER Section 7.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility's I&C systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility's I&C systems based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. The staff's evaluation of the preliminary design of the NWMI production facility's I&C systems does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the NWMI production facility's I&C systems, as described in the FSAR submitted as part of NWMI's operating license (OL) application.

7.4.1 Summary Description

The staff evaluated the sufficiency of NWMI's summary description of its production facility's I&C systems, as described in NWMI PSAR Section 7.1, "Summary Description," for the issuance of a construction permit using the 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.

NWMI PSAR Section 7.1 discusses the I&C design in terms of RPF processes and systems including SNM preparation and handling processes, radioisotope extraction and purification processes, process utility and support systems, CAAS, radiation monitoring systems, facility ventilation system, and mechanical utility systems. NWMI PSAR Section 7.1 states that the FPC system and the BMS provide monitoring and control functions. The summary description is supported by a schematic showing the preliminary concept for the I&C system configuration.

As stated in Section 7b.1 of the ISG Augmenting NUREG-1537, Parts 1 and 2, the description of the I&C systems should, in part, provide "a summary description of the I&C systems, including

the design bases; the safety, considerations, and objectives; the operational characteristics of the production facility that determine or limit the I&C design; and the ways in which the various subsystems constitute the whole and interact to contribute to its essential functions. This summary should also include schematic, logic, and flow diagrams illustrating the various subsystems."

During its review, the staff noted that NWMI PSAR Section 7.1 identifies how and where the processes or systems are monitored and controlled without identifying any specific I&C technical aspects, philosophy, or objectives of the instrumentation. The discussion did not address redundancy, diversity, or isolation of functions except for the ESFs which are stated to be independent, hard-wired analog controls. In its responses to RAIs 7.1 through 7.4 (Reference 31) regarding the I&C systems, the applicant states that the I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the applicant stated that the preliminary design of the I&C systems (e.g., details regarding the design bases, technical aspects, safety, philosophy, and objective for all I&C components that monitor and control RPF processes or systems) was not developed for approval of the safety of any design feature or specification. The applicant noted that concepts like redundancy, independence, and diversity of systems are specifically identified as necessary in NWMI PSAR Sections 7.2 through 7.6. The applicant further stated that for the construction permit application, the preliminary design of the I&C systems is considered functional and at a conceptual level and that the intent at this stage was to describe the design methodology and provide reasonable assurance that the final design will conform to the design bases with an adequate margin for safety.

The staff found that this response addressed the acceptance criteria of NUREG-1537, Part 2, Section 7.1, because NWMI sufficiently described the I&C systems in the PSAR for the staff to understand the design methodology and demonstrated an adequate design basis for a preliminary design. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR, as it is not expected to significantly impact the construction of the facility.

NUREG-1537, Part 1, Section 7.1 states, in part, that the general description of each category of I&C subsystems should include the types of parameters monitored, the number of channels designed to monitor each parameter, and the actuating logic. NUREG-1537, Part 2, Section 7.1 states, in part, that the acceptance of the summary description should be based on its completeness in addressing the factors listed in NUREG-1537, Part 1.

NWMI PSAR Section 7.1 identifies how and where the processes or systems are monitored and controlled. NWMI didn't describe the types of parameters monitored, the number of channels monitoring each parameter, or the actuation logic. In response to RAI 7.1-1 (Reference 31), the applicant stated that NWMI PSAR Section 7.2 does not address specific aspects of the I&C system, although NWMI PSAR Tables 7-4 through 7-12 list the location and types of parameters anticipated to be monitored. The applicant further stated that for the construction permit application, the preliminary design of the I&C systems is considered functional and at a conceptual level and that the intent at this stage was to describe the design methodology and provide reasonable assurance that the final design will conform to the design bases with an adequate margin for safety.

The staff found that this response addressed the acceptance criteria of NUREG-1537, Part 2, Section 7.1, because NWMI sufficiently described the I&C systems in the PSAR for the staff to understand the design methodology and demonstrated an adequate design basis for a preliminary design for a construction permit. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided, in the FSAR when NWMI finalizes its design because it is not expected to significantly alter the construction of the facility. The staff will confirm that all aspects of the final design conform to the design basis during the evaluation of NWMI's FSAR submitted as part of the OL application.

NUREG-1537, Part 1, Section 7.1 states, in part, that the general description of each category of I&C subsystems should include a summary of the HMI principles used in the location of I&C. NUREG-1537, Part 2, Section 7.1 states, in part, that the acceptance of the summary description should be based on its completeness in addressing the factors listed in NUREG-1537, Part 1.

During its review, the staff noted that NWMI PSAR Section 7.1 discusses the I&C design in terms of RPF processes and systems and that the target fabrication process, target receipt and disassembly process, target dissolution process, molybdenum recovery and purification process, and low-dose liquid waste handling will be controlled by operators at local HMIs. NWMI PSAR Section 7.1 also identifies that operators at local HMIs will control the plant air system, gas supply system, process chilled water chillers, process steam boilers, demineralized water system, chemical supply system, and standby electric power system. NWMI PSAR Section 7.1 uses several different terms (i.e., operator interface displays, operator interface terminals, and HMIs) when referring to operator-controlled equipment. The applicant stated in its responses to RAIs 7.1 through 7.4 regarding the I&C systems (Reference 31) that the I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the applicant stated that the preliminary design of the I&C subsystems, including specific details on HMI, was not developed for approval of the safety of any design feature or specification. The applicant stated that to be consistent in the PSAR, terms like "operator interface displays" and "operator interface terminals" will be replaced with the single term, HMI (e.g., pages 7-I, 7-iv, 7-4, 7-15, 7-17, 7-18, 7-20, and 7-21). The applicant further stated that for the construction permit application, the preliminary design of the I&C systems is considered functional and at a conceptual level and that the intent at this stage was to describe the design methodology and provide reasonable assurance that the final design will conform to the design bases with an adequate margin for safety.

The staff finds that this response addressed the acceptance criteria of NUREG-1537, Part 2, Section 7.1, because NWMI sufficiently described the production facility I&C systems in the PSAR for the staff to understand the design methodology and demonstrated an adequate design basis for a preliminary design for a construction permit. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided in the FSAR when NWMI finalizes its design because it is not expected to significantly alter the construction of the facility. The staff will confirm that all aspects of the final design conform to the design basis during the evaluation of NWMI's FSAR submitted as part of the OL application.

Based on its review, the staff finds that the NWMI production facility I&C systems are designed to perform functions commensurate with the complexity of the processes therein and that the

description of the NWMI production facility I&C systems contains a sufficient level of detail for an overall understanding of the design methodology, functions, and relationships of the I&C systems to the preliminary design of the facility and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 7b.1. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided, in the FSAR, as it is not expected to significantly impact the construction of the facility.

Therefore, the staff concludes that the description of the NWMI production facility I&C systems, as described in NWMI PSAR Section 7.1, and as supplemented by the applicant's responses to RAIs, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

7.4.2 Design of Instrumentation and Control Systems

The staff evaluated the sufficiency of the design of the NWMI production facility's I&C systems, as described in NWMI PSAR Section 7.2, "Design of Instrumentation and Control Systems," and as supplemented by the applicant's responses to RAIs, for the issuance of a construction permit by evaluating the design criteria, design basis requirements, system description, and system performance analysis of the I&C systems using the guidance and acceptance criteria from Section 7b.2, "Design of Instrumentation and Control Systems," of the ISG Augmenting NUREG-1537, Parts 1 and 2, and the guidance from Section 7.2, "Design of Instrumentation and Control Systems," of NUREG-1537, Parts 1 and 2. NWMI PSAR Table 7-1 lists the standards and guidance used to support the design basis for the I&C systems.

NUREG-1537, Part 1, Section 7.2.3, "System Description," states, in part, that the system description in the PSAR should include equipment and major components as well as block, logic, and schematic diagrams. NUREG-1537, Part 1, Section 7.2.3 also states, in part, that the applicant should submit hardware and software descriptions and software flow diagrams for digital computer systems and that the applicant should describe how the system operational and support requirements will be met, how the operator interface requirements will be met, and should address the methodology and acceptance criteria used to establish and calibrate the trip or actuation setpoints, or interlock functions. The staff requested additional information to understand the relationship among all of the major I&C components.

In its response to RAI 7.2-1 (Reference 31), the applicant states that the I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the applicant states that the preliminary design of the I&C systems describing all of the equipment and major I&C components (e.g., block, logic, and schematic diagrams, software flow diagram, and description of how system operational and support requirements and operator interface requirements are met) was not developed for approval of the safety of any design feature or specification.

With respect to trip or actuation setpoints, the applicant states that as discussed in NWMI PSAR Section 7.2.4.1, "Facility Trip and Alarm Design Basis," and Section 7.2.4.2, "Analysis," trip or actuation setpoints for systems in Section 7.2 will be established to indicate a warning when a given parameter is approaching a setpoint and alarm/trip when it has reached a setpoint, both at the HMI and the control station, as appropriate. Alarm/trip setpoints will be established at levels that are protective of systems relied on for safety, as described in the PSAR (and follow-on

FSAR), particularly IROFS. The applicant explained that this means that alarm/trip setpoints will be established to provide reasonable assurance that these systems will be consistent with the design requirements and limitations established by the bounding analysis provided in the PSAR and follow-on FSAR. The applicant further stated that for the construction permit application, the preliminary design of the I&C systems is considered functional and at a conceptual level and the intent at this stage was to describe the design methodology and provide reasonable assurance that the final design will conform to the design bases with an adequate margin for safety.

The staff finds that the applicant addressed the format and content guidance of NUREG-1537, Part 1, Section 7.2.3, by providing sufficient detail of the design criteria, design bases, and system description for the NWMI production facility I&C system in the PSAR, related to the acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 7b.2, and demonstrates an adequate design basis for a preliminary design. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR, as it is not expected to significantly impact the construction of the facility.

NUREG-1537, Part 1, Section 7.2.4, "System Performance Analysis," states, in part, that the applicant should conduct a performance analysis of the proposed system to ensure that the design criteria and design bases are met and that licensing requirements for the performance of the system are specified. The analysis should describe the operation of the I&C system and present the analysis of how the system design meets the design criteria and design bases including a discussion of accuracy, reliability, adequacy and timeliness of I&C system action, trip setpoint drift, quality of components, and redundancy, independence, and impact of single failures. The staff requested additional information to understand the operation of the integrated I&C system.

In its response to RAI 7.2-2 (Reference 31), the applicant states that the I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions to provide reasonable assurance that the final design will conform to the design basis. In addition, the applicant stated that the preliminary design of the I&C systems describing the detailed methodology and operation of the integrated FPC system as it relates to ESF managing, monitoring, and actuation was not developed for approval of the safety of any design feature or specification.

The applicant indicated that NWMI PSAR Section 7.1 states, in part, "Engineered safety feature (ESF) systems will operate on actuation of an alarm setpoint reached for a specific monitoring instrument/device. For redundancy, this will be in addition to the FPC system or BMS ability to actuate ESF as needed."

NUREG-1537, Part 1, Section 7.2.5, "Conclusion," states that the applicant should summarize why the system design is sufficient and suitable for performing the functions stated in the design basis. The staff requested additional information to understand the suitability for performing the I&C functions stated as part of the design basis of the integrated I&C system.

In its response to RAI 7.2-3 (Reference 31), the applicant states that the preliminary design of I&C systems was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the applicant stated that the preliminary design of the I&C systems describing the detailed methodology and operation of the integrated I&C systems

was not developed for approval of the safety of any design feature or specification. The applicant further stated that NWMI PSAR Chapter 7.0, Table 7-2, will be expanded in the FSAR to provide a cross-reference to the specific section of each I&C section and how the system is suitable for performing the functions stated for each design basis applicability item.

Based on its review, the staff finds that the description of the NWMI production facility I&C systems contains a sufficient level of detail for an overall understanding of the functions and relationships of the I&C system to the preliminary design of the facility and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 7b.2.

Therefore, the staff concludes that the design of the NWMI production facility I&C systems, as described in NWMI PSAR Section 7.2, and as supplemented by the applicant's responses to RAIs, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration and will be provided in the FSAR when NWMI finalizes its design because it is not expected to significantly alter the construction of the facility. The staff will confirm that all aspects of the final design conform to the design basis during the evaluation of NWMI's FSAR submitted as part of the OL application.

7.4.3 Process Control Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production FPC systems, as described in NWMI PSAR Section 7.3, "Process Control Systems," for the issuance of a construction permit by evaluating the design criteria, design basis requirements, system description, and system performance analysis of the uranium recovery and recycle system, target receipt and disassembly system, target dissolution system, molybdenum recovery and purification system, waste handling system, and CAAS using the guidance and acceptance criteria from Section 7b.3, "Process Control Systems," of the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review procedures in the ISG Augmenting NUREG-1537, Part 2, Section 7b.3, the staff confirmed by reviewing the information in NWMI PSAR Table 7-1 that process control system information for all normal functions and systems described in other chapters of the PSAR is addressed in this section and verified that all design bases are justified, as presented in NWMI PSAR Chapter 7.0 and other relevant chapters of the PSAR.

The ISG Augmenting NUREG-1537, Part 2, Section 7b.3 states, in part, that the system should be designed with sufficient control of reactivity for all required production and SNM fuel reconditioning process operations. NWMI PSAR Table 7-3 lists the anticipated monitored and controlled parameters that may be used for reactivity control such a tank levels, flowrates, and uranium density. Additionally, NWMI PSAR Table 7-4 contains a preliminary list of interlocks and permissive switches to control processes to support the control of reactivity. The staff requested additional information to understand the key parameters that are monitored to ensure adequate criticality control.

In its response to RAI 7.3-1 (Reference 31), the applicant states that the I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the applicant stated that the preliminary design of the

I&C systems describing how the key parameters are monitored to ensure adequate criticality control (e.g., instruments to detect deviations from nominal concentrations and quantities, status of software development procedures) was not developed for approval of the safety of any design feature or specification.

Based on its review, the staff finds that the description of the NWMI production FPC systems contains a sufficient level of detail for an overall understanding of the functions and relationships of the I&C systems to the preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 7b.3.

Therefore, the staff concludes that the preliminary design of the NWMI production FPC systems is sufficient and meets the applicable regulatory requirements and acceptance criteria of NUREG-1537, Part 2 for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration and will be provided in the FSAR when NWMI finalizes its design because it is not expected to significantly alter the construction of the facility. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

7.4.4 Engineered Safety Features Actuation Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility ESF actuation systems, as described in NWMI PSAR Section 7.4, "Engineered Safety Features Actuation Systems," for the issuance of a construction permit by reviewing the system description, annunciation and display, and system performance analysis of the ESF actuation systems using the guidance and acceptance criteria from Section 7.5, "Engineered Safety Features Actuation Systems," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 7.5, the staff compared the design criteria and bases of the ESF actuation systems with the ESFs and accident scenarios, as well as compared the design and functional descriptions of the ESF actuation systems with the applicable criteria and functions in NWMI PSAR Chapter 6.0, "Engineered Safety Features," and NWMI PSAR Chapter 13.0, "Accident Analysis."

The ISG Augmenting NUREG-1537, Part 2, Section 7b.4, "Engineered Safety Features Actuation Systems," states, in part, that this section of the PSAR should describe the actuation systems for any ESFs discussed in NWMI PSAR Chapters 6.0 or 13.0. NUREG-1537, Part 1, Section 7.5, states, in part, that the applicant should describe the ESF actuation systems in sufficient detail to describe the functions required of the ESFs and the operation of the systems. The staff requested additional information to understand the functions and operation of the ESF actuation system.

In its response to RAI 7.4-1 (Reference 31), the applicant states that the preliminary design of the I&C systems was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the applicant stated that the preliminary design of the I&C systems describing the functionality and operation required of the ESFs was not developed for approval of the safety of any design feature or specification. NWMI PSAR Table 7-13 provides information on the anticipated technical means by which an ESF would be actuated. The staff notes that this mechanism is not described further in NWMI PSAR Section 7.4 because

the design has not been finalized, however this is not expected to significantly alter construction and can reasonably be left for later consideration during the staff's review of the FSAR submitted as part of the OL application.

The staff found that this response addressed the acceptance criteria of NUREG-1537, Part 2, Section 7.5 and the ISG Augmenting NUREG-1537, Part 2, Section 7b.4, and demonstrated a sufficient design basis for a preliminary design. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR, as it is not expected to significantly impact the construction of the facility.

Based on its review, the staff finds that the description of the NWMI production facility ESF actuation systems contains sufficient information for an overall understanding of the functions and relationships of the I&C system to the preliminary design of the facility and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.5, allowing the staff to make the following findings: (1) the applicant analyzed postulated accident scenarios at the facility, including accidents for which consequence mitigation by the ESFs is required or planned, and (2) the design considerations of the ESF actuation systems give reasonable assurance that the final design will detect changes in measured parameters as designed and will initiate timely actuation of the applicable ESFs.

Therefore, the staff concludes that the level of detail in the design of the NWMI production facility ESF actuation systems, as described in NWMI PSAR Section 7.4 and as supplemented by the applicant's responses to RAIs, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration and will be provided in the FSAR when NWMI finalizes its design because it is not expected to significantly alter the construction of the facility. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

7.4.5 Control Console and Display Instruments

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility control console and display information, as described in NWMI PSAR Section 7.5, "Control Console and Display Instrumentation," for the issuance of a construction permit using the 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.

Consistent with the review procedures of NUREG-1537, Part 2, Section 7.6, the staff compared the design bases and functional requirements of the control console and display information with other facility systems, compared the design of the control console with the acceptance criteria, and studied the arrangement of parameter displays, control devices, and the planned operator station to determine whether the operator can quickly understand information and take proper action.

NUREG-1537, Part 1, Section 7.6, states, in part, that the applicant should describe how the manual control inputs (i.e., pushbuttons, switches, and other equipment) have been grouped, oriented, and located with respect to the relevant display instruments. Further, the description and analysis should address how the output instruments are placed and should include drawings or photographs showing the arrangement of the display instruments and console

control equipment. NUREG-1537, Part 2, Section 7.6 states that the objective of the review is to evaluate whether displays and operator control systems are designed and located to promote ease and efficiency and should include descriptive information such as logic, functional control and schematic diagrams, and equipment location drawings.

During its review, the staff noted that NWMI PSAR Section 7.5 provides a high-level description of the control room and local HMIs and does not provide specific information on how the controls are physical grouped, oriented, or located with respect to the relevant display instruments and does not provide logic or functional control and schematic diagrams. This information is not expected to alter construction of the production facility and therefore can be reasonably be left for later consideration in the FSAR.

Based on its review, the staff finds that the description of the control console and display information contains a sufficient level of detail for an overall understanding of the functions and relationships of the I&C system to the preliminary design of the production facility and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.6, allowing the staff to make the following findings: (1) the applicant indicated that systems important to the safe and effective operation of the facility (i.e., FPC system, BMS, CAAS, facility crane, closed-circuit television system, radiation monitoring systems, and all facility on-site and off-site communications) will be displayed at the control console or be present in the control room, and (2) the annunciator and alarm panels on the control console will give assurance of the operability of systems important to adequate and safe facility operation.

Therefore, the staff concludes that the preliminary design of the NWMI production facility control console and display information, as described in NWMI PSAR Section 7.5 and as supplemented by the applicant's responses to RAIs, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration and will be provided in the FSAR when NWMI finalizes its design because it is not expected to significantly alter the construction of the facility. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

7.4.6 Radiation Monitoring Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility radiation monitoring systems, as described in NWMI PSAR Section 7.6, "Radiation Monitoring Systems," for the issuance of a construction permit, in part, by reviewing the descriptions of the radiation monitoring equipment, as well as the description of the CAAS in NWMI PSAR Section 7.3.7, "Criticality Accident Alarm System," using the guidance and acceptance criteria from Section 7.7, "Radiation Monitoring Systems," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 7.7, the staff compared the design bases for the radiation monitoring systems with giving reliable indication of the presence of radiation or release of radioactive material in the various areas monitored and in the monitored effluent streams from the facility.

Based on its review, the staff finds that the description of the NWMI production facility radiation monitoring systems contains a sufficient level of detail for an overall understanding of the functions and relationships of the I&C system to the preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.7, allowing the staff to make

the following findings: (1) the applicant described the preliminary design of the radiation monitoring system and the preliminary design is applicable to the anticipated sources of radiation; (2) the PSAR discusses all likely radiation and radioactive sources anticipated at the NWMI production facility and describes equipment, systems, and devices that will give reasonable assurance that all such sources will be identified and accurately evaluated; and (3) the radiation monitoring systems described in the PSAR give reasonable assurance that dose rates and effluents at the facility will be acceptably detected, and that the environment and the health and safety of the facility staff and public will be acceptably protected.

Therefore, the staff concludes that the level of detail of the NWMI production facility radiation monitoring systems, as described in NWMI PSAR Section 7.6, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration and will be provided in the FSAR when NWMI finalizes its design because it is not expected to significantly alter the construction of the facility. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR.

7.4.7 Probable Subjects of Technical Specifications

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant's identification and justification for the selection of those variables, conditions, or other items that are determined to be probable subjects of TSs with special attention given to those items that may significantly influence the final design. The evaluation of the TSs is provided in SER Chapter 14.

NWMI PSAR Chapter 14.0, "Technical Specifications," states that the integrated safety analysis (ISA) process identified SSCs that are defined as IROFS. The importance of these SSCs will also be reflected in the TSs. Each IROFS will be examined and translated into a limiting condition for operation (LCO). This translation will involve identifying the most appropriate specification to ensure operability and a corresponding surveillance periodicity for the IROFS.

The PSAR also provided an outline for the TSs that will be prepared during the development of the OL application. This outline includes actions, administrative controls, LCOs, limiting safety system settings, safety limits, and surveillance requirements.

In response to RAI 14.0-1 (Reference 13), NWMI developed a table of the potential items or variables that are expected topics of TSs. This table was subsequently incorporated in Chapter 14.0 of the NWMI PSAR as Table 14-1, "Potential Technical Specifications." NWMI identifies the CAAS as a probable subject of TSs based on its involvement with preventing releases of radioactive materials in the event of an accident.

7.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility I&C systems, including probable subjects of TSs, as described in NWMI PSAR Chapter 7.0, and finds that preliminary design of the I&C systems, including the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets the applicable regulatory requirements and acceptance criteria in NUREG-1537, Part 2.

Based on these findings the staff makes the following conclusions for the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the production facility I&C systems, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis of the production facility I&C systems and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that: (i) the construction of the NWMI production facility will not endanger the health and safety of the public, and (ii) construction activities can be conducted in compliance with the Commission's regulations.

(4) The issuance of a permit for the construction of the production facility would not be inimical to the common defense and security or to the health and safety of the public.

8 ELECTRICAL POWER SYSTEMS

Electrical power systems are designed for operation of the proposed Northwest Medical Isotopes, LLC (NWMI or the applicant) production facility. In addition to the NWMI production facility's normal electrical power (NEP) system, the facility has an emergency electrical power system, comprising the diesel-generator-powered standby electrical power (SEP) system and several uninterruptable power supplies (UPSs). Given a loss of normal electrical service, the SEP and UPSs provide sufficient electrical power 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. The UPSs provide power to certain systems and equipment that are considered items relied on for safety (IROFS), which are needed to protect workers and the public, in case of postulated design-basis events involving the loss of NEP.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility electrical power systems, as presented in Chapter 8.0, "Electrical Power Systems," of the NWMI preliminary safety analysis report (PSAR), Revision 3. As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area which are discussed below. In the SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

8.1 Areas of Review

The staff reviewed PSAR Chapter 8.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design of the NWMI production facility electrical power systems for the purposes of issuance of a construction permit. As part of this review, the staff evaluated descriptions and discussions of the electrical power systems, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI production facility electrical power systems was evaluated to ensure the sufficiency of principal design criteria; design bases; and information relative to types of major equipment, general arrangement and interconnections, and high-level functional descriptions, to provide reasonable assurance that the final design will conform to the design bases. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables,

conditions, or other items that are determined to be probable subjects of technical specifications (TSs) for the facility, with special attention given to those items that may significantly influence the final design.

Areas of review for this chapter included normal and emergency electrical power systems. Within these review areas, the staff assessed the preliminary analysis of the NEP systems to ensure the safe operation and shutdown of the NWMI production facility, including the response of the facility to interruptions of normal electrical service, the ability of the facility to be maintained in a safe condition with and without the availability of normal electrical service, the monitoring and control of routine releases, and the prevention of uncontrolled releases of radioactive material in the event that NEP service is interrupted. The staff examined the ranges of power required; the electrical power distribution schematic diagram, NWMI PSAR Figure 8-1, "Radioisotope Production Facility Electrical One Line Diagram," design and performance characteristics, and probable subjects for TSs.

The staff also assessed the preliminary design and analysis of the NWMI production facility 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 facility workers and the public.

8.2 Summary of Application

NWMI PSAR Section 8.1, "Normal Electrical Power Systems," provides a high-level description of the NWMI production facility NEP system. The NEP system receives 480-volt, 3-phase, 60-hertz, alternating current from the local utility, Columbia Water and Light, via the Grindstone Substation. The NEP system is used for normal operation and normal shutdown of the facility. The total power requirement of the RPF will be approximately 2,998 kilowatts (kW).

NWMI PSAR Section 8.1 states that the design basis of the NEP system is to provide sufficient and reliable power to all systems and components requiring electrical power for normal operations, including the electrical requirements of the systems, equipment, instrumentation, controls, communications, and devices related to the safety functions. The NEP system supports safety-related (SR) and non-SR systems during normal operations and normal shutdown. In the event of loss of normal power, several SR UPSs provide power to certain SR systems and components, considered IROFS, for protection of workers and the public, until the standby diesel generator (SDG) automatically comes on line and the automatic transfer switch shifts the SEP loads to the SDG bus. The SDG powers the SEP system, which supplies certain SEP loads to allow the facility to continue to operate on a limited basis, and also extends the supply of power to the UPS loads.

NWMI PSAR Section 8.2, "Emergency Electrical Power Systems," describes the NWMI production facility emergency electrical power systems. The emergency power systems consist of the diesel-generator-powered SEP and several UPSs, including unit devices, rack-mounted, and/or larger capacity cabinet units. The emergency electrical power is the temporary substitute of normal electric power in the event of a loss-of-offsite power (LOOP). Emergency electrical systems are designed to prevent damage to the facility and releases of radioactivity to the environment. While the facility is designed for passive shutdown, if normal electrical service is interrupted, certain functions require emergency electrical power for maintaining the facility in a safe condition following shutdown. As described in PSAR Section 8.2, in the event of a LOOP, the SEP provides power to allow the facility to continue to operate on a limited basis. The UPSs will be designed to provide reliable power for the SR equipment required for facility instrumentation, control, monitoring, and other vital functions (e.g., fire alarms, emergency

lighting, and radiation monitoring) needed to shut down the facility and maintain it in a safe shutdown condition. Although not described in detail in the PSAR, the staff notes that UPSs typically consist of direct current storage batteries, battery chargers and inverters, and supply distribution panels for SR loads. The UPSs are designed to provide emergency power to SR loads until the SDG can provide stable electrical power.

NWMI PSAR Table 8-1, "Summary of Radioisotope Production Facility and Ancillary Facilities Electrical Loads," provides the list of the systems and equipment served by the NEP, the SEP, and the UPSs. The systems that are served by the UPSs are facility process control and communication, fire protection, radiation monitoring and the criticality accident alarm system (CAAS), safeguards and security, and certain parts of the general facility electrical system, such as emergency lighting. All other systems are designed to fail safe in the event of a LOOP. Facility operation on a limited basis can continue once the SDG comes on line because many of the NEP loads can be powered by the SEP, which then also takes over to provide power to the UPSs and their loads.

NWMI PSAR Figure 8-1 shows NWMI Drawing NWMI-01-DWG-EP-0601, Revision B, "Electrical One-Line Diagram 15kV Site and RPF Building Distributions." Notably absent from this diagram are the UPSs. The absence of UPSs on the on-line diagram was discussed during the July 11, 2017, meeting of the Advisory Committee on Reactor Safeguards (ACRS) Northwest Medical Isotopes Subcommittee. The applicant stated during this meeting that the exact number and location of the UPSs are yet to be finally determined (Reference 21). NWMI PSAR Section 8.1 states that NWMI PSAR Figure 8-1 will be updated for the final design and submitted as part of the operating license (OL) application.

8.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 8.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility's electrical power systems for the issuance of a construction permit under 10 CFR Part 50. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described by NWMI, and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the

application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9) and "Final Interim Staff Guidance [ISG] 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," (Reference 10) 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" (Reference 11). The staff's review in Chapter 2, "Site Characteristics," of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

8.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility's electrical power systems are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.35, "Issuance of construction permits."
- 10 CFR 50.40, "Common standards."

8.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).

- 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 (Reference 9).

- "Final Interim Staff Guidance [ISG] 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 (Reference 10).

- "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 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society standards) has been used in the staff's review of the PSAR. The use of additional guidance is 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 PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

8.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 8.0 to assess the sufficiency of the preliminary design and performance of the NWMI production facility's electrical power systems for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance of the electrical power systems is determined by ensuring the design and performance are consistent with the design bases, which meet the applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 8.3, "Regulatory Basis and Acceptance

Criteria," of this SER. A summary of the staff's technical evaluation is described in SER Section 8.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility normal and emergency power systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility normal and emergency electrical power systems based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. The staff's evaluation of the preliminary design of the NWMI production facility electrical power systems does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the NWMI production facility electrical power systems, as described in the FSAR submitted as part of NWMI's OL application.

8.4.1 Normal Electrical Power System

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility NEP system, as described in NWMI PSAR Section 8.1, for the issuance of a construction permit using the guidance and acceptance criteria from Section 8.1, "Normal Electrical Power Systems," of NUREG-1537, Parts 1 and 2. The staff review included the off-site power service, power distribution system, and the systems and equipment served by the NEP, as shown in NWMI PSAR Table 8-1.

Consistent with the review procedures in NUREG-1537, Part 2, Section 8.1, the staff: (1) compared the design bases of the normal electrical systems with the requirements of systems and components that rely on electrical power, (2) confirmed that the design characteristics and components of the normal electrical system could provide the projected range of services, (3) analyzed possible malfunctions, accidents, and interruptions of electrical services to determine their effect on safe facility operation, and (4) determined if proposed redundancy of electrical circuits is sufficient to ensure safe operation and shutdown and to avoid uncontrolled release of radioactive material.

Based on its review, the staff finds that the level of detail provided on the NWMI production facility's NEP systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 8.1 allowing the staff to make the following findings: (1) the design bases and functional characteristics of the NEP systems will support all required loads, and (2) the design of the NEP system provides that, in the event of the loss or interruption of electrical power, the facility can be safely shut down and maintained in a safe shutdown condition.

Therefore, the staff concludes that the preliminary design of the NWMI production facility NEP systems, as described in NWMI PSAR Section 8.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis (e.g., the design and location of electrical wiring that prevents inadvertent electromagnetic interference between the electrical power service and SR instrumentation and control circuits) can reasonably be left for later consideration since the facility's design bases support all required loads and safe shutdown. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

8.4.2 Emergency Electrical Power Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility emergency electrical power systems, as described in PSAR Section 8.2, for the issuance of a construction permit using the guidance and acceptance criteria from Section 8.2, "Emergency Electrical Power Systems," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 8.2, the staff compared the design bases of the emergency electrical power system with the requirements for emergency electrical power for systems and components requiring electrical power and compared the design and functional characteristics with the design bases to verify compatibility. The staff review included the SEP and UPSs and their loads, seismic and environmental qualification, independence, single-failure criterion, and safe shutdown.

NWMI PSAR Chapter 8.0 does not provide detailed information on seismic or environmental qualification of electrical equipment important to safety, and it does not give the safety/seismic classification of each individual component. However, the general approach to seismic and environmental qualification of electrical systems and components is described in NWMI PSAR Chapter 3.0, "Design of Structures, Systems, and Components."

8.4.2.1 *Seismic Qualification of Electrical Equipment Relied on for Safety*

NWMI PSAR Table 3-24, "System Safety and Seismic Classification and Associated Quality Level Group," lists the NEP system and the SEP system as having components that are classified as SR and are classified as Seismic Classification C-I and Quality Level Group QL-1. However, NWMI PSAR Section 8.1.1, "Design Basis of the Normal Electric Power System," clarifies this by stating, in part, that there are no items relied on for safety (IROFS) applicable to the NEP system, per Chapter 13.0, "Accident Analysis," Section 13.2.5, "Loss of Power."

NWMI PSAR Subsection 3.5.1.3.2, "Seismic Classification for Structures, Systems, and Components," states:

> SSCs identified as IROFS will be designed to satisfy the general seismic criteria to withstand the effects of natural phenomena (e.g., earthquakes, tornados, hurricanes, floods) without loss of capability to perform their safety functions. ASCE 7, Chapter 11, sets forth the criteria to which the plant design bases demonstrate the capability to function during and after vibratory ground-motion associated with the safe-shutdown earthquake conditions.
>
> The seismic classification methodology used for the RPF complies with the preceding criteria, and with the recommendations stated in Regulatory Guide 1.29, *Seismic Design Classification*. The methodology classifies SSCs into three categories: seismic Category I (C-I), seismic Category II (C-II), and non-seismic (NS).
>
> Seismic C-I applies to both functionality and integrity, while C-II applies only to integrity. SSCs located in the proximity of IROFS, the failure of which during a

safe-shutdown earthquake could result in loss of function of IROFS, are designated as C-II. Specifically:

- C-I applies to IROFS. C-I also applies to those SSCs required to support shutdown of the RPF and maintain the facility in a safe shutdown condition.

- C-II applies to SSCs designed to prevent collapse under the safe-shutdown earthquake. SSCs are classified as C-II to preclude structural failure during a safe-shutdown earthquake, or where interaction with C-I items could degrade the functioning of a safety-related SSC to an unacceptable level or could result in an incapacitating injury to occupants of the main control room.

- NS [non-seismic] SSCs are those that are not classified seismic C-I or C-II.

With respect to the methodology for seismic qualification of electrical equipment relied on for safety (i.e., SR and/or important to safety), NWMI PSAR Section 3.4.2, "Seismic Qualification of Subsystems and Equipment," discusses the methods by which the facility systems and components are qualified to ensure functional integrity. As described in NWMI PSAR Section 3.4.2, based on the characteristics and complexities of the subsystem or equipment, seismic qualification may be by rigorous analysis, testing, or a combination of analysis and testing.

NWMI PSAR Section 3.4.2.2, "Qualification by Testing," states that in accordance with NRC Regulatory Guide 1.100, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants," active electrical equipment important to or relied on for nuclear safety will be required to be seismically qualified in accordance with IEEE Standard 344, "IEEE Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations."

NWMI PSAR Subsection 3.5.2.5.2, "Instrumentation and Electrical," states, in part:

> C-I instrumentation and electrical equipment (identified in Table 3-24) is designed to resist and withstand the effects of the postulated DBEQ [design-basis earthquake] without functional impairment. The equipment will remain operable during and after a DBEQ. The magnitude and frequency of the DBEQ loadings that each component experiences will be determined by its location within the RPF. In-structure response curves at various building elevations will be developed to support design. The equipment (e.g., batteries and instrument racks, control consoles) has test data, operating experience, and/or calculations to substantiate the ability of the components and systems to not suffer loss of function during or after seismic loadings due to the DBEQ. This information will be completed during final design of the RPF and provided in the Operating License Application.

Based on its review, the staff finds that the general approach to seismic qualification of electrical equipment described in the PSAR is consistent with the maturity of the design in that the details of seismic qualification are highly dependent on specific items of equipment, their design-basis earthquake functional requirements and locations. Therefore, the staff concludes that the general approach and information provided in the PSAR is sufficient for the purposes of issuance of a construction permit for the NWMI production facility as it describes the methods by which the facility systems and components are qualified to ensure functional integrity. Further details of the seismic qualification of electrical equipment important to safety can reasonably be left for later consideration in the FSAR. The staff will evaluate the FSAR and associated documents during the OL application review.

8.4.2.2 *Environmental Qualification of Electrical Equipment Relied on for Safety*

NWMI PSAR Table 3-22, "Design Criteria Requirements," states that for environmental and dynamic effects, the NWMI production facility design criterion is to provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions, but further states that SSCs important to safety are designed to accommodate effects of, and to be compatible with, the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. As further described in PSAR Table 3-22, due to the low temperature and pressure of the NWMI production facility processes, dynamic effects due to pipe rupture and discharging fluids are not applicable to the facility.

NWMI PSAR Section 3.5.2, "Radioisotope Production Facility," states, in part:

> Safety-related systems and components will be qualified using the applicable guidance in the [IEEE] Standard IEEE 323, *IEEE Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations*. The qualification of each safety-related system or component needs to demonstrate the ability [to] perform the associated safety function:
>
> - Under environmental and dynamic service conditions in which they are required to function [and]
> - For the length of time the function is required

Further, this section states, in part, "Additionally, non-safety-related components and systems will be qualified to withstand environmental stress caused by environmental and dynamic service conditions under which their failure could prevent satisfactory accomplishment of the safety-related functions."

NWMI PSAR Section 3.5.2.6, "Qualification Methods," states:

> Environmental qualification of safety-related mechanical, instrumentation, and electrical systems and components is demonstrated by tests, analysis, or reliance on operating experience. Qualification method testing will be accomplished either by tests on the particular equipment or by type tests performed on similar equipment under environmental conditions at least as severe as the specified conditions. The equipment will be qualified for normal and accident environments. Qualification data will be maintained as part of the permanent plant record in accordance with the NWMI QAPP [Quality Assurance Program Plan].

Based on its review, the staff finds that the general approach to environmental qualification of electrical equipment described in the PSAR is consistent with the maturity of the design in that the details of environmental qualification are highly dependent on specific items of equipment, their design-basis event functional requirements and locations. Therefore, the staff concludes that the general approach and information provided in the PSAR is sufficient for the purposes of issuance of a construction permit for the NWMI production facility. Further details of the environmental qualification of electrical equipment important to safety can reasonably be left for later consideration in the FSAR because the worst-case design-basis event is not expected to subject SR electrical equipment to harsh environments. The staff will evaluate the FSAR and associated documents during the OL application review.

8.4.2.3 *Independence*

With regard to independence, NWMI PSAR Section 3.5.2 states, in part, that the NWMI production facility is designed to meet IEEE 603, "Standard Criteria for Safety Systems for Nuclear Power Generating Stations," for separation and isolation of SR systems and components. Based on its review, the staff finds that this level of detail on electrical independence is sufficient for the purposes of issuance of a construction permit for the NWMI production facility because the design bases seek to avoid common mode failures. Further details of independence can reasonably be left for later consideration in the FSAR. The staff will evaluate the FSAR and associated documents during the OL application review.

8.4.2.4 *Single-Failure Criterion*

With regard to the single-failure criterion, NWMI PSAR Section 3.5.1.2, "Classification Definitions," states, in part, that:

> Single failure is considered a random failure and can include an initiating event (e.g., component failure, natural phenomenon, external man-made hazard) or consequential failures. Mechanical, instrumentation, and electrical systems and components required to perform their intended safety function in the event of a single failure are designed to include sufficient redundancy and independence. This type of design verifies that a single failure of any active component does not result in a loss of the capability of the system to perform its safety functions. Mechanical, instrumentation, and electrical systems and components are designed to ensure that a single failure, in conjunction with an initiating event, does not result in the loss of the RPF's ability to perform its intended safety function. Design techniques such as physical separation, functional diversity, diversity in component design, and principles of operation, will be used to the extent necessary to protect against a single failure.

Based on its review, the staff finds that this level of detail on single-failure criterion is sufficient for the purposes of issuance of a construction permit for the NWMI production facility because the design bases consider physical separation, functional diversity, diversity in component design, and principles of operation to protect against single failure. Further details of the single-failure criterion can reasonably be left for later consideration in the FSAR. The staff will evaluate the FSAR and associated documents during the OL application review. In addition, based on discussions during meetings of the ACRS Northwest Medical Isotopes Subcommittee, the applicant committed to examine the possible effects of malfunctioning electrical equipment resulting in possible unexpected effects of interaction between otherwise unrelated, independent, and separate circuits (e.g., so-called "hot shorts") caused by various credible hazards (e.g., fire, explosions, flooding, earthquakes, etc.). The staff is tracking this issue in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER.

8.4.2.5 *Safe Shutdown*

NWMI PSAR Section 8.1.2, "Design for Safe Shutdown," states that in the event of the loss of NEP, UPSs automatically provide power to the NWMI production facility systems and components that support the safety functions protecting workers and the public. UPSs support the process and facility monitoring and control systems, facility communication and security

systems, emergency lighting, fire alarms, and radiation protection and the CAAS until the SDG is running and powering the SEP loads.

During its review, the staff noted certain inconsistencies in the information presented on the emergency electrical power systems. Specifically, NWMI PSAR Section 8.1.2, Revision 0, stated that the UPSs will be designed to operate for up to 90 minutes, except that the UPS for the fire protection system will be designed to operate for up to 24 hours. The 90-minute value was also stated in NWMI PSAR, Revision 0, Sections 8.2.4 and 8.2.5. However, NWMI PSAR Section 3.5.2.7.9, Revision 0, "Standby Electrical Power," stated that the design basis value for the UPSs is to "maintain power availability for a minimum of 120 [minutes] post-accident…."

In response to request for additional information (RAI) 8.2-1 (Reference 57), the applicant stated: "PSAR Sections 8.1.2 and 8.2 were changed to 120 minutes to reflect the design basis in PSAR Section 3.5.2.7.9." The staff finds that this response resolves the identified inconsistency. The staff reviewed revision 3 to NWMI PSAR Chapter 8.0 and confirmed that the applicant's proposed resolution was incorporated in the PSAR.

NWMI PSAR Section 8.2, Revision 0, states that a 1,000-kW (1,341 hp) diesel generator will provide SEP. However, PSAR Section 8.2.2, Revision 0, "Ranges of Emergency Electrical Power Required," states, in part, that: "The total peak SEP required for the RPF is 1,140 kW (1,528 hp)." Further, Table 8-1, Revision 0, lists the facility electrical loads and shows that the total SEP required is 1,178.6 kW (1,585 hp). In addition, NWMI PSAR Chapter 19.0, Revision 0, "Environmental Review," Table 19-60, "Emissions for Standby Emergency Diesel Generator," cites 2,600 kW as the basis for diesel generator emissions.

In response to RAI 8.2-2 (Reference 57), the applicant stated: "The column headings in Table 8-1 of PSAR Chapter 8.0 were changed from '... power requirement' to '... peak power load' to be consistent with the description preceding the table. PSAR Section 8.2.2 will be modified to reflect the peak power of 1,178.6 kW (1,585 hp), as determined from Table 8-1. PSAR Chapter 19.0 used a larger estimate to ensure that emissions were bounded."

The staff finds that the applicant's explanation in its RAI response regarding the SEP DG power estimate of 2,600 kW to bound emissions in NWMI PSAR Chapter 19.0 (Table 19-60) is satisfactory in that this value is conservative as compared to the values provided in NWMI PSAR Chapter 8.0. Changing the power rating cited in NWMI PSAR Section 8.2.2 "Ranges of Emergency Electrical Power Required," to 1,178.6 kW (1,585 hp) to be consistent with Table 8-1 is also satisfactory in that it resolves the identified inconsistency. The staff reviewed the most recent revision to NWMI PSAR Chapter 8.0 and confirmed that the applicant's proposed resolution was incorporated in the PSAR. However, the first paragraph of PSAR Section 8.2 in Revision 3 of PSAR Chapter 8.0 still states, in part, that "A 1,000-kW (1,341 hp) diesel generator will provide SEP." Thus, neither the capacity of the SEP DG given as 1,000 kW (1,341 hp) in NWMI PSAR Section 8.2 nor the discrepancy between this value and that given in NWMI PSAR Table 8-1 and NWMI PSAR Section 8.2.2 was addressed in response to an RAI or corrected in subsequent revisions to NWMI PSAR Chapter 8.0.

The staff finds that this inconsistency is acceptable for the purposes of issuing a construction permit since the peak power estimates used in NWMI PSAR Chapter 8.0 are bounded by the SEP DG power estimates used to bound emissions in NWMI PSAR Chapter 19.0. The staff will review details of the fuel consumption rates at the peak load values in the FSAR in order to ensure that there is sufficient diesel fuel capacity for the complete range of 11-14 hours of operation as stated in NWMI PSAR Section 8.2. Additionally, based on its review, the staff finds

that this level of detail on safe shutdown is sufficient for the purposes of issuance of a construction permit for the NWMI production facility. Further details of safe shutdown can reasonably be left for later consideration in the FSAR. The staff will evaluate the FSAR and associated documents during the OL application review.

Based on its review, the staff finds that the level of detail provided on the NWMI production facility emergency electrical power systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 8.2, allowing the staff to make the following findings: (1) the design bases and description of functional characteristics of the facility's emergency electrical power systems are sufficient to provide the necessary range of SR services; (2) the design and operating characteristics of the source of emergency electrical power are basic and reliable, ensuring availability if needed; and (3) the design of the emergency electrical power system should not interfere with safe facility shutdown or lead to facility damage if the system malfunctions during normal operation.

Therefore, the staff concludes that the preliminary design of the NWMI production facility emergency electrical power systems is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR.

8.4.3 Probable Subjects of Technical Specifications

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of TSs for the NWMI production facility electrical power systems, with special attention given to those items which may significantly influence the final design.

NWMI PSAR Section 8.1.9, "Technical Specifications," (for the NEP system) states, "As evaluated in Chapter 13.0, the RPF is designed to safely shut down without NEP for occupational safety and for protection of the public and environment. The NEP system will not require a technical specification per the guidelines in Chapter 14.0, "Technical Specifications."

NWMI PSAR Section 8.2.13, "Technical Specifications," (for the emergency power systems) states, "As evaluated in Chapter 13.0, the RPF is designed to safely shut down without SEP consistent with occupational safety and protection of the public and the environment. The UPS systems, as required, are anticipated to be part of the technical specification for the system being supported. The SEP system will not require a technical specification per the guidelines in Chapter 14.0."

Based on the information provided in NWMI PSAR Sections 8.1.9 and 8.2.13, and in NWMI PSAR Chapter 14.0, the staff finds that the applicant's identification and justification for the UPS being the probable subject of a TS because of its required safety function to provide electrical power to engineering safety features, emergency lighting, radiation monitoring, and shutdown instrumentation and control during a loss of NEP is sufficient and meets the applicable regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. A detailed evaluation of TSs, including limiting conditions for operation and surveillance requirements, will be performed during the review of the NWMI OL application.

8.5 Summary and Conclusions

The staff evaluated descriptions and discussions of the NWMI production facility electrical power systems, including probable subjects of TSs, as described in PSAR Chapter 8.0 and finds that the preliminary design of the electrical power systems, including the principal design criteria; design bases; and information relative to general arrangement, major SSCs, and a high-level functional description: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in or referenced in applicable guidance. Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the NWMI production facility electrical power systems, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis of the electrical power systems and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that taking into consideration the site criteria contained in 10 CFR Part 100, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public. There is reasonable assurance that: (i) the construction of the NWMI production facility will not endanger the health and safety of the public, and (ii) construction activities can be conducted in compliance with the Commission's regulations.

9 AUXILIARY SYSTEMS

This chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility auxiliary systems, as presented in Revision 3 of Chapter 9.0, "Auxiliary Systems," of the NWMI preliminary safety analysis report (PSAR), as supplemented with requests for additional information (RAIs) responses. The preliminary design description of the NWMI production facility auxiliary systems in PSAR Chapter 9.0 focuses on those structures, systems, and components (SSCs) and associated equipment that constitute the auxiliary safety systems and includes the overall design bases, system descriptions and classifications, including functional requirements and system architecture, operational analyses and safety functions, instrumentation and controls (I&C), and probable topics for technical specifications (TSs). As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, SSCs related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

9.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 9.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design of the NWMI production facility auxiliary systems for the purposes of issuance of a construction permit. As part of this review, the staff evaluated descriptions and discussions of the NWMI production facility auxiliary systems, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI production facility auxiliary systems was evaluated to ensure the sufficiency of principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions, to provide reasonable assurance that the final design will conform to the design bases. The information provided by the applicant in NWMI PSAR Chapter 9.0, was also evaluated to determine whether it was adequate to provide reasonable assurance that a 10 CFR Part 50 construction permit for the NWMI production facility could be issued in accordance with applicable regulatory requirements and guidance on the basis that the facility could be constructed without undue risk to the health and safety of the public. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items, which are determined to be probable subjects of TSs for the facility, with special attention given to those items which may significantly influence the final design. The staff documented its review of NWMI's probable subjects of TSs for the facility in Chapter 14, "Technical Specifications," of this SER.

9.2 Summary of Application

NWMI PSAR Section 9.1, "Heating Ventilation and Air Conditioning Systems" describes the heating, ventilation, and air conditioning (HVAC) systems that provide clean air to the NWMI production facility at required temperatures and humidity for personnel and equipment, handle process off-gassing, and act to contain airborne radioactivity or toxic material and limit their offsite release to protect the health and safety of workers and the public. The information in PSAR Section 9.1 includes the design bases, system description, including drawings and specifications of principal components and any special materials, operational analysis and safety function, I&C requirements, and probable topics for TSs.

NWMI PSAR Section 9.1.1, "Design Basis," addresses the design basis elements of the ventilation system and the offgas treatment system (OTS). The PSAR states that the ventilation system is designed to provide confinement of hazardous chemical fumes and airborne radiological materials and conditioning of the NWMI production facility environment for facility personnel and equipment. It enumerates five specific ventilation system design basis elements. Additionally, the PSAR states that the OTS will provide primary system functions to protect on-site and off-site personnel from radiological and other industrial related hazards, listing seven specific OTS design basis functions. Additional design basis information is provided in NWMI PSAR Chapter 3.0, "Design of Structures, Systems, and Components."

NWMI PSAR Section 9.1.2, "System Description," describes the NWMI production facility ventilation system, including the air supply, process ventilation and exhaust subsystem. The PSAR describes the system of cascading ventilation zones with successively lower atmospheric pressures through which air flows from areas of lowest concentration of contaminants to the highest. The clean zone, mostly occupied spaces, is at a positive pressure, fed by the air supply subsystem.

The air supply subsystem draws in outside air and heats or cools it as required for the space or equipment being supplied. The various exhaust systems draw from various zones and spaces to maintain the desired differential pressures between zones and across high-efficiency particulate air (HEPA) filters and to collect radioactive and chemical contaminates in the air for treatment before release to the environment. NWMI states in the PSAR that various means, mainly HEPA filtration and activated carbon, will help ensure that air exhausted to the atmosphere meets Title 40 of the *Code of Federal Regulations* Part 61, "National Emission Standards for Hazardous Air Pollutants," 10 CFR Part 20, "Standards for Protection against Radiation," and applicable State law. The exhaust stack is to be monitored for effluents to ensure compliance. NWMI PSAR Table 9-1, "Facility Areas and Respective Confinement Zones," lists all of the spaces in the production facility and shows in which ventilation/confinement zone it is located.

NWMI PSAR Section 9.1.2.1, "Confinement," describes the confinement function, explaining that confinement, an engineered safety feature of the HVAC system, is the boundary that surrounds radioactive materials and the associated ventilation system. In this section, Figures 9-1, "Ground Level Confinement"; 9-2, "Upper Level Confinement"; and 9-3, "Lower Level Confinement," are floor plans of the ground level, upper level, and lower level, respectively, of the NWMI production facility, showing the various confinement zone boundaries.

NWMI PSAR Section 9.1.2.2, "Supply Air System," describes the supply air subsystem followed by Figure 9-4, "Ventilation System Diagram 1," and Figure 9-5, "Ventilation System Diagram 2,"

which are one-line, piping and instrumentation diagrams (P&ID) schematically showing the system configuration, including ducting, fans/blowers, filters, dampers, and instrumentation such as flow cell venturis, differential pressure cells, and pressure cells.

NWMI PSAR Section 9.1.2.3, “Exhaust Air System,” provides a functional description of the exhaust systems, including those for Zone I, Zones II and III, the laboratory exhaust system, and the process vessel ventilation treatment system. Supplemented by Figure 9-6, “Process Flow Diagram for Process Vessel Ventilation Treatment,” a flow diagram (functional block diagram) of the process vessel ventilation treatment system, NWMI PSAR Section 9.1.2.3.4, “Process Vessel Ventilation Treatment System,” describes the process vessel ventilation treatment system. Major components of the process vessel ventilation treatment system are the iodine removal units (IRUs), which employ iodine guard beds. IRUs and iodine guard beds are described in general terms in the PSAR. The several subsystems comprising the iodine removal system for the NWMI production facility are discussed, including the following:

- IRU for target dissolution offgas system
- IRU for uranium (U), molybdenum (Mo), and waste accumulation tanks
- General process vessel vent
- Waste handling systems

NWMI PSAR Section 9.1.2.4, “Cleanroom Subsystem,” covers the cleanroom subsystem. NWMI PSAR Section 9.1.2.5, “Physical Layout and Location,” provides a brief general description of the location of the major ventilation system components, such as air handling units, supply and exhaust fans, filter plenums, and heat recovery coils.

PSAR Section 9.1.2.6, “Principles of Operation,” is a discussion of the ventilation system principles of operation.

PSAR Section 9.1.3, “Operational Analysis and Safety Function,” states that NWMI PSAR Chapter 11.0, “Radiation Protection and Waste Management,” and Chapter 13.0, “Accident Analysis,” provide an analysis of normal and off-normal operation of the production facility HVAC system. NWMI PSAR Section 9.1.3 also discusses how the system provides defense-in-depth and what portions and functions have been defined as items relied on for safety (IROFS).

NWMI PSAR Section 9.1.4, “Instrumentation and Control Requirements,” states that HVAC system control and monitoring is discussed in NWMI PSAR Chapter 7.0, “Instrumentation and Control Systems.” NWMI PSAR Table 9-2, “Indications for Facility Ventilation System Parameters,” summarizes the system parameters and indicates whether they are monitored or alarmed. NWMI PSAR Section 9.1.4 further states that the system sequence of operation will be developed and provided in the operating license (OL) application.

NWMI PSAR Section 9.1.5, “Required Technical Specifications,” states that TSs associated with the ventilation system, if applicable, will be discussed in PSAR Chapter 14.0, “Technical Specifications,” as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR.

NWMI PSAR Section 9.2, “Material Handling,” consists of a single paragraph, which states, “The RPF does not handle or store reactor fuel. Material handling activities are discussed in [PSAR] Chapter 4.0, ‘Radioisotope Production Facility Description,’ Sections 4.3 and 4.4, and are analyzed in Chapter 13.0.”

NWMI PSAR Section 9.3, “Fire Protection Systems and Programs” describes the NWMI production facility fire protection systems and programs.

NWMI PSAR Section 9.3.1, “Design Basis,” states that the fire protection system design provides detection and suppression of fires in the production facility, including notification, transmitting the notification to the central alarm station and control room, suppressing small fires, and preventing small fires from becoming large fires. Additional information on the design basis is provided in NWMI PSAR Chapter 3.0.

NWMI PSAR Section 9.3.2, “System Description,” includes the fire suppression subsystem, the fire detection and alarm subsystem, fire extinguishers, operational analysis and safety function, the production facility fire areas, other related production facility systems, and related architectural features. The discussion in the PSAR provides a functional description of the system.

NWMI PSAR Section 9.4, “Communication Systems” provides a preliminary, high-level, functional overview of the NWMI production facility communication system. It discusses the design basis and provides a high-level functional description of the systems, explaining that production facility communication systems will relay information during normal and emergency conditions for general operations and emergencies within the production facility.

NWMI PSAR Section 9.5, is “Possession and Use of Byproduct, Source, and Special Nuclear Material.” The design basis for possession and use of byproduct, and special nuclear material (SNM), as given in NWMI PSAR Section 9.5.1, “Design Basis,” is that the NWMI production facility is designed to ensure that (a) no uncontrolled release of radioactive materials (solid, liquid, or airborne) from the facilities can occur and (b) personnel exposures to radiation, including ingestion or inhalation, do not exceed limiting values in 10 CFR Part 20, and are consistent with the NWMI as-low-as-is-reasonably-achievable (ALARA) program as described in NWMI PSAR Chapter 11.0.

NWMI PSAR Section 9.5.2, “System Description,” defines SNM, byproduct material, and source material, states the types of byproduct and SNM to be handled in the RPF, and states that no source material will be present.

NWMI PSAR Section 9.5.3, “Operational Analysis and Safety Function,” states that the criticality safety of SNM is discussed in NWMI PSAR Chapter 4.0, “Radioisotope Production Facility Description,” and Chapter 6.0, “Engineered Safety Features,” and the material control and accounting of SNM is discussed in NWMI PSAR Chapter 12.0, “Conduct of Operations,” Section 12.13, “Material Control and Accounting Program.” The byproduct materials associated with the NWMI production facility process are addressed in NWMI PSAR Chapter 4.0, and byproduct materials within the waste processing and storage areas are described in NWMI PSAR Section 9.7.2, “Control and Storage of Radioactive Waste,” and NWMI PSAR Chapter 11.0, Section 11.2, “Radioactive Waste Management.”

NWMI PSAR Section 9.5.4, “Instrumentation and Control Requirements,” states that I&C requirements for the processes associated with the possession and use of byproduct materials and SNM for the NWMI production facility are discussed in NWMI PSAR Chapter 7.0, and NWMI PSAR Section 12.13.

NWMI PSAR Section 9.5.5, “Required Technical Specifications,” states, “The technical specifications associated with the possession and use of byproduct materials and SNM, if applicable, will be discussed in [FSAR] Chapter 14.0 as part of the Operating License Application.”

NWMI PSAR Section 9.6, “Cover Gas Control in Closed Primary Coolant Systems,” describes the production facility systems that handle radioactive gases from process vessels. The information in NWMI PSAR Section 9.6 includes the design bases, system description, operational analysis and safety function, and I&C requirements.

NWMI PSAR Section 9.6.1, “Design Basis,” states that information on the design basis of cover gas control in the closed primary coolant system is provided in NWMI PSAR Chapter 3.0, Section 3.5.2.7, “Radioisotope Production Facility Specific System Design Basis Functions and Values.”

NWMI PSAR Section 9.6.2, “System Description,” explains how the cover gas control function is accomplished in the process chilled water system by the “sweep” gas system supplied to the cooling water tanks by the plant air supply system. The process vessel vent system collects the purge gas from each of the tanks and merges the collected vent subsystems into the main facility ventilation system for treatment and filtration.

NWMI PSAR Section 9.6.3, “Operational Analysis and Safety Function,” references NWMI PSAR Chapter 13.0, which discusses the potential for ignition of combustible solids and liquids or explosive gasses in close proximity to process streams.

NWMI PSAR Section 9.6.4, “Instrumentation and Control Requirements,” states that I&C requirements for cover gas control in the closed primary coolant system are discussed in NWMI PSAR Chapter 7.0.

NWMI PSAR Section 9.6.5, “Required Technical Specifications,” states that the TS associated with cover gas control in the closed primary coolant system, if applicable, will be discussed in Chapter 14.0 of the final safety analyses report (FSAR) as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR and evaluated by the staff in Chapter 14 of this SER.

NWMI PSAR Section 9.7, “Other Auxiliary Systems,” describes the auxiliary systems not captured in other chapters of the NWMI PSAR in Sections 9.7.1 through 9.7.4, as listed below. The information in these PSAR sections includes the design basis, system description, operational analysis and safety function, I&C requirements, and potential topics for TSs of the other auxiliary systems. The other auxiliary systems, described in NWMI PSAR Section 9.7, that are important to the safety of workers and the public, and the protection of the environment include the following:

- Utility Systems (NWMI PSAR Section 9.7.1)
- Control and Storage of Radioactive Waste (NWMI PSAR Section 9.7.2)
- Analytical Laboratory (NWMI PSAR Section 9.7.3)
- Chemical Supply (NWMI PSAR Section 9.7.4)

NWMI PSAR Section 9.7.1, states, in part, “The utility systems will provide heating, cooling, process water, compressed gases, instrument, motive force, and other functions to support uranium processing, waste handling, and ventilation,” for the NWMI production facility. The utility systems include the following subsystems as described in the associated NWMI PSAR subsections:

- Process Steam (NWMI PSAR Section 9.7.1.2.1)
- Chilled Water (NWMI PSAR Section 9.7.1.2.2)
- Demineralized Water (NWMI PSAR Section 9.7.1.2.3)
- Plant and Instrument Air (NWMI PSAR Section 9.7.1.2.4)
- Gas (industrial/process) Supply (NWMI PSAR Section 9.7.1.2.5)
- Purge Gas (NWMI PSAR Section 9.7.1.2.6)

NWMI PSAR Section 9.7.1.1, “Design Basis,” states that the utility systems design basis is provided in Chapter 3.0, Section 3.5.2.7.

NWMI PSAR Section 9.7.1.2, “System Description,” provides the system descriptions for the utility systems, including various diagrams, system piping and instrumentation diagrams (P&IDs), and tables.

NWMI PSAR Section 9.7.1.3, “Operational Analysis and Safety Function,” states that PSAR Chapter 13.0 presents the associated accident analysis, discussing defense-in-depth measures and IROFS.

NWMI PSAR Section 9.7.1.4 “Instrumentation and Control Requirements,” states that utility system I&C requirements are discussed in PSAR Chapter 7.0.

NWMI PSAR Section 9.7.1.5, “Required Technical Specifications,” states that utility system TSs, if applicable, will be discussed in Chapter 14.0, “Technical Specifications,” of the FSAR as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR.

NWMI PSAR Section 9.7.2 states that the radioactive waste control and storage systems for the production facility are designed to ensure that (1) any potential malfunctions do not cause accidents or uncontrolled release of radioactivity, and (2) in the event of radioactivity release, potential radiation exposures would not exceed 10 CFR Part 20 limits and remain consistent with ALARA.

NWMI PSAR Section 9.7.2.1, “Design Basis,” states that the waste handling system design basis is provided in PSAR Section 3.5.2.7.

NWMI PSAR Section 9.7.2.2, “System Description,” provides the system descriptions for radioactive control and storage systems, including various diagrams, system P&IDs, and tables. These systems include: (a) high-dose liquid handling; (b) low-dose liquid handling; (c) spent resin de-watering; (d) solid waste encapsulation; (e) high-dose waste decay; (f) high-dose waste handling; (g) waste handling; and (h) waste staging and shipping building.

NWMI PSAR Section 9.7.2.3, “Operational Analysis and Safety Function,” refers to PSAR Chapter 13.0 which presents the associated accident analysis and identifies IROFS.

NWMI PSAR Section 9.7.2.4, “Instrumentation and Control Requirements,” states that radioactive waste system I&C requirements are discussed in PSAR Chapter 7.0.

NWMI PSAR Section 9.7.2.5, “Required Technical Specifications,” states that radioactive waste system TSs, if applicable, will be discussed in Chapter 14.0 of the FSAR as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the PSAR.

NWMI PSAR Section 9.7.3, “Analytical Laboratory,” provides a high-level, functional description of the analytical laboratory, in which samples from various stages of Mo-99 production, and U recycling processes of the production facility are analyzed.

NWMI PSAR Section 9.7.3.1, “Design Basis,” provides that the analytical laboratory will enable analysis of (1) mass, concentration, and purity of SNM, (2) concentration of Mo-99 product and product impurities, (3) process stream chemical and radionuclide concentrations, and (4) chemical and radionuclide analysis for waste handling and disposition.

NWMI PSAR Section 9.7.3.2, “System Description,” provides that the laboratory will be equipped with the necessary equipment with which to analyze hazardous (including radioactive) process samples, including hoods, glove boxes, counters for analysis apparatus and instruments, and storage for tools, equipment and supplies. This subsection provides NWMI PSAR Figure 9-35, “Analytical Laboratory Layout.”

NWMI PSAR Section 9.7.3.3, “Operational Analysis and Safety Function,” refers to NWMI PSAR Chapter 13.0, which contains the relevant accident analysis. Defense-in-depth measures focus on adherence to procedures for sampling, analysis, waste/residue disposal, and radiological, chemical, and equipment safety. No IROFS were identified by NWMI for the analytical laboratory.

NWMI PSAR Section 9.7.3.4, “Instrumentation and Control Requirements,” states that analytical laboratory I&C requirements are discussed in NWMI PSAR Chapter 7.0.

NWMI PSAR Section 9.7.3.5, “Required Technical Specifications,” states that analytical laboratory TSs, if applicable, will be discussed in Chapter 14.0 of the FSAR as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR.

NWMI PSAR Section 9.7.4, “Chemical Supply,” states that the chemical supply system provides for storage and supply of chemicals to process systems.

NWMI PSAR Section 9.7.4.1, “Design Basis,” states that the system is designed to supply solutions in the required concentrations for use in the NWMI production facility processes, including target dissolution, Mo-99 recovery and purification, and waste management.

NWMI PSAR Section 9.7.4.2, “System Description,” states that the system comprises tanks and cabinets for storage of flammable materials, storage and segregation of incompatible materials, and storage of solid process chemicals. The system description is illustrated by various diagrams and tables.

PSAR Section 9.7.4.3, “Operational Analysis and Safety Function,” refers to NWMI PSAR Chapter 13.0, for the chemical supply system-related accident analysis, discusses

defense-in-depth safety measures, including compliance with relevant provisions of U.S. Environmental Protection Agency and Occupational Safety and Health Administration regulations, and lists preliminary designated IROFS.

NWMI PSAR Section 9.7.4.4, "Instrumentation and Control Requirements," states that the chemical supply system I&C requirements are discussed in NWMI PSAR Chapter 7.0.

NWMI PSAR Section 9.7.4.5, "Required Technical Specifications," states that the chemical supply system TSs, if applicable, will be discussed in Chapter 14.0 of the FSAR as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR.

9.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 9.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility auxiliary systems for the issuance of a construction permit under 10 CFR Part 50. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) Safety features or components, if any, which require research and development have been described by NWMI, and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9) and "Final Interim Staff Guidance [ISG] 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," (Reference 10) 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" (Reference 11). The staff's review in Chapter 2, "Site Characteristics," of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

9.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility auxiliary systems are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.35, "Issuance of construction permits."
- 10 CFR 50.40, "Common standards."

9.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- 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 (Reference 9).
- "Final Interim Staff Guidance [ISG] 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 (Reference 10).
- "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 (Reference 11).

The ISG Augmenting NUREG-1537, Parts 1 and 2 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, Parts 1 and 2 it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

9.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 9.0 to assess the sufficiency of the preliminary design and performance of the NWMI production facility auxiliary systems for the issuance of a construction permit, in accordance with 10 CFR Part 50. The sufficiency of the preliminary design of the NWMI production facility auxiliary systems is determined by ensuring the design is consistent with the design bases, which meet the applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 9.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the staff's technical evaluation is described in Section 9.5, "Summary and Conclusions," of this SER.

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility auxiliary systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility auxiliary systems based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. The staff's evaluation of the preliminary design of the NWMI production facility auxiliary systems does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the NWMI production facility auxiliary systems, as described in the FSAR submitted as part of NWMI's OL application.

9.4.1 Heating, Ventilation, and Air Conditioning Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility HVAC systems, as described in NWMI PSAR Section 9.1, for the issuance of a construction permit in accordance with the applicable guidance as cited in Section 9.3 of this SER, including the information on design basis, system description, operational analysis and safety function, I&C requirements, and topics of required TSs. The purpose of the review of the preliminary design of the HVAC systems is to (a) verify that the design bases reflect all applicable functional, structural, and safety requirements, all applicable/relevant regulatory requirements and guidance, and all applicable/relevant industry guidance, endorsed or recognized by the staff, and (b) verify that the preliminary design is consistent with the design bases and provides reasonable assurance that construction of the facility can be conducted such that the as-built facility is consistent with the approved design. Thus, emphasis in the review at this stage was placed on evaluating the completeness and consistency of design basis information.

NWMI PSAR Section 9.1.1 provides the design basis for the NWMI production facility HVAC systems with additional design basis information given in PSAR Chapter 3.0. The PSAR also states that the ventilation system is designed to provide confinement of hazardous chemical fumes and airborne radiological materials and conditioning of the production facility environment for facility personnel and equipment.

NWMI PSAR Section 9.1.2 provides a discussion of the NWMI production facility ventilation system. NWMI states that the ventilation system will maintain a series of cascading pressure zones to draw air from the cleanest areas of the facility to the most contaminated areas. Zone IV will be a clean zone that is independent of other ventilation zones and will be positively pressurized with respect to the atmosphere. Zone III will be the cleanest of the potentially contaminated zones. It is considered to be a tertiary confinement barrier and includes the walls, floor, ceiling, and doors of the corridor that surround the operating galleries and the mechanical mezzanine. Zone II is the secondary confinement subsystem and includes the walls, floors, ceilings, and doors of the laboratories including gloveboxes, HEPA filter rooms, and the Zone II ventilation exhaust subsystem. Zone I is the initial confinement barrier and includes gloveboxes, vessels, tanks, piping, hot cells and the Zone I exhaust subsystem.

NWMI PSAR Section 9.1.2.3.1, “Zone I Exhaust System,” states, in part, “Space temperature control will not be provided for Zone I spaces unless thermal loads are expected to cause temperatures to exceed equipment operating ranges without additional cooling.” To gain an understanding of the HVAC temperature control for the Zone 1 ventilation system, the staff requested additional information in RAI 9.1-5. In its response to RAI 9.1-5 (Reference 57), the applicant states, “The need for HVAC space temperature control in Zone I will be evaluated and determined during the final design phase by performing a heat balance on the Zone I ventilation system. The maximum heat load on the ventilation system is anticipated to be dominated by heat losses from equipment in the Zone I ventilated areas (rather than decay heat) when operating at the maximum uranium throughput. Temperature control will also be evaluated for a loss of ventilation scenario. Results of the evaluation (including space temperature control systems that may be identified by the heat balance) will be described in the FSAR as part of the Operating License Application.” The staff finds the HVAC preliminary design basis is acceptable because it ensures acceptable temperature and humidity control and the staff also finds that the applicant’s response deferring the answer to the question to the OL is acceptable for purposes of the issuance of a construction permit as per 10 CFR 50.35(a)2.

The staff evaluated the diagrams and tables provided in NWMI PSAR Section 9.1.2 to determine whether the level of completeness of the design as presented and consistency with the system description is sufficient and acceptable at this stage. The staff finds that the system diagrams and tables provided are acceptable because they provide an understanding of the HVAC airflow to prevent an inadvertent diffusion or other uncontrolled release of radioactive material from the production facility and supports the HVAC design basis and is sufficient for the purposes of issuance of a construction permit for the NWMI production facility.

9.4.1.1 *Operational Analysis*

The staff evaluated the operational analyses and safety functions addressed in NWMI PSAR Section 9.1.4, which states that PSAR Chapters 11.0 and 13.0 provide an analysis of normal and off-normal operation of the production facility HVAC system. NWMI PSAR Chapter 11.0, Section 11.1.1.1, "Airborne Radiation Sources," presents the normal release analysis. NWMI PSAR Chapter 13.0, Section 13.2, "Analysis of Accidents with Radiological and Criticality Safety Consequences," evaluates various accident sequences that involve failure of the ventilation components, radiological spills, and the release of high-dose solutions, vapors, or gases from within the hot cell liquid confinement, secondary confinement, or shielding boundary.

Defense-in-Depth

NWMI PSAR Section 9.1.3 explains that failure of the air balance system is not in itself an accident, but represents the failure of a system designed to mitigate other accidents that lead to an airborne release of radionuclides in the form of particulates or gases. Systems that will mitigate these releases include the primary confinement and primary OTS, which will capture particulates, absorb iodine, and absorb Xenon and Krypton and other gaseous radionuclides, to slow the release allowing decay to more stable isotopes. Uranium solutions will also be processed in closed systems with filtered process ventilation systems to remove the small amounts of radioactive material normally released.

Items relied on for Safety

Based on the NWMI PSAR Chapter 13.0 analysis, the hot cell secondary confinement (Zone I exhaust ventilation subsystem) is designated as an IROFS (RS-03, "Hot Cell Secondary Confinement Boundary"). The operations, equipment, and components of this system are to ensure the confinement of hazardous materials during normal and abnormal conditions, including natural phenomena, fires, and explosions. Components of the dissolver offgas subsystem and the process vessel ventilation system are also designated as IROFS.

Safety Functions

NWMI PSAR Section 9.1.3 states that the safety functions of the confinement system are discussed in more detail in NWMI PSAR Chapter 6.0, Section 6.1, "Summary Description." NWMI PSAR Chapter 13.0 evaluates a fire that could cause the carbon retention beds to ignite, leading to the release of radionuclides into the exhaust stack. Based on analysis of this accident, the exhaust stack height was identified as an IROFS (FS-05, "Exhaust Stack Height"). This analysis is discussed in more detail in NWMI PSAR Chapter 13.0. This passive engineered control is designed and fabricated with a fixed height for safe release of gaseous effluents. NWMI PSAR Section 9.1.2.3.1, "Zone I Exhaust System," states that the height of the exhaust stack is 23 meters (75 feet).

Based on its review of NWMI PSAR Section 9.1.3 and the other related PSAR references, the staff finds that the information provided on operational analysis and safety function of the HVAC system is acceptable because it ensures that sources of airborne radioactive material are diluted, diverted, and filtered, and is sufficient for the purposes of issuance of a construction permit for the NWMI production facility. Further details of the HVAC system can reasonably be left for later consideration in the FSAR once the final design is completed. The impacts of the changes to the HVAC system from the preliminary design to the final design will be evaluated by the staff in the FSAR and associated documents during the OL application review.

9.4.1.2 *Instrumentation and Controls*

The staff evaluated the NWMI production facility HVAC I&C requirements addressed in NWMI PSAR Section 9.1.4, which explains that HVAC system control and monitoring is discussed in NWMI PSAR Chapter 7.0 (see staff evaluation in SER Section 7.0). NWMI PSAR Table 9-2 summarizes the HVAC system parameters and whether they are monitored or alarmed. NWMI PSAR Section 9.1.4 states that the system sequence of operation will be developed and provided in the OL application. Based on its review, the staff finds that the information on HVAC system I&C in NWMI PSAR Section 9.1.4 is acceptable because it provides details on the operating and design features of the HVAC system and is sufficient for the purposes of issuance of a construction permit for the NWMI production facility. Further details of the HVAC system I&C can reasonably be left for later consideration in the FSAR. The staff will evaluate the FSAR and associated documents during the OL application review.

9.4.1.3 *Summary of Findings*

Based on its review, the staff finds that the level of detail of the information provided on the NWMI production facility HVAC systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.2, “Ventilation System,” allowing the staff to make the following findings:

(1) A review of the preliminary design bases and functional and safety characteristics of the HVAC systems shows that the proposed systems are adequate to control the release of airborne radioactive effluents during the full range of the production facility operations in compliance with the regulations.

(2) The applicant has discussed all sources of radioactive material that could become airborne in the NWMI production facility from a full range of facility operations. The analyses provide reasonable assurance that the radioactive material is controlled by the HVAC system and could not inadvertently escape from the NWMI production facility. They provide reasonable assurance that the distributions and concentrations of the airborne radionuclides in the NWMI production facility are limited by operation of the HVAC system so that during the full range of NWMI production facility operations, no potential occupational exposures would exceed the design bases derived in Chapter 11.0 of the NWMI PSAR.

(3) The applicant has considered the height and flow rate of the stack that exhausts production facility air to the unrestricted environment for the design-basis dose rates derived in Chapter 11.0 of the NWMI PSAR for the maximum exposed personnel in the unrestricted environment.

(4) The HVAC system is an integral part of the confinement system at the production facility. The design of the confinement system and analysis of its operation provide reasonable assurance that it will function to limit normal airborne radioactive material to the extent analyzed in this chapter and Chapter 11.0 of the NWMI PSAR. The potential radiation doses, therefore, should not exceed the limits of 10 CFR Part 20 and are consistent with NWMI's ALARA program.

Therefore, the staff concludes that the preliminary information from the design of the NWMI production facility HVAC system, as described in NWMI PSAR Section 9.2, is sufficient to give the staff an understanding of how the application meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR. The staff will confirm that the final design conforms to an acceptable set of design bases during the evaluation of NWMI's FSAR.

9.4.2 Handling and Storage of Reactor Fuel

NWMI PSAR Section 9.2 states that the production facility does not handle or store reactor fuel. Material handling activities are discussed in NWMI PSAR Chapter 4.0, Section 4.3, "Radioisotope Extraction System," and Section 4.4, "Special Nuclear Material Processing and Storage," and are analyzed in Chapter 13.0. The staff finds that this section is not applicable to the NWMI production facility for the reasons stated.

9.4.3 Fire Protection Systems and Programs

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility fire protection systems and programs, as described in NWMI PSAR Section 9.3, for the issuance of a construction permit by reviewing the design bases and components of the system using the guidance and acceptance criteria from Section 9.3, "Fire Protection Systems and Programs," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 9.3, the staff evaluated the discussions of potential fires; provisions for early detection, including during those times when areas are not occupied; methods for isolating, suppressing, and extinguishing fires; passive features designed into the production facility to limit fire consequences; response organization training and availability to fight fires as detailed in the emergency plan; designs of production facility systems that can ensure safe production facility shutdown in the event of fire; and potential radiological consequences to the public, the staff, and the environment if firefighting efforts are unsuccessful.

As described in NWMI PSAR Section 9.3 the fire protection system at the production facility is divided into two subsystems: the fire suppression subsystem and the fire detection and alarm subsystem. Along with fire rated walls and assemblies, these subsystems are designed to provide notification of a fire event, suppress small fires, and prevent small fires from becoming large fires.

The fire suppression subsystem, described in NWMI PSAR Section 9.3.2.1, "Fire Suppression Subsystem," consists of an automatic sprinkler system, a HEPA filter plenum deluge, glovebox fire suppression, and fire hydrants. NWMI states that the automatic sprinkler system is designed in accordance with National Fire Protection Association (NFPA) 13. The need for installation of sprinklers in the hot cells will be determined and finalized in the FSAR.

Because of the possibility of runoff fire water containing hazardous materials, a fire runoff storage system will be used to hold runoff water for sampling prior to release to the environment. Additionally, the production facility will be equipped with HEPA filters. The HEPA filter fire protection system consists of heat detectors in the ducts that, when high temperature are detected, will activate a water cooling system. If the HEPA filters ignite, a direct water spray onto the filter can be manually activated.

NWMI states that four fire hydrants will be located on the exterior of the building at each corner. The PSAR states that the hydrant subsystem is designed in accordance with NFPA 24, "Standard for the Installation of Private Fire Service Mains and Their Appurtenances," and the International Fire Code, 2012 Edition. Fire hydrants will be connected to the municipal water supply. NWMI will determine during final design whether facility operations will use an on-site dedicated fire water supply and/or use the City of Columbia fire water supply. This item is being tracked as a regulatory commitment by the applicant in Appendix A.4, "Regulatory Commitments Identified through Meeting with the Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee," of this SER.

The fire detection and alarm subsystem, described in NWMI PSAR Section 9.3.2.2, "Fire Detection and Alarm Subsystem," consists of various fire detection and notification systems. The primary method of detecting fires is through fire suppression device monitoring that will provide notification of a sprinkler or deluge valve activating, indicating a possible fire in that area. In areas like computer rooms or egress hallways, where water damage is a concern or life safety is especially important, smoke and heat detectors will be used. Heat detectors will also be used in gloveboxes and smoke detectors will be installed in some ventilation systems as necessary to prevent spread of smoke and contaminants to the environment or between areas in the production facility. The performance of fire detection systems can be affected by radiation or the presence of dust, and thus it is important to choose the right system for the environment in which it will be used. NWMI stated that the selection of specific detection systems will be included in the FSAR and will be informed by relevant standards. The fire protection system will have an associated central alarm panel. Alarms will be relayed to the Columbia Fire Department via the central alarm station.

The fire protection and alarm system will be powered by a dedicated circuit. In the event of a power outage, 24 hours of backup battery power will be available in accordance with NFPA standards.

As described in NWMI PSAR Section 9.3.3.1, "Radioisotope Production Facility Fire Areas," the production facility is divided into fire areas based on the hazards present with the objective of limiting the spread of fire, protecting personnel, and minimizing damage to the production facility. Fire areas are separated by at least two-hour fire rated barriers. All penetrations and fire doors in a barrier have the same fire rating as the barrier. Fire-rated barriers are designed and will be constructed in accordance with NFPA 221, "Standard for High Challenge Fire Wall, Fire Walls, and Fire Barrier Walls," and the International Building Code. The staff finds that the use of NFPA 221 is an acceptable way to demonstrate that the design basis for fire barriers is adequate.

The PSAR states that the Columbia Fire Department will respond in the event of a fire. The department will be notified of a fire either automatically through smoke or heat detectors or manually though a fire alarm pull station. The Columbia Fire Department also services the University of Missouri - Columbia Research Reactor (MURR) and is familiar with hazardous and radioactive materials. The time within which the fire department must respond will be

determined in the OL application. The staff finds acceptable that the fire department, which the PSAR states will respond to the production facility in the event of a fire and has a base knowledge of radiation hazards as related to the suppression of fires as it serves the MURR facility.

NWMI examines potential fire hazards and ignition sources (both internal and external) for the different areas of the facility in the construction permit application. NWMI states that the fire protection system is not necessary to prevent or mitigate high or intermediate consequence accidents in the production facility. The staff evaluated the accident analyses related to potential fire hazards and ignition sources as part of its review of Chapter 13.0, which is documented in Chapter 13 of this SER.

9.4.3.1 *Summary of Findings*

Based on its review, the staff finds that the level of detail provided in the NWMI PSAR on the fire protection systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.3 allowing the staff to make the following findings:

(1) Fire-rated barriers between fire areas will be two-hour rated assemblies at a minimum and provide adequate protection against spread of fires from one area to another.

(2) The fire department serves the MURR and has a base knowledge of nuclear facility hazards as related to the suppression of fires.

(3) The ventilation system is designed to prevent the spread of contamination, through the use of fire dampers and HEPA filters, during the event of a fire. The final ventilation system design and operation will be evaluated with the submission of the FSAR.

(4) The fire suppression and detection systems, insofar as the systems are currently designed, provide protection against fires and fire spread because they are designed to meet NFPA requirements. The fire hazard analysis and fire protection training plan will be reviewed when the NWMI FSAR is submitted. Future consideration of selection of systems and finalization of the design can reasonably be left for later consideration in the FSAR and OL application.

Therefore, the staff concludes that the preliminary design of the NWMI production facility fire protection systems and programs, as described in NWMI PSAR Section 9.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR.

9.4.4 Communication Systems

In accordance with applicable guidance cited in Section 9.3 of this SER, the staff evaluated the sufficiency of the preliminary design of the NWMI production facility communication systems, as described in NWMI PSAR Section 9.4 for the issuance of a construction permit, including the design basis, system description, operational analysis and safety function, I&C requirements, and topics for potential TSs.

Consistent with the review procedures in NUREG-1537, Part 2, the staff considered the design basis of the communication systems in order to ensure the full range of communication that will be used in the NWMI production facility during normal and emergency conditions. Thus, in this portion of the review, the staff evaluated the completeness and consistency of design basis information for a preliminary design.

NWMI PSAR Section 9.4.1, "Design Basis," states that the communications system design basis is to provide communications during normal and emergency conditions between vital areas of the production facility. The section further states that this communications capability will include the ability of operators or other designated staff members to announce an emergency and provide two-way communications between all operational areas and the control room. Design of the telecommunication system will also comply with Electronic Industries Alliance and Telecommunications Industry Association requirements.

NWMI PSAR Section 9.4.3, "Operational Analysis and Safety Function," states that PSAR Chapter 13.0 identifies and evaluates adverse events and accident sequences. The accident analysis has not identified the need to credit the communication systems.

The staff evaluated the system description of the NWMI production facility communication systems to determine its adequacy for issuance of a construction permit and in particular, its consistency with its design basis. The staff finds that the information provided in the PSAR description is consistent with the design basis information because the system is designed to provide communications during emergency and normal operations and has the capability for operators or other designated NWMI staff to announce and provide two-way communication between the NWMI staff during emergencies. The evaluation of the detailed communication systems can reasonably wait for later consideration and will be reviewed in the FSAR submitted as part of the OL application. Therefore, the staff finds the preliminary information sufficient and acceptable for the purposes of the issuance of a construction permit in accordance with 10 CFR Part 50.

9.4.4.1 *Summary of Findings*

Based on its review, the staff finds that the level of detail provided on the NWMI production facility communication systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.4, allowing the staff to make the following findings:

(1) The production facility communication systems are designed to provide two-way communication between all locations essential for safe facility operation.

(2) The communication systems enable facility-wide announcement of emergencies.

Therefore, the staff concludes that the preliminary design of the NWMI production facility communication systems, as described in NWMI PSAR Section 9.4, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR.

9.4.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

The staff evaluated the sufficiency of the preliminary design of NWMI's program for possession and use of byproduct, source, and SNM in the production facility for the issuance of a construction permit. The staff reviewed NWMI PSAR Section 9.5, to gain an understanding of how byproduct materials, and irradiated SNM are processed; the types and quantities of radionuclides authorized; the rooms, spaces, equipment, and procedures to be used; the general types of uses, such as research and development, processing, or packaging for shipment; the provisions for controlling and disposing of radioactive wastes, including special drains for liquids and chemicals, and air exhaust hoods for airborne materials; the relationship between these auxiliary facility designs and the physical security and emergency plans; and probable topics for TSs and their bases, including testing and surveillance, 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.

Consistent with the review procedures of NUREG-1537, Part 2, Section 9.5, the staff evaluated the design bases, system description, operational analysis and safety function, and topics for potential TSs. The staff compared the design bases for the auxiliary systems that process byproduct material in the production facility with other chapters of NWMI PSAR, especially Chapters 11.0 and 12.0, and evaluated agreement with the acceptance criteria of NUREG-1537, Part 2, Section 9.5.

Based on its review, the staff finds that the production facility design with respect to the byproduct and SNM that will be used in the production facility demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.5, allowing the staff to make the following findings:

(1) The auxiliary facilities and systems are designed for the possession and use of byproduct and SNM produced by the facility. The design bases include limits on potential personnel exposures that are in compliance with 10 CFR Part 20 and are consistent with the facility ALARA program.

(2) The design provides reasonable assurance that uncontrolled releases of radioactive material to the public will not occur.

Therefore, the staff concludes that the preliminary design of the NWMI program for the possession and use of byproduct, source, and SNM in the production facility, as described in NWMI PSAR Section 9.5, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR.

9.4.6 Cover Gas Control in Closed Primary Coolant Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility cover gas control system within the process coolant system described in NWMI PSAR Section 9.6 for the issuance of a construction permit 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 other relevant guidance as cited in Section 9.3 of this SER.

Consistent with the review procedures of NUREG-1537, Part 2, Section 9.6, the staff evaluated the cover gas control systems to ensure that:

- The design and functional description conforms to the design bases.
- The design, functions, and potential malfunctions of the systems that perform the cover gas function should not cause accidents to the facility or uncontrolled releases of radioactivity.
- In the event radioactive material is released by the operation of the systems that perform this function, potential radiation exposures should not exceed the limits of 10 CFR Part 20 and should be consistent with the facility ALARA program.

NWMI PSAR Section 9.6 provides a high-level functional description of the NWMI production facility cover gas process function, addressing design basis, system description, operational analysis and safety function, and I&C. The systems in the production facility that constitute the "closed primary coolant system," are two of the three process chilled water systems used to cool process vessels. Within the process chilled water systems that use cover gas, the cover gas function is performed by the plant air supply system (NWMI PSAR Section 9.7.1.2.4), the cooling water collection tanks, and the process vessel vent system (NWMI PSAR Section 9.1.2.3.4) to ensure that hydrogen and oxygen mixtures produced by radiolytic decomposition of process vessel cooling water in the process chilled water system (NWMI PSAR Section 9.7.1.2.2) are diluted by sweep/purge gas and kept below 25 percent of the lower flammability limit (LFL) of 5 percent for hydrogen gas. NWMI states that this function is designed to prevent hydrogen explosions that could result in damage/injury to production facility SSCs/personnel and possibly uncontrolled releases of radioactivity. The staff reviewed the design basis value of reducing hydrogen buildup below 25 percent of the LFL and finds that it is acceptable for a preliminary design. Potential accidents related to hydrogen buildup are evaluated by NWMI in its integrated safety analyses (ISA) and discussed in Chapter 13 of the SER

NWMI PSAR, Section 9.6.1 states that information on the design basis of cover gas control in the closed primary coolant system (process-chilled water system) is provided in Chapter 3.0, Section 3.5.2.7.

9.4.6.1 *Operational Analysis and Safety Function*

NWMI PSAR Section 9.6.3 states that the associated accident analysis is in PSAR Chapter 13.0 and that the tanks associated with the cooling system are not anticipated to require IROFS controls. The staff evaluated the accident analyses in Chapter 13.0 of the NWMI PSAR.

9.4.6.2 *Instrumentation and Control Requirements*

NWMI PSAR Section 9.6.4 states that I&C requirements for cover gas control in the closed primary coolant system (i.e., process chilled water) are discussed in NWMI PSAR Chapter 7.0.

9.4.6.3 *Summary of Findings*

Based on its review, the staff finds that the level of detail provided on the NWMI production facility function of cover gas control in closed primary coolant systems satisfies the applicable

acceptance criteria of NUREG-1537, Part 2, Section 9.6, allowing the staff to make the following findings:

(1) The preliminary design is consistent with the design basis. Specifically, the coolant collection tanks, sweep/purge gas system, plant air supply system, and process vessel vent system are designed to work together to capture and treat the expected offgases at their anticipated concentrations of constituents under normal and accident conditions and to ensure that the design-basis pressures and especially the design maximum allowable hydrogen concentration can be maintained.

(2) Processing (diluting) and disposing of radiolytic gases have been incorporated into the design to ensure the safety of personnel and to prevent the release of radioactivity due to hydrogen explosions.

(3) The coolant collection tanks, sweep/purge gas system, plant air supply system, and process vessel vent system have been designed to perform the cover gas control in closed primary coolant systems functions required by the design bases.

Therefore, the staff concludes that the preliminary design of the NWMI production facility cover gas control in closed primary coolant systems, as described in NWMI PSAR Section 9.6, is sufficient to meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR. The staff will confirm that the final design conforms to the design basis during the evaluation of NWMI's FSAR.

9.4.7 Other Auxiliary Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility's other auxiliary systems, as described in NWMI PSAR Section 9.7, for the issuance of a construction permit by reviewing the systems (described below), using the guidance and acceptance criteria from Section 9.7, "Other Auxiliary Systems," of NUREG-1537, Parts 1 and 2 and the ISG Augmenting NUREG-1537. The staff review covered design bases, system descriptions, operational analysis and safety functions, and I&C requirements to verify that:

- The preliminary designs of the other production facility auxiliary systems are consistent with their design bases.

- Any malfunction could not create conditions or events that could cause an unanalyzed accident or uncontrolled release of radioactive material beyond those analyzed in Chapter 13.0 of the PSAR.

- The auxiliary system could not prevent safe production facility shutdown.

Consistent with the review procedures of NUREG-1537, Part 2, Section 9.7, the staff compared the design and functional descriptions of the other auxiliary systems with their design bases. The staff reviewed the discussion and analyses of the functions and potential malfunctions with respect to safe production facility operation and shutdown, the effect on production facility safety systems, and the potential for these auxiliary systems to initiate or affect the uncontrolled release of radioactive material.

Fundamental to the review of the preliminary design of the NWMI production facility's other auxiliary systems are (1) verifying that the design bases reflect all applicable functional, structural, and safety requirements, all applicable/relevant regulatory requirements and guidance, and all applicable/relevant industry guidance, endorsed or recognized by the staff, and (2) that the preliminary design is consistent with the design bases and provides reasonable assurance that construction of the production facility can be conducted such that the as-built facility is consistent with the approved design.

The other NWMI production facility auxiliary systems that are important to the safety of workers and the public, and for the protection of the environment, include the following:

- Utility systems (NWMI PSAR Section 9.7.1)
- Control and storage of radioactive waste (waste management) NWMI PSAR Section 9.7.2)
- Analytical laboratory (NWMI PSAR Section 9.7.3)
- Chemical supply (NWMI PSAR Section 9.7.4)

9.4.7.1 *Utility Systems*

NWMI PSAR Section 9.7.1, "Utility Systems," states:

> The utility systems will provide heating, cooling, process water, compressed gases, instrument, motive force, and other functions to support uranium processing, waste handling, and ventilation. The utility systems will include the following subsystems:
>
> - Process steam
> - Process chilled water
> - Demineralized water
> - Plant and instrument air
> - Gas supply, which supplies nitrogen, helium, hydrogen, and oxygen
> - Purge/sweep gas

NWMI states that the utility systems are designed to ensure that any potential malfunctions do not cause accidents in the production facility or an uncontrolled release of radioactivity. The systems are designed to ensure that in the event radioactive material is released by the operation of one of these systems, potential radiation exposures would not exceed the limits of 10 CFR Part 20 and are consistent with the NWMI ALARA program. NWMI states that no function or malfunction of the auxiliary systems will interfere with or prevent safe shutdown of the production facility.

NWMI PSAR Section 9.7.1 states that the design basis for the utility system is provided in NWMI PSAR Chapter 3.0, Section 3.5.2.7.

NWMI PSAR Section 9.7.1.2 provides a functional description of each of the utility systems, including the diagrams, system P&IDs, and tables cited in Section 9.2, "Summary of Application," of this SER.

NWMI PSAR Section 9.7.1.3 states that PSAR Chapter 13.0 evaluates the accident sequences that involve fissile solution or solid materials being introduced into systems not normally designed to process these solutions or solid materials. The accident analysis associated with

utilities addresses fissile solution leaks across a mechanical boundary between process vessels or backflows into a utility system, addressing defense-in-depth measures and identifying IROFS.

NWMI PSAR Section 9.7.1.4 states that utility system I&C requirements are discussed in NWMI PSAR Chapter 7.0.

Based on its review of the NWMI production facility utility systems, the staff finds that the level of detail in NWMI PSAR Section 9.7.1 demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7. Detailed design information of the safety aspects of the utility systems will be reviewed by the staff in the FSAR submitted as part of the OL application.

Therefore, the staff concludes that the preliminary design of the NWMI production facility utility systems, as described in NWMI PSAR Section 9.7.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

9.4.7.2 *Control and Storage of Radioactive Waste*

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility radioactive waste control and storage systems, as described in NWMI PSAR Section 9.7.2, for the issuance of a construction permit using the guidance and acceptance criteria from Section 9.7 of NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 9.7.2.1 states that the design basis for the waste management system for the production facility is in NWMI PSAR Section 3.5.2.7. NWMI PSAR Section 3.5.2.7.6, "Waste Handling," lists the design basis functions for this system as follows:

- Receive liquid waste that is divided into high-dose source terms and low-dose source terms to lag storage
- Transfer remotely loaded drums with high-activity solid waste via a solid waste drum transit system to a waste encapsulation cell
- Encapsulate solid waste drums
- Load drums with solidification agent and low-dose liquid waste
- Load high-integrity containers with solidification agent and high-dose liquid waste
- Handle and load a waste shipping cask with radiological waste drums/containers
- Safety-related functions:
    - Maintain sub-criticality conditions through mass limits
    - Prevent spread of contamination to manned areas of the facility that could result in personnel exposure to radioactive materials or toxic chemicals

- Provide shielding, distance, or other means to minimize personnel exposure to penetrating radiation

Design Basis Values

- Maintain primary fission product boundary during and after normal operations, shutdown conditions, and DBEs

- 30-year design life with the exception of common replaceable parts (e.g., pumps)

The waste management systems described in NWMI PSAR Section 9.7.2 addresses each of the design basis functions:

- Separate collection tanks provide separation of high-dose and low-dose liquid wastes. Lag storage is provided in each of the systems producing waste input to the high-dose collection tank. NWMI states that the high-dose liquid waste collection tank volume is sufficient to provide some additional lag storage.

- NWMI PSAR Section 9.7.2.2.4, "Solid Waste Encapsulation," describes operators using a drum transfer cart to move drums containing solid wastes through the maintenance gallery to the high-dose waste treatment hot cell where the drums are filled with cement grout. The final design will be evaluated at the FSAR stage to ensure that this manual operation is conducted consistent with the applicant's commitment to ALARA in radiation protection.

- Both high-dose liquid waste and low-dose liquid waste are described as being solidified. The solidification agent(s) proposed and the process(es) used to assure an acceptable solidified product meeting the waste acceptance criteria of the disposal site will be evaluated at the FSAR stage.

- NWMI PSAR Section 9.7.2.2.5, "High-Dose Waste Decay," describes high-dose waste decay capabilities. In its response to RAI 9.7-5b (Reference 20), the applicant provided decay times for both high-integrity containers (HICs) containing high-dose waste from MURR targets and HICs containing high-dose waste from Oregon State University TRIGA Reactor targets. Based on the information provided and the rate of HIC production also presented in the response, the high-dose decay cell should have adequate capacity for decay in storage and limited interruption of the ability to transport high-dose waste for disposal for a period of weeks. The staff will evaluate the storage capacity after the final design is completed and submitted in the FSAR as part of OL review.

- NWMI PSAR Section 9.7.2.2.7, "Waste Handling," provides a summary description of how waste containers are handled for loading into transportation casks.

NWMI PSAR Section 9.7.2.2 presents information regarding the systems and components used to perform the design basis functions.

NWMI PSAR Section 9.7.2 also includes a process flow drawing and states that operation of the high-dose liquid waste system is performed on a batch basis, with inputs to the system and

between successive components in the system being isolated, sampled, and analyzed before each transfer. The staff finds that this section of the PSAR provides sufficient information for a preliminary design to indicate that sufficient liquid waste storage and processing capacity should be available. The staff will evaluate the liquid waste storage and processing capacity as part of the review of the final design submitted in the FSAR.

NWMI PSAR Section 9.7.2.3 identifies the IROFS for the waste handling system as derived from the ISA summary.

NWMI PSAR Section 9.7.2.4 states that radioactive waste control and storage system I&C requirements are discussed in NWMI PSAR Chapter 7.0. NWMI PSAR Section 7.3.6, "Waste Handling System," provides generic design criteria, acknowledging that the detailed waste handling system controls are still being developed. NWMI PSAR Table 7-11, "Waste Handling System Control and Monitoring Parameters," provides a list of parameters to be monitored and the location of controls. Table 7-12, "Waste Handling System Interlocks and Permissive Signals," indicates that all interlocks and permissive signals will be controlled through programmable logic controllers and that none are considered safety related. NWMI stated that details of waste handling system controls will be provided along with the system performance analysis and conclusion for each waste process system in the OL application.

Based on its review, the staff finds that the level of detail provided in NWMI PSAR Section 9.7.2 on control and storage of radioactive waste demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7, allowing the staff to make the following findings:

(1) The waste control and storage systems have been designed to perform functions required by the design bases.

(2) The potential malfunctions that could affect operations have been considered in the design of the waste control and storage systems.

Therefore, the staff concludes that the preliminary design of the NWMI production facility radioactive waste control and storage systems, as described in NWMI PSAR Section 9.7.2, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

9.4.7.3 *Analytical Laboratory*

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility analytical laboratory, as described in NWMI PSAR Section 9.7.3, for the issuance of a construction permit using the guidance and acceptance criteria from Section 9.7 of NUREG-1537, Parts 1 and 2, and other relevant guidance as cited in Section 9.3 of this SER. Consistent with the review procedures of NUREG-1537, Part 2, Section 9.7 and the ISG Augmenting NUREG-1537, the staff evaluated the analytical laboratory, including design basis, system description, operational analysis and safety function, and I&C requirements to ensure that:

- The design and functional description conforms to the design bases.

- The design, functions, and potential malfunctions of the analytical laboratory should not cause accidents to the facility or uncontrolled releases of radioactivity.

- In the event radioactive material is released by the operation of the analytical laboratory, potential radiation exposures should not exceed the limits of 10 CFR Part 20 and should be consistent with the facility ALARA program.

- No function or malfunction of the analytical laboratory should interfere with or prevent safe shutdown of the production facility.

In addition, NUREG-1537, Part 1, Section 9.5, states, in part, that the applicant should discuss laboratories for the production facility. This discussion should address design basis, system description, operational analysis and safety function, I&C requirements, and required TSs for any such auxiliary laboratories. The applicant should specify the types and quantities of radionuclides authorized, as well as the general types of experiments or uses. Radiological design bases for handling radioactive materials and radioactive waste should be derived from Chapter 11.0 of the NWMI PSAR. These design bases may apply to chemical, fume, and air exhaust hoods; to drains for radioactive liquids; and to radiation shields. The discussions should show how the physical security and emergency plans apply to the licensed spaces and possession of byproduct materials. The applicant should discuss the bases for special operating procedures.

NWMI PSAR Section 9.7.3.3 states that NWMI PSAR Chapter 13.0 evaluates the accident sequences that involve miscellaneous chemical safety process upsets in areas without significant fissile or high-dose licensed material present (chemical storage areas and the laboratory). The accidents analyzed that are associated with the analytical laboratory include Accident Sequence S.R.31, “Chemical Burns from Contaminated Solutions during Sample Analysis.”

NWMI states that it will follow set protocols on sampling and analysis to identify the sampling locations, sampling techniques, containers to be used, transport routes to take, analysis procedures, reagents to use, equipment requirements, and disposal protocol for the sample residue material. Each of these procedures will be evaluated for standard safety protocols, including requirements in the safety datasheets for the chemicals used and safety requirements for the equipment used.

NWMI PSAR Section 9.7.3.4 states that analytical laboratory I&C requirements are discussed in NWMI PSAR Chapter 7.0. The staff evaluated analytical laboratory I&C requirements in Section 7.0 of this SER.

NWMI PSAR Section 9.7.3.5 states that analytical laboratory TSs, if applicable, will be discussed in Chapter 14.0 of the NWMI FSAR as part of the OL application. Topics for potential TSs were included in Chapter 14.0 of the NWMI PSAR and are evaluated by the staff in Chapter 14 of this SER. The staff finds that it is reasonable to identify and justify the selection of TSs once the design becomes final.

Based on its review, the staff finds that the level of detail provided in PSAR Section 9.7.3 on the NWMI production facility analytical laboratory demonstrates an adequate design basis for a

preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7, allowing the staff to make the following evaluations findings:

(1) The analytical laboratory has been designed to perform functions required by the design bases.

(2) The potential malfunctions that could affect operations have been considered in the design of the analytical laboratory.

Therefore, the staff concludes that the preliminary design of the NWMI production facility analytical laboratory, as described in NWMI PSAR Section 9.7.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

9.4.7.4 *Chemical Supply System*

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility chemical supply system, as described in PSAR Section 9.7.4, for the issuance of a construction permit using the guidance and acceptance criteria from Section 9.7 of NUREG-1537, Parts 1 and 2, the ISG augmenting NUREG-1537, and other relevant guidance as cited in Section 9.3 of this SER. Consistent with the review procedures of NUREG-1537, Part 2, Section 9.7, the staff evaluated the chemical supply system, including design basis, system description, operational analysis and safety function, and I&C requirements, to ensure that:

- The design of the chemical supply system is consistent with the design bases.
- No function or malfunction of the chemical supply system should interfere with or prevent safe shutdown of the production facility.

NWMI PSAR Section 9.7.4.1 states that the chemical supply system design basis for the production facility is to provide chemical solutions mixed to the required concentrations that are used within the target dissolution, Mo-99 recovery and purification, and waste management systems. The system will provide nitric acid (HNO_3), sodium hydroxide (NaOH), reductant and nitric oxide (NO_x) absorber solutions, hydrogen peroxide (H_2O_2), and fresh uranium ion exchange (IX) resin.

NWMI PSAR Section 3.5.2.7.24, “Chemical Supply System,” provides the following chemical supply system design basis functions:

- Provide storage capability for nitric acid, sodium hydroxide, reductant, and nitrogen oxide absorber solutions, hydrogen peroxide, and fresh uranium IX resin
- Segregate incompatible chemicals (e.g., acids from bases)
- Provide transfer capability for chemical solutions mixed to required concentrations and used in target dissolution, Mo-99 recovery and purification, and waste management systems

NWMI PSAR Section 3.5.2.7.24 provides the following chemical supply system design basis values:

30-year design life with the exception of common replaceable parts (e.g., pumps)

NWMI PSAR Section 9.7.4.2 provides a functional description of the chemical supply system, including the diagrams and tables listed in Section 9.2 of this SER.

NWMI PSAR Section 9.7.4.3 states, in part, that "Chapter 13.0 evaluates accident sequences that involve miscellaneous chemical safety process upsets in areas without significant fissile or high-dose licensed material present (e.g., chemical storage areas and the laboratory). The backflow of fissile or radioactive solutions into auxiliary systems (e.g., chemical supply) was also analyzed and two preventive IROFS identified."

NWMI PSAR Section 9.7.4.3 further states, in part, that "Defense-in-depth - NWMI will comply with U.S. Environmental Protection Agency and Occupational Safety and Health Administration regulations for the design, construction, and operation of chemical preparation and storage areas in the production facility. Chemical handling procedures will be provided to operators to ensure safe handling of chemicals according to applicable regulatory requirements and consistent with the material safety datasheets."

NWMI PSAR Section 9.7.4.4 states that I&C requirements for the chemical supply system are discussed in NWMI PSAR Chapter 7.0.

NWMI PSAR Section 9.7.4.5 states that TSs for the chemical supply system, if applicable, will be discussed in Chapter 14.0 of the NWMI FSAR as part of the OL application. Topics for potential TSs were included in Chapter 14.0 of the PSAR and are evaluated by the staff in Chapter 14 of the SER. The staff finds that it is reasonable to identify and justify the selection of TSs once the design becomes final.

Based on its review, the staff finds that the level of detail provided in NWMI PSAR Section 9.7.4 on the NWMI production facility chemical supply system demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7.

Therefore, the staff concludes that the preliminary design of the NWMI production facility chemical supply system, as described in NWMI PSAR Section 9.7.4, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

9.4.7.5 *Summary of Findings*

Based on its review, the staff finds that the level of detail provided in NWMI PSAR Section 9.7 on the NWMI production facility's other auxiliary systems demonstrates an adequate design

basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7, allowing the staff to make the following findings:

(1) The systems have been designed to perform the functions required by the design bases.

(2) The functions and potential malfunctions that could affect production facility operations or initiate uncontrolled releases of radioactive material have been considered in the design of the systems.

(3) The strategy and content of what will be required for TSs as discussed in PSAR Chapter 14.0 gives reasonable assurance that the systems will be operable, as required by the design bases.

Therefore, the staff concludes that the preliminary design of the NWMI production facility's other auxiliary systems, as described in NWMI PSAR Section 9.7, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis, will be provided and can reasonably be left for later consideration, in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR.

9.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility's auxiliary systems, as described in NWMI PSAR Chapter 9.0, and finds that the preliminary design of the auxiliary systems, including the principal design criteria, design bases, and information relative to general arrangement, major SSCs, and a high-level functional description provides reasonable assurance that the final design will conform to the design basis and meets all applicable regulatory requirements and acceptance criteria in or referenced in the applicable guidance.

Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the NWMI production facility auxiliary systems, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to compete the safety analysis of the auxiliary systems, and which can be reasonably left for later consideration, will be provided in the FSAR.

(3) There is reasonable assurance that the production facility can be constructed and operated at the proposed location without undue risk to health and safety of the public.

(4) The applicant provides reasonable assurance of compliance with the regulations including 10 CFR Part 20, and the health and safety of the public will not be endangered.

(5) The issuance of a permit for the construction of the production facility will not be inimical to the common defense and security or to the health and safety of the public.

10 EXPERIMENTAL FACILITIES

Northwest Medical Isotopes, LLC (NWMI or the applicant) preliminary safety analysis report (PSAR) Chapter 10.0, "Experimental Facilities," states that the NWMI Radioisotope Production Facility (RPF) "will not have any laboratory-scale facilities designed or used for experimental or analytical purposes that relate to the processing of irradiated materials containing special nuclear material…."

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) evaluated the descriptions and discussions of the NWMI production facility as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.2, "Definitions," in the PSAR and finds that the preliminary design of the NWMI production facility does not include experimental facilities. The staff concludes that an evaluation using the guidelines of "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" (Reference 11), for experimental facilities is not required because:

(1) NWMI proposes to produce medical radioisotopes and has not described experimental, educational, or other service uses for its facility; and

(2) There are no experimental facilities penetrating, located near, or that are an integral part of the facility, as described in the NWMI PSAR.

11 RADIATION PROTECTION AND WASTE MANAGEMENT

The purposes of the radiation protection and waste management programs are to ensure safety of the proposed Northwest Medical Isotopes, LLC (NWMI or the applicant) production facility (NWMI production facility or facility) and to provide protection to the NWMI staff, members of the public, and the environment. The radiation protection and waste management programs, identified by the analyses in the NWMI preliminary safety analysis report (PSAR), should be conducted using the appropriate methods and engineering design criteria.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary development of the NWMI radiation protection and waste management programs as presented in Chapter 11.0, "Radiation Protection and Waste Management," of the NWMI PSAR, Revision 3 (Reference 60), and contained in responses to staff requests for additional information (RAIs). As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In the SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

11.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 11.0 against the applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of NWMI's radiation protection and waste management programs for the purposes of issuance of a construction permit under 10 CFR Part 50. As part of this review, the staff evaluated descriptions and discussions of the NWMI production facility radiation protection and waste management programs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary development of the NWMI production facility radiation protection and waste management programs was evaluated to ensure the sufficiency of the design criteria, design bases, and information relative to construction to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications (TSs) for the facility, with special attention given to those items which may significantly influence the final design. The staff documented its review of NWMI's probable subjects of technical TSs for the facility in Chapter 14, "Technical Specifications," of this SER.

Areas of review for PSAR Chapter 11.0 included the following:

- The capability of the programs to identify and discuss all expected radiation and radioactive sources, to include airborne, liquid, and solid sources, and radioactive wastes.

- The design and effectiveness of the radiation protection program required by 10 CFR 20.1101, “Radiation protection programs.”

- The ability to maintain worker and public doses and radiological releases through an as low as is reasonably achievable (ALARA) program, including: (1) a description of the methods to establish, change, and manage policy for the ALARA program; and (2) a description of how the ALARA program is implemented for all activities at the production facility to maintain radiation doses of all personnel and the public and releases of effluents to the unrestricted area ALARA.

- The procedures and equipment at the production facility for routinely monitoring and sampling workplaces and other accessible locations to identify and control potential sources of radiation exposure and releases of radioactive materials.

- The design bases for the equipment and procedures utilized for controlling radiation exposures to personnel and releases of radioactive materials from the production facility.

- The capability of the dosimetry and other methods to effectively assess exposure to radiation and radioactive materials.

- The capability of the programs for contamination control to meet all applicable requirements of the regulations and the production facility ALARA program.

- The capability of the environmental monitoring program to: (1) comply with any commitments made by the applicant; (2) establish preoperational baselines used to ascertain natural background so that the radiological impact of production facility operation on the environment can be determined; (3) promote compliance with environmental quality requirements through the production facility policy and procedures; (4) ensure that the written plans and the bases of procedures for implementing the environmental monitoring programs, including changes, are reviewed for adequacy and approved by authorized personnel; and (5) establish the environmental surveillance program, including information on the selection of sampling and other program parameters.

- The capability to manage radioactive wastes, to include: (1) philosophy of and approach to management of the wastes; (2) organization of the management function; (3) program staffing and position descriptions and program personnel responsibilities and qualifications (4) any review and audit committees related to radioactive waste management; (5) training for staff; (6) plans for shipping, disposal, and long-term storage; (7) program documentation and records, including availability and retention; (8) audits of the effectiveness of the program; (9) bases of procedures; and (10) bases of TSs.

- The effectiveness of the radioactive waste control plans at the production facility to include methods to decrease and minimize the formation of radioactive wastes.

- The methods of characterizing the possible effluents, references to the applicable regulations that establish limits for release, descriptions of the identities and amounts of radionuclides in the effluents, the release points, and the characteristics of the environment to which they are released.

11.2 Summary of Application

As relevant to the review of NWMI's proposed production facility, the preliminary design description contained in PSAR Chapter 11.0 includes an identification of the nature and magnitude of radiation sources generated as a result of facility operation, the associated shielding and ventilation system requirements that help manage occupational and public radiation exposures, the radiation protection program (including ALARA considerations, radiation monitoring, and surveillance, dosimetry, and contamination controls), and environmental monitoring activities. While all specific aspects of the program are not included, enough information has been provided for the staff to make a determination of the adequacy of the program for the purposes of the issuance of a construction permit.

NWMI PSAR, Section 11.1.1.1, "Airborne Radiation Sources," describes the production of radioactive gasses that will be produced as a result of recovery and purification of molybdenum-99 (Mo-99). Targets are to be disassembled one at a time and the target material transferred to a dissolver. The irradiated target material is loaded into the dissolver basket and lowered into the dissolver assembly, and dissolved in hot nitric acid. The production of Mo-99 through this process results in fission products, activation products, and actinides, which provide the majority of radiation sources within the NWMI facility. During normal operations, airborne radioactive materials are to be contained within closed systems. NWMI plans to contain and hold these products to allow for decay, and then allow a filtered release to ensure the airborne constraint release limit of 10 CFR 20.1101(d) is maintained.

NWMI PSAR Section 11.1.1.2, "Liquid Radioactive Sources," describes that liquid radioactive sources will be generated as a result of Mo-99 recovery and purification, recycling of low-enriched uranium (LEU), and liquids resulting from treatment of offgases. During normal operations, liquid radioactive materials are to be contained within closed systems. Dissolution results in uranyl nitrate solution with Mo-99. Uranium recovery and recycle will receive the uranyl nitrate solution once the Mo-99 is removed. The Mo-99 recovery and purification system is designed to extract the Mo-99 from uranyl nitrate solution through three processing cycles of ion exchange of varying chemical processes, each producing its own liquid waste stream and passed to the waste handling system and collected in Waste Collection Tank, MR-TK-340, in the Tank Hot Cell. This section states that there will be no radioactive liquid discharges from the NWMI facility operations to the environment.

NWMI PSAR Section 11.1.1.3, "Solid Radioactive Sources," provides a summary of solid radioactive sources within the NWMI facility. Radioactive material is located in several locations within the NWMI facility, and includes fresh LEU, irradiated LEU targets, and solidified wastes. Wastes generated as a result of production will be stored to allow for radioactive decay to meet shipping and disposal requirements and then packaged in approved transportation casks and containers for transport to the appropriate disposal facility.

NWMI PSAR Section 11.1.2, “Radiation Protection Program,” addresses the following radiation protection program elements: responsibilities of key program personnel; staffing of the radiation protection program; radiation protection program independence; radiation safety committee (RSC); written radiation protection procedures; radiation protection training; and radiation safety audits. NWMI states that the radiation protection program responsibility will be vested in the Radiation Protection Manager (RPM) and that this individual will report to the Environment, Safety, and Health Manager who reports to the Chief Operating Officer (COO). A separate reporting chain to the COO is provided for the Plant Manager and his subordinates. This assures separation of the radiation safety function from the facility operating component(s), thereby facilitating independent radiation safety decisions.

NWMI PSAR Section 11.1.3, “ALARA Program,” states that the policy of NWMI is to conduct radiological operations in a manner to ensure the health and safety of its employees, contractors, and the public. The RPM is responsible for implementing the ALARA program and ensuring that adequate resources are committed to support an effective program. The RPM will prepare an annual ALARA program evaluation report that reviews: trends in radiation exposures and effluent release data; the results of audits and inspections; the use, maintenance, and surveillance of equipment used for exposure and effluent control; and, other issues that may influence program effectiveness. The Radiation Protection Program (RPP) will be independent of operations, with the RPM having direct access to the COO for radiation protection matters. The RSC will periodically review the status of projects and assess program performance.

NWMI PSAR Section 11.1.4, “Radiation Monitoring and Surveying,” provides the general framework of the NWMI facility to determine radiation levels, concentrations of radioactive material, and potential radiological hazards that could be present in the facility. This section describes the intent to detect and assess any releases of radioactive material from facility operations. Included in this section are general descriptions of instrumentation to be used and calibration commitments. This section also describes survey and personnel monitoring equipment and personnel dosimetry program implementation. The use of continuous air monitors (CAMs) for detection of airborne activity is described, as well as exhaust stack monitoring for monitoring of airborne releases.

NWMI PSAR Section 11.1.5, “Radiation Exposure Control and Dosimeter,” addresses the plan for NWMI to ensure external and internal occupational exposures are maintained ALARA. This section provides discussion of the implementation of ALARA in process design and in facility design. Access control is described, and Controlled Areas and Restricted Areas are defined. The PSAR includes definitions for a Radiation Area, High Radiation Area, Very High Radiation Areas, and Airborne Radioactivity Area, as well as the limitations on external and internal exposure. Dosimetry requirements for entry are addressed. Protective equipment and materials to be used are generally described.

NWMI PSAR Section 11.1.6, “Contamination Control,” describes general equipment and facility layout design considerations to prevent the spread of contamination to the facility and the environment. Fixed and removable contamination is defined. When establishing radiological controls for work involving potential loose or airborne contamination, the first consideration is to use techniques that will help prevent or reduce the potential for airborne radioactivity and to maintain loose surface contamination in controlled areas within ALARA levels. Access controls for contaminated areas are addressed, as well as anti-contamination techniques and the handling of potentially contaminated materials.

NWMI PSAR Section 11.1.7, “Environmental Monitoring,” discusses the applicant’s proposed radiological environmental monitoring program (REMP). NWMI will conduct a baseline environmental survey prior to construction to document radiological conditions prior to commencement of operations. This section describes the use of environmental dosimetry posted at the site boundary and lot line to monitor any dose attributable to NWMI operations. Airborne effluent is to be continuously monitored. Groundwater sampling is not planned, because NWMI does not plan to discharge any radioactive liquids directly to the environment. While biota monitoring is not planned for, NWMI intends to evaluate an ingestion exposure pathway through the evaluation of milk samples.

NWMI PSAR Section 11.2.1, “Radioactive Waste Management Program,” addresses the radioactive waste management program, including management responsibilities for the program; the quantities of gaseous, liquid, and solid wastes expected to be generated; and the manner in which waste streams will be partitioned, treated and controlled, packaged, and disposed. The applicant discusses the following aspects of the program: (1) responsibilities of management and supervisory positions; (2) operating procedures; (3) record keeping and document controls; and (4) waste management audits.

NWMI PSAR Section 11.2.2, “Radioactive Waste Management Controls,” addresses the waste NWMI foresees being produced by operations at the NWMI facility. Waste classes as described are consistent with NRC guidance and NWMI commits to generate procedures to identify, characterize, and separately treat the different waste streams in the final safety analysis report (FSAR). NWMI will implement pollution prevention and waste minimization activities that review associated processes and procedures to ensure that the kinds and amounts of waste generated are minimized.

NWMI PSAR Section 11.2.3, “Release of Radioactive Waste,” describes the approach that NWMI will use with respect to the release of radioactive waste. As previously stated, NWMI does not intend to release any liquid radioactive waste and airborne radioactive waste will be held for decay and filtered, such that release levels are less than those defined in Appendix B, “Annual Limits on Intake [ALIs] and Derived Air Concentrations [DACs] of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” of 10 CFR Part 20, “Standards for Protection against Radiation.” This section states that the majority of the radioactive waste being shipped from the NWMI facility will require special containers to provide for the protection of the public and the environment. Each of these containers is designed to meet applicable NRC and U.S. Department of Transportation standards.

NWMI PSAR Section 11.3, “Respiratory Protection Program,” describes the respiratory protection program, and states that a respiratory protection program will be used only when the heating, ventilation, and air conditioning (HVAC) or other engineering controls cannot be applied to control the intake of radioactive material. The respiratory protection program includes the following elements: (1) air sampling; (2) surveys and, when necessary, bioassays; (3) performance testing of respirators for operability; (4) written procedures for all key program elements; and (5) determination by a physician that the individual user is medically fit to use respiratory protection equipment.

NWMI states in PSAR Chapter 11.0 that its radiation protection program will be designed to protect the radiological health and safety of its workers and the public. NWMI states that the program will be structured to comply with the regulatory requirements of 10 CFR Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” and

10 CFR Part 20. The program will be designed to include the elements of an ALARA program, radiation monitoring and surveying, exposure control, dosimetry, contamination control, and environmental monitoring.

11.3 Regulatory Basis and Acceptance Criteria

The staff reviewed the NWMI PSAR Chapter 11.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility radiation protection and waste management programs for the issuance of a construction permit under 10 CFR Part 50. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 9). The staff's review in Chapter 2, "Site Characteristics," of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

11.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the radiation protection and waste management programs at the proposed NWMI production facility are as follows:

- 10 CFR Part 20, "Standards for Protection against Radiation."
- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.35, "Issuance of construction permits."
- 10 CFR 50.40, "Common standards."

11.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- 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 (Reference 9).
- "Final Interim Staff Guidance [ISG] 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 (Reference 10).
- "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 (Reference 11).

The ISG Augmenting NUREG-1537, Parts 1 and 2 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, Parts 1 and 2, it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of items relied on for safety (IROFS), and

establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537, Part 2.

As appropriate, the 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) in its review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

11.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 11.0 to assess the sufficiency of the radiation protection and waste management programs for the issuance of a construction permit, in accordance with 10 CFR Part 50. The sufficiency of the radiation protection and waste management programs is demonstrated by acknowledgement and commitments to applicable regulatory requirements, guidance, and acceptance criteria, as discussed in SER Section 11.3, "Regulatory Basis and Acceptance Criteria." A summary of the staff's technical evaluation is described in SER Section 11.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the radiation protection and waste management programs may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the radiation protection and waste management programs based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with an adequate margin for safety. The staff's evaluation of the preliminary design of the NWMI production facility radiation protection and waste management programs does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the NWMI production facility radiation protection and waste management programs, as described in the FSAR submitted as part of NWMI's operating license (OL) application.

11.4.1 Radiation Sources

The staff evaluated the sufficiency of the information provided on the radiation sources, as described in NWMI PSAR Section 11.1.1 and as summarized above in SER Section 11.2, for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.1, "Radiation Sources," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 11.1.1, the staff evaluated the discussion of potential sources of radiation in the facility, as presented in NWMI PSAR Section 11.1.1 and other relevant chapters of the PSAR. The staff compared the

description of the types of radioactive materials present with the applicable process description, including radionuclide inventories and mass balances and chemical and physical forms, to verify that all radioactive materials associated with the process have been identified. The staff reviewed the description and discussion of all sources of radiation to verify that they are described in sufficient detail to provide the bases for the design and assessment of personnel protective measures and radiation doses. The staff confirmed that all solid, liquid, and gas sources of radiation at the facility are described and discussed in sufficient detail to permit evaluation of all significant radiological exposures related to normal operation, utilization, maintenance, and radioactive waste management including processing and shipment.

NWMI PSAR Section 1.3.2.2.1, "Target Fabrication Process Description," states that LEU feed will be in the form of acid-deficient uranyl nitrate solution, consisting of fresh, scrap, and recycled LEU. The uranium target material is loaded into aluminum target elements, filled with helium or air cover gas, seal-welded, and quality checked. Following irradiation provided by a designated research reactor and return to the NWMI facility, targets are disassembled and target material transferred to a collection container, and lowered into a dissolver. Purification and separations are conducted to remove unwanted isotopes from the recovered Mo-99 product. A part of the waste solutions will contain LEU, which is processed for recovery and recycle. The nature of much of these summarized processes are carried out in hot cells, not only due to radiological and criticality concerns, but also due to containment and filtration of the associated gases. All of these processes are carried out within the biological shield of the NWMI facility, as discussed in NWMI PSAR Chapter 4.0, "Radioisotope Production Facility Description." The NWMI facility biological shield provides an integrated system of features that protects workers from the high-dose radiation generated during the processing to recover Mo-99. The primary function of the biological shield is to reduce radiation dose rates and accumulated doses in occupied areas so as to not exceed the limits expressed in 10 CFR 20.1201, "Occupational dose limits for adults."

Target fabrication processes include the storage of LEU target material and targets, production of useable LEU from fresh and recycled LEU, and assembly and loading of LEU targets for irradiation. Targets are packaged and shipped to a network of university reactors for irradiation. Once irradiation is complete, the targets are returned to the NWMI facility in a shipping cask, with a decay period of at least 8 hours prior to further processing. Receipt activities are completed in staggered fashion, with four targets processed at a time, including transfer to the disassembly hot cell. From there, targets are moved to hot cells for dissolution and then Mo-99 recovery and purification.

Confinement is used as the primary engineered safety feature (ESF) incorporated into the preliminary hazards analysis and is detailed in NWMI PSAR Chapter 6.0, "Engineered Safety Features." Confinement is designed to limit the exchange of effluents between enclosures and its external environment to controlled monitored pathways. Along with confinement, sufficient negative pressure is to be maintained to prevent uncontrolled leakage outside the confined area. In addition, IROFS associated with the confinement system were derived from the accident analysis in NWMI PSAR Chapter 13.0, "Accident Analysis." The IROFS associated with the confinement system are designed to control the release of radioactive material and maintain radiation levels below applicable radiation exposure limits, as prescribed by 10 CFR Part 20, for the protection of workers and the public.

NWMI PSAR Section 11.1.1.1 states that targets are to be disassembled one at a time and the target material transferred to a dissolver. The irradiated target material is loaded into the dissolver basket, lowered into the dissolver assembly, and dissolved in nitric acid.

The production of Mo-99 through this process results in fission products, activation products, and actinides, which provide the majority of radiation sources within the NWMI facility. Airborne radioactive sources within the NWMI facility will consist of radioactive gases released during the recovery and purification of Mo-99. Radioactive gases will originate from three areas in the RPF, shown in NWMI PSAR Figure 11-1, "Radioisotope Production Facility Airborne Radiation Source Areas." These are the Target Fabrication Area (within the RPF, but outside the NWMI production facility), Tank Hot Cell (within the production facility), and Waste Management Area (within the production facility). NWMI PSAR Table 11-1, "Gaseous Radioactive Source," provides an extensive breakdown of the gaseous radioactive sources from routine operation from the weekly throughput of eight irradiated targets, not including decay. The basis of this bounding inventory is found in NWMI-2013-CALC-006, "Overall Summary Material Balance - MURR Target Batch" (Reference 72). The offgas expected consists of nitrogen oxide, nitric acid vapors, water vapor, and fission products. Nitrogen oxide and nitric acid vapors will be removed through a treatment subsystem of condensers and absorbers.

Fission product gases are released from the targets during processing. Gases containing fission products will go through a series of cleanup columns. The primary functions of the fission gas retention equipment are to remove radioiodine from the gas stream and delay the release of noble gases to allow release from the stack. Iodine will be absorbed from the offgas stream by the iodine removal unit, an ESF. Each iodine removal unit is expected to remove a significant percentage of iodine from the inlet stream. In conjunction with the dissolver offgas primary absorber and iodine guard bed, a decontamination factor of 10^5 is anticipated. An iodine radiation detector will be placed downstream of each iodine guard bed to verify adequate iodine removal. Other gaseous fission products will be delayed by absorption beds to allow for sufficient decay. For noble gases, gas release will be delayed prior to release from the stack. Preliminary analysis indicates xenon-133 controls the required delay, with a 60-day hold planned. Following processing through the primary absorber referred to above, a secondary absorber provides the bulk of the delay of 50 to 60 days.

As stated in 10 CFR 20.1101(d), licensees are required to establish a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughter products, such that the individual member of the public likely to receive the highest dose is not expected to receive a total effective dose equivalent (TEDE) in excess of 0.1 millisievert (mSv) (10 millirem [mrem]) per year from these emissions. NWMI used the guidance of Regulatory Guide (RG) 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors" (Reference 68), to evaluate the constraint requirement. The regulatory guide states that one method of demonstrating compliance with the requirement is through the use of computer codes.

As discussed in NWMI PSAR Section 11.1.1.1.2, NWMI used Level 4 of the COMPLY computer model, Version 1.6 (Reference 42), to demonstrate compliance with 10 CFR 20.1101(d) for the NWMI facility for normal operations. NWMI PSAR Table 11-2, "Radionuclide Stack Release Source Term Input to COMPLY," was developed by combining the effluent from each of the systems that is vented to the process vessel vent system and applying appropriate decontamination factors. This source term is based on the processing of eight (8) University of Missouri-Columbia Research Reactor (MURR) targets, 8 hours after irradiation is completed. Decay of krypton and xenon is included, as indicated above. The dose analysis considered the release of airborne radionuclides and exposure to off-site individuals through direct exposure and potential environmental pathways, such as the ingestion of leafy vegetables, meat, and milk. Meteorological data for the area and planned construction dimensions were used. The maximum dose to the public at the nearest receptor (30 feet (9.1 meter) from the NWMI facility)

under normal operating conditions was determined to be 0.036 milli-Sievert per year (mSv/yr) (3.6 millirem per year [mrem/yr]). Activities in the NWMI facility are designed such that the estimated annual doses to the maximally exposed individual and the nearest resident are below the dose constraint of 10 mrem/yr (0.1 mSv/yr) as specified in 10 CFR 20.1101(d).

In NWMI PSAR Section 4.1.2.1, "Process Design Basis," NWMI indicated that the nominal process design capability was 12 targets per week from MURR for up to 52 weeks per year, and approximately 30 targets per year to be received from Oregon State University (OSU). The staff noted that this exceeded the source term used in the COMPLY code, as described above, and issued RAI 11.1-1 (Reference 13) to obtain clarification on the impact to public dose from this increased throughput. NWMI stated in response to RAI 11.1-1 (Reference 17) that this section would be updated in the FSAR as part of the OL application and that the basis would be consistent with nominal operating conditions. The staff is tracking this issue in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER. The primary dose contributor would be the noble gas xenon, and the offgas system's planned retention for decay, which is described in NWMI PSAR Section 11.1.1.1.2, would ensure that releases of xenon would remain below release limits. The staff finds that NWMI's response to RAI 11.1-1 is acceptable because it sufficiently clarifies the basis for the source term based on number of targets. Additionally, the staff notes that NWMI stated during the August 23, 2017, Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee meeting that routine radioactive release calculations provided in the FSAR would be based on the maximum amount of targets that its license would allow to be processed.

In NWMI PSAR Section 11.1.1.3, the applicant states that the processing of 30 targets from OSU will not occur until after approximately 48 hours of decay has occurred prior to receipt of the 30 targets at the NWMI facility, resulting in less radioactivity than the eight MURR targets evaluated in the application.

NWMI PSAR Section 11.1.1.2 states that liquid radioactive sources will be generated from Mo-99 recovery and purification, recycling of LEU, and liquids resulting from treatment of process gases. Dissolution of the irradiated targets results in uranyl nitrate solution with Mo-99. Uranium recovery and recycling will receive the uranyl nitrate solution once the Mo-99 is removed. The Mo-99 recovery and purification system is designed to extract the Mo-99 from uranyl nitrate through three cycles of ion exchange of varying chemical processes, each producing its own liquid waste stream and passed to the waste handling system, collected in Waste Collection Tank MR-TK-340 in the tank hot cell.

Liquid waste is split into high-dose and low-dose streams by concentration. The high-dose fraction will be adjusted and mixed with adsorbent material. Part of the low-dose liquid fraction is expected to be suitable for recycling to selected systems as process water. Water that is not recycled will be adjusted and then mixed with adsorbent material. No radioactive liquid discharges from the NWMI facility are planned for the sewer or the environment. PSAR Table 11-3, "Liquid Radioactive Source," provides the liquid waste inventory anticipated from the generic processing scheme described above, which is the effluent from the dissolver based on eight targets, 8 hours post-irradiation in a 1-week period. Any liquid radioactive waste will be treated and/or solidified prior to being packaged and shipped to a disposal facility.

NWMI PSAR Section 11.1.1.3 states that radioactive material is located in several locations within the NWMI facility, and includes fabricated material, irradiated material, and processed material. The process starts with LEU in the target fabrication area. NWMI PSAR Table 1-1,

"Special Nuclear Material Inventory of Target Fabrication Area," identifies the approximate mass of material for the fabrication process to support the weekly throughput of eight targets processed per week. NWMI PSAR Table 1-2, "Special Nuclear Material Inventory of Irradiated Material Areas," approximates the material on return from irradiation. NWMI will specify the possession limits that it is requesting in the OL application, but these tables are representative of the materials to carry out the process defined in the construction application.

Fresh LEU, irradiated LEU target material, and solidified waste make up the solid radioactive waste sources. Normally, solid radioactive material is contained in tanks and shielded hot cells within restricted areas. NWMI PSAR Table 11-4, "Solid Radioactive Source," provides a summary of the solid radioactive source term in the NWMI facility. This is based on the projected eight MURR targets, eight hours post-irradiation, representing one work week. The table includes the eight MURR targets and accumulated high-dose and low-dose waste from processing, neglecting decay, and was further explained in NWMI-2013-CALC-006. NWMI-2013-CALC-006 uses the general inventory of radioactive material and waste from the radioisotope extraction system, described in NWMI PSAR Chapter 4.0. Each of the sub-processes of disassembly, dissolution, and purification all contribute to the inventory, and are delineated in their respective sections in Chapter 4.0, but are listed in NWMI PSAR Table 11-4.

The staff reviewed the description of expected radiation sources and associated doses including the inventories, chemical and physical forms, and locations of radioactive materials, and other facility radiation and operational parameters related to radiation safety presented in the NWMI PSAR. 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 confirm that the application identifies the potential radiation safety hazards associated with the NWMI facility and provides an acceptable basis for development and independent review of the radiation protection program.

Based on its review, the staff finds that the level of detail provided for the preliminary design satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.1. The staff finds that the applicant sufficiently identified and described in the PSAR the potential radiation sources and associated doses including the inventories, chemical and physical forms, and locations of radioactive materials, and other facility radiation and operational parameters related to radiation safety. The staff also finds that the bases for identifying potential radiation safety hazards with the process and facility descriptions have been compared to verify that such hazards were accurately and comprehensively identified in the PSAR. Furthermore, the staff finds that, as described in the PSAR, the potential radiation safety hazards associated with the NWMI production facility provide an acceptable basis for the development of the radiation protection program. The staff review also finds that analyses of system operations show that planned releases of airborne radioactive material to the unrestricted environment will not expose the public to doses that exceed the limits of 10 CFR Part 20. Further information on radiation sources can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive material throughout the facility so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that the radiation sources of the NWMI production facility meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.2 Radiation Protection Program

The staff evaluated the sufficiency of the information provided on the radiation protection program, as described in NWMI PSAR Section 11.1.2, for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.2, "Radiation Protection Program," of NUREG-1537, Parts 1 and 2. Consistent with the review procedures of NUREG-1537, Part 2, Section 11.1.2, the staff evaluated: (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 reviewed NWMI PSAR Section 11.1.2 to evaluate commitments by NWMI to implement the requirements of 10 CFR 20.1101 for its radiation protection program. The application includes commitments related to key program personnel, radiation protection program staffing, independence of the radiation protection program from facility operations, establishment and functioning of a RSC, development of radiation protection procedures, providing radiation protection training, conducting radiation safety audits, and record-keeping activities. In response to RAI 11.1-2a (Reference 17), NWMI states that it will provide its radiation protection program as part of its OL application. The staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 11.1.2 states that NWMI management is committed to conducting radiological operations in a manner that ensures the health and safety of employees, contractors, and the public. NWMI commits to protecting workers, the public, and the environment from unacceptable exposure to ionizing radiation sources. NWMI commits to ensuring that radiation exposure to workers and the public, and releases of radioactivity to the environment, are maintained below regulatory limits. NWMI states that the radiation protection program will protect the radiological health and safety of workers and members of the public and comply with the regulatory requirements in 10 CFR Part 19 and 10 CFR Part 20.

NWMI PSAR Section 11.1.2.1, "Responsibilities of Key Program Personnel," states that the NWMI COO has overall responsibility for the operation of the NWMI facility, including radiation protection. A detailed NWMI organization chart is provided in NWMI PSAR Chapter 12.0, "Conduct of Operations," Figure 12-1, "Northwest Medical Isotopes, LLC Organization Chart," and displays the organizational reporting hierarchy. The COO reports directly to the President and Chief Executive Officer for operational aspects of the company, including safety, quality, security and safeguards, and regulatory licensing. The organizational structure identifies internal and external functions for NWMI, including interface responsibilities for multiple organizations.

NWMI PSAR Section 11.1.2.3, "Independence of the Radiation Protection Program," states that the NWMI radiation protection program is established independent of facility operations, which helps ensure that the radiation protection program 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 ALARA.

NWMI PSAR Section 11.1.2.1.1, “Plant Manager,” identifies the responsibilities of the Plant Manager. The NWMI Plant Manager, another direct reporter to the COO, is responsible for the safe operation of the NWMI facility, including the protection of workers and the public against radiation exposure resulting from facility operations and materials. The Plant Manager is responsible for ensuring compliance with applicable NRC, State, and local regulations.

NWMI PSAR Section 11.1.2 states that NWMI policy is to maintain a radiation protection program commensurate with the scope of NWMI facility operations, and to the extent practical, use procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are consistent with the ALARA program. NWMI plans to perform an annual review of the content and implementation of the radiation protection program.

NWMI PSAR Section 11.1.2 states that NWMI established administrative exposure limits below the regulatory limits specified in 10 CFR Part 20 in order to ensure that those dose limits are not exceeded and to emphasize ALARA principles. The administrative occupational exposure limit is set at 2 rem/year. Constraints on atmospheric releases from the NWMI facility have been established to ensure that no member of the public would be expected to receive a TEDE in excess of 0.1 mSv/yr (10 mrem/yr).

NWMI PSAR Section 11.1.2 states that the ALARA goal and dose investigation level is set at 500 mrem/yr. In NWMI PSAR Section 11.1.2 and in its response to RAI 11.1-2d (Reference 17), NWMI described its definition of “dose investigation level,” stating that if an individual exceeded 500 mrem TEDE in a year, it would trigger an investigation by the radiation protection staff to determine the basis of the exposure, if the individual would normally not be expected to receive that dose. Additionally, NWMI explained that the routine TEDE for the workers was not expected to approach this level. Furthermore, NWMI added that the investigation process might include interviews with the individual and their immediate supervisor and a review of radiation work permits (RWPs) and procedures.

NWMI PSAR Section 11.1.2, Table 11-5, “Estimated Radioisotope Production Facility Controlled and Restricted Area Dose Rates,” provides dose rates for a variety of areas within the NWMI facility. In its response to RAI 11.1-2a, which requested the basis of the dose rates, NWMI explained that these values were either based on actual shielding calculations or were the goals and/or endpoints of the shielding analysis. NWMI indicated that the table will be updated in the FSAR. The staff finds this response acceptable because it sufficiently clarifies the basis for the dose rates. The staff is tracking this issue in Appendix A of this SER. In NWMI PSAR Section 11.1.2, NWMI stated that dosimetry is anticipated to be required in any radiologically restricted area. Additionally, NWMI plans to add information in its FSAR describing the area monitoring program to be implemented in order to demonstrate compliance with exposure limits.

NWMI PSAR Section 12.2, “Review and Audit Activities,” states that the Plant Manager establishes the Review and Audit Committee to ensure that appropriate technical expertise is available for review and audit activities. NWMI PSAR Section 12.2.1, “Composition and Qualifications,” states that the Review and Audit Committee will provide the Plant Manager and NWMI management an independent assessment of NWMI facility operations. The number and qualifications of members of the committee and potential use of members from outside the organization will be established in the FSAR as part of the NWMI OL application. With respect

to independence of auditors, NWMI PSAR Section 12.2.4, “Audit Function,” states that individuals with immediate responsibility for an area cannot perform an audit in their area of responsibility. NWMI will establish relationships with outside expertise in NWMI facility audits. With respect to operations of the Review and Audit Committee, NWMI PSAR Section 12.2.2, “Charter and Rules,” states that a charter will be established to address items such as meeting frequency, quorum for meeting, and protocols. NWMI PSAR Section 12.2 states that a report of the activities of the Review and Audit Committee will be provided to the COO. NWMI PSAR Section 12.2.3, “Review Function,” identifies a minimum list of items that will be reviewed by the committee. Included in this list are the radiation protection program, new procedures, new equipment, reportable occurrences, and operating abnormalities.

NWMI PSAR Section 11.1.2.1.2, “Safety, Health and Licensing Manager,” states the role of the NWMI Safety, Health, and Licensing (SH&L) Manager, who has overall responsibility for development and implementation of programs addressing worker safety and health. The SH&L Manager is responsible for NRC licensing, any State and local permitting, and compliance monitoring for license and permits. Safety and health is independent of operations and the SH&L Manager has the authority to shut down NWMI facility operations that are judged to be unsafe. The SH&L Manager also has responsibility for nuclear criticality safety, environmental protection, chemical safety, fire protection, security, emergency preparedness, and the integrated safety analysis.

NWMI PSAR Section 11.1.2.1.3, “Radiation Protection Manager,” states that the NWMI RPM reports directly to the SH&L Manager, who reports directly to the COO. While the SH&L Manager is tasked with overall responsibility for NRC licensing, the RPM is primarily responsible for the radiation protection program and, organizationally, has direct access to the COO in matters of radiological protection.

The RPM has primary responsibility for the development and implementation of programs affecting personnel radiation exposures and environmental impacts due to operations of the NWMI facility. The RPM is responsible for the following, described in Section 11.1.2.1.3 of the NWMI PSAR:

- Establishing and implementing the radiation protection program for the NWMI facility.
- Serving as the facility Radiation Safety Officer.
- Generating and maintaining procedures associated with the radiation protection program.
- Reviewing and auditing the radiation protection program to ensure compliance with regulations and associated regulatory guides.
- Adequate staffing of the radiation protection program for implementation.
- Establishing and maintaining the ALARA program.
- Establishing and maintaining the respiratory protection program.
- Monitoring internal and external worker doses.

- Complying with radioactive materials possession limits.
- Responsible for the calibration and quality assurance of radiological instrumentation.
- Establishing and maintaining the radiation safety training program.
- Performing annual audits of the radiation protection program.
- Establishing and maintaining the radiological environmental monitoring program.
- Posting restricted areas and developing occupancy guidelines.

NWMI PSAR Section 11.1.2.4, "Radiation Safety Committee," states that NWMI plans to use a Radiation Safety Committee to review the status of projects, performance, trends, and aspects of facility operations. The RPM chairs the Radiation Safety Committee and the committee is made up of staff from quality assurance (QA), operations, maintenance, and technical support, as deemed appropriate by the Plant Manager. The committee meets at least semi-annually. Minutes of the meetings are forwarded to all managers.

NWMI monitors performance through a graded approach to items and activities that affect the quality-related SSCs. The QA program is described in NWMI PSAR Chapter 12.0, Appendix C, "Quality Assurance Program Plan for the Design, Construction, and Operation of the Radioisotope Production Facility," and outlines responsibilities from the COO to facility staff for engagement in quality performance. Requirements for the QA organization include not only the review and implementation of procedures, but also the administration of corrective action and nonconformance, and the monitoring and implementation of the QA program plan through assessment, audit, and surveillance.

NWMI PSAR Chapter 12.0, Appendix C, Section C2.1.2.4.1, "Operations Manager," states that the Operations Manager reports directly to the Plant Manager and has responsibility for day-to-day NWMI facility operations activities. Inherent in this responsibility is assuring that operations are conducted safely and in compliance with license conditions.

NWMI PSAR Chapter 12.0, Appendix C, Section C2.1.2.5.1, "Shift Supervisors," states that the shift supervisors report to the Operations Manager and are first-line supervision for the safe operation of the NWMI facility. Shift supervisors will authorize day-to-day activities, including control of access to the facility, deliveries and shipments, work activities, equipment startup and shutdown, and directing abnormal and emergency actions.

NWMI PSAR Chapter 12.0, Appendix C, Section C2.1.3, "Staffing," states that NWMI will provide sufficient resources in personnel and materials to safely conduct operations. Staffing levels, staffing considerations, overtime restrictions, detailed procedures, and routine operations will be defined in the FSAR as part of NWMI's OL application. On-site personnel are required to work safely and to follow the rules, regulations, and procedures that have been established for their protection and the protection of the public. Personnel whose duties require (1) working with radioactive material, (2) entering restricted areas, (3) controlling facility operations that could affect effluent releases, or (4) directing the activities of others, are trained so that they understand and effectively carry out their responsibilities.

NWMI PSAR Section 12.1.4, “Selection and Training of Personnel,” states that the Procedures and Training Manager will be responsible to the Plant Manager for the development and implementation of training that ensures satisfactory operational performance in the areas of nuclear, industrial, and radiological safety. NWMI commits to ANSI/ANS 15.4-2007, “Selection and Training of Personnel for Research Reactors” (Reference 44), for the selection and training of personnel, including record maintenance and retention.

In NWMI PSAR Section 11.1.2.2, “Staffing of the Radiation Protection Program,” NWMI commits to providing sufficient resources in staffing and equipment for implementing an effective radiation protection program. The RPM will have a bachelor’s degree (or equivalent), as a minimum, in an engineering or scientific field and 4 years of applicable nuclear experience. NWMI commits that other members of the radiation protection staff will be trained and qualified consistent with ANSI/ANS 15.11-2009, “Radiation Protection at Research Reactor Facilities” (Reference 59).

NWMI PSAR Section 11.1.2.8, “Radiation Work Control Procedures,” states that all work performed in restricted areas of the NWMI facility will be performed under a RWP and consistent with the guidance RG 8.10, “Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable” (Reference 81). Procedures will be used to control radiation protection activities to ensure that the activities are carried out in a safe, effective, and consistent manner. Routine and non-routine activities will be performed under an RWP. Radiation protection procedures are to be prepared, reviewed, and approved to carry out activities related to the radiation protection program. Radiation protection procedures will be reviewed and revised, as necessary, by the radiation protection supervisor to incorporate any facility or operational changes.

NWMI PSAR Section 12.3, “Procedures,” states that operating procedures will provide appropriate direction to ensure that the NWMI facility is operated within its design basis and in compliance with TSs. Operating procedures will be written, reviewed, approved by appropriate management, controlled, and monitored to ensure that content is technically correct and that the wording and format are clear and concise. Procedure changes, including substantive and minor changes and temporary deviations, will comply with guidance in ANSI/ANS-15.1-2007, “The Development of Technical Specification for Research Reactors” (Reference 43).

NWMI PSAR Section 11.1.2.8 states that the RWPs will be developed with a limited duration and validity, except for standing RWPs, such as tours of the NWMI facility by shift personnel. The RPM, or designee, will approve an RWP. A designee must meet specific training requirements. The general idea is that an RWP will consider all necessary precautions, such as personal protective equipment, applicable stay times, recordkeeping, and required technician oversight. The issue and closure of an RWP will be the responsibility of the RPM. Shift supervisors are responsible for authorization of work activities in accordance with the RWP. RWPs will require the following:

- Review of planned activities and changes to activities inside restricted areas, or work with licensed material for potential to cause radiation exposures exceeding action levels or produce contamination.

- Specifying requirements for safety controls, personnel protective equipment, personnel monitoring, respiratory equipment, air sampling requirements, and technician oversight.

- Posting of RWPs at access points to restricted areas.

- Clear definition of work scope allowed.
- RWP closure.
- Record retention.

NWMI PSAR Section 11.1.2.5, “Training Programs,” states that all staff and visitors entering restricted areas will receive training commensurate with the radiological hazard to which they may be exposed. Visitors will be provided with trained escorts who have received radiation protection training. The design and implementation of the radiation protection training program will comply with the requirements of 10 CFR 19.12, “Instruction to workers.” Records of training will be maintained in accordance with 10 CFR Part 20.2110, “Form of records.”

Radiation protection training for NWMI facility staff will take into consideration a worker’s normally assigned work activities. The extent of these instructions will be commensurate with the radiological health protection considerations appropriate for the workplace. The development and implementation of the radiation protection training program will be consistent with the guidance provided in the following regulatory guidance documents:

- ASTM E1168-95, “Standard Guide for Radiological Protection Training for Nuclear Facility Workers” (Reference 91)
- ANSI/ANS-15.11, “Radiation Protection at Research Reactor Facilities” (Reference 59)
- RG 8.10, “Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable” (Reference 81)
- RG 8.13, “Instruction Concerning Prenatal Radiation Exposure” (Reference 69)
- RG 8.29, “Instruction Concerning Risks from Occupational Radiation Exposure” (Reference 74)

NWMI states that the level of radiation protection training is based on the potential radiological health risks associated with an employee's work responsibilities and incorporates the provisions of 10 CFR 19.12. In accordance with 10 CFR 19.12, any individual working at the facility who is likely to receive, in a year, a dose in excess of 1 mSv (100 mrem) shall be:

- Kept informed of the storage, transfer, or use of radioactive material.
- Instructed in the health protection problems associated with exposure to radiation and radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed.
- Required to observe, to the extent within the worker's control, the applicable provisions of the NRC regulations and licenses for the protection of personnel from exposure to radiation and radioactive material.

- Instructed of their responsibility to report promptly to the facility management, any condition which may cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and radioactive material.

- Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and radioactive material.

- Advised of the various notifications and reports to individuals that a worker may request in accordance with 10 CFR 19.13, "Notifications and reports to individuals."

Retraining of previously trained personnel will be performed for radiological, chemical, industrial, and criticality safety at least annually. The retraining program will also include procedure changes and updating and changes in required skills. Changes to training will be implemented, when required, due to incidents potentially compromising safety or if changes are made to the facility or processes. Records of training will be maintained in accordance with the NWMI records management system. Training programs will be established in accordance with NWMI PSAR Section 12.10, "Radioisotope Production Facility Operator Training and Requalification." The radiation protection sections of the training program will be evaluated at least annually by the SH&L Manager. The program content will be reviewed to ensure that it remains current and adequate to ensure worker safety.

NWMI PSAR Section 12.2.4 states that all aspects of facility operations, including radiation protection and laboratory programs, emergency preparedness, physical security, and operator training and requalification, will be audited every 2 years. NWMI PSAR Section 12.2.3, "Review Function," states that the radiation protection program will be audited annually, at a minimum, by the Review and Audit Committee, to review all functional elements of the program, and meet the requirements of 10 CFR 20.1101(c). Deficiencies identified during an audit will be entered into the NWMI corrective action program.

NWMI PSAR Section 12.6, "Records," states that the records management program will define the process for managing NWMI facility records and will be consistent with the requirements of applicable regulations. NWMI PSAR Section 11.1.2.9, "Recordkeeping," states that, for additional radiation protection program commitments applicable to records and reports, NWMI will meet the following:

- 10 CFR Part 20, Subpart L, "Records," and Subpart M, "Reports"

- 10 CFR 70.51, "Records requirements"

- 10 CFR 50.71, "Maintenance of records, making of reports"

- ANSI/ANS-15.8, "Quality Assurance Program Requirements for Research Reactors" (Reference 45)

- ANSI/ANS-15.11, "Radiation Protection at Research Reactor Facilities" (Reference 59)

Included in the NWMI record-keeping commitments are program provisions such as content; audits; reviews; survey results, including air sampling; area monitoring and personnel monitoring, both internal and external; and corrective action program referrals.

Based on its review, the staff finds that the description of the radiation protection program presented in the NWMI PSAR complies with the applicable requirements and that the level of detail provided on the radiation protection program is adequate and satisfies the regulations in 10 CFR 20.1101 and the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.2. Commitments related to key program personnel, radiation protection program staffing, independence of the radiation protection program from facility operations, establishment and functioning of a RSC, development of radiation protection procedures, providing radiation protection training, conducting radiation safety audits, and record-keeping activities are included in the application.

The staff review also finds, consistent with the guidance in NUREG-1537, Part 2, Section 11.1.2, that the applicant describes: (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 NWMI's description of the radiation protection program provides reasonable assurance of NWMI management's commitment to radiation protection in order to protect the facility staff, the environment, and the public from exposure to radiation.

The staff finds that further information on the radiation protection program can be reasonably left for later consideration in the FSAR since it is not expected to impact construction of the facility, and because the facility's design bases support the control of radioactive material throughout the facility so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that NWMI's description of its radiation protection program is sufficient, and therefore NWMI meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.3 ALARA Program

The staff evaluated the sufficiency of the information provided on the NWMI program for maintaining worker and public doses and radiological releases ALARA, as described in NWMI PSAR Section 11.1.3 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.3 of NUREG-1537, Part 2. Consistent with the review procedures of NUREG-1537, Part 2, Section 11.1.3, the staff review included an assessment of the applicant's ALARA program to ensure that: (1) radiation doses received by facility staff and members of the public are maintained ALARA; (2) the highest levels of facility management are committed to the ALARA program; (3) exposure records are periodically reviewed, analyzed for trends and factors, and methods evaluated for reducing exposures; and

(4) sufficient emphasis and resources are given to ALARA considerations during design, construction, operation, maintenance, and disposal activities.

NWMI PSAR Section 11.1.3.1, “ALARA Policy,” states that NWMI’s policy is to conduct radiological operations in a manner to ensure the health and safety of its employees, contractors, visitors, and the public. NWMI is committed to ensuring that radiation exposures to workers and the public, and that releases of radioactivity to the environment, are maintained below regulatory limits. Deliberate actions will be taken to further reduce exposures and releases in accordance with a process focused on keeping exposures or releases ALARA. NWMI is fully committed to implementing an ALARA program that consistently reflects this policy.

NWMI PSAR Section 11.1.3.2, “Approach to ALARA Program,” states that NWMI is committed to the implementation of an ALARA program. The objective of the program is to make every reasonable effort to maintain facility exposures as far below the dose limits of 10 CFR 20.1201 as practical, and to maintain the radiation exposures to the public below the dose constraints of 10 CFR 20.1301, “Dose limits for individual members of the public.” The goals of the NWMI ALARA program are to ensure that occupational exposures and environmental releases are as far below regulatory limits as reasonably achievable.

NWMI PSAR Section 11.1.3.2 states that the NWMI facility design incorporates ALARA principles into processes, systems, and components. As the design matures, NWMI staff continues to evaluate suggested approaches to reduce radiation dose to workers and the public. Areas where facility personnel are expected to spend significant time are designed so that dose rates are maintained ALARA. The areas with higher doses rates will be minimized. Radiation areas will be established to minimize the spread of contamination and reduce unnecessary exposure of personnel to radiation. NWMI states that 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 alarms 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 NWMI ALARA program is supported at the highest levels of management for the facility.

NWMI PSAR Section 11.1.3.2 states that the RPM is responsible for implementing the NWMI ALARA program and ensuring that adequate resources are committed to support an effective program. An annual ALARA program evaluation report will be prepared that summarizes (1) radiological exposure and effluent release data for trends; (2) audits and inspections; (3) use, maintenance, and surveillance of equipment used for exposure and effluent control; and (4) other issues, as appropriate, that may influence the effectiveness of the radiation protection and ALARA programs. Copies of the report will be submitted to the COO, Radiation Safety Committee, and Plant Manager.

NWMI PSAR Section 11.1.3.2 states that the Radiation Safety Committee will review the effectiveness of the ALARA program at least every quarter and determine if exposures, releases, and contamination levels are in accordance with ALARA principles. The committee will also evaluate the results of assessments made by the Radiation Protection organization and reports of facility radiation levels, contamination levels, and employee exposures for identified categories of workers and types of operations. The Radiation Safety Committee report will be forwarded to all facility managers for their review.

NWMI PSAR Section 11.1.3.2 states that the design and implementation of the ALARA program will be consistent with the guidance provided in RGs 8.2, "Administrative Practices in Radiation Surveys and Monitoring," 8.13, "Instruction Concerning Prenatal Radiation Exposure," 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," and 8.37, "ALARA Levels for Effluents from Materials Facilities" (References 71, 69, 74, and 76, respectively). The overall operation of the facility will be consistent with the guidance provided in RG 8.10. NWMI commits to following the guidance of RG 4.21, "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning" (Reference 47), to minimize, to the extent possible, contamination of the facility and the environment, the generation of radioactive waste, and facilitate decommissioning.

NWMI PSAR Section 11.1.5.1, "Process Design for ALARA," and Section 11.1.5.2, "Facility Design for ALARA," provide examples of ALARA considerations which were incorporated into the NWMI facility and process designs in order to reduce personnel radiation exposures. A few examples are listed below:

- Modularization of components.
- HVAC system designed to maintain airflow patterns from lowest to highest potential for contamination.
- Conduct of maintenance and repair in lower radiation areas.
- Remote operation of equipment.
- Processing of irradiated targets under sub-atmospheric pressure.
- Equipment and component design to reduce the need for repair or maintenance.
- Equipment and piping design to minimize accumulation of radioactive materials.
- Remote cleaning and decontamination.

Based on its review, the staff finds that the level of detail provided on the ALARA program satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.3, and is consistent with the applicable guidance contained in RG 8.10. Specifically, the staff finds that the applicant's ALARA program helps to ensure that: (1) radiation doses received by facility staff and members of the public are maintained ALARA; (2) the highest levels of facility management are committed to the ALARA program; (3) exposure records are periodically reviewed, analyzed for trends and factors, and methods evaluated for reducing exposures; and (4) sufficient emphasis and resources are given to ALARA considerations during design, construction, operation, maintenance, and disposal activities.

Additionally, the staff finds that the applicant has clearly defined an ALARA program that has guided the design of plant features to ensure that occupational and public exposures will be maintained at the lowest practicable level; the applicant has designated a responsible individual for developing the ALARA program and formally evaluating its effectiveness annually; and a number of ALARA features have been included in plant design, such as attention to shielding to avoid radiation streaming situations, inclusion of maintenance features that provide for remote handling and flushing of components, features that minimize build-up of radioactive material in pipes, tanks, and other components, and separation of components and use of shielding whenever practical. The staff will review NWMI's ALARA program again during its review of the OL application.

Based on the information provided above, the staff concludes that the ALARA program is adequate and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.4 Radiation Monitoring and Surveying

The staff evaluated the sufficiency of the information provided on the NWMI radiation monitoring equipment and surveying program, as described in NWMI PSAR Section 11.1.4 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.4, "Radiation Monitoring and Surveying," of NUREG-1537, Part 2. The staff also considered the design of the instrumentation systems used for both routine and special radiation monitoring and sampling consistent with the applicable acceptance criteria in NUREG-1537, Part 2. The staff also evaluated the locations of air sampling or monitoring equipment to measure airborne concentrations of radioactive material to which people are exposed. The staff coordinated this review with the Chapter 7.0, "Instrumentation and Control Systems," review, and evaluated the design of the radiation instrumentation systems used for radiation monitoring and dosimetry, consistent with the acceptance criteria. The staff also considered whether these radiation monitors and alarm systems will be maintained, operated, calibrated, and subjected to surveillance in compliance with the appropriate standards and are addressed in the TSs. The staff reviewed the facility warning and annunciator systems to ensure they are designed to alert personnel to a radiological hazard or abnormal condition in sufficient time to enable them to respond in a planned appropriate manner. Finally, the staff also confirmed that the interface between the radiation monitoring system and the ESFs and the discussion of the radiation monitoring system in the emergency plan are appropriate.

NWMI PSAR Section 11.1.4 states that radiation surveys will be conducted for two purposes: (1) to ascertain radiation levels, concentrations of radioactive materials, and potential radiological hazards that could be present in the facility; and (2) to detect releases of radioactive material from facility equipment and operations. Radiation surveys will focus on those areas of the facility where the occupational radiation dose limits could potentially be exceeded.

Measurements of airborne radioactive material and/or bioassays will be used to determine that internal occupational exposures to radiation do not exceed the dose limits specified in 10 CFR Part 20, Subpart C, "Occupational Dose Limits."

NWMI PSAR Section 11.1.4 states that NWMI has established written procedures to ensure compliance with the requirements of 10 CFR Part 20, Subpart F, "Surveys and Monitoring." The procedures include program objectives, sampling procedures, and data analysis methods. Equipment selection is to be based on the type of radiation being monitored. The procedures will be developed for each instrument used, including the frequency and method of calibration, and the maintenance and calibration requirements. The survey program procedures will also specify the frequency of measurements and the recordkeeping and reporting requirements. The radiation survey and monitoring programs will be consistent with the guidance provided in the following references:

- RG 8.2, "Administrative Practices in Radiation Surveys and Monitoring" (Reference 71)
- RG 8.4, "Personnel Monitoring Device – Direct-Reading Pocket Dosimeters" (Reference 77)
- RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data" (Reference 78)

- RG 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program” (Reference 80)

- RG 8.25, “Air Sampling in the Workplace” (Reference 73)

- RG 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses” (Reference 75)

- ANSI N13.1, “Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities” (Reference 82)

- ANSI N13.6, “Practice for Occupational Radiation Exposure Records Systems” (Reference 83)

- ANSI N13.11, “Dosimetry-Personnel Dosimetry Performance Criteria for Testing” (Reference 84)

- ANSI N13.27, “Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters (Reference 85)”

- ANSI N323, “Radiation Protection Instrumentation Testing and Calibration – Air Monitoring Instruments” (Reference 86)

- ANSI/ANS 15.11, “Radiation Protection at Research Reactors” (Reference 59)

- ANSI/HPS N13.22, “Bioassay Programs for Uranium” (Reference 87)

- ANSI/HPS N13.30, “Performance Criteria for Radiobioassay” (Reference 88)

- NUREG-1400, “Air Sampling in the Workplace” (Reference 93)

NWMI PSAR Section 11.1.5.5.1, “Restricted Areas,” states that within the NWMI facility, access to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Personnel who have not been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

NWMI PSAR Section 11.1.4.1.1, “Personnel Monitoring,” states that three basic types of personnel monitoring equipment will be used at the facility: count rate meters (friskers), hand and foot monitors, and portal monitors. Friskers typically consist of handheld probes connected to a count rate meter and are used to ensure effective control of the spread of contamination. Handheld friskers will typically be placed in locations where conditions restrict the use of other monitors or for short-term use, as necessary, to ensure effective control of the spread of contamination. Instructions for the use of these instruments will be posted in a prominent location near the instrument. Hand and foot monitors typically consist of multiple detectors arranged to monitor only hands and feet. Hand and foot monitors will be used in applications where personnel need frequent egress. Portal monitors can quickly scan large surface areas of the body. Portal monitors will typically use large area beta and/or gamma sensitive detectors to monitor personnel.

NWMI PSAR Section 11.1.4 states that calibrations will be performed in accordance with established written procedures and documented prior to the initial use of, and a pre-determined frequency for, each airflow measurement instrument (used to measure flow rates for air or effluent sampling) and each radioactivity measurement instrument. Periodic operability checks will also be performed in accordance with established written procedures. Calibrations will be performed and documented on each airflow measurement and radioactivity measurement instrument, as follows:

- At least annually (or according to manufacturers' recommendations, whichever is more frequent)
- After failing an operability check
- After modifications or repairs to the instrument that could affect its proper response
- When the instrument is believed to have been damaged

Unreliable instruments will be removed from service until repairs are completed. Portal monitors, hand and foot monitors, and friskers will have the required sensitivity to detect alpha contamination on personnel to ensure that radioactive materials do not spread to the areas outside of the restricted areas. Instruments will be calibrated with sources that are within ±5 percent of the reference value and are traceable to the National Institute of Standards and Technology or equivalent.

NWMI PSAR Section 11.1.4 states that all personnel who enter restricted areas will be required to wear National Voluntary Laboratory Accreditation-compliant personnel dosimeters. Personnel will also be required to survey themselves prior to exiting restricted areas that may have the potential for contamination. All personnel whose duties require entry into restricted areas will wear individual external dosimetry devices (e.g., passive dosimeters such as thermoluminescent dosimeters (TLDs) that are sensitive to beta, gamma, and neutron radiation). External dosimetry devices will be evaluated at least quarterly to ascertain external exposures.

NWMI PSAR Section 11.1.6.1, “Routine Monitoring to Detect Contamination,” states that contamination survey monitoring will be performed for all process areas and areas in which radioactive materials are handled or stored. Surveys will include routine checks of non-process areas, including areas normally not contaminated. Monitoring will include direct radiation and removable contamination measurements. Survey procedures will be based on the potential for contamination of an area and operational experience. All restricted areas will be surveyed at least weekly. The change rooms will be surveyed at least daily. Various instruments, such as proportional counters and thin window Geiger-Mueller tubes, will be used at the NWMI facility to evaluate contamination levels.

NWMI PSAR Chapter 11.1.2.9, states that NWMI will maintain records of the radiation protection program (including program provisions, audits, and reviews of the program content and implementation), radiation survey results (air sampling, bioassays, external-exposure data from monitoring of individuals, internal intakes of radioactive material), and results of corrective action program referrals, RWPs, and planned special exposures. For additional program commitments applicable to records and reports, activities in the NWMI facility will meet the following:

- 10 CFR Part 20 Subpart L, “Records,” and Subpart M, “Reports”

- 10 CFR 50.71, “Maintenance of records, making of reports”
- 10 CFR 70.51, “Records requirements”
- ANSI/ANS 15.8, “Quality Assurance Program Requirements for Research Reactors” (Reference 45)
- ANSI/ANS 15.11, “Radiation Protection at Research Reactor Facilities” (Reference 59)

Based on its review, the staff finds that the level of detail provided on radiation monitoring and surveying satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.4, allowing the staff to make the following findings: (1) the fixed and portable equipment used for radiation monitoring and sampling inside the production facility are appropriate for the tasks needed to be performed; (2) the general types of monitoring and surveillance equipment appear appropriate to the production facility; and (3) the commitments to implement a program consistent with NUREG-1537 and the ISG augmenting NUREG-1537 give reasonable assurance that radioactive material and associated radiation exposures will be detected, monitored, and sampled consistent with the 10 CFR Part 20 requirements and the facility ALARA program.

The staff also finds that the design of the instrumentation systems used for both routine and special radiation monitoring and sampling is effective to adequately monitor the production facility for radioactivity, and that the locations of air sampling or monitoring equipment are effective to measure airborne concentrations of radioactive material. The staff review also finds that radiation monitors and alarm systems will be maintained, operated, calibrated, and subjected to surveillance in compliance with the appropriate standards and will be addressed in the TSs. The staff finds that the production facility warning and annunciator systems are designed to alert personnel to a radiological hazard or abnormal condition in sufficient time to enable them to respond in a planned appropriate manner. Finally, the staff also confirmed that the interface between the radiation monitoring system and the ESFs and the discussion of the radiation monitoring system in the emergency plan are appropriate. Further information on radiation monitoring and surveying can be reasonably left for later consideration in the FSAR because the facility’s design bases support the control of radioactive material and monitoring for radiation throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR. Based on the information provided above, the staff concludes that the radiation monitoring and surveying program is adequate and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.5 Radiation Exposure Control and Dosimetry

The staff evaluated the sufficiency of the information provided on the NWMI radiation exposure control and dosimetry provisions, as described in NWMI PSAR Section 11.1.5, for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.5, “Radiation Exposure Control and Dosimetry,” of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria of NUREG-1537, Part 2, Section 11.1.5, the staff examined the facility exposure control and dosimetry programs for both external exposures and internal exposures to facility personnel and the public, and exposures to the environment, to confirm that

plans and the bases of procedures for the control of external dose to workers and the public consider equipment and equipment design, shielding, radiation monitors and alarms, personnel protective equipment, and external radiation monitoring dosimetry. The staff also considered whether procedures for the control of internal exposure consider equipment and equipment design, engineered controls, personnel protective equipment, radiation monitors, alarms and samplers, bioassay methods, frequency, and action levels, and the models and methods used for internal dose evaluation.

The staff reviewed the engineered controls used to ensure radiation protection safety for each of the sources of radiation and radioactive material described in NWMI PSAR Section 11.1.1. The staff considered whether radiation protection measures have been implemented for sources of radiation and radioactive material. The staff reviewed that the radiation dose limits and bases were identified and the plans and programs to control doses were documented. The staff reviewed the descriptions of facility exposure conditions and methods used to derive administrative radiation dose limits. The staff evaluated the radiation protection engineered controls (e.g., the provisions of shielding, ventilation systems, and remote handling systems) to evaluate whether the design to reduce the potential for uncontrolled exposure or release was incorporated in the facility. The staff also reviewed the record keeping used to establish the conditions under which individuals were exposed to radiation.

The staff reviewed the engineered radiation exposure controls employed at the NWMI facility to determine whether the applicant provided sufficient information about 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 staff reviewed whether the entry control devices employed were adequate to alert workers to, or prevent entry into, radiological areas, including high-radiation or very-high radiation areas, and whether the confinement system design provided reasonable assurance that uncontrolled radiological releases to the unrestricted environment, controlled area, or the restricted work area should not occur during any anticipated normal operations.

NWMI PSAR Section 11.1.5, states that NWMI management is committed to protecting NWMI facility workers, the public, and the environment from unacceptable exposure to radiation sources. NWMI's policy is to conduct radiological operations in a manner that ensures the health and safety of employees, contractors, and the public. In achieving this objective, NWMI ensures that radiation exposure to workers and the public, and releases of radioactivity to the environment, are maintained below regulatory limits. Deliberate actions will be taken to further reduce exposures and releases in accordance with a process focused on keeping exposures and releases ALARA.

In 10 CFR Part 20, a "controlled area" is defined as an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. Due to the presence of administrative and physical barriers, members of the public do not have direct access to the controlled area of the facility and must be processed by security and authorized to enter the facility. NWMI PSAR Section 11.1.5.5.1 states that training for access to a controlled area is provided commensurate with the radiological hazard. Within the NWMI facility, access to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Personnel who have not been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

NWMI PSAR Section 11.1.5.3, “Control of Entry,” describes that the NWMI facility will include areas locked to limit access and alarms and signals that alert workers to or prevent unauthorized entry into radiation areas, high radiation areas, and very high radiation areas. Radiological zones with varied definitions and span of control have been designated for the facility site. The purpose of these zones is to: (1) control the spread of contamination; (2) control personnel access to avoid unnecessary exposure of personnel to radiation; and (3) control access to radioactive sources present in the facility. Public access to radiological zones is restricted as detailed in this section and as directed by facility management. Areas where personnel spend substantial amounts of time are designed to minimize the exposure received when routine tasks are performed, in accordance with the ALARA principles.

The following paragraphs describe the application of radiological area definitions in 10 CFR Part 20 to the NWMI facility and how the radiation protection program is implemented to protect workers and the general public on the NWMI site:

- Unrestricted area

  NWMI PSAR Section 11.1.5.5.3, “Unrestricted Areas,” states that for the NWMI facility, the areas not specifically included within the definitions of restricted and controlled areas will be considered unrestricted areas. These areas can be accessed by facility personnel and by the public. The unrestricted area is governed by the limits in 10 CFR 20.1301,” with the TEDE to individuals from the licensed operation not to exceed 1 mSv (100 mrem) in a year (exclusive of background radiation) or exceed 0.02 mSv (2 mrem) in any 1 hour.

- Controlled area

  NWMI PSAR Section 11.1.5.5.2, “Controlled Area,” states that for the NWMI facility, the controlled area is the area within the perimeter fence but outside the restricted area and the Administrative Building, as shown in NWMI PSAR Figure 11-5, “Controlled and Unrestricted Areas.” The area fence will limit public access to the controlled area of the site. Training for access to a controlled area will be provided commensurate with the radiological hazard. Area monitoring will demonstrate compliance with public exposure limits for such visitors. All NWMI personnel or contractor employees who work only in the controlled area will be subject to the exposure limits for the public, as stated in 10 CFR 20.1301.

- Restricted area

  NWMI PSAR Section 11.1.5.5.1 states that within the NWMI facility, access to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Personnel who have not been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

NWMI PSAR Section 11.1.5.5.1 also provides that additional areas defined below may exist within the restricted area. These areas may be temporary or permanent. The areas are posted

to inform workers of the potential hazard in the area and to help prevent the spread of contamination. These areas are conspicuously posted in accordance with the requirements of 10 CFR Part 20 and are defined in the application as follows:

- A “radiation area” is defined as an area where radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (5 mrem) in 1 hour (hr) at 30 centimeters (cm) from the radiation source or from any surface that the radiation penetrates.

- A “high radiation area” is defined as an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (100 mrem) in 1 hr at 30 cm from the radiation source or 30 cm from any surface that the radiation penetrates.

- A “very high radiation area” is defined as an area, accessible to individuals, in which radiation levels exceed 5 Sievert (Sv) (500 rem) in 1 hr at 1 meter (m) from the source or from any surface that the radiation penetrates. The hot cells within the NWMI facility are an example of a very high radiation area. The hot cells will be radiologically shielded and isolated from access to individuals by the use of engineered physical barriers, including structural shield blocks and locked shield doors.

- An “airborne radioactivity area” is defined as an area, room, or enclosure where airborne radioactive materials either exist in concentrations that exceed the derived air concentrations (DAC) specified in 10 CFR Part 20, Appendix B, “Annual Limits on Intake [ALIs] and Derived Air Concentrations of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” or where an individual present in the area without respiratory protection equipment could exceed, during the hours the individual is present in a week, an intake of 0.6 percent of the ALI or 12 DAC-hr. There are no identified permanent airborne radioactive areas with the NWMI facility.

NWMI PSAR Section 11.1.5.5.1 states that areas that are designated as high radiation or very high radiation areas will not be accessible to individuals during routine operation of the NWMI facility. These areas will be radiologically shielded and isolated from access to individuals by the use of engineered physical barriers that include structural shield blocks and/or locked shield doors.

In its response to staff RAI 11.1-3a (Reference 17), which requested the requirements (e.g., dosimetry, personal protective equipment, etc.) and access controls for entering the NWMI facility, NWMI indicated that the entire NWMI facility is a controlled area and that each door will have a two-credential access (e.g., fob/PIN, fob/biometric, or biometric/PIN) to access the Restricted Area within the NWMI facility. Furthermore, the RPP will require personnel to access dosimetry and portable survey instrumentation, as needed per the Radiation Work Permit, before entering the Restricted Area. Specific information on survey monitoring for individuals exiting the Restricted Area will be described in the FSAR. The staff is tracking this issue in Appendix A of this SER, and finds NWMI’s response acceptable because it provides sufficient assurance that NWMI has incorporated ALARA into its preliminary design.

NWMI PSAR Section 11.1.5.2 describes the engineered features built into the NWMI facility design, which are active or passive features designed to mitigate the consequences of accidents and to keep radiological exposures to workers, the public, and the environment within

acceptable values. Some of these features, as well as other ways in which radiation exposures are controlled, are listed below:

- Controlling HVAC system contamination by maintaining ventilation flow patterns from areas of lower radioactivity to higher radioactivity.
- Remote operation of processes, as well as the ability to conduct maintenance on equipment remotely.
- Facility Layout, to ensure access to a given area does not require passing through a higher radiation zone area.
- Processing irradiated targets and purification of Mo-99 under sub-atmospheric pressure.
- Providing redundancy of equipment or components to reduce the need for immediate repair to allow for reduction in radiation levels via decay.
- Training facility personnel in emergency evacuation procedures.
- Modularization of components.

NWMI PSAR Section 11.1.5.4, "Protective Equipment and Materials," states that personnel working within the restricted area will be required to wear appropriate personal protective clothing. Protective clothing, as prescribed by the RWP, will be selected based on the contamination level in the work area, anticipated work activity, worker health considerations, and consideration for non-radiological hazards present. Areas requiring protective clothing will be posted at each of the associated entry points. Radiation protection management and technical staff will be responsible for determining the need for protective clothing in each work area and for documenting the requirements in the RWP.

NWMI PSAR Section 11.1.6, "Contamination Control," states that when establishing radiological controls for work involving potential airborne radioactivity, the first consideration will be to use techniques that help prevent or reduce the potential for airborne radioactivity and maintain loose surface contamination in controlled areas within ALARA levels. Based on air sampling results and work evolutions, the RPM will select the appropriate respiratory protection required. Airborne radioactivity concentrations will be minimized to the extent practical by the use of engineered controls (e.g., confinement, ventilation, etc.). Respiratory protection equipment requirements will be specified on the area RWP.

NWMI PSAR Section 11.1.5.6.2, "External Dose," states that external dose will primarily be received from the fission products produced from irradiated targets and associated processing. All personnel whose duties require entry into restricted areas will wear individual external dosimetry devices (e.g., passive dosimeters such as TLDs that are sensitive to beta, gamma, and neutron radiation). External dosimetry devices will be evaluated at least quarterly to ascertain external exposures. The ALARA goal on radiation exposure is set at 5 mSv/yr (500 mrem/yr) based on an administrative limit of 10 percent of the NRC limit of 0.05 Sv/yr (5 rem/yr) given in 10 CFR 20.1201. NWMI PSAR Section 11.1.5.6.2 states that if 25 percent of the ALARA goal (1.25 mSv [125 mrem]) is exceeded in any quarter, an investigation will be performed to determine what types of activities may have contributed to the worker's external exposure. This investigation may include procedural reviews, efficiency studies of the air-handling system, cylinder storage protocol, and work practices, and the results will be

documented. The RPM will be informed whenever an administrative limit is exceeded. The RPM will be responsible for determining the need for, and recommending, investigations or corrective actions to the responsible manager(s).

NWMI PSAR Section 11.1.5.6.1, "Internal Dose," states that internal exposures for selected personnel are evaluated via direct bioassay (e.g., in vivo body counting), indirect bioassay (e.g., urinalysis), or an equivalent technique. For soluble (Class D) uranium, 10 CFR 20.1201(e) limits worker intake to no more than 10 milligrams of soluble uranium in a week. This limit is to protect workers from the toxic chemical effects of inhaling Class D uranium. If the facility annual administrative limit is exceeded, as determined from bioassay results, an investigation will be performed to determine what types of activities may have contributed to the worker's internal exposure. Continuous air monitoring in airborne radioactivity areas may be performed to complement the bioassay program. Alarm setpoints on the CAMs in the airborne radioactivity areas may be used to provide an indication that internal exposures may be approaching the action limit. The NWMI facility annual administrative limit for the TEDE will be 0.02 Sv (2 rem). Internal doses will be evaluated at least annually.

NWMI PSAR Section 11.1.2.9 states that NWMI will report to the NRC any event that results in an occupational exposure to radiation exceeding the dose limits in 10 CFR Part 20 within the time specified in 10 CFR 20.2202, "Notification of incidents." NWMI will prepare and submit an annual report of the results of individual monitoring to the NRC, as required by 10 CFR 20.2206, "Reports of individual monitoring."

NWMI PSAR Section 7.6.3.1, "Air Monitoring," states that radiation area monitor (RAMs) detector units will be housed in an environmentally suitable container that is mounted in a duct, on a wall, or other suitable surface. The sensitivity of each detector will be sufficient to have the alarm setpoint an order of magnitude higher than the detector threshold. Detectors are designed to be operational over a wide range of temperatures. Sensors will be mounted as close as practical to the most probable radiation sources with no objects, persons, pillars, and piping that could serve as shielding. The sensors will also be mounted so as to minimize inaccuracies due to any directionality of the detector. The RAMs are to be located in areas where personnel may be present and where radiation levels could become significant based on the following considerations:

- Occupancy status of the area, including time requirements of personnel in the area, the proximity to primary and secondary radioactive sources.
- Potential for increase in the background radiation level.
- Desirability of surveillance of infrequently visited areas.

NWMI PSAR Section 7.6.3.1 states that when the radiation (dose or dose rate) exceeds pre-determined levels, alarms will actuate in the control room and at selected detector locations. Visual alarms are to be accompanied by a simultaneous alarm annunciator at the selected detector locations and in the control room. The annunciator windows for the monitors will be located in the control room. The alarm can be manually reset when the alarm conditions are corrected. The local alarm horns and warning lights will remain on until the radiation level is below the preset level.

In its response to staff RAI 11.1-7 (Reference 17), which requested a description of the area monitoring plan and equipment NWMI intends to use to demonstrate compliance with public

exposure limits, NWMI provided a general description of equipment and frequency of evaluation. Area monitoring is anticipated to be comprised of a combination of passive monitoring (TLDs changed out monthly or quarterly) and active monitoring systems (energy compensated Geiger-Mueller detector systems with local and remote monitoring capability). NWMI indicated that further details on the area monitoring program will be provided in the FSAR. The staff is tracking this issue in Appendix A of this SER, and finds that NWMI's response provides sufficient information for a preliminary design.

Based on its review, the staff finds that the level of detail provided on radiation exposure control and dosimetry provisions satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.5. The staff finds that NWMI's Restricted Area, Controlled Area, and Unrestricted Area definitions, proposed access controls, and area radiological posting methodology is consistent with the applicable requirements of 10 CFR Part 20 because they include required elements important to radiation exposure control. The staff finds that NWMI's use of exposure control and dosimetry programs for both external exposures and internal exposures of production facility personnel and the public, and exposures to the environment, is consistent with applicable regulations and guidance because it helps provide reasonable assurance that doses will be maintained ALARA and within applicable regulations. The staff finds that the plans and bases of procedures for the control of external dose to workers and the public consider equipment and equipment design, shielding, radiation monitors and alarms, personnel protective equipment, and external radiation monitoring dosimetry, which is also consistent with applicable regulations and guidance because these considerations help ensure adequate radiation exposure control. The staff additionally finds that the procedures for the control of internal exposure consider equipment and equipment design, engineered controls, personnel protective equipment, radiation monitors, alarms and samplers, bioassay methods, frequency, and action levels, and the models and methods used for internal dose evaluation, consistent with applicable regulations and guidance because these considerations are important for adequate control and assessment of internal radiation exposures.

The staff finds that the engineered controls used to ensure radiation protection safety for each of the sources of radiation and radioactive material are adequately described in NWMI PSAR Section 11.1.1. The staff finds that radiation protection measures have been implemented for sources of radiation and radioactive material. The staff finds that the applicant's proposed radiation dose limits and bases were identified and the plans and programs to control doses were adequately documented. The staff finds that the descriptions of facility exposure conditions and methods used to derive administrative radiation dose limits were adequately documented. The staff finds that radiation protection engineered controls (e.g., the provisions of shielding, ventilation systems, and remote handling systems) effective to reduce the potential for uncontrolled exposure or release were incorporated in the facility. The staff finds that the record keeping used to establish the conditions under which individuals were exposed to radiation was adequately described.

The staff finds that the applicant discusses the procedures for use of personal dosimetry at the facility. The staff finds that provisions have been made for external and internal radiation monitoring of all individuals required to be monitored. The staff finds that the proposed dosimetry program is consistent with the requirements of 10 CFR Part 20 because it will help ensure adequate dose monitoring. The 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.

The staff finds that further information on radiation exposure control and dosimetry can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive material and dose rates throughout the facility so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR. The staff also finds that certain information related to radiation exposure control and dosimetry (e.g., requirements for personnel dosimetry use) is not expected to impact construction of the facility.

Based on the information provided above, the staff concludes that the facility design features for radiation exposure control and dosimetry provisions meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.6 Contamination Control

The staff evaluated the sufficiency of the information provided on the NWMI contamination control program, as described in NWMI PSAR Section 11.1.6 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.6, "Contamination Control," of NUREG-1537, Part 2.

Consistent with the review criteria of NUREG-1537, Part 2, Section 11.1.6, the staff considered the elements of the NWMI contamination control program to ensure that:

- The program scope demonstrates understanding of problems caused by radioactive contamination;
- Procedures will be established to prevent radioactive contamination to the extent possible;
- The bases of procedures show that routine monitoring of locations, equipment, and personnel for contamination will be established and maintained;
- The bases of procedures show that no materials, equipment, or personnel will be permitted to leave an area known to be or suspected of being contaminated without being appropriately monitored;
- The contamination control program includes provisions to avoid, prevent, and remedy the occurrence and the spread of contamination;
- Contamination control training is established as part of comprehensive radiation protection and radioactive waste management training, as needed; and
- The contamination control program includes provisions for recordkeeping in accordance with 10 CFR Part 20 regarding occurrence and spread of contamination, sufficient in content and retention for cleanup of contamination, maintenance, and planning for eventual decommissioning of the facility.

The staff reviewed the plan in the construction permit application for ensuring control of radioactive contamination for NWMI. This included review and evaluation of the following:

- The depth and breadth of the plan and bases of procedures for anticipating, identifying, controlling further spread of, remedying, and recording information about occurrences of radioactive contaminating materials.

- Provisions for routine monitoring and access control to identify radioactive contamination and to assess and limit personnel exposures.

- The bases for TSs that control activities that have the potential to cause or spread contamination.

NWMI PSAR Section 11.1.6 describes the NWMI contamination control including the general equipment and facility layout design considerations to prevent the spread of contamination to the facility and the environment. When establishing radiological controls for work involving potential loose or airborne contamination, NWMI first considered techniques that help prevent or reduce the potential for airborne radioactivity and to maintain loose surface contamination in controlled areas within ALARA levels. NWMI defines two types of contamination as follows:

- Loose (removable) contamination, which can be removed from surfaces by smears and may contribute to airborne radioactivity and/or personnel contamination from routine activities. Loose contamination poses both an internal and external radiation hazard.

- Fixed contamination, which is not smearable and may only be reduced by using approved decontamination techniques, procedures, and equipment. Fixed contamination does not readily contribute to airborne radioactivity and/or personnel contamination from routine activities. Fixed contamination poses an external radiation hazard.

When establishing radiological controls for work involving potential airborne radioactivity, the first consideration was to use techniques that help prevent or reduce the potential for airborne radioactivity and maintain loose surface contamination in controlled areas within ALARA levels. Access to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Contaminated material and equipment that are removed from a restricted area will be appropriately packaged in preapproved containers, inventoried, and monitored prior to release. Personnel who have not been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

NWMI PSAR Section 11.1.6.2, “Access Control to Contaminated Areas,” states that access to and egress from a restricted area will be through one of the monitor stations at the particular restricted area boundary. Access to and egress from each radiation area, contaminated area, or airborne radioactivity area within the restricted area may also be individually controlled. A contamination monitor (e.g., frisker, hand and foot monitor, or portal monitor), step-off pad, and container for any discarded protective clothing may be provided at the egress point from certain areas to prevent the spread of contamination.

The access control program will be established to ensure that:

- Signs, labels, and other access controls are properly posted and operative.
- Restricted areas prevent spread of contamination and have appropriate signage.
- Step-off pads, change facilities, protective clothing facilities, and personnel monitoring instruments are provided in sufficient quantities and locations.

NWMI PSAR Section 11.1.6.2 also states that action levels for skin and personal clothing contamination at the point of egress from restricted areas and any additional designated areas within the restricted area (e.g., a contaminated area that is provided with a step-off pad and contamination monitor) will not exceed 2.5 becquerel (Bq)/100 square centimeters (cm^2) (150 disintegrations per minute [dpm]/100 cm^2) alpha or beta/gamma contamination (corrected for background).

NWMI PSAR Section 11.1.2.5 states that all personnel and visitors entering restricted areas will receive training that is commensurate with the radiological hazard to which they may be exposed. The level of radiation protection training will be based on the potential radiological health risks associated with the employee's work responsibilities and incorporate the provisions of 10 CFR 19.12. The radiation protection training program will take into consideration a worker's normally assigned work activities. Abnormal situations involving exposure to radiation and radioactive material, which can reasonably be expected to occur during the life of the facility, will also be evaluated and factored into the training.

NWMI PSAR Section 9.1.2, "System Description," provides a description of the NWMI facility ventilation system which includes air supply, process ventilation, and exhaust air systems and associated filters, fans, dampers, ducts, and control instrumentation. The building management system (BMS) is an instrumentation and control subset of the NWMI facility process control system. The BMS functions primarily to monitor the facility ventilation systems and monitor and control the mechanical utility systems.

NWMI PSAR Section 9.1.2 states that the NWMI facility will be ventilated such that airflows travel from areas of lower potential for contamination to areas of higher potential. To this end, the ventilation system will have four confinement zone designations, from lowest to highest potential for contamination. Zone IV is a non-confinement zone. NWMI PSAR Figures 9-1 through 9-3 identify the different confinement zones of each level, and include administration support areas, truck bays, and maintenance utility areas. Zones progress to Zone I, with the potential for highest contamination, which includes glove boxes, vessels, tanks, piping, and hot cells. NWMI PSAR Table 9-1, "Facility Areas and Respective Confinement Zones," provides the confinement description for each specific area. The final design of the ventilation system will be provided in the FSAR as part of NWMI's OL application; the staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 9.1.2 states that each ventilation zone will have four exhaust subsystems. Each exhaust filter train will consist of prefilters, two stages of high-efficiency particulate air (HEPA) filters, carbon adsorbers, and isolation dampers. An exhaust stack monitoring and sampling system will be provided on each stack. Stack monitoring and interlocks will monitor discharge and signal changing of filter trains during normal and abnormal operations.

The exhaust stacks will be provided with continuous monitors for noble gases, particulates, and iodine. The stack monitoring system design basis is to continuously monitor the radioactive stack releases.

NWMI PSAR Section 11.1.4.1.2, "Air Monitoring," describes the air monitoring, using CAMs, which will be provided within the NWMI facility to provide indication of airborne activity. The CAMs will be operated to collect continuous samples. Portable CAMs may also be deployed when deemed necessary (e.g., non-standard maintenance activities). Continuous airborne radioactivity monitors will provide indication of the airborne activity levels in the restricted areas of the facility. When deemed necessary, portable air samplers may be used to collect a sample on filter paper for subsequent analysis in the laboratory. Monitor data will be collected for regular analysis and documentation. Monitors will be equipped with alarms. The alarms activate when airborne radioactivity levels exceed predetermined limits. The limits will be set with consideration given to both toxicity and radioactivity. The objective of the radiation monitoring system is to provide control room personnel with a continuous record and indication of radiation levels at selected locations where radioactive materials may be present, stored, handled, or inadvertently introduced.

NWMI PSAR Section 11.1.2.8 states that all work performed in a restricted area will be performed under an RWP. Routine and non-routine activities will be performed under an RWP that provides a description of the work to be performed (i.e., defines the authorized activities). The RWP will summarize the results of recent dose rate surveys, contamination surveys, airborne radioactivity results, and other relevant information. RWP procedures will require review of planned activities, changes to activities inside restricted areas, or work with licensed materials for the potential to cause radiation exposures that exceed action levels or produce radioactive contamination. Specific requirements for any necessary safety controls, personnel monitoring devices, protective clothing, respiratory protective equipment, and air sampling equipment are included.

NWMI PSAR Section 11.1.2.5 states that personnel who have previously been trained for radiological, chemical, industrial, and criticality safety will receive (retraining) refresher training at least annually. The retraining program will review procedure changes and any updates and changes in required skills. Changes to the training resulting from incidents potentially compromising safety or changes to the facility or processes will be incorporated as required.

Based on its review, the staff finds that the NWMI contamination control program helps ensure the control of radioactive contamination so that there is reasonable assurance that the health and safety of the facility staff, the public, and the environment will be protected. The staff finds that the level of detail provided on contamination control satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.6, allowing the staff to make the following finding: the description and level of detail on the contamination control program will meet the requirements of 10 CFR 20.1406, "Minimization of contamination." The staff finds that the contamination control program scope is consistent with the potential problems which could be caused by contamination; procedures will be established to prevent contamination; routine monitoring will help identify and control contamination; personnel will be properly monitored and assessed for potential contamination; contamination control will be part of the overall radiation protection training provided to the workers; and recordkeeping will be maintained in accordance with the requirements of 10 CFR Part 20.

The staff finds that further information on contamination control can reasonably be left for later consideration in the FSAR because the facility's design bases support the control of radioactive material throughout the facility so that the health and safety of the public and workers will be

protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR. The staff also finds that certain information related to contamination control (e.g., requirements for personnel contamination monitoring) is not expected to impact construction of the facility.

Based on the information provided above, the staff concludes that the contamination control program meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.7 Environmental Monitoring

The staff evaluated the sufficiency of the information provided on the proposed NWMI environmental monitoring program, as described in NWMI PSAR Section 11.1.7 for the issuance of a 10 CFR Part 50 construction permit using the requirements in 10 CFR 20.1302, "Compliance with dose limits for individual members of the public," and the guidance in Section 11.1.7, "Environmental Monitoring," of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2.

10 CFR 20.1302 requires that the licensee make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301. The staff review focused on the adequacy of the proposed NWMI environmental monitoring program to provide confidence that a significant radiological impact on the environment from the facility would be detected, and the type and magnitude of the radiological impact would be determined. Additionally, the staff review of the proposed NWMI environmental monitoring program was used to verify the effectiveness of plant measures which are used to control the release of radioactive material and to verify that measurable concentrations of radioactive materials and levels of radiation are not higher than expected based on effluent measurements and modeling of the environmental exposure pathways.

Consistent with the review criteria of NUREG-1537, Part 2, Section 11.1.7, the staff evaluated whether the NWMI PSAR discusses the environmental quality commitments that the program should address and the standards that were used in the development of the program. The staff reviewed the methods used to establish the preoperational baseline conditions. The staff performed a qualitative review to evaluate the sufficiency of the methods and techniques to sample and analyze the radiological effect of facility operation. The staff considered whether the environmental monitoring program would be capable of detecting and assessing a significant radiological impact on the environment from the facility.

NWMI PSAR Section 11.1.7 states that the NWMI facility REMP will meet the requirements of 10 CFR 20.1302, and will be used to verify:

- Effectiveness of plant measures used to control the release of radioactive material, and
- Measurable concentrations of radioactive materials and levels of radiation are not higher than expected based on effluent measurements and modeling of environmental exposure pathways.

Methods for establishing and conducting environmental monitoring are provided in RG 4.1, "Radiological Environmental Monitoring for Nuclear Power Plants" (Reference 66) and

NUREG-1301, “Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors,” (Reference 92) which provides detailed guidance on conducting effluent and environmental monitoring. Although the guidance provided in RG 4.1 and NUREG-1301 was originally written for nuclear power plants, due to the similarities between the airborne releases of radioactivity from nuclear power plants and the NWMI facility, NWMI states that it is appropriate to use the guidance of RG 4.1 and NUREG-1301 in the development of the NWMI environmental monitoring program.

NWMI PSAR Section 11.1.7.1, “Verification of Compliance,” states that environmental monitoring data will be compared against permits and environmental reports to ensure compliance, in accordance with the guidance in RG 4.1, and NUREG-1301.

NWMI PSAR Section 11.1.7.3, “Establishment of Baseline Environmental Quality,” states that background radiation values will be obtained during the baseline environmental survey by monitoring TLDs at multiple locations and that the survey will be conducted prior to construction and NWMI facility operation.

NWMI PSAR Section 11.1.7.4, “Environmental Surveillance Program,” states that the following radiation exposure pathways will be considered for monitoring under the NWMI REMP:

- Waterborne exposure pathway;
- Direct radiation exposure pathway monitoring using TLDs;
- Airborne exposure pathway monitored using continuous air samples; and
- Ingestion exposure pathway.

NWMI PSAR Section 11.1.7.4.1, “Waterborne Exposure Pathway Monitoring,” states that NWMI plans for no liquid discharge from the radiologically controlled area and no release of water from the facility to the adjacent environment that would affect surface water. There is no plan to sample adjacent surface water or aquatic life. The groundwater aquifer beneath the proposed NWMI facility site is the Mississippian aquifer. NWMI states that there are no defined liquid effluent release pathways, and that the groundwater is not expected to be contaminated due to operation of the NWMI facility. Groundwater sampling will not be included in the radiological environmental monitoring plan.

NWMI PSAR Section 11.1.7.4.2, “Direct Exposure Pathway Monitoring,” states that TLDs will be used to provide measurements of direct radiation from radioactive materials located at the NWMI facility, radioactivity in airborne effluent, and the deposition of airborne radioactivity onto the ground. NUREG-1301 recommends 40 TLD locations and that at least one TLD be located a significant distance from the facility as a control to measure background radiation dose. NWMI states that sixteen TLDs will be placed on the lot line, with a TLD placed at all four corners of Lot 15, and the remaining TLDs placed at approximately equal distances from each other. TLDs will also be located at the site boundary to evaluate the direct radiation dose. Seven TLDs will be located outside at entry points to the building where personnel may congregate or spend time outside of the NWMI facility building.

NWMI PSAR Section 11.1.7.4.3, “Airborne Exposure Pathway Monitoring,” states airborne effluent releases from the NWMI facility will contribute to off-site doses. The airborne effluent exhaust from the vent stacks is expected to contain measurable quantities of noble gas radioactivity (e.g., Xenon and Krypton). Radioactive iodine, radioactive particulates, and tritium could also be present in the airborne effluent exhaust. However, most of the off-site exposure

due to airborne effluent releases will be associated with noble gas and radioactive iodine releases. NWMI states that the tritium release rate would be a small fraction of the noble gas rates provided in Table 11-2 (several orders of magnitude less). NWMI also states that the dose contribution from tritium would be a small fraction of the dose contributions, and that the total public dose from all routine gaseous releases including tritium would remain well below 10 CFR Part 20 limits.

NWMI PSAR Section 11.1.7.4.3 states that Regulatory Position C.3.b of RG 4.1 indicates that airborne sampling should be included in the environmental monitoring programs for nuclear power plants. Since the NWMI facility includes airborne effluent releases and radioactivity in the airborne effluent can result in measurable off-site doses, the REMP will include airborne sampling. The airborne effluent exhaust from the vent stacks is expected to contain measurable quantities of noble gas radioactivity (e.g., Xenon and Krypton). Radioactive iodine, radioactive particulates, and tritium could also be present in the airborne effluent exhaust. Four CAMs will be located near the facility fence line, with one CAM being located in the direction of the prevailing wind (i.e., north-northwest) and the other three CAMs being located in the remaining cardinal directions (i.e., 90 degrees) from the first CAM location (i.e., west-southwest, south-southeast, and east-northeast). The CAM locations are shown in Figure 11-6 of the NWMI PSAR. An additional CAM will be located a sufficient distance from the NWMI facility, in the least prevalent wind direction, to provide background information for airborne activity.

NWMI PSAR Section 11.1.7.4.4, “Ingestion Exposure Pathway Monitoring,” states that the extent of sampling to be done to consider doses from the ingestion pathway will be evaluated. NWMI states that particulates and iodine radionuclides are not expected to be present in measurable quantities in NWMI facility airborne effluent releases and biota monitoring will not be performed. If stack monitoring should indicate the presence of iodine or particulates in measurable quantities, or if the effluent monitor sample results indicate the presence of iodine or particulates in quantities large enough to result in a calculated dose at the property line that exceeds 10 percent of the dose constraint (i.e., 1 mrem/yr), a sampling plan will be developed. Milk samples are considered a better indicator of radioactive iodine in the environment than vegetation. Should effluent monitoring indicate measurable iodine release, a gamma isotopic analysis and Iodine-131 analysis will be performed on the samples following the guidance provided in Table 3.12-1, “Radiological Environmental Monitoring Program,” of NUREG-1301.

Based on its review, the staff finds that the level of detail provided on the NWMI environmental monitoring program satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.7. The REMP described is appropriate for the facility and its projected impact, and the proposed REMP is consistent with the applicable portions of the NUREG-1537 and the ISG Augmenting NUREG-1537.

The staff finds that there is reasonable assurance that provisions of the environmental monitoring program will be effective to help ensure the safety of the public and the protection of the environment. The staff also finds that plans are identified to provide reasonable assurance that an environmental monitoring program can be effectively implemented and sustained during the day-to-day operation of the facility, and that any radiological impact on the environment will be accurately assessed. The staff finds that the proposed NWMI facility may release small quantities of radionuclides to the environment, but that the effluent activity releases would be managed to ensure compliance with applicable Federal, State, and local requirements. The staff did not find any identified abnormal sources of radiation onsite or within the vicinity of the site that would cause radiation levels to be any higher than the expected natural background radiation level. Finally, the staff finds that the background radiation values will be obtained

during the baseline environmental survey by monitoring TLDs at multiple locations, and that this survey is to be conducted prior to construction and prior to NWMI facility operation. The staff will review NWMI's environmental monitoring program again during its review of the OL application.

Based on the information provided above, the staff concludes that the design of the REMP meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.8 Radioactive Waste Management Program

The staff evaluated the sufficiency of the information provided on the NWMI radioactive waste management program, as described in NWMI PSAR Section 11.2.1 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.2.1, "Radioactive Waste Management Program," of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria of NUREG-1537, Part 2, Section 11.2.1, the staff evaluated how the radioactive waste management program fits into the facility's overall management structure, how such wastes are identified and segregated effectively, how the waste management organization, with support from the radiation protection organization, will ensure that radioactive wastes are continuously controlled from formation to ultimate safe disposal, and what organizational entities are assigned responsibilities in the radioactive waste management program.

NWMI PSAR Section 11.2.1 states that the waste management program will be coordinated with the radiation protection program, and program management will report to the Plant Manager. NWMI PSAR Section 11.1, "Radiation Protection," describes the program and procedures for controlling and assessing radioactive exposures associated with radioactive sources, including radioactive waste streams. The goal of the waste management program is to minimize waste generation, minimize exposure of personnel, and to protect the public and environment. In response to RAI 11.2 1b (Reference 17), NWMI committed to provide an official charter describing the authority, duties, and responsibilities of personnel in the Waste Management organization. This information will be described in the FSAR as part of NWMI's OL application. The staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 11.2.1.1, "Waste Management Policy," states that NWMI management is committed to the ALARA philosophy for radioactive waste management. NWMI's policy is to conduct waste management operations in a manner that ensures the health and safety of employees, contractors, and the public, and to comply with all Federal, State, and local laws and regulations for generation, storage, packaging, transportation, and disposal of wastes generated at the NWMI facility. NWMI PSAR Section 11.2.1.2, "Waste Management Procedures," states that procedures will be developed to provide for efficient and safe conduct of waste management operations.

NWMI PSAR Section 11.2.1.3, "Organizational Responsibilities," states that the Plant Manager will have direct responsibility for operation of the NWMI facility, and NWMI PSAR Section 11.2.1.3.2, "Waste Management Lead," states that the Waste Management Lead will have responsibility for implementing the waste management policy, including the development of procedures, shipping radioactive waste from the facility, providing technical input into the

design of equipment, processes, and training program for waste management, and conducting self-assessments of the waste management operations.

NWMI PSAR Section 11.2.1.4, "Training," states that the radioactive waste management training program will be closely coordinated with the radiation protection training program to emphasize the importance placed on radiological safety of NWMI facility personnel and the public.

Based on its review, the staff finds that the applicant has described the design of the program to manage radioactive wastes in sufficient detail for the staff to conclude that NWMI has developed the bases for a complete and effective program; the program includes review, audit, and assessment provisions; and the program complies with all applicable regulations.

The staff finds that the description of the NWMI waste management program gives reasonable assurance that radioactive wastes will not escape the control of the facility and will not pose a risk of undue radiation exposure to the facility staff, the environment, and the public.

The staff finds that the level of detail provided on the radioactive waste management program satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.2.1. Personnel will be appropriately instructed to perform functions under the program in accordance with the requirements and facility systems are designed in a manner that will provide the capability to obtain the data needed to comply with the requirements. The staff finds that further information on the radioactive waste management program can reasonably be left for later consideration in the FSAR because the facility's design bases support the control of radioactive waste and other radioactive material throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR. The staff also finds that certain information related to radioactive waste management (e.g., descriptions of the Waste Management Organization) is not expected to impact construction of the facility.

Based on the information provided above, the staff concludes that the radioactive waste management program meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.9 Radioactive Waste Management Controls

The staff evaluated the sufficiency of the information provided on the radiation waste management controls, as described in NWMI PSAR Section 11.2.2 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.2.2, "Radioactive Waste Control," of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria in NUREG-1537, Part 2, Section 11.2.2, the staff reviewed the applicant's processes and procedures used to evaluate the production and handling of radioactive waste material. The staff considered whether appropriate monitoring and sampling will be performed and sufficient analyses will be completed to assess the extent of the radiation exposure from waste products. The staff reviewed whether the applicant sufficiently described methods to: (1) avoid inadvertent exposure of personnel or uncontrolled escape of the radioactive materials; (2) define and maintain continuous control of radioactive materials that require treatment and management as waste; and (3) reduce the quantities of radioactive waste.

NWMI PSAR Section 11.2.2 states that the NWMI facility processes that will produce radioactive waste are described in NWMI PSAR Chapter 4.0. NWMI will implement pollution prevention and waste minimization activities that review associated processes and procedures to ensure that the kinds and amounts of waste generated are minimized. Waste management control will include methods to avoid inadvertent exposure of personnel or uncontrolled escape of the radioactive materials, and maintain continuous control of radioactive materials that require treatment and management as waste.

NWMI PSAR Section 11.2.3.3, "Gaseous Radioactive Waste," states that production facility process waste gases will be processed by the offgas system which is design to filter and/or retain radioactive isotopes in the facility until the resulting release is at levels less than those defined in Table 2 of 10 CFR Part 20, Appendix B. NWMI PSAR Chapter 9.0, "Radioisotope Production Facility Auxiliary Systems," Section 9.1, "Heating Ventilation and Air Conditioning Systems," provides a detailed description of the process vessel vent system and the Zone I and Zone II HVAC treatment systems. Liquid waste resulting from these processes will be directed to the high-dose waste collection tank and processed through the high-dose waste treatment system, where the waste will be solidified.

Based on its review, the staff finds that the radiation waste management controls describe the methods by which the waste products from all procedures and processes will be monitored or otherwise assessed for radioactive material contents. The staff finds that, as needed, controls will be established on the waste streams and products designed to prevent uncontrolled exposures or escape of radioactive waste. The staff finds that the descriptions of the plans and procedures provide reasonable assurance that radioactive wastes will be controlled at all times in a manner that protects the environment and the health and safety of the facility staff and the public. Additionally, the staff finds that the applicant describes efforts to evaluate the generation of radioactive wastes at the facility to determine if there are ways to reduce the amount of waste produced.

The staff noted that descriptions of the Waste Staging and Storage Building (NWMI PSAR Section 9.7.2.2.8, "Waste Staging and Shipping Building (Class A Storage)") as well as plans and procedures to provide reasonable assurance that radioactive wastes will be controlled at all times in a manner that protects the environment and the health and safety of the facility staff and the public will be presented in the FSAR as part of the NWMI OL application.

The staff finds that the level of detail provided on the radiation waste management controls supports the preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.2.2, allowing the staff to make the following findings: (1) appropriate controls are described for radioactive waste management on the waste streams and products designed to prevent uncontrolled exposures or escape of radioactive waste; and (2) the applicant has described programmatic measures to evaluate the generation of radioactive wastes at the facility to define actions to maintain and control waste generation.

The staff finds that further information on the radioactive waste management controls can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive waste and other radioactive material throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that the design of the radioactive waste management controls meets the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.10 Release of Radioactive Waste

The staff evaluated the sufficiency of the information provided on the release of radioactive waste, as described in NWMI PSAR Section 11.2.3 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.2.3, "Release of Radioactive Waste," of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2. Consistent with the review criteria of NUREG-1537, Part 2, Section 11.2.3, the staff evaluated the discussions on release of radioactive waste for compliance with the regulations in Subpart K, "Waste Disposal," of 10 CFR Part 20.

NWMI PSAR Section 11.2.3 describes radioactive waste effluents expected to be released from the restricted to the unrestricted area. The discussion includes the type and quantities of radionuclides, methods and locations of release, methods of assessing the potential doses to people in the unrestricted area, and methods of comparing the consequences of releases with limits in applicable regulations.

NWMI PSAR Section 11.2.3.1, "Solid Radioactive Waste," describes the release of solid waste from the facility for disposal. The PSAR states that the majority of solid waste produced in the NWMI facility will be the high- and low-dose waste discussed in NWMI PSAR Chapter 9.0. Samples of this waste will be analyzed in the NWMI facility laboratory to ensure that the waste meets the disposal facility waste acceptance criteria. This waste will be stored for radioactive decay to meet shipping and disposal requirements, and then packaged in approved transportation casks for transport to the disposal facility. Additional information on the basis for waste volume projections provided in the PSAR for laboratory facilities and facility support waste will be further defined in the FSAR as part of NWMI's OL application. The staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 11.2.3.2, "Liquid Radioactive Waste," states that the NWMI facility will not release any radioactive liquid waste. NWMI PSAR Section 11.2.3.3, "Gaseous Radioactive Waste," states that gases from the NWMI facility process and HVAC system will be processed as described in NWMI PSAR Chapters 4.0 and 9.0, respectively. The offgas system is designed to filter and/or retain these isotopes in the facility until the resulting release is at levels less than those defined in Table 2 of 10 CFR Part 20, Appendix B. Additional information on the offgas and ventilation systems will be provided in the FSAR as part of the OL application; the staff is tracking this issue in Appendix A of this SER. The gaseous radioactive emissions will be released through the NWMI facility's three exhaust stacks. Monitoring of the effluent is described in NWMI PSAR Section 11.1.4.1.2.

Based on its review, the staff finds that the discussions provide reasonable assurances that releases of airborne effluents from the facility and releases of solid waste from the facility for disposal will not exceed applicable regulations and will not pose unacceptable radiation risks to the environment.

The staff finds that the level of detail provided on the release of radioactive waste satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.2.3. The staff finds that radionuclides have been sufficiently identified by quantities, other relevant characteristics, release points, and relevant environmental parameters; and releases of radioactive effluents will

likely be sufficiently managed, controlled, and monitored so that limits in applicable regulations would not be exceeded. The staff finds that further information on the release of radioactive waste can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive waste and other radioactive material throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that NWMI's description of its plan for release of radioactive waste is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.11 Respiratory Protection Program

The staff evaluated the sufficiency of the information provided on the respiratory protection program, as described in NWMI PSAR Section 11.3, "Respiratory Protection Program," for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.3, "Respiratory Protection Program," of the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria in the ISG Augmenting NUREG-1537, Part 2, Section 11.3, the staff examined whether the NWMI respiratory protection program provides adequate protection of personnel from airborne concentrations exceeding the limits of Appendix B to 10 CFR Part 20. The staff reviewed the proposed radiation protection equipment for providing the appropriate degree of personal protection. The staff evaluated the description of respirator selection, training, fit testing, storage, maintenance, repair, and QA.

NWMI PSAR Section 11.3 describes the NWMI respiratory protection program. The program documentation states that the use of engineering controls is preferred over the use of respirators to minimize radioactive materials in the air. However, there may be a need for confinement to control the concentrations of radioactive material in the air to maintain the TEDE ALARA.

NWMI PSAR Section 11.3 states that the radiological respiratory protection program is designed to comply with the requirements of ANSI Z-88.2, "American National Standard Practices for Respiratory Protection" (Reference 89); 10 CFR Part 20, Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," and 29 CFR 1910.134, "Respiratory Protection." Respirators will only be issued if the RPM determines that engineering controls may be ineffective, the total effective dose will be reduced by wearing respirators, and/or the physical stress of wearing a respirator will not interfere with workers' health and safety. Engineering controls include the following:

- Control of access
- Limitation of exposure times
- Use of respiratory protection equipment
- Other controls

NWMI PSAR Section 11.3 states that the NWMI facility design and analysis of the NWMI facility ventilation system ensures that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur during normal operational states and to mitigate the consequences of design basis accidents (e.g., maintaining a series of cascading pressure

zones to draw air from the cleanest area to the most contaminated area of the RPF. In addition, the distribution and concentrations of any airborne radionuclides are limited by operation of the ventilation system so that during the full range of facility operations, no potential occupational exposures would exceed the design bases (e.g., 10 CFR Part 20). The NWMI HVAC system, also referred to as the ventilation system, is designed to ensure that temperature, relative humidity, and air exchange rates are within the design-basis limits for personnel and equipment and to ensure that all normal sources of airborne radioactive material are controlled so that occupational doses do not exceed the requirements of 10 CFR Part 20. The PSAR states that the system design is consistent with NWMI's ALARA program and includes ESFs built in.

NWMI PSAR Section 11.3 states that the facility ventilation system will maintain a series of cascading pressure zones to draw air from the cleanest areas of the facility to the most contaminated areas. Zone IV will be a clean zone that is independent of the other ventilation zones. Zone IV will be slightly positively pressurized with respect to the atmosphere. Zone III will be the cleanest of the potentially contaminated areas, with each subsequent zone being more contaminated and having lower pressures.

NWMI PSAR Section 9.1.2.2, "Supply Air System," states that the NWMI facility supply air system will provide conditioned air for facility workers and equipment and supply makeup air for NWMI facility exhaust air systems. A common supply air system will provide filtered and conditioned 100 percent outdoor air to all Zone III areas and some Zone II areas that require makeup air in addition to that cascaded from Zone III. Three separate exhaust systems will maintain zone pressure differentials and containment: (1) the Zone I exhaust system will service the hot cell, waste loading areas, target fabrication enclosures, and process offgas subsystems in Zone I; (2) the Zone II/III exhaust system will service exhaust flow needs from Zone II and Zone III in excess of flow cascaded to interior zones; and (3) a laboratory exhaust system will service fume hoods in the laboratory area. In response to RAI 11.3-1a (Reference 17), NWMI has committed to provide additional information on the facility ventilation system, including details of how the irradiated target receipt area will transition between ventilation Zones II and III during operating/maintenance activities, will be provided in the FSAR as part of the OL application; the staff is tracking this issue in Appendix A of this SER.

In NWMI PSAR Chapter 6.0 and Section 9.1.2.1, "Confinement," state that confinement is an ESF that is credited as being in place as part of the preliminary hazards analysis. Confinement is defined as an enclosure of the facility (e.g., the hot cell area in the NWMI facility) that is designed to limit the exchange of effluents between the enclosure and its external environment to controlled or defined pathways. The primary safety objective of the confinement system is to protect on-site workers, the public, and the environment. Personnel protection control features (e.g., adequate shielding and ventilation control) will minimize hazards normally associated with radioactive or chemical materials. The secondary design objective of the confinement system is to minimize the reliance on administrative or complex active engineering controls and provide a confinement system that is as simple and fail-safe as reasonably possible. Confinement includes the capability to maintain sufficient internal negative pressure to ensure in-leakage (i.e., prevent uncontrolled leakage outside the confined area), but need not be capable of supporting positive internal pressure or significantly shielding the external environment from internal sources of direct radiation.

NWMI PSAR Section 6.2.1, "Confinement System," states that confinement will be provided by a combination of the enclosure boundaries (e.g., walls, floor, and ceiling), enclosure ventilation, and ventilation control system. The enclosure boundaries will restrict bulk quantities of process materials, potentially present in solid or liquid forms, to the confinement and limit leakage of

gaseous components from the enclosure boundary by the control of the ventilation system. The ventilation and ventilation control systems will control the release of the gaseous components (including gas phase components and solid/liquid dispersions) to the confinement.

NWMI PSAR Section 11.1.2.8 states that all work performed in restricted areas will be performed under an RWP. Precautions to be taken by those performing the task, including personal protective equipment to be worn while working (e.g., gloves, respirators, personnel monitoring devices), stay-times or dose limits for work in the area, recordkeeping requirements (e.g., time or dose spent on job), and the attendance of a radiation protection technician during the work, will be defined in the RWP. The RPM or designee will approve the RWP.

NWMI PSAR Section 11.1.5.4 states that based on air sampling results and work evolutions, the RPM will select the appropriate respiratory protection required. Airborne radioactivity concentrations will be minimized to the extent practical by the use of engineered controls (e.g., containment, ventilation). When establishing radiological controls for work involving potential airborne radioactivity, the first consideration will be to use techniques that help prevent or reduce the potential for airborne radioactivity and maintain loose surface contamination in controlled areas within ALARA levels. Respiratory protection equipment requirements will be specified on the area RWP.

NWMI PSAR Section 11.3 states that if the decision is made to permit the use of respiratory protection equipment to limit the intake of radioactive material, only National Institute of Occupational Safety and Health (NIOSH)-certified equipment will be used. The respiratory protection program will meet the requirements of 10 CFR Part 20, Subpart H. The respiratory protection program will include the following elements:

- Air sampling to identify the potential hazard, select proper equipment, and estimate doses.

- Surveys and when necessary, bioassays, to evaluate actual intakes.

- Performance testing of respirators for operability (user seal-check for face-sealing devices and functional check for others) immediately prior to each use.

- Limitations on periods of respirator use and relief from respirator use.

- Determination by a physician that the individual user is medically fit to use respiratory protection equipment. This evaluation will be done prior to initial fitting of a face-sealing respirator, before the first field use of non-face sealing respirators, and either every 12 months thereafter, or periodically at a frequency determined by a physician.

- A respirator fit test will require a minimum fit factor of at least 10 times the assigned protection factor for negative pressure devices, and an overall fit factor of at least 500 for any positive pressure, continuous flow, and pressure-demand devices. The fit testing will be performed before the first field use of tight-fitting, face-sealing respirators. Subsequent testing will be performed at least annually thereafter. Fit testing must be performed with the face-piece operating in the negative pressure mode.

NWMI PSAR Section 11.3 also states that personnel using respirators will be informed that they may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief. Respirator use within the NWMI facility will provide for vision correction and adequate communication and allow for concurrent use of other safety or radiological protection equipment. Radiological protection equipment will be used in such a way as to not interfere with the proper operation of the respirator.

NWMI PSAR Section 11.3 states that atmosphere-supplying respirators will be supplied with respirable air of a quality that meets or exceeds the specifications of Compressed Gas Association (CGA) G-7, "Compressed Air for Human Respiration" (Reference 90), and CGA G-7.1, "Commodity Specification for Air" (Reference 94) and the requirements included in the regulations of the Occupational Safety and Health Administration, 29 CFR 1910.134(i)(1)(ii)(A) through (E).

NWMI PSAR Section 11.3 states that the NWMI radiological respiratory protection program will include written procedures for each of the following:

- Monitoring, including air sampling and bioassays
- Supervision and training of respirator users
- Fit testing
- Respirator selection
- Breathing air quality
- Inventory and control
- Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment
- Recordkeeping

NWMI PSAR Section 11.3 states that records of the respiratory protection program (including training for respirator use and maintenance) will be maintained in accordance with the NWMI records management program.

Based on its review, the staff finds that the respiratory protection program provides adequate protection of personnel because it will include use of ventilation systems and respirator equipment to help prevent airborne concentrations from exceeding the limits of Appendix B to 10 CFR Part 20. The staff finds that the proposed radiation protection equipment for providing the appropriate degree of personal protection and the description of respirator selection, training, fit testing, storage, maintenance, repair, and QA are adequate to ensure effective protection to the workers.

The staff finds that NWMI committed to provide an acceptable radiation protection program that includes a program to control airborne concentration of radioactive material with engineering controls and respiratory protection. In response to RAI 11.1-2a, NWMI stated it will provide its radiation protection program as part of its OL application; the staff is tracking this issue in Appendix A of this SER. The staff finds that the level of detail provided on the respiratory protection program satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 11.3, allowing the staff to make the following finding: the program is generally consistent (given the level of detail available at the facility design stage) with RG 8.15, and Subpart H and Appendix A of 10 CFR Part 20.

The staff finds that further information on the respiratory protection program can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive material throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that the design of the respiratory protection program meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility radiation protection and waste management programs, as described in NWMI PSAR Chapter 11.0, and finds that the preliminary design criteria of the radiation protection and waste management programs, including the principal design criteria, design bases, and information relating to materials of construction, general arrangement, and approximate dimensions: (1) provide reasonable assurance that the final design will conform to the design basis, and (2) meet all applicable regulatory requirements and acceptance criteria discussed in NUREG-1537 and the ISG augmenting NUREG-1537. Based on these findings, the staff has made the following conclusions regarding issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed production facility design criteria for radiation protection and waste management, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis of the radiation protection and waste management programs, and which can reasonably be left for later consideration, will be provided in the FSAR.

(3) There is reasonable assurance that: (i) safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed production facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(4) There is reasonable assurance: (i) that the construction of the NWMI production facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations.

(5) NWMI is technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

(6) The issuance of a permit for the construction of the facility would not be inimical to the common defense and security or to the health and safety of the public.

12 CONDUCT OF OPERATIONS

The conduct of operations involves the administrative aspects of facility operation, the 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.

This chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the NWMI production facility conduct of operations, as presented in Chapter 12.0, "Conduct of Operations," of the NWMI preliminary safety analysis report (PSAR), Revision 3, and as supplemented by the applicant's responses to requests for additional information (RAIs). As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

12.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 12.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary aspects of the NWMI production facility operation, the 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 for the purposes of issuing a construction permit under 10 CFR Part 50.

Specific areas of review for this chapter included the organizational structure, responsibilities of individuals and groups, selection and training of personnel, organizational aspects of radiation protection, and the facility safety program; the composition and qualification of the NWMI audit committee members, charter and rules of the audit committees, conduct of the review functions, and conduct of the audit functions; procedures, and procedural controls, to include the minimum topics for which procedures are required, the process for the review and approval of procedures, and the process for making substantive, minor, and temporary changes to procedures; preliminary emergency plan; and quality assurance (QA) program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility.

In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items, which are determined to be probable subjects of technical

specifications (TSs) for the facility, with special attention given to those items which may significantly influence the final design of the facility. The staff documented its review of NWMI's probable subjects of TSs for the facility in Chapter 14, "Technical Specifications," of this SER.

The staff did not review certain administrative information, procedures, plans, or programs that are related to the operation of the facility and do not affect construction. This includes information related to the actions to be taken after a reportable event or a violation of the facility safety limits; submission of timely information to the NRC in the form of annual reports and special reports (e.g., reportable events, violations of safety limits, changes in key personnel, changes in transient or accident analysis); facility records, including review and retention guidelines; security planning; operator training and requalification plan; proposed tests to determine operability of the facility and the timing of a report that summarizes the results of the startup tests; or proposed material control and accounting (MC&A) plan.

The staff also did not review environmental information as described in Section 12.12, "Environmental Reports," of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content" (Reference 8), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria" (Reference 9). The staff's evaluation of NWMI's environmental information, submitted as Chapter 19.0, "Environmental Review" (Reference 1), of the NWMI PSAR, is documented in NUREG-2209, "Environmental Impact Statement for the Construction Permit for the NWMI Medical Radioisotope Production Facility" (Reference 22).

12.2 Summary of Application

NWMI PSAR Section 12.1, "Organization," describes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure. The organizational structure includes internal and external functions for NWMI, including interface responsibilities for multiple organizations.

NWMI PSAR Section 12.2, "Review and Audit Activities," discusses review and audit activities. The Plant Manager is responsible to establish review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. Committee activities will be summarized and reported to the Chief Operating Officer (COO). Independent audits of the facility will be conducted periodically and will be specified in the final safety analysis report (FSAR).

NWMI PSAR Section 12.3, "Procedures," provides a description of the operating procedures. As described by NWMI, the operating procedures will provide appropriate direction to ensure that the NWMI production facility is operated normally within its design basis, and in compliance with TSs. Operating procedures will be written, reviewed, and approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct and the wording and format are clear and concise. Procedures will be prepared, approved, canceled and implemented in accordance with the NWMI procedure program. The extent of detail in a procedure will be 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 will be documented. A controlled copy of all operations procedures will be maintained in the control room or equivalent area. Activities and tasks will be performed consistent with approved implementing procedures.

NWMI PSAR Sections 12.4, “Required Actions,” 12.5, “Reports,” 12.6, “Records,” 12.8, “Security Planning,” 12.10, “Operator Training and Requalification,” 12.11, “Startup Plan,” and 12.13, Material Control and Accountability Program,” states that the information regarding these sections will be provided in the operating license (OL) application.

NWMI PSAR Section 12.7, “Emergency Planning,” provides a draft emergency preparedness plan, which is identified as Appendix A, “Northwest Medical Isotopes, LLC Radioisotope Production Facility Emergency Response Plan,” to Chapter 12.0 of the NWMI PSAR. NWMI states that this information will be updated in the FSAR as part of the OL application.

NWMI PSAR Section 12.9, “Quality Assurance,” provides a description of the NWMI QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. The applicant provided the NWMI Quality Assurance Program Plan (QAPP) in Chapter 12.0, Appendix C, “Quality Assurance Program Plan for the Design, Construction, and Operation of the Radioisotope Production Facility,” of the NWMI PSAR.

12.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 12.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary NWMI organization, review and audit activities, procedures, actions, plans, and programs for the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, “Issuance of construction permits,” a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final FSAR.

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, “Reactor Site Criteria,” the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility’s site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the

Licensing of Non-Power Reactors, Format and Content," (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9) and "Final Interim Staff Guidance [ISG] 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," (Reference 10) 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" (Reference 11). The staff's review in Chapter 2, "Site Characteristics," of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

12.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the preliminary NWMI organization, review and audit activities, procedures, actions, plans, and programs are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.40, "Common standards."
- 10 CFR Part 50, Appendix E, Part II, "Preliminary Safety Analysis Report."

12.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- 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 (Reference 9).
- "Final Interim Staff Guidance [ISG] 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 (Reference 10).

- "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 (Reference 11).

- ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research and Test Reactors" (Reference 45).

- Regulatory Guide (RG) 2.5, "Quality Assurance Program Requirements for Research and Test Reactors" (Reference 95).

The ISG Augmenting NUREG-1537, Parts 1 and 2 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, Parts 1 and 2, it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of items relied on for safety (IROFS), and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, and American National Standards Institute/American Nuclear Society (ANSI/ANS) standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

12.4 Review Procedures and Technical Evaluation

The staff evaluated the technical information presented in NWMI PSAR Chapter 12.0 to assess the sufficiency of the preliminary plan for the NWMI production facility conduct of operations for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary plan for the NWMI conduct of operations is determined by ensuring the preliminary plan for the NWMI conduct of operations meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in SER Section 12.3, "Regulatory Basis and Acceptance Criteria." A summary of the staff's technical evaluation is described in SER Section 12.5, "Summary and Conclusions."

12.4.1 Organization

NWMI PSAR Section 12.1 describes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure for the NWMI production facility. The organizational structure includes internal and external functions for NWMI, including interface responsibilities for multiple organizations. The organization structure facilitates the execution of the conduct of operations program.

The staff evaluated the sufficiency of the preliminary plan for the NWMI organization, as described in NWMI PSAR Section 12.1, in part by reviewing the organizational structure, the responsibilities of individuals and groups, the staffing for operations, the selection and training of personnel, the organizational aspects of radiation protection, and the facility safety program, using the guidance and acceptance criteria from Section 12.1, "Organization," of the ISG Augmenting NUREG-1537, Parts 1 and 2, and of NUREG-1537, Parts 1 and 2.

Consistent with the review criteria in Chapter 14, "Technical Specifications," of NUREG-1537, Part 2, Section 12.1, and ANSI/ANS-15.1-2007, "The Development of Technical Specifications for Research Reactors" (Reference 43), Reaffirmed in 2013, the staff evaluated the description of the NWMI review and audit activities to ensure that the PSAR provides a basis for the TS requirements for the organization activities.

The review procedures of NUREG-1537, Part 1, Section 12.1.1, "Structure," state that the description of the organizational structure should include the radiation safety function and indicate how the staff implementing that function interacts with the staff responsible for reactor operations and the top administrative officials. The multilevel chart should show the relationship of the review and audit function to the organizational structure. The persons implementing the review and audit function should communicate with the management of the reactor facility, but should report to an organizational level above this management to ensure independence of the review and audit function.

The NWMI PSAR provides the functional organization in Figure 12-1, "Northwest Medical Isotopes, LLC Organization Chart," and NWMI PSAR, Section 12.1, states that the staff implementing the radiation safety function supports on-shift plant operations and interacts with Executive Management through the chain of command. In addition, the NWMI QA Manager reports directly to the COO and will have the independent oversight responsibility for the implementation of the QAPP. Oversight activities include auditing for compliance with regulatory requirements and conformance with organizational processes and procedures.

NWMI PSAR Section 12.1.3, "Staffing," states, that "NWMI will provide sufficient resources in personnel and materials to safely conduct operations. Facility staffing considerations, including minimum staffing levels, allocation of control functions, overtime restrictions, facility status updates during turnover between shifts, procedures, training, and availability of senior operators during routine operations, will be defined in the Operating License Application." The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it is not expected to impact construction of the facility.

NWMI PSAR Section 12.1.6, "Production Facility Safety Program," states, in part, that "[th]e RPF safety program will be developed and integrated with the radiological safety and other facility safety programs and will use the methods described in 10 CFR 50, 'Domestic Licensing of Production and Utilization Facilities'; 10 CFR 70.61, 'Performance Requirements'; and 10 CFR 70.62, 'Safety Program and Integrated Safety Analysis,' as appropriate. Further details

of the facility safety program will be provided in the Operating License Application." The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it is expected to be based on the final design and is not expected to impact construction of the facility.

Based on its review, the staff finds that the level of detail provided on the NWMI preliminary plan for organization activities is adequate and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.1, allowing the staff to make a finding that the applicant's commitments to develop and conduct organization activities are consistent with guidance and provide reasonable assurance that the NWMI organization activities will comply with applicable requirements.

Therefore, the staff finds the information in NWMI PSAR Section 12.1 is sufficient and meets the applicable guidance and regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. Further information as may be required to complete the review of NWMI's organization (e.g., staffing considerations and production facility safety program) can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

12.4.2 Review and Audit Activities

NWMI PSAR Section 12.2 discusses review and audit activities. The Plant Manager is responsible to establish review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. These activities are summarized and reported to the COO. Independent audits of the NWMI facility operations will be conducted periodically and their scope will be specified in the NWMI OL application.

The staff evaluated the sufficiency of the preliminary NWMI review and audit activities, as described in NWMI PSAR Section 12.2, in part, by reviewing the composition and qualification of the committee members, charter and rules of the committee, conduct of the review function, and conduct of the audit function, using the guidance and acceptance criteria from Section 12.2, "Review and Audit Activities," of NUREG-1537, Parts 1 and 2.

Consistent with the review criteria in Chapter 12 of NUREG-1537, Part 2, Section 12.2, and ANSI/ANS-15.1-2007, the staff evaluated the description of the NWMI review and audit activities to ensure that the PSAR provides a basis for the TS requirements for the review and audit function.

NUREG-1537, Part 1, Section 12.2 states that the applicant should explicitly state who holds the approval authority and should specify how the review and audit committees communicate and interact with facility management and corporate management.

NWMI PSAR Section 12.2 discusses the establishment of the review and audit committees and states they report to the COO. However, NWMI PSAR Section 12.2.1, "Composition and Qualifications," states, in part, that "[t]he minimum number and qualifications of the committee members and the potential use of members from outside the organization will be identified in the Operating License Application." NWMI PSAR also states in Section 12.2.2, "Charter and Rules," that details on the charter and rules for the Review and Audit Committee will be

provided in the FSAR. The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it is not expected to impact construction of the facility.

NUREG-1537, Part 2, Section 12.2, Acceptance Criteria, states, in part, that "[t]he applicant should give the details of the review function…The reviews should include 10 CFR 50.59 ["Changes, tests, and experiments"] safety reviews." NWMI PSAR, Section 12.2.3, "Review Function," include this in the minimum list of items that will be reviewed by the Review and Audit Committee.

In addition, NUREG-1537, Part 1, Section 12.2.4, "Audit Function," states, in part, that "[t]he applicant should list and discuss the items that must be audited by the committee. In addition to audits by the facility committee, the licensee may consider entering into an auditing agreement with other non-power reactor facilities to bring in staff members from other non-power reactors to perform an audit."

NWMI PSAR, Section 12.2.4 includes audit frequency, areas of the facility operation subject to audits, logistics, responsibilities and a list of examples of activities to be audited.

Based on its review, the staff finds that the level of detail provided on the NWMI plan for review and audit activities is adequate and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.2, allowing the staff to make a finding that the applicant's commitments to develop and conduct review and audit activities provide reasonable assurance that the NWMI review and audit activities will comply with applicable requirements.

Therefore, the staff finds the information in NWMI PSAR Section 12.2 is sufficient and meets the applicable guidance and regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. Further information as may be required to complete the review of NWMI's review and audit activities (e.g., details on the Review and Audit Committee) can reasonably be left for later consideration since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

12.4.3 Procedures

The staff evaluated the sufficiency of the preliminary NWMI production facility procedures, as described in NWMI PSAR Section 12.3, using the guidance and acceptance criteria from Section 12.3, "Procedures," in NUREG-1537, Parts 1 and 2.

Consistent with the review criteria of Chapter 12 of NUREG-1537, Part 2, Section 12.3, and ANSI/ANS 15.1-2007, the staff evaluated the description of the NWMI procedure activities to ensure that the PSAR provides a basis for the TS requirements for procedures.

NUREG-1537, Part 1, Section 12.3, states, in part, that "[t]he applicant should discuss the basic topics that the procedures do or will cover…The applicant should discuss the methodology used for developing procedures, including the approval process. The applicant should also discuss the process required to make changes to procedures including substantive and minor permanent changes, as defined in ANSI/ANS-15.1-1990, and temporary deviations to deal with special or unusual circumstances during operation. The applicant should note that 10 CFR 50.59 may apply to changes to procedures."

NUREG-1537, Part 2, Section 12.3, Acceptance Criteria, states, in part, that "[t]he applicant should discuss the method for the review and approval of procedures. The method should involve staff from reactor operations, radiation protection, and reactor administration and the review committee, as appropriate to the procedure under review and approval." NUREG-1537, Part 2, Section 12.3 also states, in part, that "[t]he applicant should propose a method for making changes to procedures. This method should cover minor changes with little or no safety significance, substantive changes that are safety significant, and temporary deviations caused by operational needs."

NWMI PSAR, Section 12.3 discusses operating procedures and the procedure program. It generally discusses the use of procedures and that the process for making changes and revisions is documented as follows. Operating procedures will be written, reviewed, approved by appropriate management, controlled, and monitored to ensure that the content is technically correct and the wording and format are clear and concise. Procedures will be prepared, approved, revised, canceled, and implemented in accordance with the NWMI procedure program. Procedure changes, including substantive and minor changes and temporary deviations to deal with special or unusual circumstances during facility operations, will comply with ANSI/ANS-15.1-2007 requirements. The details of the NWMI production facility operating procedures will be specified in the FSAR. The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it is expected to be informed by the final design and is not expected to impact construction of the facility.

Based on its review, the staff determined that the level of detail provided on the NWMI procedure development and review activities is adequate for the issuance of a construction permit because it meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.3.

Therefore, the staff finds the information included in NWMI PSAR Section 12.3, is sufficient to meet the guidance and applicable regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. Further information as may be required to complete the review of NWMI's operating procedures can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

12.4.4 Required Actions

The staff evaluated the sufficiency of the preliminary plan for NWMI required actions, as described in NWMI PSAR Section 12.4, using the guidance and acceptance criteria from Section 12.4, "Required Actions," in NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.4 states that required actions to be taken in the event of a violation of a facility safety limit or the occurrence of a reportable event will be developed for submission in the FSAR.

Using the guidance in NUREG-1537, Part 2, the staff finds it reasonable for the applicant to provide this information in the OL application since it is expected to be based on the final design and is not expected to impact construction of the facility.

Therefore, further information as may be required to complete the review of NWMI's required actions can reasonably be left for later consideration in the FSAR since this information is not

necessary for the review of a construction permit application. NWMI will provide this information in the FSAR to be submitted as part of an OL application.

12.4.5 Reports

The staff evaluated the sufficiency of the preliminary NWMI plans for submitting reports to the NRC, as described in NWMI PSAR Section 12.5, using the guidance and acceptance criteria from Section 12.5, "Reports," in NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.5, states, in part, that "A list of reports to be submitted to the NRC, and associated frequency, will be provided in the Operating License Application."

Using the guidance in NUREG-1537, Part 1, the staff finds it acceptable for the applicant to provide its plans for submitting reports to the NRC in the OL application since it is not expected to impact construction of the facility.

Therefore, further information as may be required to complete the review of NWMI's plan for submitting reports to the NRC can reasonably be left for later consideration since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application. Detailed information regarding reports during the design and construction phase is described in the NWMI PSAR Chapter 12.0, Appendix C.

12.4.6 Records

The staff evaluated the sufficiency of the preliminary NWMI plan for its records management program, as described in NWMI PSAR Section 12.6 and Appendix C, using the guidance and acceptance criteria from Section 12.6, "Records," in NUREG-1537, Parts 1 and 2 and ANSI/ANS-15.8-1995.

NWMI PSAR Section 12.6, states, "[t]he records management program will define the process for managing facility records and will be consistent with the requirements of the applicable regulations." The records management program includes the identification, generation, authentication, maintenance, and disposition of records. A detailed discussion of records management regarding operations will be provided in the FSAR.

Using the guidance in NUREG-1537, the staff finds it acceptable for the applicant to provide this information in the OL application since it is not expected to impact construction of the facility.

Therefore, further information as may be required to complete the review of NWMI's plan for records management can reasonably be left for later consideration since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application. The detailed discussions on type of records, retention period and procedure adherence during the design and construction phase of the facility are described in NWMI PSAR Chapter 12.0, Appendix C.

12.4.7 Emergency Planning

The regulations in Part II to Appendix E of 10 CFR Part 50 state that the PSAR should address the site layout and location, consideration of access routes, surrounding population distribution, land use, and jurisdictional boundaries. The ISG Augmenting NUREG-1537, Part 2, Section 12.7.1,

"Introduction," provides the guidelines for reviewing applications and references in NUREG-0849 "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors" for the review and evaluation of emergency plans at non-power reactors (Reference 79). The guidance provided in NUREG-0849, Section 1.0, "Introduction," calls for the emergency plan to provide a description of the facility, including authorized power level, location, and access routes to the facility. In addition, the owner and operator of the facility should be identified, and the objectives of the emergency plan explained. The staff notes that the NWMI Emergency Response Plan (ERP), Revision 1 is contained within Revision 3 of the NWMI PSAR.

Section A1.0, "Introduction," of the NWMI ERP, states that the NWMI production facility is located on Lot 15 in Discovery Ridge, which is a research park development in Columbia, Missouri. The facility owner and operator is identified as Northwest Medical Isotopes, LLC, of Corvallis, Oregon. The objectives of the NWMI ERP is to describe NWMI's response to radiological and other emergencies occurring at the facility and to minimize the consequences of such emergencies. There is no specific power level identified for this facility, as there is no reactor located at the NWMI production facility.

In an RAI dated January 25, 2017 (Reference 14), the staff requested that the applicant provide a legible figure of the facility, or an electronic copy that could be manipulated to facilitate resolution of building names, numbers, and labels, roads and parking lots, site boundaries showing fences and gates, major site features, access routes, and water bodies within approximately 1 mile (1.6 kilometers [km]) of the NWMI production facility site. The staff also asked the applicant to provide a general area map covering a radius of approximately 10 miles (16.1 km) from the NWMI production facility, which included the location of sensitive facilities near the site, such as hospitals, schools, nursing homes, nearest residence, fire department, prisons, environmental sampling locations, and other structures and facilities that are important to emergency management as described in the NWMI ERP as described in the PSAR.

In a March 6, 2017, letter (Reference 18), and an amended response dated April 28, 2017 (Reference 19), to RAI 12A-1a and RAI 12A-1b, the applicant provided a replacement for Figure A-3, which is referred to as Figure 1 in the RAI response. The applicant also provided new Figures 2, 3, 4, and 5 in the RAI response, which provide building names, numbers, and labels, roads and parking lots, site boundaries showing fences and gates, and major site features, including access routes, and bodies of water within one mile of the NWMI site. The new Figure 4 also shows the location of sensitive facilities near the site. Due to the small size of Figure 4 and Figure 5, the staff noted the low resolution provided limited usefulness. A larger version of Figures 4 and 5 should be made available at the time of the OL application. The staff reviewed the responses to RAI 12A-1a and RAI 12A-1b and concluded that the information provided is consistent with the guidance in NUREG-0849, and ISG Augmenting NUREG-1537, Part 2. Therefore, the staff finds the RAI responses acceptable. The staff noted that in the PSAR, Revision 1, the applicant has incorporated Figures 1, 4, and 5 of the RAI response as Figures A-3, A-4, and A-5 in Revision 1 of the PSAR. The applicant did not incorporate Figures 2 and 3 of the RAI response into Revision 1 of the PSAR.

The staff finds the information in the application, as supplemented by the response to the RAIs, and as partially incorporated into PSAR Revision 1, concerning the site layout and location, consideration of access routes, surrounding population distribution, land use, and jurisdictional boundaries, authorized power level, and the identification of the owner and operator of the facility, and the explanation of the objectives of the NWMI ERP are acceptable and meet the relevant requirements of 10 CFR Part 50, Appendix E, Part II, and the guidance and criteria

provided in the applicable guidance. The staff concludes that this preliminary information meets the applicable regulatory requirements and acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. In addition, 10 CFR 50.34(a)(10) requires a discussion of preliminary plans for coping with emergencies in accordance with 10 CFR Part 50, Appendix E. Further information can reasonably be left for consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application in accordance with 10 CFR 50.34(b)(6)(v).

While there are no specific regulatory requirements in 10 CFR Part 50, Appendix E, Part II related to definitions, ISG Augmenting NUREG-1537, Part 2, Section 12.7.2, "Definitions," provides the guidelines for reviewing applications and references in NUREG-0849 for the review and evaluation of emergency plans at non-power reactors. Section 2.0, "Definitions," of NUREG-0849, states that the emergency plan should provide definitions for terms that are unique to the facility and should include phrases with meanings specific to the facility. As such, the staff reviewed the terms defined as having special meaning and the list of acronyms and abbreviations provided in the NWMI ERP. The staff finds the defined terms, acronyms, and abbreviations to be complete and used consistently throughout the document. The staff also finds the information acceptable and determined that the definitions, acronyms, and abbreviations are consistent with the guidelines provided in NUREG-0849, Section 2.0. The staff concludes that the preliminary information provided meets the applicable acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. Further information can reasonably be left for consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section A, require a description of the onsite and offsite organizations for coping with emergencies and the means for notification in the event of an emergency, and of persons assigned to the emergency organization. 10 CFR Part 50, Part II, Section B calls for the emergency plan to describe contacts and arrangements made with local, State, and Federal governmental agencies with responsibilities for coping with emergencies. Section G, of Appendix E, Part II of 10 CFR Part 50, calls for the emergency plan to describe the time and means to be employed to notify local and State governments in the event of an emergency. The guidance in NUREG-0849 Section 3.0, Organization and Responsibilities," and ISG Augmenting NUREG-1537, Part 2, Section 12.7.3, "Organization and Responsibilities," identifies criteria for evaluating the emergency organization including the onsite emergency organization and 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.

The staff reviewed Section A3.0, "Organization and Responsibilities," of the NWMI ERP contained within the PSAR, to evaluate the applicant's proposed emergency organization, and in an RAI letter dated January 25, 2017, submitted six RAIs related to this subsection. The applicant responded to RAIs 12A-2a, 12A-2b and 12A-2c, RAI 12A-3, RAI 12A-4, and RAI 12A-5 by letter dated March 6, 2017 (Reference 18), as supplemented by a letter dated April 28, 2017 (Reference 19).

In RAI 12A-2a, the staff requested that the applicant describe what contacts and arrangements have been made and documented with local, State, and Federal governmental agencies with responsibility for coping with emergencies at the NWMI production facility site. In response, the applicant stated, in part, that no formal agreements have been made. The applicant indicated that only introductory conversations have taken place with supporting organizations. Continued

interactions with these organizations and the development of appropriate agreements are anticipated in the development of the OL application.

In RAI 12A-2b and 12A-2c, the staff requested that the applicant clarify the organizational responsibility for the support function of the Missouri Office of Emergency Coordination, as stated in Section A3.1.2, "State Agencies," to the NWMI ERP, as it relates to the formal radiological emergency preparedness program. Also, in RAI 12A-2c, the staff requested that the applicant clarify whether the Missouri State Emergency Management Agency, under the Missouri Department of Public Safety, has responsibility for the State's formal radiological emergency preparedness program. In its response (References 18 and 19), the applicant indicated that the Missouri Office of Emergency Coordination will be replaced with the Missouri State Emergency Management Agency, and Section A3.1.2 and Section A3.3.3, "Interfaces Between the Facility Emergency Organization, Off-Site Local Support Organizations, and State and Federal Agencies," of Appendix A to the NWMI ERP will be updated to include the organizational responsibilities for this agency. The staff noted that these changes have been incorporated into NWMI ERP as described in the PSAR.

In RAI 12A-3, the staff requested that the applicant identify the 24-hour on-shift staff positions designated and trained to perform the initial responsibilities for the Emergency Director, Emergency Coordinator, Radiation Safety Officer, and Radiological Assessment Team positions, until these positions are filled by responding emergency personnel. In response (References 18 and 19), the applicant stated the staff positions were intended to be by title, not by individual. The positions would be staffed as 24-hour on-shift positions. Individuals who fill these staff positions will be identified in the emergency plan implementation procedures (EPIPs), which will be developed and submitted as part of the NWMI OL application.

In RAI 12A-4, the staff requested that the applicant confirm if the specified notification times are included in the NWMI ERP for: (1) prompt notification of off-site response authorities, normally within 15 minutes of the declaration of an emergency classification, and (2) notification of the NRC Operations Center, as soon as possible but no later than 1 hour after a declared emergency. In response to RAI 12A-4, the applicant stated that Section A4.2, "Notice of Unusual Events," and Section A4.3, "Alert," of the NWMI ERP would be revised in the PSAR to include the specified notification times. The staff noted that these changes have been incorporated into NWMI ERP as described in the PSAR.

In RAI 12A-5, the staff requested clarification of what position would be responsible for authorizing reentry to the facility after an evacuation. In response to RAI 12A-5, the applicant indicated the NWMI ERP would be revised to clarify this was the responsibility of the Emergency Coordinator.

The staff reviewed the responses to RAIs 12A-2a, 12A-2b, 12A-2c, 12A-3, 12A-4, and 12A-5 and finds that the information provided is consistent with the guidelines in NUREG-0849, and the ISG Augmenting NUREG-1537. Therefore, the staff concludes that the responses to these RAIs are acceptable. The staff verified that the proposed changes in the RAI responses have been incorporated in the ERP Revision 1 of the PSAR.

Based on the discussion above, the RAI responses, and the PSAR as revised in Revision 3, the staff finds that the information provided in the NWMI ERP, Section A3.0, meets the applicable regulatory requirements and acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. Further information can be reasonably left for later consideration in, and

the information, as amended will be evaluated following the receipt of, the FSAR and ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section C requires that protective measures be taken within the site boundary to protect health and safety in the event of an accident.

The acceptance criteria in NUREG- 0849, Section 4.0, “Emergency Classification System,” and from the ISG Augmenting NUREG-1537, Part 2, Section 12.7.4, “Emergency Classification System,” states, in part, that the emergency plan should contain an emergency classification system consistent with the planning standard and EPIPs in an appendix to the emergency plan.

The staff reviewed Section A4.0, “Emergency Classification System,” of the NWMI ERP, which provides for classification of personnel or operational emergencies which are less severe events. Events associated with personnel injuries, radiation doses greater than occupational doses, skin doses, internal contamination, area radiation monitors, air radiation monitors, and events that cause significant damage to the NWMI production facility complex are included in the classification system. The classification system also describes other more severe events which would lead to classification as a notification of unusual event or higher classifications.

The NWMI ERP does not at this time include references to emergency plan implementing procedures. These procedures are not needed because 10 CFR 50.34(a)(10) requires that only a discussion of preliminary plans be included in an application for a construction permit.

The staff finds that the information provided in the NWMI ERP, Section A4.0, is sufficient to meet regulatory requirements and acceptance criteria for the issuance of a construction permit. Further information can reasonably be left for later consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section H require a preliminary analysis reflecting the need to 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 acceptance criteria in NUREG-0849, Section 5.0, “Emergency Action Levels,” and from the ISG Augmenting NUREG-1537, Part 2, Section 12.7.5, “Emergency Action Levels,” states, in part, that the emergency action levels (EALs) should be appropriate to the specific facility and consistent with the emergency classes discussed in Section 12.7.4, and to the extent possible, specify the effluent monitors used to project dose rates and radiological effluent releases at the site boundary. In addition, the EALs should be comparable to the U.S. Environmental Protection Agency’s (EPA) early phase protective action guides (PAGs) described in EPA 400-R-92-001.

The staff reviewed Section A5.0, “Emergency Action Levels,” of the NWMI ERP and submitted four RAIs (Reference 14) related to EALs. The applicant provided its responses to RAI 12A-8, RAI 12A-9a, RAI 12A-9b, and 12A-9c by letter dated April 28, 2017 (Reference 19).

In RAI 12A-8, the staff requested that the applicant specify the effluent monitors used to project dose rates and radiological effluent releases, and include the set points in the EALs to initiate protective actions as per the guidance in NUREG-0849. In response to RAI 12A-8, the applicant stated it will provide the information related to the instrumentation, manufacturer, detection methodology, and set points in the NWMI OL application. The staff reviewed the

response to RAI 12A-8 and concluded that the information concerning effluent monitors is acceptable because the requested information is not needed for the issuance of a construction permit, particularly since the design of the facility is not final. Therefore, the staff finds that the response to this RAI is acceptable.

In RAIs 12A-9a, 12A-9b and 12A-9c, the staff requested that the applicant: (a) clarify the basis for the inclusion of a general emergency classification in NWMI PSAR Chapter 12.0, Appendix A, Section 5.0; (b) explain why the site area emergency and general emergency EALs are identical in Table A-1 of the NWMI ERP, and (c) explain why there is no security-related action level as discussed in ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors" (Reference 96) associated with an alert. In response to RAIs 12A-9a, 12A-9b and 12A-9c, the applicant stated that NWMI-2013-021, Chapter 13, "Accident Analysis," in NWMI PSAR Revision 3, shows that maximum dose to the general public will not reach the EALs defined for a site area emergency or a general emergency in ANSI/ANS-15.16-2015. Accordingly, these two classifications will be removed from the NWMI ERP. The applicant also stated that NWMI ERP Table A-1 will be amended such that the EAL descriptions are consistent with the guidance in ANSI/ANS-15.16-2015, to include security related classifications as appropriate. The staff noted that these changes have been incorporated into PSAR Revision 1.

The staff reviewed the response to RAIs 12A-9a, 12A-9b and 12A-9c, and finds that information provided meets the requirements of Appendix E to 10 CFR Part 50, and conforms to the guidance of NUREG-0849, Section 5.0; ISG Augmenting 1537, Part 2, Section 12.7.5; EPA 400-R-92-001, and ANSI-ANS-15.16-2015. Therefore, the staff concludes that these RAI responses acceptable. The staff verified that the proposed changes in the RAI responses have been incorporated in Revision 1 of the NWMI ERP as described in the PSAR.

The staff concludes that the information provided in the NWMI ERP, Section A5.0, as amended by the response to RAIs, meet regulatory requirements and acceptance criteria for the issuance of a construction permit. Further information can reasonably be left for later consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section H require a preliminary analysis reflecting the need to include methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations within and outside the site boundary, including the capabilities for dose projection and dispatch of radiological monitoring teams within the emergency planning zone (EPZ).

The acceptance criteria from NUREG-0849, Section 6.0 for the "Emergency Planning Zones," the ISG Augmenting NUREG-1537, Part 2, Section 12.7.6, "Emergency Planning Zones," and in RG 2.6, "Emergency Planning For Research and Test Reactors and Other Non-Power Production and Utilization Facilities" (Reference 97), supplementing ANSI/ANS-15.16-2015, Section 3.6, "Emergency Planning Zones," state, in part, that the emergency plan should identify the 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 early phase EPA PAGs. The guidance only calls for the identification of an area that would be impacted by a plume exposure exceeding the early phase EPA PAGs. No ingestion pathway EPZ is needed to meet established guidance.

The staff reviewed Section A6.0, "Emergency Planning Zone," of the NWMI ERP, which states that the EPZ for the NWMI facility is the area within the operations boundary as indicated in

Figure A-3. The applicant stated that NWMI-2013-021, PSAR Chapter 13, Revision 2, shows that the maximum dose to the general public will not reach the EALs defined for a site area emergency or a general emergency in ANSI/ANS-5.16-2015.

The staff finds that the applicant has identified an EPZ, and sized the EPZ such that doses to individuals beyond the EPZ are not projected to exceed the PAGs, and provides an acceptable basis as discussed in Revision 2 of Chapter 13, of NWMI-2013-021. As such, the staff concludes that the information provided in the NWMI ERP, Revision 1, Section A6.0, "Emergency Planning Zones," meet regulatory requirements and acceptance criteria for the issuance of a construction permit. Further information can reasonably be left for later consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50 Appendix E, Part II, Section C require a description of the protective measures to be taken to protect health and safety in the event of an accident, procedures by which these measures are to be carried out, and expected response of offsite agencies in the event of an emergency. ISG Augmenting NUREG-1537, Part 2, Section 12.7.7, "Emergency Response," provides the guidelines for reviewing applications and references NUREG-0849, which provides the guidelines for the review and evaluation of emergency plans at non-power reactors. In particular, NUREG-0849, Section 7.0, "Emergency Response," provides criteria for emergency response measures that should be identified for each emergency.

The staff reviewed Section A7.0, "Emergency Response," of the NWMI ERP, which provides the activation process, assessment actions, corrective actions, and protective actions to be taken for each class of emergencies. The plan identifies the Emergency Coordinator as the position responsible for mobilizing that part of the facility emergency organization appropriate for the emergency and notifying offsite support agencies. Specific procedures have not been developed, however, the information can reasonably be left for development to support an OL application.

The staff finds that the information provided in the NWMI ERP, Section A7.0, meets the regulatory requirements and acceptance criteria for the issuance of a construction permit. Further evaluation of this information, as amended, will occur following the receipt of the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50 Appendix E, Part II, Sections D and E, require a description of the features of the facility to provide for: (a) onsite first aid and decontamination; (b) emergency transportation of onsite individuals to offsite treatment facilities, and (c) provisions to be made for emergency treatment at offsite facilities of individuals injured as a result of licensed activities. The ISG Augmenting NUREG-1537, Part 2, Section 12.7.8, "Emergency Facilities and Equipment," and NUREG-0849, Section 8.0, "Emergency Facilities and Equipment," provide criteria for evaluating plans for providing first aid, decontamination, and transportation of injured personnel.

The staff reviewed Section A7.0, Section A8.3, "First Aid, Decontamination, and Medical Facilities," and Section A3.1.4, "Local Agencies," of the NWMI ERP, which identifies the University of Missouri Health Systems Ambulance Service as providing transportation services, and the University Hospital and Boone Hospital, both in Columbia, as available to provide offsite medical treatment. The plan also states that first aid and decontamination kits will be provided

in the facility complex. A shower room will be provided in the facility complex and personnel decontamination facilities are also available at the University Hospital.

The staff finds that the information provided in the NWMI ERP meets the regulatory requirements and acceptance criteria in applicable guidance documents for the issuance of a construction permit. Further evaluation of this information, as amended, will occur following the receipt of the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section H require a preliminary analysis reflecting the need to include facilities, systems and methods to identify the degree of seriousness and potential scope of radiological consequences within and outside the site boundary. Additionally, there is to be an onsite facility for use in assessing the consequences of a potential radiological accident. ISG Augmenting NUREG-1537, Part 2, Section 12.7.8 and NUREG-0849, Section 8.0, "Emergency Facilities and Equipment," provides criteria for evaluating plans for providing an emergency support center (ESC), representative types of monitoring and sampling equipment, and communication equipment.

The staff reviewed Section A8.0, "Emergency Facilities and Equipment," of the NWMI ERP to evaluate what emergency facilities and equipment will be available. This section describes the ESC as being the production facility Control Room, it identifies various portable and fixed radiological monitors located throughout the facility, sampling equipment, instruments for specific radionuclide identification and analysis, personnel monitoring equipment and smoke and fire detection equipment. Communications equipment include installed telephones and a public-address system, both with backup power supplies, portable radios, a building intercom system, and the expectation that individuals may also have cell phones.

The staff finds that the information provided in the NWMI ERP, Revision 1 of the PSAR, meet regulatory requirements and acceptance criteria in applicable guidance documents for the issuance of a construction permit. Further evaluation of this information, as amended, will occur following the receipt of the FSAR and the ERP revision submitted with the NWMI OL application.

There are no specific regulatory requirements in 10 CFR Part 50, Appendix E, Part II, related to recovery. ISG Augmenting NUREG-1537, Part 2, Section 12.7.9 "Recovery," provides the guidelines for reviewing applications and references NUREG-0849 for the review and evaluation of emergency plans at non-power reactors. Section 9.0, "Recovery" of NUREG-0849, states that the emergency plan specify that recovery procedures will be written and approved as needed.

The staff reviewed Section A9.0," Recovery," of the NWMI ERP and determined that it outlines a task group to be formed to support recovery actions, including the development and approval of procedures as necessary, and preparation of a report after any event.

The staff finds the recovery process as identified in the NWMI ERP to be consistent with the guidelines provided in NUREG-0849, Section 9.0. The staff concludes that the preliminary information provided meets the applicable acceptance criteria and is therefore sufficient for the issuance of a construction permit. Further evaluation of this information, as amended, will occur following the receipt of the FSAR and the ERP revision submitted with the NWMI OL application.

Under 10 CFR Part 50, Appendix E, Part II, Section F describes the requirement for both employee training for those employees required to respond to an emergency and for non-employees who might be called upon in the event of an emergency. The acceptance criteria for information on training from the ISG Augmenting NUREG-1537, Part 2, Section 10.0, "Maintaining Emergency Preparedness," and NUREG-0849, Section 10.0, "Maintaining Emergency Preparedness," calls for a description of training, the review and updating of emergency plans and procedures, and the inventory of supplies that would be used in emergencies.

The staff reviewed Section A10.0, "Maintaining Emergency Preparedness," of the NWMI ERP, to evaluate the applicant's maintenance of emergency preparedness, and in an RAI letter dated January 25, 2017 (Reference 14), submitted two RAIs related to this subsection. The applicant's responses to RAIs 12A-6a and 12A-6b are contained in Reference 18.

In RAI 12A-6a, the staff requested that the applicant provide details of the training program to include the criteria stated in ISG Augmenting NUREG-1537, Part 2, Section 10.0, to include administration of the training program, frequency of training, estimated hours of initial and retraining, and training on the use of protective equipment. In response to RAI 12A-6a, the applicant stated it will amend Section A10.1, "Initial Training and Periodic Retraining Program," Section A3.3.1, "Normal Facility Organization," and Section A3.3.2, "Authorities and Responsibilities of Facility Emergency Personnel," of the NWMI ERP, to clarify responsibilities for administering the training program. The applicant indicated planned frequencies of training, and the project hours of training to be provided. The applicant also specified that training on the use of protective equipment would be included.

In RAI 12A-6b, the staff requested that the applicant describe the training to be provided for first aid and rescue personnel. In response to RAI 12A-6b, the applicant stated training for first aid responders is described in Section A8.3.1, "First Aid Training," of the NWMI ERP, which includes training such as the American National Red Cross Standard Multimedia Course. Additionally, as members of the RPF emergency organization, first aid personnel would participate in annual training, as described in Section A10.1 of the NWMI PSAR.

The staff reviewed the responses to RAIs 12A-6a and 12A-6b and finds that the information as amended concerning the training program is acceptable and meets the guidance in NUREG-0849. Therefore, the responses to these RAIs are acceptable. The staff verified that the proposed changes in the RAI responses are incorporated in Revision 1 of the NWMI ERP as described in the PSAR.

The staff reviewed the information provided in NWMI PSAR Chapter 12.0, Appendix A, Section A10.2, "Emergency Drills," pertaining to emergency drills. ISG Augmenting NUREG-1537, Part 2, Section 12.7.10, states that an adequate emergency plan should demonstrate several criteria related to emergency drills and qualifications. In RAI 12A-7, the staff requested that the applicant clarify how the conduct of drills, as described in PSAR Chapter 12, Appendix A, Section A10.2, demonstrates the guidance in Section 12.7.10 of ISG Augmenting NUREG-1537, Part 2. In response to RAI 12A-7, the applicant stated it would amend Section A10.2 to address the criteria in Section 12.7.10 of ISG Augmenting NUREG-1537, Part 2. The applicant also indicated that Section A10.4.2 (1) in NWMI PSAR Chapter 12, Appendix A, would be revised to include quarterly checks to verify the ability to communicate with off-site response agencies. The staff verified that the proposed changes in the RAI responses are incorporated in Revision 1 of the NWMI ERP as described in the PSAR.

The staff reviewed the response to RAI 12A-7 and concluded that the information in the NWMI ERP as described in the PSAR concerning conductance of emergency drills is in accordance with the applicable guidance and is acceptable. Therefore, the response to RAI 12A-7 is acceptable.

The staff finds that the preliminary information provided in the NWMI ERP as described in the PSAR, and in the applicant's responses to RAIs meets the acceptance criteria identified in the ISG Augmenting NUREG-1537, Part 2, Section 12.7, "Emergency Planning," NUREG-0849, ANSI/ANS-15.16-2015, and EPA 400-R-92-001, and therefore, meets the requirements of 10 CFR Part 50, Appendix E, Part II, and is sufficient for the issuance of a construction permit. Further evaluation of this information will occur following the receipt of the NWMI FSAR and the NWMI ERP revision submitted with the NWMI OL application.

In conclusion, the staff concludes that the preliminary information provided meets the applicable regulatory requirements and acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. Further information can reasonably be left for later consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

12.4.8 Quality Assurance

Chapter 12.0, Appendix C, of the NWMI PSAR states that the NWMI QAPP is based on ANSI/ANS-15.8-1995 and 10 CFR 70.64(a)(1), "Quality standards and records." NWMI concluded that these standards and requirements are sufficient for use in the development of the NWMI QAPP, which is to be applied to the design, fabrication, construction, operation, and decommissioning of the NWMI production facility.

The staff evaluated the sufficiency of the NWMI QAPP, as described in Appendix C of NWMI PSAR Chapter 12.0, in part, by determining whether the applicant satisfied the relevant requirements of 10 CFR 50.34(a)(7) and by using the guidance from Section 12.9, "Quality Assurance," of NUREG-1537, Parts 1 and 2. This guidance refers QA reviewers to ANSI/ANS-15.8, as endorsed by RG 2.5, for the review of an applicant's QA program. The following is an evaluation of the NWMI QAPP as described in Appendix C of NWMI PSAR Chapter 12.0. Since the staff's review of the NWMI construction permit is limited to those activities licensed under 10 CFR Part 50, the staff did not evaluate NWMI's QAPP against the requirements of 10 CFR 70.64(a)(1).

In Section C1.0, "Introduction," of the NWMI QAPP, the applicant describes the applicability, scope, and its consistency with ANSI/ANS 15.8-1995. NWMI states that its QA program described in Section C1.2, "Application," of the NWMI QAPP, will be applied to NWMI activities, consistent with their importance to safety and reliability. NWMI states it will apply a graded approach to those items and activities that could affect the quality of safety-related SSCs and other components not specifically designated as safety related. NWMI activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

The staff finds that NWMI provided an adequate description of the QAPP that follows the standard. NWMI commits to the full standard and describes the applicability of the standard to its facility with a graded quality approach. The graded approach is a process established to determine the level of analysis, documentation, and the actions necessary to comply with specific requirements, commensurate with the safety significance. The staff finds that the

description of the NWMI QA program application meets the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and is therefore acceptable.

Section C1.4, “Definitions,” of the NWMI QAPP provides a list of key definitions used throughout the document. The NWMI QAPP defines safety-related, non-safety-related, safety-related IROFS, and non-safety-related IROFS. The staff finds that the definitions are in accordance with ANSI/ANS-15.8-1995 and consistent with definitions for safety-related and non-safety-related SSCs provided in NWMI PSAR Section 3.5.1.3, “Nuclear Safety Classifications for Structures, Systems, and Components.”

Section C2.0, “Design, Construction, and Modifications,” and its associated subsections described below, of the NWMI QAPP describe the QA program developed by NWMI to provide the safety and reliability during the design and construction of the NWMI production facility.

Section C2.1, “Organization,” of the NWMI QAPP describes the NWMI organizational structure, functional responsibilities, levels of authority, and lines of communication for establishing, executing, and verifying implementation of activities within the scope of the QAPP. NWMI QAPP Section C2.1 states that the Quality Assurance Manager will have an independent oversight responsibility of the QAPP. The Quality Assurance Manager will report directly to the COO, who will have overall responsibility for the NWMI QA program.

The NWMI QAPP also specifies that the COO will report directly to the president CEO for operational aspects of the company, including safety, quality, security and safeguards, environmental stewardship, and regulatory licensing affairs. The COO will be responsible for all the external operations of NWMI, including supplier organizations, and integrating all quality requirements as defined in the QAPP across the internal and external organizations.

The NWMI QAPP provides for independence between the organization responsible for performing an activity or function and the organization responsible for quality oversight activities (i.e., QA and quality control).

The staff finds that the NWMI organizational controls in NWMI QAPP Section C2.1 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable.

Section C2.2, “Quality Assurance Program,” of the NWMI QAPP documents the requirements for establishing, implementing, and managing the QA program. The program implements a graded approach to quality, as described in Section C2.2.2, “Requirements,” of the NWMI QAPP. Quality Level (QL)-1 classification implements the full measure of the NWMI QAPP and will be applied to all safety-related SSCs. QL-2 includes the quality activities performed by NWMI, generally on a continuing basis, that are applied to ensure that the items are available and reliable to perform their safety functions when needed that are not QL-1. QL-3 includes non-safety-related quality activities performed by NWMI that are deemed necessary. As described in NWMI PSAR Section 3.5.1, “General Design Basis Information,” safety-related IROFS are classified QA Level 1. At a minimum, safety-related non-IROFS are classified as QA Level 2, and non-safety-related SSCs are classified as QA Level 3.

As described in NWMI QAPP Section C2.2.1, “Program Hierarchy,” the QAPP is implemented on all NWMI work activities that include safety-related components. In addition, the QAPP may be supplemented by project-specific QA plans. The NWMI QA program is inclusive of this QAPP and applicable implementing procedures as necessary to effectively address

requirements. All NWMI activities and tasks will be performed consistent with approved implementing procedures. NWMI procedures will be delineated, managed, and maintained by the Quality Manager, with support from NWMI staff.

Additionally, NWMI QAPP Section C2.2, describes provisions for the appropriate and necessary indoctrination and training of personnel who perform activities affecting quality, to ensure that suitable proficiency is achieved and maintained. When required, qualification and selection of personnel will be conducted consistent with requirements established in applicable NWMI procedures. The scope of indoctrination will include administrative and technical objectives, as well as the requirements of applicable codes, standards, and the NWMI QAPP. Records of personnel training and qualification will be maintained. NWMI also stated that the full QAPP applies to all QL-1 components and all IROFS are considered QL-1.

The staff finds that the NWMI PSAR Appendix C definitions for QL-1, QL-2, and QL-3 classifications, are adequate to represent a graded approach to quality, as described in NWMI QAPP Section C2.2. The staff further finds that the NWMI programmatic controls are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and are therefore acceptable for the issuance of a construction permit.

Section C2.3, “Design Control,” of the NWMI QAPP establishes a design control process to control the design, design changes, and modifications subject to the provisions of the QAPP. The NWMI QAPP states that procedures will identify the process and include the provisions for the control of design documents, control of software, and implementation of required rules, regulations, codes, and standards. In addition, the section describes specific procedures and responsibilities for the implementation of this section of the QAPP.

Section C2.3.2, “Requirements,” of the NWMI QAPP establishes that applicable design inputs, including design bases, performance requirements, regulatory requirements, codes, and standards, are to be identified and documented.

Section C2.3.1, “Responsibility,” of the NWMI QAPP states that NWMI personnel have responsibility for identifying and controlling the design interfaces and will coordinate activities among participating organizations. This section states that the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, will be verified for each application. Deviations from the established design inputs will be documented and controlled. The design organization will ensure that the final design is relatable to the design input by adequate documentation. Computer design programs used to develop any portion of the facility design or to analyze the design will be controlled. When a design program must be developed, the program will be controlled to ensure that it is fully documented and validated. When changes to previously validated computer programs are made, documented re-validation will be performed for the change and include appropriate benchmark testing.

This section also states that design verification will be performed by competent persons other than those who designed the item. Design verification will be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations. Qualification testing will be defined in formal test plans and will include appropriate acceptance criteria. Testing will demonstrate the adequacy of performance that simulates the most adverse design conditions. Test results will be documented and verified to have met the test requirements. Such documents and records will be collected, stored, and maintained for the life of the safety-related item.

Section C2.3.2 describes how changes to design inputs for final designs, field changes, and temporary and permanent modifications to SSCs or computer codes shall be documented, justified, and subject to design control measures commensurate with those applied to the original design. These measures include evaluation of effects of those changes on the overall design and on any analysis on which the design is based. NWMI states in QAPP Section C2.3.2 that qualification testing will be performed to demonstrate the adequacy of performance of SSCs under conditions that simulate the most adverse design conditions. NWMI also stated in NWMI QAPP Section C2.3.3, "Design Changes," that engineering change control procedures have been developed for the RPF design and construction to ensure that modifications to safety-related SSCs, IROFS, or computer codes, will be based on a defined design and safety function of the component.

The staff finds that the NWMI programmatic and design change controls in NWMI QAPP Section C2.3 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support issuance of a construction permit.

Section C2.4, "Procurement Document Control," of the NWMI QAPP establishes controls necessary to ensure that correct quality requirements will be formally and effectively communicated to NWMI suppliers of items and services. The NWMI QAPP stipulates that procurement documents at all procurement levels identify the documentation required to be submitted for information, review, or approval by NWMI. The procurement documents control includes sufficient technical and quality requirements to ensure that the items or services will satisfy the needs of the purchase and all documents at all procurement levels require the documentation to be reviewed by the purchaser. Procurement documents will require the supplier to report non-conformances associated with the items or services being procured.

The staff finds that the NWMI procurement document controls described in NWMI QAPP Section C2.4 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.5, "Procedures, Instructions, and Drawings," describes the NWMI measures to ensure that quality activities are based on documented instructions, procedures, or drawings, as appropriate. These documents will include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

The staff finds that the NWMI controls for instructions, procedures, and drawings described in NWMI QAPP Section C2.5 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.6, "Document Control," describes the NWMI process to control the review, approval, and distribution of documents, including changes thereto, which prescribe activities affecting quality. It states that the program and implementing procedures will establish the requirements for identification, review and approval, and distribution of documents. Major changes to controlled documents will be reviewed and approved by the same organizations that performed the review of the original issue.

The staff finds that the NWMI document controls described in NWMI QAPP Section C2.6 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.7 describes the NWMI measures to ensure that purchased items and services conform to procurement documents. These measures include supplier evaluation and selection, source surveillance and inspection, and audits and review of supplier documents, as applicable.

As described in Section C2.7.2.2, "Supplier Selection," the NWMI QAPP requires that the selection of suppliers be based on evaluation of their capabilities to provide items or services consistent with the requirements of the procurement documents.

Section C2.7.2.4, "Supplier's Performance," of the NWMI QAPP requires that measures be established to control the supplier's performance. Evaluation methods will include review of supplier plans and procedures, source surveillance or inspection, QA assessments, receipt inspections deviations, waivers, and corrective actions. NWMI states that it will require that suppliers verify and provide evidence of the quality of their products.

In NWMI QAPP Section C2.7.2.5, "Supplier-Generated Documents," NWMI states that it will establish methods to control and approve supplier-generated documents. Based on the complexity of the product and importance to safety, NWMI states that it will independently verify the quality of supplier's product using source surveillances, inspections, audits, or review of supplier's non-conformances, dispositions, waivers, and corrective actions.

NWMI QAPP Section C2.7.2.6, "Item or Service Acceptance," describes the NWMI process to ensure that purchased items and services conform to procurement specifications. NWMI states that it will use one or more of the following methods to accept an item or service: supplier Certificate of Conformance, source verification, receipt inspection, or post-installation testing. Receipt inspection will include, as appropriate, verification by objective evidence such features as proper configuration, identification and cleanliness, shipping damage, and indication of fraud or counterfeit. Documented evidence of acceptability must be completed prior to placing an item in service, and these controls are also applicable to software.

The staff finds that the NWMI controls for purchased items and services described in NWMI QAPP C2.7 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.8, "Identification and Control of Items," describes the NWMI measures to ensure that only correct and accepted items are used or installed. Identification will be maintained on the items or in documents traceable to the items, or in a manner that ensures identification is established and maintained as described in this section.

The staff finds that the NWMI controls for identification and control of items described in NWMI QAPP Section C2.8 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.9, “Control of Special Processes,” describes the NWMI measures to ensure that approved special process procedures are used by qualified personnel, and consistent with specified codes and standards, including acceptance criteria for the process. NWMI states that special processes will be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Records for qualified personnel, processes, and equipment associated with special processes will be maintained, as appropriate.

The staff finds that the NWMI controls for special processes described in NWMI QAPP Section C2.9 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.10, “Inspections,” describes the NWMI inspection process to verify the quality and conformance of the item to specified requirements. The inspection process will be applicable to procurement, construction, modification, maintenance, and experiment fabrication. Inspections will be performed by persons other than those who performed the work being inspected, but may be from the same organization. The inspection process requires that to verify conformance of an item or activity to specified requirements or the continued applicability of an item in service, the inspection shall be planned, executed, and implemented. Inspection activities require that such activities shall be documented and controlled by instructions, procedures, drawings, checklist, travelers, or other appropriate means.

The staff finds that the NWMI controls for inspection described in NWMI QAPP Section C2.10 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.11, “Test Control,” describes the NWMI requirements for planning, conducting, and documenting tests to specific requirements that provide evidence of product or computer program acceptability. Test results will be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Computer programs to be used for operational control will be tested consistent with an approved verification and validation plan and will demonstrate required performance over the range of operation of the controlled function or process. NWMI also stated that testing activities will be completed under the QA program of the organization that is completing the work.

NWMI states in the PSAR that all suppliers of computer software will be required to verify and provide evidence of the quality of their software products. In addition, methods to control and approve supplier generated documents will be established. Based on the complexity of the product and importance to safety, NWMI states that it will independently verify the quality of supplier products. NWMI-QA-PRO-029 Testing Procedure, identifies the process by which computer testing will be completed.

The staff finds that the NWMI controls for testing described in NWMI QAPP Section C2.11 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.12, “Control of Measuring and Test Equipment [M&TE],” describes the NWMI measures to ensure that tools, gauges, instruments, and other M&TE used for activities affecting quality are controlled, calibrated, or adjusted at specified periods, to maintain accuracy

within specified limits. Frequency of the calibration of M&TE shall be defined and based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions that might affect measurement control.

Out-of-calibration devices will be tagged and segregated, until calibration has been restored. Records of calibration and repair, including as-found conditions, shall be maintained to indicate calibration and the capability of the M&TE.

The staff finds that the NWMI controls for M&TE described in NWMI QAPP Section C2.12 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

In Section C2.13, "Handling, Storage, and Shipping," the NWMI QAPP requires that handling, storage, and shipping of items be performed consistent with work and inspection instructions, drawings, specifications, shipping instructions, or other pertinent documents specified for the use in the conducting the activity.

The staff finds that the NWMI controls for handling, storage, and shipping described in NWMI QAPP Section C2.13 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and are therefore acceptable to support the issuance of a construction permit.

Section 2.14, "Inspection, Test, and Operating Status," of the NWMI QAPP requires that the status of inspection and test activities be identified on the items or in documents traceable to the items. Identification of inspection and test status will ensure that required inspection and test activities were performed and will prevent inadvertent installation or operation of items that have not passed the required inspections or tests.

The staff finds that the NWMI controls for inspection, test, and operating status described in NWMI QAPP C2.14 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

Section C2.15, "Control of Nonconforming Items," of the NWMI QAPP describes the necessary measures to control nonconforming items, to prevent their inadvertent use or installation. These controls include measures for identification, documentation, evaluation, segregation (as appropriate), and disposition of nonconforming items. Recommended dispositions, such as "use-as-is," "reject," "repair," or "rework," will be identified, documented, and approved.

In Section C2.15.2.2, "Disposition," of the NWMI QAPP, NWMI states that it will document the technical justification for the acceptability of a nonconforming item dispositioned as "repair," or "use-as-is." Non-conformances to design requirements of items dispositioned as "repair," or "use-as-is," will be subject to design control measures commensurate with those applied to the original design. Nonconforming items dispositioned as "repair," or "rework," will be re-examined consistent with applicable procedures and appropriate acceptance criteria. In response to RAIC2.15-1 (Reference 31), NWMI described the procedures and applicability of non-conforming items and 10 CFR Part 21, "Reporting of Defects and Noncompliance," evaluations. The applicant also described the applicability of regulations during the design and constructions phases of the facility via procedures.

The staff finds that the NWMI controls for nonconforming items and services described in NWMI QAPP Section C2.15 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

Section C2.16, "Corrective Actions," of the NWMI QAPP requires that conditions adverse to quality be identified promptly and corrected as soon as practical. The corrective actions will be consistent with the design requirements, unless those requirements were faulty.

In the case of a significant condition adverse to quality, the cause of the condition will be investigated and corrective action to prevent recurrence will be taken. NWMI states that it will perform the evaluation of significant conditions adverse to quality for reporting to the NRC when required in accordance with 10 CFR Part 21 reporting requirements.

The staff finds that the NWMI controls for corrective actions described in NWMI QAPP Section C2.16 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

Section C2.17, "Quality Records," of the NWMI QAPP specifies procedures that describe the necessary measures to ensure that, at minimum, sufficient records of the following activities be maintained and appropriately stored: inspection and test results, results of QA reviews, QA procedures, and engineering reviews and analyses for design or changes and modifications. The NWMI records management will be implemented, and enforced consistent with written procedures, instructions, or other documentation.

NWMI QAPP Section C2.17 also states that records shall be classified as "lifetime," or "non-permanent," by NWMI customers as applicable. Both kind of records will be delineated with implementing procedures. As for the design and construction phase of the facility, all records are maintained according to procedure requirements. Records will be stored in a location that provides damage prevention from moisture, temperature, and pestilence. Provisions will be specified for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage. NWMI requires that records that be maintained by a supplier be accessible to NWMI. However, the staff needed clarification on what is defined as a quality record. In response to RAI C2.17-1 (Reference 31), NWMI stated that the Quality Records procedures identify the process by which quality records are identified and maintained. NWMI QAPP C2.17.2, "Requirements," states that NWMI's Quality Records procedure describes the quality documents relevant to the final design and construction (including modifications).

NWMI stated in the PSAR that lifetime records will be classified consistent with the recommendations found in ANSI/ANS-15.8.

The staff finds that the NWMI controls for quality records described in NWMI QAPP Section C2.17 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

Section C2.18, "Assessments," of the NWMI QAPP describes the process and expectations to implement a system of audits, assessments, and surveillance of activities affecting quality during the design and construction phase for the production facility. The assessments will be

completed during design, construction, and modification to evaluate the effectiveness of the quality program implementation in those areas.

NWMI QAPP Section C2.18 also states that assessments will be performed consistent with written procedures or checklists. Assessment results will be documented and reviewed by the management personnel responsible for the area assessed. Management of the assessed organization will investigate adverse findings and schedule corrective actions. The adequacy of the responses will be evaluated by the assessing organization. Assessment records will include plans, reports, written replies, and records of completion of corrective actions.

NWMI requires that personnel conducting assessments have the requisite training and experience in the area of the assessment.

The staff finds that the NWMI controls for assessments described in NWMI QAPP Section C2.18 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support a construction permit.

Section C3, "Facility Operations," of the NWMI QAPP outlines the elements of a QA program for conduct of operation at the NWMI production facility. NWMI states in this section that additional detail on its QA program for the conduct of operations will be submitted as part of its OL application. The staff finds it acceptable for the applicant to defer the submission of this information until the OL application since it relates to the administration and conduct of activities related to operation of the facility and is not expected to impact construction of the facility. The NWMI QAPP also states that some requirements of the QA program for operations may be found in other documents, such as the training program, emergency preparedness plan, security plan, and TSs, and would not be duplicated in the QA program.

The information provided in NWMI QAPP Section C3 including its subsections, pertains to the operations of the NWMI production facility, and specific details are not necessary for the issuance of a construction permit since 10 CFR 50.34(a)(7) only requires that an applicant for a construction permit provide a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Therefore, further information as may be required to complete the review of NWMI's QA program for the conduct of operations can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

NWMI has included a section heading for the future inclusion of NWMI QAPP Section C5.0, "Decommissioning," in its OL application. The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it relates to the administration and conduct of activities related to facility decommissioning and is not expected to impact construction of the facility.

Since the proposed NWMI QAPP Section 5.0 pertains to the decommissioning of the NWMI production facility, specific details are not necessary for the issuance of a construction permit because 10 CFR 50.34(a)(7) only requires that an applicant for a construction permit provide a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Therefore, further information as may be required to complete the review of NWMI's QA program for decommissioning can reasonably be left for later

consideration in the FSAR since this information is not necessary for the review of aconstruction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

Based on its review, the staff finds that the information in NWMI PSAR Chapter 12.0, Section 12.9 in conjunction with Appendix C1, is sufficient and meets the guidance in ANSI/ANS-15.8-1995 and the QA requirements in 10 CFR 50.34(a)(7), which requires that an applicant for a construction permit provide a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Therefore, the staff finds that NWMI has met the applicable guidance and regulatory requirements for the issuance of a construction permit, and, as such, is acceptable for implementation during the design and construction of the NWMI production facility. Further information as may be required to complete the review of NWMI's QA program for the conduct of operations and decommissioning can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a construction permit application. Further evaluation of the NWMI QAPP will occur following the receipt of the NWMI FSAR. The staff will also review any updates to the NWMI QAPP submitted by NWMI to the NRC prior to or after the issuance of a materials license under 10 CFR Part 70, as described in Section C2.20 of the NWMI QAPP.

The staff will review NWMI's design changes and design control process to verify that the construction and design process effectively implements NRC requirements and other licensing design commitments made by NWMI, including implementation of the NWMI QAPP, as part of the staff's construction inspection program, as described in NRC Inspection Manual Chapter (IMC) 2550, "Non-Power Production and Utilization Facilities Licensed Under 10 CFR Part 50: Construction Inspection Program (CIP)."

The objectives of IMC 2550, include: (1) verification of the development of QA procedures, instructions, and other documents that are consistent with the NWMI QAPP; and (2) verification of the effective implementation of the NWMI QAPP, including timely implementation of organizational staffing, procedures, instructions, QA activities, design controls, engineering controls, and administrative controls necessary to achieve quality objectives.

In order to provide reasonable assurance that regulatory requirements and licensee commitments for QA are adequately included in the design, procurement, and construction of the NWMI production facility, the staff recommends that the construction permit include the following condition:

> NWMI shall implement the QA program described, pursuant to 10 CFR 50.34(a)(7), in Revision 3 of the NWMI PSAR, including revisions to the quality QA program in accordance with the provisions below.
>
> NWMI may make a change to its previously accepted QA program description included in Revision 3 of the NWMI PSAR, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the QA program description that do not reduce the commitments must be submitted to the NRC within 90 days. Changes to the PSAR QA program description that do reduce the commitments must be submitted to the NRC and receive NRC approval before implementation, as follows:
>
> - Changes made to the previously accepted QA program description must be submitted as specified in 10 CFR 50.4.

- The submittal of a change to the PSAR QA program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the PSAR QA program description commitments previously accepted by the NRC. The letter need not provide the basis for changes that correct spelling, punctuation, or editorial items.

- A copy of the forwarding letter identifying the changes must be maintained as a facility record for three years.

- Changes to the QA program description included in the NWMI PSAR shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

12.4.9 Operator Training and Requalification

The staff evaluated the sufficiency of the NWMI operator training and requalification program, as described in NWMI PSAR Section 12.10, using the guidance and acceptance criteria from Section 12.10b, "Production Facility Operator Training and Requalification," in the ISG Augmenting NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.10 states that the NWMI production facility operator training and requalification program will be described in the FSAR.

The staff finds that the information provided regarding NWMI's operator training and requalification program, can reasonably be left for later consideration in the NWMI FSAR since it is not expected to impact construction of the production facility.

12.4.10 Startup Plan

The staff evaluated the sufficiency of the preliminary NWMI startup plan, as described in NWMI PSAR Section 12.11, using the guidance and acceptance criteria from Section 12.11, "Startup Plan," in the ISG Augmenting NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.11 states that the startup plan will be developed and described in the FSAR.

Using the guidance in NUREG-1537, Part 1, the staff considered this statement in the PSAR and concluded that further information regarding the operation of the NWMI production facility is not necessary for the issuance of a construction permit given that a startup plan should be based on a final design.

Therefore, the staff finds that the information provided is adequate, and further information regarding the startup plan, as described in NWMI PSAR Section 12.11, can reasonably be left for later consideration in the NWMI FSAR.

12.4.11 Environmental Reports

The staff did not review environmental information as described in Section 12.12, "Environmental Reports," of NUREG-1537, Parts 1 and 2. Parts 1 and 2 of the ISG Augmenting NUREG-1537, state that this section of Chapter 12.0 has been superseded by Chapter 19.0, "Environmental Review." The staff's evaluation of NWMI's environmental information, submitted as Chapter 19.0, "Environmental Review," of the NWMI PSAR, is documented in NUREG-2209.

12.4.12 Material Control and Accounting Plan

The staff evaluated the sufficiency of the preliminary NWMI MC&A plan, as described in NWMI PSAR Section 12.13, using the guidance and acceptance criteria from Section 12.13, "Material Control and Accounting Plan," in the ISG Augmenting NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.13 states that the MC&A program will be described in the FSAR.

The staff considered the statement in the PSAR and concludes that, since NWMI has not requested a license to possess special nuclear material (SNM) during construction, a MC&A plan is not necessary at this time. A MC&A plan will be necessary when NWMI applies for a license to possess SNM under 10 CFR Part 70.

Therefore, the staff finds that the information on NWMI's MC&A plan, as described in NWMI PSAR Section 12.13, is acceptable and that further information can reasonably be left for later consideration in the evaluation of the NWMI FSAR or if NWMI applies for a license to possess SNM.

12.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI organization, including probable subjects of TSs, as described in Chapter 12.0 of the NWMI PSAR, and finds that the preliminary plan for the NWMI conduct of operations meets the applicable guidelines of the ISG Augmenting NUREG-1537, Part 2 and NUREG-1537, Part 2, as follows:

(1) The staff finds that the level of detail provided on NWMI's organization activities is adequate and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.1, allowing the staff to make a finding that the applicant's commitments to develop and conduct organization activities provide reasonable assurance that the NWMI organization activities will comply with applicable requirements and be consistent with guidance.

(2) The staff finds that the level of detail provided on the NWMI review and audit activities is adequate and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.2, allowing the staff to make a finding that the applicant's commitments to develop and conduct review and audit activities provide reasonable assurance that the NWMI review and audit activities will comply with applicable requirements.

(3) The staff finds that the level of detail provided for the NWMI procedure development and review activities is adequate for the issuance of a construction permit and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.3.

(4) The staff finds that further information on required actions, reports, and records can reasonably be left for later consideration in the FSAR.

(5) The staff finds that the preliminary information on emergency planning provid meets the applicable regulatory requirements and acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. Further information can reasonably be left for later consideration in the FSAR and revised ERP, and evaluation of this information will occur following the receipt of the NWMI FSAR and the NWMI ERP revision submitted with the NWMI OL application.

(6) The staff finds that further information on security planning can reasonably be left for later consideration in the FSAR.

(7) The staff finds that the information to be included in NWMI PSAR Section 12.9 is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit. Further information on NWMI QA program requirements during operations and decommissioning can reasonably be left for later consideration in the FSAR, and further evaluation of the NWMI QAPP will occur following the receipt of the NWMI FSAR. The staff will also review any updates to the NWMI QAPP submitted by NWMI to the NRC prior to or after the issuance of a materials license under 10 CFR Part 70, as described in Section C2.20 of the NWMI QAPP. The staff will review NWMI's design changes and design control process to verify that the construction and design process effectively implements NRC requirements and other licensing design commitments made by NWMI, including implementation of the NWMI QAPP, as part of the staff's construction inspection program, as described in NRC IMC 2550. In order to provide reasonable assurance that regulatory requirements and licensee commitments for QA are adequately included in the design, procurement, and construction of the NWMI production facility, the staff recommends that the construction permit include the condition described in Proposed Permit Condition 3 in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER.

(8) The staff finds that information on the operator training and requalification program, startup plan, and MC&A plan can reasonably be left for later consideration in the FSAR.

Based on these findings and subject to the condition referenced above, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) There is reasonable assurance that, taking into consideration the site criteria contained in 10 CFR Part 100, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(2) There is reasonable assurance: (i) that the construction of the NWMI production facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations.

(3) The The issuance of a permit for the construction of the production facility would not be inimical to the common defense and security or to the health and safety of the public.

(4) The applicant is technically qualified to engage in the proposed activities in accordance with the Commission's regulations.

13 ACCIDENT ANALYSIS

This chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary accident analysis of the NWMI production facility as presented in Chapter 13.0, "Accident Analysis," of the NWMI preliminary safety analysis report (PSAR), Revision 3, and NWMI's responses to requests for additional information (RAIs).

The accident analysis for the NWMI production facility 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 facility is capable of accommodating disturbances in the functioning of structures, systems, and components (SSCs). Additionally, the accident analysis demonstrates that facility controls have been identified to ensure that identified credible accidents, as defined in Section 3.3, "Definitions of Likelihood and Likelihood Categorization," of the NWMI Integrated Safety Analysis (ISA) Summary, could not lead to unacceptable radiological and non-radiological consequences to workers and the public.

SER Chapter 13, "Accident Analysis," provides an evaluation of the preliminary accident analysis of the NWMI production facility presented in PSAR Chapter 13.0, wherein NWMI describes accident-initiating events and scenarios, determination of consequences and identification of safety-related SSCs. The applicant has chosen to use an ISA methodology which was derived from Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," consistent with "Final Interim Staff Guidance (ISG) 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" (Reference 11), (see Chapter 13.3.2 of this SER) to demonstrate compliance with 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," for the production facility. This chapter also outlines the applicant's ISA methodology and its application to the NWMI production facility to define items relied on for safety (IROFS). As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, SSCs related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a 10 CFR Part 50 production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70 license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

13.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 13.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the accident analysis of the preliminary design for the purposes of issuance of a construction permit. As part of this

review, the staff evaluated descriptions and discussions of NWMI's accident analysis, with attention to the ISA methodology, design and operating characteristics, unusual or unique design features, and principal safety considerations. The accident analysis of the preliminary design was evaluated to ensure the sufficiency of principal design criteria; design bases; and general information relative to materials of construction, arrangement of structures and components, and approximate dimensions, as needed, to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items, which are determined to be probable subjects of technical specifications (TSs) for the production facility. SSCs were also evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of the consequences of accidents.

Areas of review for this section included the application of the ISA process to perform accident analysis, accidents with radiological consequences, and accidents with hazardous chemicals. Within these areas of review, the staff assessed processes conducted within the production facility; accident initiating events; loss of confinement; external events; critical equipment malfunction; inadvertent nuclear criticalities; facility fires; and chemical accident descriptions, mitigated and unmitigated consequences, and IROFS. The staff also reviewed the aforementioned areas in relation to the ISA Summary.

13.2 Summary of Application

NWMI states in PSAR Chapter 13 that its facility accident analysis, performed using the ISA methodology process as described in 10 CFR Part 70, provides the bases for establishing safety limits and designating IROFS for facility operations. A technical basis for control of those limits is provided in the PSAR and in supporting information for the ISA. Some portion of this technical basis is expected to be included in TSs. The accidents analyzed in this chapter also support the establishment of the design basis limits for the SSCs in the NWMI production facility processes. The facility design has design features and analysis assumptions that are important for understanding the bases of the accident analysis as it applies to the design of the facility. NWMI identified, through a systematic process, a variety of event types that are expected to be prevented or mitigated to acceptable limits for the credible accidents related to the production facility. NWMI states that production facility accident scenarios and analyses for the construction permit are based on the preliminary design of the facility and are considered preliminary from an operating licensing and final design standpoint.

NWMI PSAR Section 1.2.2, "Consequences from the Operation and Use of the Facility," states that there are potential exposures to the public from postulated accidents and that dose to workers and the public from postulated accidents are within the limits of 10 CFR 20.1201, Occupational dose limits for adults," and 10 CFR 20.1301, "Dose limits for individual members of the public."

NWMI PSAR Chapter 13.0 describes accident analysis methodology, accidents with radiological consequences, and accidents with hazardous chemicals for the NWMI production facility. The PSAR provides details on processes conducted within the facility; accident initiating events; loss of confinement; external events; critical equipment malfunction; inadvertent nuclear criticalities; facility fires; and chemical accident descriptions, consequences, IROFS, and surveillance requirements. The NWMI production facility design basis is supported by information provided in NWMI PSAR Chapter 13.0 through discussions related to the use of an ISA methodology which includes a process to determine anticipated events, assess the associated risk, and designate the IROFS needed to achieve acceptable risk levels. As stated in the PSAR, the

accident analysis performed by NWMI considers the radiological consequences, chemical consequences, fire analysis, and criticality status of accidents defined as credible in the NWMI production facility.

NWMI PSAR Chapter 13.0 documents the basis for the identification and evaluation of accident scenarios in the NWMI production facility as follows:

- Implementation of an ISA methodology which includes a preliminary hazard analyses (PHA) performed using guidance from ISG Augmenting NUREG-1537, Part 1.

- The list of accident initiating events identified in the ISG Augmenting NUREG-1537, Part 1, Section 13b.1.2, "Accident Initiating Events."

- Experience of the hazard analysis team.

- Preliminary design and design basis evaluations in the PSAR for the processes in the NWMI production facility.

- The determination of IROFS needed to prevent or mitigate credible accidents.

NWMI PSAR Section 13.1, "Accident Analysis Methodology and Preliminary Hazards Analysis," Table 13-9, "Adverse Event Summary for Target Fabrication and Identification of Accident Sequences Needing Further Evaluation"; Table 13-10, "Adverse Event Summary for Target Dissolution and Identification of Accident Sequences Needing Further Evaluation"; Table 13-11, "Adverse Event Summary for Molybdenum Recovery and Identification of Accident Sequences Needing Further Evaluation"; Table 13-12, "Adverse Event Summary for Uranium Recovery and Identification of Accident Sequences Needing Further Evaluation"; Table 13-13, "Adverse Event Summary for Waste Handling and Identification of Accident Sequences Needing Further Evaluation"; Table 13-14, "Adverse Event Summary for Target Receipt and Identification of Accident Sequences Needing Further Evaluation"; Table 13-15, "Adverse Event Summary for Ventilation System and Identification of Accident Sequences Needing Further Evaluation"; and Table 13-16, "Adverse Event Summary for Node 8.0 and Identification of Accident Sequences Needing Further Evaluation," discuss initiating events that could release fission products from irradiated targets while in process, in storage, or being transferred within the facility.

NWMI PSAR Sections 13.2.2, "Liquid Spills and Sprays with Radiological and Criticality Safety Consequences," and 13.2.4, "Leaks into Auxiliary Services or Systems with Radiological and Criticality Safety Consequences," discuss the potential for a criticality incident with either low-dose uranium solutions or high-dose uranium solutions. NWMI PSAR Section 13.2.2.9, "Mitigated Estimates," states "The controls selected and described above will prevent a criticality associated with accidental spills and sprays of SNM [special nuclear material]." An accidental criticality is shown to be highly unlikely, as the facility has been designed with passive engineering design features and other safety-related (SR) controls to prevent criticality and assure that processes remain subcritical. Additionally, administrative controls and SR SSCs provide control on enrichments and target solution uranium concentration to further prevent inadvertent criticality. NWMI PSAR Sections 13.2.2 and 13.2.4 identify areas within the facility where an inadvertent criticality is possible and discuss controls that are used to reduce the likelihood of an inadvertent criticality. Additional criticality safety analysis discussion and the staff's review can be found in Chapter 6, "Engineered Safety Features," of this SER.

13.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 13.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary accident analysis for the issuance of a construction permit under 10 CFR Part 50. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be provided in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 9). The staff's review in Chapter 2 of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

13.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of NWMI's preliminary accident analysis are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."

- 10 CFR 50.40, “Common standards.”

- 10 CFR 20.1201, “Occupational dose limits for adults.”

- 10 CFR 20.1301, “Dose limits for individual members of the public.”

13.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI’s construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with 10 CFR regulatory requirements, the staff used:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996 (Reference 8).

- 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 (Reference 9).

- “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 (Reference 10).

- “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 (Reference 11).

- “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” NUREG-1520, Revision 1, May 2010 (Reference 24).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word “reactor” appears in NUREG-1537, it can be understood to mean “radioisotope production facility” as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, “Performance requirements,” designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term “performance requirements” when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for an RPF license, only that their use

may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

13.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff evaluated the technical information presented in NWMI PSAR Chapter 13.0, Revision 3 (Reference 60), as supplemented with NWMI's responses to RAIs to assess the sufficiency of the preliminary design and performance of NWMI's accident analysis for the issuance of a construction permit, in accordance with 10 CFR Part 50. The sufficiency of the NWMI preliminary accident analysis is determined by ensuring that the design and performance meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 13.3, "Regulatory Basis and Acceptance Criteria," of this SER. The results of this technical evaluation are summarized in SER Section 13.5, "Summary and Conclusions." The technical review focused on the NWMI production facility. The target fabrication process was examined to determine whether operations in this area could introduce radiological and chemical hazards that significantly increased the accident consequences for the NWMI production facility licensed under the regulations of 10 CFR Part 50.

For the purposes of issuing a construction permit, the preliminary accident analysis may be adequately described at a conceptual level. The staff's evaluation of the preliminary accident analysis does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the NWMI production facility, as described in the FSAR submitted as part of NWMI's operating license (OL) application.

For SER Sections 13.4.1 through 13.4.10, the staff evaluated the sufficiency of the preliminary identification, analysis, and determination of consequences of accident-initiating events and scenarios, as described in NWMI PSAR Sections 13.1 and 13.2, "Analysis of Accidents with Radiological and Criticality Safety Consequences," in part, by reviewing the processes conducted inside the production facility, accident initiating events, loss of confinement, external events, loss of normal electric power, mishandling or malfunction of equipment, inadvertent nuclear criticality in the production facility, and fires, using the guidance and acceptance criteria from Section 13b.1, "Radioisotope Production Facility Accident Analysis Methodology," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

For SER Sections 13.4.1 through 13.4.10, consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, the staff reviewed NWMI's accident methodology and analysis. The staff evaluated credible accidents identified in the ISA Summary; instruments, controls and automatic protective systems assumed to be operating normally before an initiating event; the identification of single malfunctions; the discussion of sequence of events and components and systems damaged during the accident scenario; mathematical models and analytical methods employed; radiation source term; and that

potential radiation consequences to workers and public were presented and compared with acceptable limits.

13.4.1 Accident Analysis Methodology and Preliminary Hazards Analysis

The applicant evaluated the processes that occur within the NWMI facility through the performance of an ISA. The applicant documented the results of the evaluation in NWMI PSAR Chapter 13.0 and in an ISA Summary. NWMI PSAR Section 13.1.1 describes the different types of accident analysis methodologies as they are applied to the NWMI ISA. More specifically, NWMI defined accident likelihood categories, consequence severity categories, and a risk matrix that combined various likelihood and consequence categories to determine acceptable and unacceptable scenarios. These categories and the risk matrix are consistent with the guidance in NUREG-1520. In addition, NWMI described several accident analysis methodologies to include accident consequence analysis, what-if and structured what-if analyses, hazards and operability (HAZOP) study method event and fault tree analyses, and failure modes and effects analyses.

NWMI PSAR Section 13.1.3, "Preliminary Hazards Analysis Results," describes the preliminary hazards analysis results based on the methodologies and hazard criteria from Section 13.1.1, "Methodologies Applied to the Radioisotope Production Facility Integrated Safety Analysis Process." Specifically, the NWMI production facility accident sequence evaluation used what-if, structured what-if, and HAZOP methods to analyze each process node and identify certain accident sequences that require additional assessment via the quantitative risk analysis (QRA) process. The remaining steps of the process include determining IROFS and boundary definition packages based on the results of the QRA, establishing management measures, and incorporating the IROFS into the design and facility documentation.

The staff evaluated the steps of the ISA process and the following specific analyses of radiological and criticality accidents to assess the applicant's implementation of its ISA methodology:

- Spills and spray accidents
- Dissolver offgas accidents
- Leaks into the auxiliary systems accidents
- Loss of electrical power
- Natural phenomena accidents
- Other accidents analyses

The staff reviewed the qualification of the ISA team members and notes that one member has experience in ISA, PHA, and industrial safety experience and that one member has experience in fire protection. At least one member has expertise in nuclear criticality safety (NCS) and radiological safety. The staff further notes that, given the number and anticipated functionality of administrative controls, the current ISA team does not include expertise in human reliability. To be consistent with the guidance in the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, and for the purposes of the construction permit, expertise in human reliability is not required on the ISA team; however, for the FSAR the staff will further evaluate the technical bases for the failure frequencies or probabilities of administrative controls.

The staff finds that Chapter 13.0 of the NWMI PSAR and the ISA Summary are consistent with the ISG Augmenting NUREG-1537, Part 2, Section 13b.1 guidance in that the applicant's ISA

methodology reviews the systems and operating characteristics of the NWMI production facility that could affect safe operation or shutdown. Furthermore, NWMI PSAR Chapter 13.0 and the ISA Summary demonstrate that the applicant applied its ISA methodology to identify limiting accidents, analyze the evolution of the scenarios, and evaluate the consequences. The staff will confirm additional analyses and the details of the ISA process and specific technical topics, such as ISA team qualification, the designation of credible accident sequences, administrative controls, and supporting management measures, during its evaluation of NWMI's FSAR, which will be based on NWMI's final design.

Based on its review, the staff finds that the level of detail provided on ISA processes demonstrates an adequate basis for a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following findings:

(1) The applicant's use of ISA methodologies as described in 10 CFR Part 70 and the ISG Augmenting NUREG-1537, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, and identification of management measures provide reasonable assurance that the applicant's ISA process contains the elements that support the adequate identification of capabilities and features to prevent or mitigate potential accidents and protect the health and safety of the public and workers.

(2) The definitions of accident likelihood categories (i.e., highly unlikely, unlikely and credible), consequence severity categories, and the risk matrix are consistent with the guidance in NUREG-1520 and are acceptable for use in the ISA analysis.

(3) The various methodologies that NWMI described (e.g., HAZOP, fault tree analysis) are accepted approaches in accident analysis and ISA development.

(4) The performance of a preliminary hazards analysis, which include accident sequence evaluations, is sufficient to identify accident sequences that require additional quantitative evaluation.

(5) The preliminary ISA performed by the applicant provides the basis to establish that the design of the production facility including the associated SSCs can adequately assure that acceptable risk to the workers and public can be established and maintained.

(6) Evaluations performed by the applicant provide reasonable assurance that all production facility nuclear processes will be subcritical during normal and credible abnormal operating conditions and that high consequence accidents will be controlled to be highly unlikely, and that intermediate consequence accidents will be controlled to be unlikely.

Therefore, the staff concludes that NWMI's preliminary accident analysis methodology, as described in NWMI PSAR Section 13.1.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will evaluate the results of the NWMI analysis of accident initiating events as part of the review of the final design in the FSAR, which will be submitted as part of the OL application.

13.4.2 Accident Initiating Events

NWMI PSAR Section 13.1.2, "Accident-Initiating Events," describes several accident-initiating events that are included in the PHA. Specifically, NWMI identified criticality accidents, losses of electric power, external events, critical equipment malfunctions, operator errors, fires and explosions, and other events potentially related to unique production facility operations. In addition, NWMI developed top-level accident sequence categories in order to compare them to the accident initiating events described in NUREG-1537, Part 1, and to demonstrate that the PHA considers a full range of accident initiating events. The PHA is also broken down into eight primary nodes, each with associated sub-processes, which are cross referenced against the top-level accident sequence categories. The applicant described the other aspects of the safety program similar to that discussed in 10 CFR 70.62, "Safety program and integrated safety analysis" (referenced in the ISG Augmenting NUREG-1537, Part 2, as an acceptable way to demonstrate compliance with 10 CFR Part 50 for radioisotope production facilities). The staff evaluated process information as described in Chapter 4.0 of the NWMI PSAR, "Radioisotope Production Facility Description," and management measures in Chapter 12.0 of the PSAR, "Conduct of Operations."

Based on its review, the staff finds that the level of detail provided demonstrates an adequate design basis for a preliminary design and is consistent with ISG Augmenting NUREG-1537, Part 2, Section 13b.1 allowing the staff to make the following findings:

(1) The applicant implemented an adequate accident analysis for the safety program based on the preliminary design consistent with 10 CFR 70.62 and adequately described the nature of the management measures that will be developed in Chapter12.0 of the NWMI PSAR, and process information as described in Chapter 4.0 of the NWMI PSAR. Analysis of the specific management measures may reasonably be left for later consideration and will be provided in the FSAR.

(2) There is reasonable assurance that NWMI has addressed significant credible accidents involving internal production facility processes, abnormal events, and process deviations and credible external events that could result in serious adverse consequences to workers and the public based on the preliminary design.

(3) The applicant identified designated engineered and administrative safety features in the production facility that are necessary to provide preventive or mitigative measures based on the preliminary design, that give reasonable assurance that the facility will operate in compliance with the performance requirements proposed by the applicant.

(4) The results of the accident analysis demonstrate, based on the preliminary design, adequate safety of the NWMI production facility by meeting the performance requirements proposed by the applicant for demonstrating acceptable risk.

(5) Credible accidents at the NWMI production facility were considered and evaluated at the preliminary design stage. The demonstrations of the risk associated with credible accidents were shown to be adequate to prevent or mitigate the release of radioactive materials, in amounts exceeding regulatory limits, to uncontrolled areas as a result of credible accidents.

(6) The applicant considered the consequences to the public and the workers for the credible chemical accidents at the NWMI production facility that reach the intermediate or high consequence thresholds as defined by the applicant consistent with the guidance in the ISG Augmenting NUREG-1537.

Therefore, the staff concludes that NWMI's analysis of accident initiating events based on the preliminary design, as described in NWMI PSAR Section 13.1.2, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50, based on the accident analysis methodologies and the PHA results described in the NWMI PSAR, Sections 13.1.1 and 13.1.3, respectively. The staff will evaluate whether NWMI has identified all credible accidents and the results of NWMI's analysis of accident initiating events as part of the review of the final design in the FSAR which will be submitted as part of the OL application.

13.4.3 Liquid Spills and Sprays with Radiological and Criticality Safety Consequences

NWMI PSAR Section 13.2.2 presents the evaluation of liquid solution spill or spray events resulting in a radiological exposure hazard to workers and the public. Spill or spray events also consider fissile solutions that may result in an inadvertent criticality. Multiple vessels and piping systems throughout the NWMI production facility contain process liquids of varying radiological and/or fissionable compositions. The PHA reduced the variety of possible spill and spray events to the configurations below that bound the range of potential initial conditions:

- High-dose uranium solutions typical of irradiated target dissolution processes.
- Molybdenum (Mo) product solution typical of the Mo purification processes.

Two high-dose uranium solutions are evaluated and documented in the construction permit application:

- Dissolver product in the production facility's irradiated target dissolution system.
- Uranium separation feed in the uranium recovery and recycle system.

The postulated accident initiating event is a process equipment failure, an operator error, or a fire/explosion. The accident scenario would progress with a spray or leak resulting in rapid draining of a solution tank.

Unmitigated spill and spray-type releases have the potential to produce direct exposure and confinement releases with high consequence to workers and the public. Hot cell shielding is designed to provide protection from uncontrolled liquid spills and sprays that result in redistribution of high-dose uranium and Mo-99 product solution in the hot cell. From a direct exposure perspective, a liquid spill does not represent a failure or adverse challenge to the hot cell shielding boundary function. However, the hot cell shielding boundary must also function to prevent migration of liquid spills to uncontrolled areas outside the shielding boundary. Liquid spill and spray-type releases occur as a result of the partial failure of process vessels to contain either the fissile solution (for areas outside of the hot cell) or to contain fissile or high-dose radiological solutions (for areas inside the hot cell). In either case, the process vessel spray release results in an event that carries with it a higher airborne radionuclide release magnitude than a simple liquid spill. The spray-type release also carries the extra hazard of potential chemical burns to eyes and skin, with the complication of radiological contamination.

Consequently, spray protection is a secondary safety function needed to satisfy performance criteria. The liquid spill and spray confinement safety function of the hot cell liquid confinement boundary IROFS is then credited for confining the spray to the hot cell and protecting the worker from sprays of radioactive, caustic, or acidic solution with the potential to cause intermediate or high consequences. The airborne filtering safety feature of the hot cell secondary confinement boundary IROFS is credited with reducing airborne concentrations in the hot cells to levels outside the hot cell boundary, which are below intermediate consequence levels for workers and the public during the event.

The NWMI calculated dose consequences, which are documented in NWMI PSAR Section 13.2.2.7.1, "Direct Exposure Consequences," demonstrate that the irradiated target dissolver product release case is the bounding case with regard to radiological dose consequences. NWMI PSAR Section 13.2.2.7.2, "Confinement Release Consequence," states that the bounding accident has been re-analyzed using the Radiological Safety Analysis Code computer code and revised dose consequence values were provided. The unmitigated total effective dose equivalent (TEDE) dose to the nearest permanent resident (432 meters (m) (1,417 feet [ft]) is 300 milli roentgen equivalent man (mrem). The maximum TEDE dose consequence to the public is 1.8 rem and occurs at a distance of 1,100 m (3,608 ft). The staff notes that this maximum dose consequence to the public correlates to a low consequence category unmitigated event. However, NWMI states that this unmitigated bounding accident scenario (spray release of dissolver product solution) is being considered as an intermediate consequence event with respect to offsite public dose consequence for the PSAR design process and will be evaluated further in the NWMI FSAR.

NWMI stated that the NWMI operating staff should not receive an occupational exposure from a spray leak or spill in the hot cells due to the shielded walls and ventilation flow rate. NWMI also stated that an additional accident scenario, a spill of Mo-99 product during container loading operations, will be re-evaluated in the NWMI OL application. Operating staff dose consequence estimates and worker stay time for this accident scenario will be provided in the NWMI FSAR submitted as part of the OL application. The staff is tracking this item in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER.

As NWMI has considered this accident to result in intermediate consequences to the offsite public, IROFS are being credited to mitigate the accident consequences. Three IROFS are identified to control radiological consequences from liquid spill and spray accidents from process vessels. The IROFS are the (a) RS-01, Hot Cell Liquid Confinement Boundary; (b) RS-03, Hot Cell Secondary Confinement Boundary; and (c) RS-04, Hot Cell Shielding Boundary.

NWMI credited the Zone I exhaust system filters (part of IROFS RS-03) to mitigate the consequences of the bounding liquid spray accident and estimated the resulting dose consequences to be 0.030 rem to the offsite public at the nearest residence and 0.18 rem to the maximally exposed off site public. The staff notes that this mitigated dose to the offsite public is reduced to the low consequence category.

Liquid spill and spray events involving solutions containing fissile material also have the potential for producing inadvertent nuclear criticalities that must be prevented. The following IROFS are identified to control nuclear criticality aspects for the production facility liquid spill and spray events: (a) Pencil Tank and Vessel Spacing Control Using Fixed Interaction Spacing of Individual Tanks or Vessels; (b) Floor and Sump Geometry Control on Slab Depth, Sump Diameter or Depth for Floor Spill Containment Berms; and (c) Double-Wall Piping.

In its response to RAI 13.1-1 (Reference 16), NWMI states that the FSAR will clearly state its intent to prevent the occurrence of a criticality accident, regardless of whether the event results in a high radiation dose. The evaluation of criticality safety can be found in Chapter 6, "Engineering Safety Features," of the SER. The staff is tracking this item in Appendix A of this SER.

The staff reviewed the liquid spill and spray events discussion and the ISA accident sequence information in NWMI PSAR Tables 13-10, 13-11, and 13-12 and determined with reasonable assurance that the applicant has adequately identified credible accident sequences and potential radiological and chemical consequences at the NWMI production facility.

Based on its review, the staff finds that the level of detail provided on NWMI's liquid spills and sprays with radiological and criticality safety consequences event demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following findings:

(1) In combination with the NCS program reviewed in Chapter 6, of this SER, there is reasonable assurance that NWMI has described a NCS program that will, if properly implemented, ensure that all facility processes are subcritical under both normal and credible abnormal conditions, and will comply with the double contingency principle.

(2) The applicant adequately considered the consequences of liquid spills and sprays involving radioactive and fissile solutions within the NWMI production facility events based on the preliminary design. Radiation doses to the public for the bounding case were shown to be within acceptable limits (low consequence category).

Therefore, the staff concludes that NWMI's preliminary analysis of the liquid spills and sprays events based on the preliminary design, as described in NWMI PSAR Section 13.2.2, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided in the FSAR. The staff will confirm that the final design conforms to the design basis during its evaluation of NWMI's FSAR.

13.4.4 Target Dissolver Off-gas Accidents with Radiological Consequences

NWMI PSAR Section 13.2.3, "Target Dissolver Offgas Accidents with Radiological Consequences," presents the evaluation of target dissolver offgas accidents resulting in a radiological exposure hazard to workers and the public. This accident is the loss of efficiency of the iodine removal unit (IRU) due to a process upset or equipment failure during dissolution of irradiated targets. The accident initial condition is assumed to be the release of iodine generated from a single dissolution of four University of Missouri – Columbia Research Reactor (MURR) targets at 8 hours post irradiation. The accident scenario would progress with a process upset that assumes that all of the iodine from the dissolution evolves from the dissolver solution and remains in the offgas stream to the IRUs, resulting in a release of iodine to the environment with a duration of 2 hours. NWMI has determined that the unmitigated likelihood of this event is "not unlikely."

Calculated dose consequences demonstrated that the target dissolution offgas release case results in an unmitigated offsite public TEDE dose of 6.65 rem at a distance of 1,100 m (3,608 ft). This is an intermediate consequence category unmitigated event.

NWMI PSAR Section 13.2.3.8, “Identification of Items Relied on for Safety and Associated Functions,” identifies and describes the safety functions of the following two IROFS to mitigate the consequences of this postulated accident:

- IROFS RS-03, “Hot Cell Secondary Confinement Boundary”
- IROFS RS-09, “Primary Off-gas Relief System”

NWMI PSAR Section 13.2.3.9, “Mitigated Estimates,” states that detailed information including worker dose estimates and frequency will be provided in the NWMI FSAR submitted as part of the OL application.

The staff reviewed the target dissolver offgas accident discussion and the ISA accident sequence information in NWMI PSAR Table 13-10, and finds that the applicant has adequately identified credible accident sequences and potential radiological and chemical consequences at the NWMI production facility.

Based on its review, the staff finds that the level of detail provided on NWMI’s target dissolver offgas accident with radiological consequences event demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following finding:

> The applicant adequately considered the consequences of a target dissolver offgas accident involving radioactive material within the facility events. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff concludes that NWMI’s analysis of the target dissolver offgas accident based on the preliminary design, as described in NWMI PSAR Section 13.2.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided, in the FSAR. The staff will confirm that the final design conforms to the design basis during its evaluation of NWMI’s FSAR.

13.4.5 Leaks into Auxiliary Services or Systems with Radiological and Criticality Safety Consequences

NWMI PSAR Section 13.2.4, “Leaks into Auxiliary Services or Systems with Radiological and Criticality Safety Consequences,” presents the evaluation of leaks into auxiliary services or systems with a radiological exposure or inhalation hazard to workers and an inhalation hazard for the public. Leaks into auxiliary services or systems also consider fissile solutions that may result in an inadvertent criticality. Multiple vessels and piping systems throughout the NWMI production facility contain process liquids of varying compositions. The bounding source term was selected by NWMI to be the dissolvers or the feed tanks in the Mo recovery and purification system. Two radionuclide liquid process streams are identified for analysis:

- the dissolver product stream, decayed 8 hours, post irradiation
- the uranium separation feed stream, decayed 504 hours, post irradiation

In each case, a jacketed vessel is assumed to be filled with the appropriate process liquid solution, with the process offgas ventilation system operating. A level monitoring system will be available to monitor tank transfers and stagnant store volumes on all tanks processing low-enriched uranium or fission product solutions.

The accident initiating event is generally described as a process equipment failure. The event is associated with leaks of enriched uranium solution into heating and/or cooling coils surrounding safe-geometry tanks or vessels. The event assumes that the primary confinement fails, which allows radioactive or fissile solutions to enter an auxiliary system. Radioactive or fissile solution leaks across the mechanical boundary between a process vessel and associated heating/cooling jacket into the heating/cooling media. Where heating/cooling jackets or heat exchangers are used to heat or cool a fissile and/or high-dose process solution, the potential exists for the barrier between the two to fail and allow fissile and/or high-dose process solution to enter the auxiliary system. If the auxiliary system is not designed with a safe-geometry configuration, or if this system exits the hot cell containment, confinement, or shielding boundary in an uncontrolled manner, either an accidental criticality is possible or a high-dose to workers or the public can occur.

Where auxiliary services enter process solution tanks, the potential exists for backflow of high-dose radiological and/or fissile process solution into the auxiliary service systems (e.g., purge air, chemical addition line, water addition line, etc.). Since these systems are not designed for process solutions, this event can lead to either accidental nuclear criticality or to high-dose radioactive exposures to workers occupying areas outside the hot cell confinement boundary.

The hazards analyses made no assumption about the geometry or the extent of the heating/cooling subsystem. Consequently, an assumption by NWMI is made that without additional control, a credible accidental nuclear criticality could occur, as the fissile solution enters into the heating/cooling system not designed for fissile solution, or as the solution exits the shielded area and creates a high worker dose consequence. If the system is not a closed loop, a direct release to the atmosphere can also occur. Either of these potential outcomes can exceed the performance criteria of one process upset, leading to accidental nuclear criticality or a release that exceeds intermediate or high consequence levels for dose to workers or the public.

NWMI has determined that the unmitigated likelihood of these postulated events is “not unlikely.” NWMI PSAR Section 13.2.4.8, “Identification of Items Relied on for Safety and Associated Functions,” identifies and describes the safety functions of several IROFS and defense-in-depth features selected to reduce the event likelihood and to mitigate the consequences of this postulated accident. The IROFS identified for these events include: (a) RS-04, hot cell shielding boundary; (b) CS-06, pencil tank and vessel spacing control; (c) CS-10, closed safe geometry heating or cooling loop with monitoring and alarm; (d) CS-27, closed heating or cooling loop with monitoring and alarm; (e) CS-20, evaporator or concentrator condensate monitoring; (f) CS-18, backflow prevention device; and (e) CS-19, safe geometry day tanks.

In its response to RAI 13.1-1 (Reference 16), NWMI states that the FSAR it will clearly state its intent to prevent the occurrence of a criticality accident, regardless of whether the event results in a high radiation dose. The evaluation of criticality safety can be found in Chapter 6 of this SER. The staff is tracking this item in Appendix A of this SER.

The staff reviewed the leaks into auxiliary services or systems event discussion and the ISA accident sequence information in NWMI PSAR Tables 13-10 and 13-12, and finds that the applicant has adequately identified credible accident sequences and potential radiological and chemical consequences at the NWMI production facility.

Based on its review, the staff finds that the level of detail provided on NWMI's leaks into auxiliary services or systems with radiological and criticality safety consequences event demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following findings:

(1) There is reasonable assurance that NWMI described an NCS program that will, if properly implemented, ensure that all facility processes are subcritical under both normal and credible abnormal conditions, and will comply with the double contingency principle.

(2) The applicant adequately considered the consequences of leaks into auxiliary services or systems involving radioactive and fissile solutions within the facility events. The consequences of the leaks into auxiliary services or systems events have been estimated and shown to be adequately mitigated or prevented by the selection of IROFS.

Therefore, the staff concludes that NWMI's analysis of the leaks into auxiliary services and systems events based on the preliminary design, as described in NWMI PSAR Section 13.2.4, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided, in the FSAR based on the final design. The staff will confirm that the final design conforms to the design basis during its evaluation of NWMI's FSAR.

13.4.6 Loss of Power

NWMI PSAR Section 13.2.5, "Loss of Power," discusses the events that could result from the sudden loss of normal electrical power. NWMI PSAR Section 13.2.5.6, "Radiation Source Term," states, "Detailed information describing radiation source terms for the loss of power event will be developed for the Operating License Application." NWMI PSAR Section 13.2.5.7, "Evaluation of Potential Radiological Consequences," states, "A detailed evaluation of potential radiological consequences … will be provided in the Operating License Application." NWMI stated that loss of power was identified as an initiating event in numerous NWMI production facility accident scenarios. NWMI's conclusion was that no additional IROFS were identified from loss of power events. The staff notes that loss of power is considered in other ISAs events but no new events were derived specifically for loss of power initiating events. In response to RAI 13.2-5 (Reference 17), NWMI stated that the summary of radiological consequences from the analysis of other accidents where loss of power was an initiator will be provided in the FSAR submitted as part of the OL application. The staff is tracking this item in Appendix A of this SER.

Based on its review, the staff finds that the level of detail provided on NWMI's loss of normal electrical power demonstrates an adequate design basis for a preliminary design and satisfies

the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following findings:

(1) All SR-IROFS are designed to fail-safe with a loss of power. Any requirement for emergency cooling or ventilation functions is provided as intended in the production facility design.

(2) The loss of normal electrical power will not result in an unsafe condition for either the production facility workers or members of the public in uncontrolled areas. NWMI PSAR Chapter 8.0, "Electrical Power Systems," describes emergency power to the production facility. The preliminary design shows the use of a safety related uninterruptible power supply to automatically provide power to systems that support safety functions which will protect facility personnel and the public.

Therefore, the staff concludes that NWMI's loss of normal electrical power event, as described in NWMI PSAR Section 13.2.5, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided, in the FSAR based on the final design. The staff will confirm that the final design conforms to the design basis during its evaluation of NWMI's FSAR.

13.4.7 Natural Phenomena Events

In NWMI PSAR Section 13.2.6, "Natural Phenomena Events," NWMI identified tornado impact, high straight-line winds, heavy rain, flooding, seismic impact, and heavy snow fall or ice buildup as natural phenomena events that can affect the NWMI production facility. These are treated as design-basis accidents. The NWMI production facility has been designed to survive a design-basis earthquake, tornado and wind loads including missiles, heavy rain and flooding, heavy snowfall and ice buildup, and keep the facility safety functions intact. The only additional IROFS added to address natural phenomena events was FS-04, Irradiated Target Cask Lifting Fixture. This fixture will be designed to prevent the cask from tipping within the fixture and prevent the fixture itself from toppling during a seismic event.

The applicant evaluated the impact of tornadoes on SSCs in NWMI PSAR Section 13.2.6.1, "Tornado Impact on Facility and Structures, Systems, and Components." The evaluation was based on the maximum sized tornado with a return frequency of 10^{-5}/year. A tornado may cause significant impacts to SSCs in the building, loss of power, and directly impact the components that are important to safety. Damage to the structure could impact SSCs important to safety or impact criticality spacing requirements. Tornado missiles could penetrate the building envelope impacting the availability and reliability of IROFS or may lead to radiological or chemical releases. The applicant stated that the return frequency of the design basis tornado is 10^{-5}/year which would make the initiating event highly unlikely and no additional IROFS are required. However, as part of the development of the FSAR, NWMI stated that it will evaluate whether initiating natural phenomena events with returns greater than the selected design basis event could cause a release exceeding 10 CFR Part 70.61 levels and thereby would necessitate IROFS.

The applicant evaluated the impact of high straight-line winds on the facility and SSCs in NWMI PSAR Section 13.2.6.2, "High Straight-Line Winds Impact the Facility and Structures, Systems, and Components." NWMI states that its evaluation demonstrates how the production facility design addresses straight-line winds with a return interval of 100 years as required by building codes. The production facility is designed as a Category IV structure, in accordance with

ASCE 7, “Minimum Design Loads for Buildings and Other Structures.” The construction of the production facility, when used with companion standards such as American Concrete Institute (ACI) 318, “Building Code Requirements for Structural Concrete,” and American Institute of Steel Construction (AISC) 360, “Specifications for Structural Steel Building,” is designed to meet the target maximum annual probabilities established in ASCE 7. The highest probability of failure, which is for a failure that is not sudden and does not lead to wide-spread progression of collapse, for a Category IV structure in ASCE 7 is 5.0×10^{-6}. The applicant states that the use of these codes at the NWMI production facility would render the high straight-line wind event highly unlikely. The staff will confirm that the applicant commits to using these codes as part of its review of the FSAR submitted as part of the OL application for the production facility.

The applicant evaluated the impact of heavy rain on the production facility and SSCs in NWMI PSAR Section 13.2.6.3, “Heavy Rain Impact on Facility and Structures, Systems, and Components.” The NWMI evaluation stated that localized heavy rain can overwhelm the structural integrity of the production facility roofing system. The evaluation determined the impact of the probable maximum precipitation (PMP) in the form of rain on the roof structure. The PMP represents the theoretical worst case of the most precipitation that is physically possible over a particular drainage area over a selected period of time. The applicant stated that the use of the PMP makes the heavy rain impact event highly unlikely. The staff will confirm that the applicant commits to using appropriate structural codes and standards to ensure the integrity of the production facility and SSCs during the review of the FSAR submitted as part of the OL application.

The applicant evaluated flooding impact to the production facility and SSCs in NWMI PSAR Section 13.2.6.4, “Flooding Impact to the Facility and Structures, Systems, and Components.” The site elevation is above the 100-year and 500-year flood plains. Floods beyond the 500-year flood can have an adverse impact on the structure and SSCs within the production facility. The impacts could include structural damage from water, damage to IROFS, and loss of moderation control to prevent criticality. NWMI states that the site will be graded to direct the storm water from localized downpours with a rainfall intensity for a 100-year storm for a 1-hour duration. Based on the location of the site, which is above the 500-year flood plain by 6.1 m (20 ft), NWMI determined that the flooding impact to the facility and SSCs event is highly unlikely. The staff will evaluate the facility grading as part of its review of the FSAR submitted as part of the OL application.

NWMI evaluated the seismic impact to the production facility and SSCs in NWMI PSAR Section 13.2.6.5, “Seismic Impact to the Facility and Structures, Systems, and Components.” A seismic event may impact the production facility structure, IROFS, and the potential for falling components impacting SSCs or causing direct damage to SSCs. Additionally, during irradiated target shipping cask unloading preparations, the shield plug fasteners are removed, which could cause worker radiation exposures if the cask is tipped over during a seismic event while it is being unloaded. Leaks of fissile solution based on damage from a seismic event could lead to a criticality event. An additional IROFS related to the irradiated target cask lifting fixture was included to address the tip over event.

NWMI stated in PSAR Section 13.2.6.5 that it is using NRC Regulatory Guide 1.60, “Design Response Spectra for Seismic Design of Nuclear Power Plants” (Reference 98), for the final seismic design adjusted to reflect the ground acceleration response of 0.2 g. However, as part of the structural analyses of the final design, NWMI stated that they will analyze the impacts of a seismic event on the SR SSCs of the safe shutdown earthquake including the impacts of higher frequency ground motions. NWMI also stated that it will determine the impacts of seismic

events with shorter return periods on SR SSCs, in order to determine whether additional IROFS may be needed to prevent or mitigate the impacts of a seismic event on the production facility consistent with the performance objectives of 10 CFR 70.61. This item is being tracked in Appendix A of this SER.

The impact of heavy snow or ice buildup on the production facility and SSCs is evaluated in Section 13.2.6.6, "Heavy Snow Fall or Ice Buildup on Facility and Structures, Systems, and Components," of the NWMI PSAR. Heavy snow or ice buildup could cause a failure of the roof which would impact the ability of SSCs to perform their safety functions. The snow load used by the applicant is the 100-year snowpack, which is equivalent to the design snow load for a Risk Category IV structure determined in accordance with ASCE 7. The provisions of the ASCE standard, when used with companion standards such as ACI 318 and AISC 360, reduce the likelihood of a failure of the structure when subjected to the design snow load in conjunction with other loads as provided by ASCE 7. The applicant states that the use of these codes at the NWMI production facility would render the heavy snow or ice buildup event highly unlikely. The staff will confirm that the applicant commits to using appropriate structural codes and standards to assure integrity of the production facility and SSCs as part of its review of the FSAR submitted as part of the OL application.

Based on its review, the staff finds that the level of detail provided on NWMI's analyzed natural phenomena events demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following finding:

> The applicant adequately considered the consequences of natural phenomena events for the preliminary design of the production facility. The consequences of natural phenomena events analyzed with respect to the performance requirements of 10 CFR 70.61 demonstrate that the safety and health of workers and the public will be adequately protected.

Therefore, the staff concludes that NWMI's analysis of natural phenomena events for the preliminary design, as described in NWMI PSAR Section 13.2.6, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided, in the FSAR based on the final design. The staff will confirm that the final design conforms to the design basis during its evaluation of NWMI's FSAR.

13.4.8 Other Accidents Analyzed

NWMI PSAR Section 13.2.7, "Other Accidents Analyzed," presents the evaluation of all other accidents identified by the PHA as requiring further evaluation. A total of 75 unique accidents are identified and described in NWMI PSAR Table 13-24, "Analyzed Accidents Sequences." The table lists each accident, a brief description of the accident sequence, and any IROFS identified as necessary to prevent or mitigate the accidents.

NWMI PSAR Table 13-25, "Summary of Items Relied on for Safety Identified by Accident Analyses," summarizes all IROFS selected to prevent or mitigate the analyzed accidents and identifies whether the IROFS are an engineered safety feature (ESF) or an administrative control.

NWMI PSAR Sections 13.2.7.1 through 13.2.7.4 identify and describe the safety functions of all remaining IROFS not previously selected to reduce the event likelihood and to mitigate the consequences of the bounding postulated accidents.

In response to staff RAI 13.2-8b (Reference 17), NWMI stated that the PHA tables for the NWMI production facility Mo system and waste handling will be updated for the hazards associated with the Mo resin as part of the ongoing ISA process, and will be reflected in the FSAR submitted as part of the OL application. The staff is tracking this issue in Appendix A of this SER.

The staff reviewed the other accidents analyzed events discussion and the ISA accident sequence information in PSAR Tables 13-9, 13-10, 13-11, and 13-12, and finds that the applicant has adequately identified credible accident sequences and potential radiological and chemical consequences at the NWMI production facility.

Based on its review, the staff finds that the level of detail provided on NWMI's other accidents analyzed events demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following findings:

- The staff has reasonable assurance that NWMI has described an NCS program that will, if properly implemented, ensure that all facility processes are subcritical under both normal and credible abnormal conditions, and will comply with the double contingency principle. Additional information regarding the review of the criticality safety program can be found in Chapter 6 of the SER.

- The applicant adequately considered the consequences of events derived from the preliminary design that may cause either radiological or chemical exposures to workers or the public with respect to the performance objectives of 10 CFR 70.61. The consequences of other potential accidents evaluated by NWMI demonstrate that radiation doses or chemical releases to the public and workers will be within acceptable limits, and the health and safety of workers and the public will be adequately protected.

Therefore, the staff concludes that NWMI's analysis of the analyzed events for other accidents based on the preliminary design, as described in NWMI PSAR Section 13.2.7, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided, in the FSAR based on the final design. The staff will confirm that the final design conforms to the design basis during its evaluation of NWMI's FSAR.

13.4.9 Analyses of Accidents with Chemical Hazards

The objective of the staff's chemical hazards review of the NWMI PSAR is to determine whether the application demonstrates that the proposed preliminary design is based on a recognition of chemical hazards associated with proposed production facility activities and the design includes appropriate features for managing these hazards. Review of chemical hazards is necessary to

determine whether the application meets the requirements of 10 CFR 50.35 for the issuance of a construction permit. In particular, the staff's review determines whether:

(1) The applicant described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and identified the major features or components incorporated therein for the protection of the health and safety of the public from chemical hazards,

(2) Such further technical and design information related to chemical hazards as may be required to complete the safety analysis, and which may reasonably be left for later consideration, will be supplied in the FSAR,

(3) Safety features or components, if any, related to chemical hazards, and which require research and development, have been described in the application and the applicant has identified and will conduct a research and development program to resolve any safety questions associated with such features or components, and

(4) There is reasonable assurance that such chemical hazard safety questions can be resolved by the date for completion of construction and, taking into consideration the siting criteria, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

The review focused on the NWMI production facility that is to be licensed under the regulations of 10 CFR Part 50. PSAR information on the target fabrication activity, that NWMI stated it will submit a separate 10 CFR Part 70 application, was examined to determine whether operations in this area could introduce chemical hazards that significantly increased the chemical hazards for the NWMI production facility licensed under the regulations of 10 CFR Part 50. The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors.

The staff reviewed the proposed NWMI production facility and operations described in the PSAR for the purpose of understanding chemical hazards that could impact the health and safety of the workers and the public. The staff examined the preliminary process description information including the chemical composition, temperature, and flow rate of process streams; information on preliminary process equipment sizes; information on the identification and analysis of chemical hazards including estimated consequences; and information on identified ESFs designed to keep exposure to workers and the public within acceptable values.

The process information is presented in Chapter 4.0 of the PSAR. The staff's review examined chemicals used in the processes and process materials. The review examined potential effects of direct release of hazardous chemicals as well as the potential for energetic chemical reactions that could release radioactive or chemically hazardous materials. While the process description information primarily described normal operations, the staff review also considered events that might occur in other operating modes including maintenance and extended shutdown.

The staff examined the location of the various process operations in the NWMI production facility and the location and size of process equipment in the various cells. The staff noted that dissolver and Mo-purification operations are conducted in limited volume cells with shielding, viewing windows, and manipulators. The staff also noted that the offgas treatment equipment that would retain volatile radionuclides as well as the uranium purification equipment are contained in the shielded and remotely operated and maintained tank hot cell.

The staff reviewed the literature on accidents that have occurred or have been postulated for similar operations. The staff made independent process calculations, such as uranium dissolution rates and material balances, as part of its review. The information describing the process made it clear to the staff that some proposed operations (e.g., target dissolution) would increase the potential for releasing radionuclides that could impact workers or the public. The chemical process operations could involve process upsets or equipment failures leading to releases of chemical or radiological materials. The review found that some portions of the processes have the potential for energetic reactions that could release and disperse larger quantities of chemically toxic or radioactive material.

The staff reviewed the NWMI-identified accidents focusing on those that could be initiated by or involve chemical hazards. These are described in Chapter 13.0 of the NWMI PSAR and in the ISA Summary. NWMI PSAR Chapter 13.0 identified and described the potential accidents that could be initiated by several types of events including loss of electrical power, external events, equipment malfunction, and operator error.

Hazards identified and analyzed by NWMI and reviewed by the staff because of their potential chemical hazard initiator include:

- Multiple scenarios involving the accumulation of flammable gas, such as hydrogen, in tanks or systems. The general accident sequence was labeled S.F.02 and was identified for target fabrication, target dissolution, Mo recovery, uranium recovery and waste handling processes. An IROFS, FS-03, the process vessel emergency purge system, was identified by NWMI for the general accident sequence. This system is also identified as part of an ESF in Chapter 6.0 of the PSAR.

- Multiple scenarios for damage to the process ventilation system due to cooling failure or fire in the reduction furnace. The general accident sequence was labeled S.F.04 and was identified for the target fabrication area. No IROFS were identified for the accident sequence.

- Multiple scenarios leading to a fire in the carbon retention bed. The description states that fire develops through exothermic reaction to contaminants in the carbon retention bed (NWMI PSAR Table 13-10). The general accident sequence was labeled S.F.05 and was identified for the target dissolution and ventilation system areas. An IROFS, FS-05, the exhaust stack height, was identified for the general accident sequence. This feature is also identified as an ESF in Chapter 6.0 of the NWMI PSAR.

- Multiple scenarios that could lead to the accumulation of combustible gas in ventilation system components. The consequences are characterized as a potential detonation or deflagration (NWMI PSAR Table 13-15). The general accident sequence was labeled S.F.06 and was identified for the ventilation system. No IROFS were identified. However, S.F.02 was considered to be a bounding sequence.

- Multiple scenarios involving fire in the nitrate extraction system. The general accident sequence was labeled S.F.07 and was identified for the target fabrication area. No IROFS were identified for the accident sequence.

- Multiple scenarios involving a non-mechanistic spray release leading to increased radiological release rate. The description mentioned deflagration as a potential

mechanism. The general accident sequence was labeled S.R.03 and was identified for target fabrication, target dissolution, Mo recovery, uranium recovery, and waste handling areas. No IROFS were identified. However, a solution spill in S.R.01 was considered to be a bounding sequence.

- Multiple scenarios where liquid or vapor would enter the process vessel ventilation system and damage the iodine retention unit leading to increased radiological release rate. The general accident sequence was labeled S.R.04 and was identified for target fabrication, target dissolution, Mo recovery, uranium recovery, waste handling, and the ventilation areas. Two IROFS were identified, RS-09, the Primary Offgas Relief System, and RS-03, the Hot Cell Secondary Confinement Boundary. These features are identified as part of an ESF in Chapter 6.0 of the NWMI PSAR.

- Multiple scenarios that could lead to loss of temperature control in the iodine retention unit leading to increased radiological release rate. The general accident sequence was labeled S.R.07 and was identified for the target dissolution area. No IROFS were identified. However, a fire in the iodine retention unit in S.R.04 was considered to be a bounding sequence.

- Multiple scenarios that could lead to loss of the iodine retention material leading to increased radiological release rate. The general accident sequence was labeled S.R.09 and was identified for the target dissolution area. No IROFS were identified. However, a fire in the iodine retention unit in S.R.04 was considered to be a bounding sequence.

- Multiple scenarios that involve a reaction with ion exchange resin where the PSAR stated that the consequences are not fully understood. The general accident sequence was labeled S.R.14 and was identified for the uranium recovery area and the accident sequence was identified as requiring further evaluation. No IROFS were identified. However, a solution spill in S.R.01 was considered to be a bounding sequence.

- Two scenarios where chemical burns occurred during sample analysis activities. The general accident sequence was labeled S.R.31 and was identified for the analytical laboratory. No IROFS were identified for the accident sequence.

- One scenario resulting in nitric acid inhalation. The accident sequence was labeled S.CS.01 and was associated with the chemical preparation and storage room. No IROFS were identified for the accident sequence.

- Several non-mechanistic chemical releases were analyzed in NWMI PSAR Chapter 19.0, “Environmental Review.” The accident scenarios were identified for the bulk chemical handling area. The analysis estimated impacts for the maximally exposed off-site individual and the nearest resident. The chemicals with the greatest impact were nitric acid and ammonia.

The PSAR presented radiological consequence estimates for a limited number of accidents that the staff considers could be initiated by or involve chemical hazards. These were:

- Accidents involving iodine release, as described in NWMI PSAR Section 13.2.3, which appears to be consistent with accident sequence S.R.04. The accident involved the release of the iodine inventory from four targets irradiated in the MURR. The PSAR

estimated the maximum total effective dose equivalent from such a release as 0.2 rem at 100 m (328 ft) from the stack (NWMI PSAR Table 13-22, “Target Dissolver Offgas Accident Total Effective Dose Equivalent”).

- The staff reviewed the NWMI calculations and made independent RASCAL (Radioisotope Assessment System for Consequence Analysis) runs using similar input parameters (e.g., source term release rate, meteorology). The staff developed comparable dose estimates for downwind receptors. The analysis demonstrates the importance of process equipment (e.g., NOx scrubber, IRU) that limit radionuclide releases to the atmosphere and therefore limit doses to downwind receptors.

- Accidents involving a generic spray release, as described in NWMI PSAR Section 13.2.2.7.2, which the staff noted appear to be consistent with accident sequence S.R.03. The consequence analysis considered the effects of a 100-liter (26-gallon) spray leak considering both unmitigated and mitigated conditions. The mitigated scenario involved a reduction in the leak path factor by a factor of 10 for iodine and 2,000 for non-iodine, non-noble gas constituents NWMI PSAR Table 13-19, “Release Consequence Evaluation RASCAL Code Inputs.” The reduction in leak path factor is tied to gravitational settling associated with airflow through the facility and the removal action of high-efficiency particulate air filtration. For a spray involving dissolver product with a high fission product concentration, the NWMI analysis predicts an unmitigated dose of 300 mrem at 432 m (1,417 ft) and 1.8 rem at 1,100 m (3,608 ft).

The staff reviewed the NWMI calculations and made independent RASCAL runs for the unmitigated scenario and obtained comparable results. The analysis shows the importance of structural features and the ventilation system (i.e., confinement features) to reduce the leakage of material from the NWMI production facility to the environment. The staff noted that the NWMI discussion of this consequence analysis identifies three IROFS which are linked to the confinement ESFs presented in NWMI PSAR Table 6-1, “Summary of Confinement Engineered Safety Features.”

The staff finds that the NWMI accident analysis covered a broad spectrum of accidents in a general, high-level manner that is sufficient for a construction permit. The information was used by NWMI to identify ESFs or controls such as IROFS that mitigate accident consequences. The staff finds that the level of the analysis is consistent with the preliminary nature of the process, process equipment design, and facility design. The staff notes that the PSAR and responses to RAIs identify information that will be updated for the OL application. The updated analysis in the FSAR, based on the final design, will include controls such as IROFS and TSs that will function to prevent or mitigate production facility accidents. The staff is tracking items, including the identification of TSs needed to prevent or mitigate the consequences of chemical accidents, in Appendix A of this SER.

In response to RAI 13.2-10 (Reference 17), NWMI stated that additional information on specific features of the NWMI production facility to prevent and/or mitigate nitric acid fume releases will be included in the FSAR as part of the OL application. The staff is tracking this item in Appendix A of this SER.

The staff found that the analysis of energetic chemical hazards in the PSAR was limited. While the NWMI PSAR stated in Section 13.1.1.2, “Accident Consequence Analysis,” that the hazard analysis would address “fires and explosions associated with chemical reactions,” such hazards were not specifically identified or analyzed. NWMI PSAR Table 13-12 describes the potential

for high temperature reagents to cause unknown impacts on the uranium ion exchange resin. The PSAR states that this accident would have to be further researched. The PSAR did not discuss the potential for energetic reactions with the Mo-purification ion exchange material or the potential for red-oil-like hazard associated with diamyl-amyl phosphonate (DAAP) used in the uranium purification system. The NWMI response to staff RAI 13.1-2c (Reference 31) discussed NWMI's plans for research and development related to the uranium ion exchange system. The staff is tracking this item in Appendix A of this SER. In order to determine the impact of deferring this evaluation until the OL, the staff conducted independent analysis of chemical hazards that could result in larger releases of activity and/or energetic reactions that could damage equipment or ESFs and injure nearby personnel. The purpose of the analysis was to gain insight into the significance of the potential accidents using preliminary design information.

The specific energetic hazards examined were (1) reactions involving organic anion exchange media for Mo-99 purification, and (2) reactions involving organic ion exchange media used for uranium purification.

(1) NWMI PSAR Table 4-42, "Strong Basic Anion Exchange Column Cycle," identifies the use of a strongly basic anion exchange resin for the second Mo purification cycle. Organic anion exchange material is a recognized hazard when combined with oxidizing material such as nitric acid. The hazard in the NWMI case appears to be reduced because of small column size (Column MR-IX-225), and the elution solution (NWMI PSAR Table 4-42). As described in NWMI PSAR Section 4.3.5.2, "Process Equipment Arrangement," the columns are cooled and the equipment is located in the thick-walled Mo Recovery Hot Cell (H106).

An evaluation of the potential damage from an ion exchange exothermic reaction was made using a correlation that related "scaled distance" for trinitrotoluene (TNT)-equivalent explosion to "side-on" overpressure that the nearest confinement barrier would experience. This correlation between scaled distance and overpressure is commonly found in the literature evaluating the effects of explosions.[1] SER Figure 13-1, "Scaled Distance-Overpressure Relationship," shows this distance-overpressure relationship. The use of this relationship is generally considered to be conservative because the energetic ion exchange reactions can often proceed at a slower, non-explosive rate resulting in reduced overpressures.

Using this approach requires a relationship between material involved in a reaction and its TNT equivalent. For the materials of interest in this effort, factors relating mass of process material to mass of TNT were drawn from an NRC-sponsored research report prepared by Pacific Northwest Laboratory.[2] The staff tested the reasonableness of this approach by applying it to an Americium ion exchange column deflagration that

[1] Methods for the calculation of physical effect, "Yellow Book," Committee for the Prevention of Disasters, third edition, 2005, Chapter 5. Section 5.3.2 discusses an approach of using an equivalent TNT mass and scaled distance to predict peak side-on overpressure.

[2] M.A. Halverson and J. Mishima, "Initial Concepts on Energetics and Mass Releases During Nonnuclear Explosive Events in Fuel Cycle Facilities," NUREG/CR-4593, PNL-5839, 1986.

occurred at the Hanford site.[3,4] The staff found that this approach produced an overpressure estimate for the Hanford event that was consistent with previous, more detailed analysis conducted for that event.[5]

The scaled distance is the distance (meters [m]) between the reaction source and the object of interest (e.g., a cell wall) divided by the cube root of the TNT mass equivalent (kilogram [kg]). The estimated column volume for the Mo ion exchange system is 0.2 liters (0.05 gallons) and the estimated energy equivalent for ion exchange resin based on Halverson and Mishima is 0.1 lb (0.045 kg) of TNT per cubic foot of material. This equates to a TNT equivalent of 0.00032 kg. Estimating the distance between the ion exchange column and the cell wall near the operator to be 18 inches (0.45 m) based on information in the PSAR, the scaled distance for the postulated Mo purification ion exchange deflagration event is 6.7 $m/kg^{1/3}$. The estimated side-on overpressure for this postulated event is about 0.36 bar (5.2 pounds per square inch [psi]). This pressure reduces rapidly with distance from the deflagration point.

NWMI PSAR Section 4.2.3.5, "Estimated Hot Cell Wall Thickness," describes the Mo recovery and purification cell as a walled concrete structure that is approximately 4-feet thick. It is expected that the hot cell wall will be able to withstand a 5-psi pressure pulse from the reaction of the organic Mo recovery column. This assessment is based on the finding that the peak overpressure in the glovebox for the Hanford ion exchange event was in the range of ten to a few tens of psi and it did not lead to failure of the glove box. The pressure caused glass windows on the glovebox to fail. There were some bulges on the side and top of the glovebox near the ion exchange column. The estimated Mo ion exchange overpressure is less than half of that estimated to have occurred in the Hanford incident and the enclosure is more substantial.

The analysis shows the importance of ion exchange mass, the distance from the ion exchange column, and the cell wall thickness in limiting accident consequences.

The staff requested additional information in RAI 13.2-8a (Reference 13) regarding NWMI's assessment of this hazard. In response to RAI 13.2-8a (Reference 31), NWMI stated that the ion exchange column was very small and single use. NWMI stated that after elution and rinsing, the column and resin are discarded as waste. NWMI also stated that the process hazard analysis for the Mo system and waste handling will be updated for hazards associated with the Mo resin and will be reflected in FSAR in the OL application. The staff is tracking this item in Appendix A of this SER.

[3] "Explosion of Cation Exchange Column in Americium Recovery Service, Hanford Plant, August 30, 1975," BNWI-1006, October 8, 1976.

[4] "Investigation of the Chemical Explosion of an Ion Exchange Resin Column and Resulting Americium Contamination of Personnel in the 242-Z Building," August 30, 1976, Energy Research and Development Administration, BNWI-1007-DEL, October 19, 1976.

[5] C. Grelecki, "Investigation of Incident in Ion Exchange Resin," HRC Report 3719, September 21, 1976 (Appendix 4 to BMWI-1006 cited above).

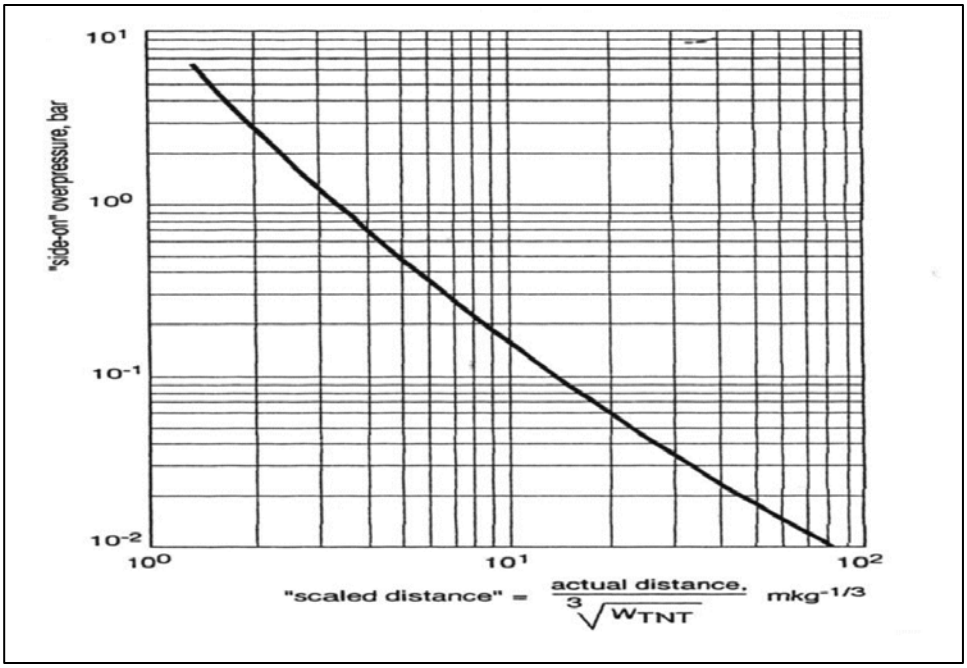

Figure 13-1 Scaled Distance-Overpressure Relationship

(2) The PSAR identifies the use of an ion exchange media in the uranium recovery system. There are two cycles of ion exchange for uranium purification with each cycle having 2 ion exchange columns (UR-IX-240/260 and UR-IX-260/480; NWMI PSAR Table 4-50, "Uranium Recovery and Recycle Process Equipment"). The ion exchange material has DAAP as an essential ingredient. Uranium that is eluted from the ion exchange system is concentrated in an evaporator following each purification cycle.

A study on the thermal decomposition of DAAP indicates that a red-oil-like phenomenon might be possible with DAAP.[6] This study shows an initial exothermic reaction at approximately 380 °Kelvin (K) (107 Celsius [°C]/210 Fahrenheit [°F]) and a second one at approximately 570 °K (297 °C/570 °F). If DAAP were to enter the concentrator as a result of resin carryover, the potential for an exothermic reaction in the evaporators may exist.

Two energetic events were postulated and analyzed by the staff. The first was a reaction in an ion exchange column and the second was a "red oil" type reaction in an evaporator. For the ion exchange column reaction analysis, the closest distance between a uranium ion exchange column and a tank hot cell wall is estimated to be 12 ft (3.65 m) based on dimensional information presented in NWMI PSAR Figures 4-4 and 4-76. For the evaporator analysis, the volume of the evaporator feed tank (NWMI PSAR Table 4-50) was used to estimated distance between the closest tank hot cell wall and the evaporator 4.5 ft (1.372 m).

[6] C.V.S. Brahmmananda Rao et. al., "Thermodynamics and kinetics of thermal decomposition of diamylamyl phosphonate-nitric acid systems," Thermochimica Acta, 545 (2012), 116-124.

Assuming the volume of ion exchange resin in the column (derived from Table 4-49, "First-Cycle Uranium Recovery Ion Exchange Column Cycle Summary"), and the density of the resin of about 1g/cc, the maximum potential TNT equivalent for a uranium purification column is 0.053 kg. The scaled distance for the ion exchange column is 9.8 $m/kg^{1/3}$. This would produce a side-on pressure of 0.2 bar or about 3 psi.

The amount of DAAP that could be involved in a concentrator "red oil" event is not discussed in the PSAR. The staff analyzed the transfer of 25 percent of a column inventory. This would be equivalent to 0.013 kg. The scaled distance for the evaporator is thus estimated to be 5.9 $m/kg^{1/3}$. This analysis indicates that the evaporator with its lower scaled distance is a greater hazard than that postulated for the ion exchange column accident because the evaporator is closer to the tank hot cell wall. The "on-side" overpressure associated with the postulated concentrator event is estimated to be 0.44 bar (6.4 psi).

The tank hot cell is estimated to have a wall thickness of 4 feet based on information in NWMI PSAR Figure 4-76, "Tank Hot Cell Equipment Arrangement." For the reasons mentioned when discussing deflagration within the Mo recovery and purification cell, the staff does not expect that deflagrations in the uranium purification system would result in leakage of hazardous material into worker occupied areas.

The staff requested additional information on NWMI's assessment of this hazard. In response to RAI 13.1-2 (Reference 31), NWMI stated that it was evaluating the adequacy of a pressure relief system for mitigating a potential accident resulting in exothermic reactions of the uranium ion exchange material. NWMI also stated that release of DAAP from ion exchange media during operation would be evaluated as part of the research and development program. The staff is tracking this item in Appendix A of this SER.

In order to support the review of PSAR accident scenarios and the preliminary IROFS, the staff reviewed the ESFs presented in Chapter 6.0 of the PSAR. The staff reviewed the ESFs and considered how they might function in mitigating the effects of accidents involving chemical hazards, both toxic material and energetic chemical processes.

In NWMI PSAR Section 6.1, "Summary Description," NWMI describes the ESFs as active or passive features designed to keep radiological exposure to workers and the public within acceptable values. NWMI PSAR Table 6-1 identifies the confinement ESFs and the associated SSC that provides the ESF. The PSAR states that SSCs important safety are those elements that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of workers and the public.

SER Table 13-1 presents the NWMI-identified ESFs that the staff considers important for mitigating the effects of potential accidents involving chemical hazards. The second column of the table presents the NWMI-identified SSCs that provide the ESF.

The staff reviewed the design criteria that NWMI was applying to the ESFs identified in SER Table 13-1. The staff finds that the ESFs identified in SER Table 13-1 would be effective in protecting the health and safety of workers and the public from chemical hazards if the ESFs were adequately designed and constructed. The staff did not identify any major hazards where accident consequences would not be mitigated by the ESFs.

The NWMI application identified principal architectural and engineering criteria for the NWMI production facility including design basis loads for the facility. The design basis wind loads for the facility is identified in NWMI PSAR Section 3.2.4, "Wind Load," and includes straight-line winds of 120 miles per hour (mph) (1,700-year recurrence interval) and tornado winds of 230 mph. The design basis seismic event is a spectrum anchored to 0.2 g peak ground acceleration as identified in NWMI PSAR Section 3.4.1.1, "Design Response Spectra."

NWMI PSAR Table 3-24, "System Safety and Seismic Classification and Associated Quality Level Group," states that the systems that contain the ESFs identified in SER Table 13-1 are classified as Seismic Category C-I systems. The staff finds this acceptable.

Table 13-1 Engineered Safety Features that Support Chemical Safety

Confinement ESF (Section 6.2.1)	SSCs providing ESFs (Table 6-1)
Hot cell liquid confinement boundary	• Confinement enclosures including penetration seals • Zone I exhaust ventilation system, including ducting, filters, and exhaust stack • Zone I inlet ventilation system, including ducting, filters and bubble-tight isolation dampers • Ventilation system control • Secondary iodine removal bed • Berms
Hot cell secondary confinement boundary	
Hot cell shielding boundary	
Primary offgas relief system	• Pressure relief device • Pressure relief tank
Process vessel emergency purge system	• Backup bottled nitrogen gas supply
Dissolver offgas iodine removal units	• Dissolver offgas iodine removal units (DS-SB-600A/B/C)
Dissolver offgas primary absorber	• Dissolver offgas primary absorber units (DS-SB-620A/B/C)
Dissolver offgas vacuum receiver/ vacuum pump	• Dissolver offgas vacuum receiver tanks (DS-TK-700A/B) • Dissolver offgas vacuum pumps (DS-P-710A/B)
Exhaust stack height	• Zone I exhaust stack

The staff finds that the PSAR adequately describes the proposed design of the NWMI production facility for the purposes of a construction permit application, and identified the major features or components incorporated therein for the protection of the health and safety of the public and workers from chemical hazards. These major features or components are the ESFs/SSCs which NWMI identified in the PSAR and are listed in SER Table 13-1 presented above. These ESFs will be designed as seismic category C-I systems.

NWMI identified ESFs and SCCs based on the preliminary accident analysis and ISA in its application. The staff finds that the identification of these features listed in SER Table 13-1 and the classification of them as safety-related systems is acceptable, based on the staff's review of the process description, the production facility equipment and design and the NWMI accident analysis/ISA, as well as the staff's independent analysis.

The staff finds that NWMI adequately identified the principal architectural and engineering criteria for the facility and the major features, such as ESFs, incorporated into the design for the

protection of the health and safety of the public and workers from chemical hazards. The staff finds that this meets the criteria in 10 CFR 50.35(a)(1) for issuing a construction permit.

In response to RAI 13.3-2 (Reference 31), NWMI states that it will provide final design and safety analysis in the FSAR, including detailed and specific analysis of chemical accidents that will support its OL application (the staff is tracking these issues in Appendix A of this SER). The staff finds that this meets the criteria in 10 CFR 50.35(a)(2) for issuing a construction permit.

NWMI has identified chemical safety research and development that it will be conducting to resolve chemical safety questions related to uranium purification (the staff is also tracking these issues in Appendix A of this SER). The staff finds that this meets the criteria in 10 CFR 50.35(a)(3) for issuing a construction permit.

The staff finds that it has reasonable assurance that the chemical safety questions related to uranium purification can be resolved before completion of construction. Additionally, considering the siting criteria, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of workers and the public from chemical hazards. This meets the criteria in 10 CFR 50.35(a)(4) for issuing a construction permit.

Therefore, the staff concludes that NWMI's analysis of accidents with chemical hazards for the preliminary design, as described in NWMI PSAR Section 13.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided in the FSAR based on the final design. The staff will confirm that the final design conforms to the design basis during its evaluation of NWMI's FSAR.

13.4.10 Probable Subjects of Technical Specifications

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of TSs for the NWMI production facility with special attention given to those items which may significantly influence the final design.

The NWMI PSAR Chapter 14.0, "Technical Specifications," states that the NWMI facility ISA process identified SSCs that are defined as IROFS. The importance of these SSCs will also be reflected in the TSs. Each IROFS will be examined and likely translated into a limiting condition for operation (LCO). This translation will involve identifying the most appropriate specification to ensure operability and a corresponding surveillance periodicity for the IROFS.

In response to RAI 13.2-9a (Reference 31), NWMI states that, because maintenance activities (i.e., removing a cover block to replace a piece of failed equipment) could change the configuration of the facility, the TSs, which will be provided as part of the OL application, will include limits on operations activities or acceptable inventories. The staff is tracking this item in Appendix A of this SER.

The PSAR also provides an outline for the TSs that will be prepared during the development of the OL application. This outline includes actions, administrative controls, LCOs, limiting safety system settings, safety limits, and surveillance requirements.

NWMI PSAR Chapter 14.0, Table 11, "Potential Technical Specifications," includes the potential items or variables that are expected topics of TSs. The staff documented its review of NWMI's probable subjects of TSs for the facility in Chapter 14, of this SER.

13.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of NWMI's accident analysis, including probable subjects of TSs, as described in NWMI PSAR Chapter 13.0 and supplemented by the applicant's responses to RAIs, and finds that the accident analysis of the preliminary design, including the principal design criteria; design bases; information relative to materials of construction, general arrangement, and approximate dimensions; and preliminary analysis and evaluation of the design and performance of SSCs of the facility: (1) provides reasonable assurance that the final design will conform to the design basis, (2) includes an adequate margin of safety, (3) demonstrates reasonable assurance that SSCs adequately provide for the prevention of accidents and the mitigation of consequences of accidents for the preliminary design, and (4) meets all applicable regulatory requirements and acceptance criteria in or referenced in the ISG Augmenting NUREG-1537, Part 2 for the issuance of a construction permit.

The staff further finds that NWMI PSAR Chapter 13.0 contains sufficient information to conclude that the ESFs would be expected to function as designed to perform their safety functions, and radioactive and chemical hazards associated with SNM can be prevented or mitigated to levels that are acceptable. Realistic, but conservative, methods were used to compute or estimate potential doses and dose commitments to the public in uncontrolled areas and to compute external radiation doses and dose commitments resulting from inhalation by the facility workers. Methods of calculating doses from inhalation or ingestion (or both) and direct exposure to gamma rays from dispersing plumes of airborne radioactive material are applicable and no less conservative than those developed in NWMI PSAR Chapter 11.0, "Radiation Protection and Waste Management."

Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the systems supporting the accident analysis, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100 the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

14 TECHNICAL SPECIFICATIONS

The principal purpose of the 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 facility descriptions and safety considerations contained in the safety analysis report (SAR).

This chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the probable subjects of TSs for the NWMI production facility, as presented in preliminary safety analysis report (PSAR) Chapter 14.0, Revision 3, "Technical Specifications," as supplemented by responses to requests for additional information (RAIs). As explained in SER Section 1.1, "Introduction," the NWMI application generally refers to the entire proposed building as the radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the RPF area where NWMI states that it plans to conduct Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing Of Production and Utilization Facilities," activities (and which encompasses most of the proposed building) as "the NWMI production facility" or "the facility" and the separate RPF area where NWMI states that it plans to conduct 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," activities as "the target fabrication area." The staff reviewed the entire application to understand the interface between and impact on the production facility activities from the target fabrication area activities, but its conclusions are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

14.1 Areas of Review

NWMI PSAR Chapter 14.0 describes the process by which the NWMI production facility TSs will be developed and written. NWMI did not develop TSs for the construction permit application, but states that it will provide these as part of its operating license (OL) application.

The staff reviewed NWMI PSAR Chapter 14.0 against applicable regulatory requirements using appropriate regulatory guidance and standards, to assess the sufficiency of NWMI's discussion of its preliminary TS methodology for the NWMI production facility for the purposes of issuance of a construction permit. Consistent with 10 CFR Part 50, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items which NWMI determined to be probable subjects of TSs for the facility, with special attention given to those items which may significantly influence the final design.

14.2 Summary of Application

As stated above and described in NWMI PSAR Chapter 14.0, the purpose of the TSs is to maintain system performance and safe operation emphasizing the safety of the public, the facility staff, and the environment.

NWMI PSAR Chapter 14.0 states that the format and content of the TSs for the NWMI production facility will be based on the guidance provided in American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.1-2007, (Reference 43) "The Development

of Technical Specifications for Research Reactors," NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," (Reference 8) and the "Final Interim Staff Guidance [ISG] 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," (Reference 10). NWMI PSAR Chapter 14.0 also states that the TSs will be consistent with 10 CFR 50.34, "Contents of applications; technical information," and will address the applicable paragraphs of 10 CFR Part 50.36, "Technical specifications." Finally, the NWMI PSAR states that the TSs will be written in consideration of the differences between the NWMI production facility and either power or research reactors, such as that the NWMI production facility has items relied on for safety (IROFS) that the TSs will need to reflect. The NWMI production facility integrated safety analysis (ISA) process identified systems, structures, and components (SSCs) that are defined as IROFS, and the importance of these SSCs will need to be reflected in the TSs included in the OL application, in accordance with 10 CFR 50.36. Each IROFS will need to be examined and will likely become the subject of a limiting condition of operation (LCO) TS. The development of each IROFS into a TS will involve identifying the most appropriate specification to ensure operability, as well as corresponding surveillance periodicity for the specification.

NWMI PSAR Chapter 14.0 also states that the proposed TSs will form a comprehensive set of parameters to ensure that normal NWMI production facility operations will not result in off-site radiation exposures in excess of the guidelines in 10 CFR Part 20, "Standards for Protection against Radiation," and also reasonably ensure that the facility will function as analyzed in the OL application. Adherence to the TSs will limit the likelihood of malfunctions and mitigate the consequences to the public of off-normal or accident events.

NWMI PSAR Chapter 14.0, Table 14-1, "Potential Technical Specifications," lists items or variables that may be probable subjects of TSs for the NWMI production facility. This table includes systems and components for prevention of inadvertent criticalities, and the prevention or mitigation of events that may cause radiological or chemical exposures to the workers and the public with respect to the requirements of 10 CFR 70.61, "Performance requirements." The table also identifies items which NWMI states will significantly influence the final design of the NWMI production facility. NWMI PSAR Chapter 14.0 further states that NWMI will submit formal TSs with the OL application as required by 10 CFR 50.36.

14.3 Regulatory Basis and Acceptance Criteria

Pursuant to 10 CFR 50.36(b), TSs, which are derived from the analyses and evaluations included in the SAR, are required to be included in each 10 CFR Part 50 license authorizing operation of a production facility. The TSs are not required to be submitted with a 10 CFR Part 50 construction permit application, but pursuant to 10 CFR 50.34(a), a 10 CFR Part 50 construction permit application shall include an identification and justification of those variables, conditions, or other items which are determined as the result of preliminary safety analysis and evaluation to be probably subjects of TSs for the facility, with special attention given to those items which may significantly influence the final design.

The staff reviewed NWMI PSAR Chapter 14.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary TS methodology for the NWMI production facility for the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits,"

a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described and identified by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9) and "Final Interim Staff Guidance [ISG] 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," (Reference 10) 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" (Reference 11). The staff's review in Chapter 2, "Site Characteristics," of this SER 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 issuance of the construction permit will not be inimical to public health and safety.

14.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the staff's evaluation of the NWMI production facility TS are as follows:

10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."

14.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).

- 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 (Reference 9).

- "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 (Reference 10).

- "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 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, ANSI/ANS standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References" of this SER.

14.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the TS methodology presented in NWMI PSAR Chapter 14.0 to assess the sufficiency of the preliminary TS methodology for the NWMI production facility for the issuance of a construction permit, in accordance with 10 CFR Part 50. The sufficiency of the NWMI production facility's TS methodology is determined by ensuring that the design and performance of the TS methodology meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 14.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the staff's technical evaluation is described in SER Section 14.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the TSs may be adequately described as probable subjects. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility based on the applicant's TS methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of the NWMI production facility does not constitute approval of the safety of any design feature or specification. Such approval, if granted, will be after an evaluation of the final design of, and proposed TSs for, the NWMI production facility, as described in the FSAR as part of NWMI's OL application.

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant's identification and justification for the selection of those variables, conditions, or other items which NWMI determined, as the result of its preliminary safety analysis and evaluation, to be probable subjects of TSs for the NWMI production facility, with special attention given to those items which may significantly influence the final design.

Consistent with the review procedures of NUREG-1537, Part 2, Chapter 14, "Technical Specifications," and the ISG Augmenting NUREG-1537, Part 2, Section 14b, "Radioisotope Production Facility Technical Specifications," the staff confirmed that NWMI states that TSs and bases will be determined, as appropriate, based on the IROFS that were derived from the ISA and are supported by appropriate references to PSAR analyses and statements. As discussed in SER Section 14.2, "Summary of Application," NWMI PSAR Chapter 14.0 states that the NWMI facility ISA process identified SSCs that are defined as IROFS. NWMI PSAR Chapter 14.0 further states that the importance of these SSCs will also need to be reflected in the TSs, that each IROFS will need to be examined and likely translated into an LCO TS, and that this translation will involve identifying the most appropriate LCO TSs to ensure operability of the SSCs, as well as a corresponding surveillance periodicity for each LCO TS. NWMI PSAR Chapter 14.0 also states that some IROFS could potentially become design features TSs requiring certain SSCs.

In SER Section 6.4.6, "Probable Subjects of Technical Specifications," the staff evaluates probable topics of TSs on criticality control and finds them acceptable.

In SER Section 7.4.7, "Probable Subjects of Technical Specifications," the staff evaluates probable topics of TSs on the criticality accident alarm system and finds them acceptable.

In SER Section 8.4.3, "Probable Subjects of Technical Specifications," the staff finds that the applicant's identification and justification for the uninterruptable power supply being the probable

subject of a TS acceptable because of its required safety function to provide electrical power to engineering safety features, emergency lighting, radiation monitoring, and shutdown instrumentation and control during a loss of normal emergency power.

NWMI PSAR Chapter 13.0 provides detail on NWMI's ISA process used to identify IROFS. The staff reviewed NWMI's ISA process in Chapter 13 of this SER.

NWMI PSAR Chapter 14.0, Table 14-1 lists items or variables that may be probable subjects of TSs. This table includes SSCs for prevention of inadvertent criticalities and the prevention or mitigation of events that may cause radiological or chemical exposures to the workers and the public with respect to the requirements of 10 CFR 70.61. In the table, NWMI also identified items or variables which it states will significantly influence the final design of the facility, including uranium mass limits on batches, samples, and approved containers; spacing requirements on targets and containers with special nuclear material; floor and sump designs; hot cell liquid confinement; process tank size and spacing; air pressure differential between zones; ventilation system filtration; hot cell shield thickness and integrity; the hot cell secondary confinement boundary; and the stack height.

The PSAR also provided an outline for the TSs that will be prepared during the development of the OL application. This outline includes actions, administrative controls, design features (including a site and facility description), LCOs, limiting safety system settings, safety limits, and surveillance requirements. In response to RAI 14.0-1 (Reference 31), NWMI stated that TSs on items involved with preventing release of radioactive materials routinely or in the event of an accident are planned for inclusion in sections of the FSAR that address LCOs and surveillance/maintenance as part of the OL application. The staff is tracking this issue in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER. The staff will perform a detailed review of the complete TSs for the NWMI production facility as part of its review of the NWMI OL application.

Based on the information provided in NWMI PSAR Chapter 14.0, as well as other chapters of the NWMI PSAR, the staff finds that NWMI has provided an identification and justification for the selection of those variables, conditions, or other items which are determined as the result of NWMI's preliminary safety analysis and evaluation to be probable subjects of TSs, with special attention given to those items which may influence the final design, in accordance with 10 CFR 50.34(a)(5), and that NWMI's identification and justification of the proposed TSs methodology is sufficient for the issuance of a construction permit. The staff also finds NWMI has stated that it will provide TSs for the proposed NWMI production facility with its OL, and the staff finds that this is acceptable, because 10 CFR 50.36(b) requires that operating licenses includes TSs, but 10 CFR 50.34(a) does not require TSs to be submitted with a construction permit application. Therefore, based on the above, the staff concludes that NWMI meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

14.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility's TS, as described in NWMI PSAR Chapter 14.0 and other relevant chapters of the NWMI PSAR, and finds that the preliminary TS methodology meets all applicable regulatory requirements and acceptance criteria in NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the production facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis of the NWMI production facility TSs, and which can reasonably be left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that (i) safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

15 FINANCIAL QUALIFICATIONS

Financial qualifications (FQs) establish whether an applicant is financially qualified to carry out the activities for which the permit or license is sought. If the application is for a construction permit, the applicant must submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle (here, low-enriched uranium [LEU]) costs.

This chapter of the safety evaluation report (SER) for the construction permit application of the Northwest Medical Isotopes, LLC (NWMI or the applicant) radioisotope production facility (RPF) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) review and evaluation of NWMI's FQs, as presented in Chapter 15.0, "Financial Qualifications," of the NWMI preliminary safety analysis report (PSAR), Revision 3 (Reference 60). As explained in SER Section 1.1.1, "Scope of Review," although NWMI states that it plans to conduct operations under separate licenses for both Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," activities within the RPF, the staff conclusions are limited to whether NWMI satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

15.1 Areas of Review

This SER Chapter provides the staff's evaluation of NWMI's FQs to construct its proposed RPF, as presented in NWMI PSAR Chapter 15.0, within which NWMI describes its financial ability to construct, operate, and decommission the NWMI RPF, and also provides information regarding foreign ownership, control, or domination (FOCD) and nuclear insurance and indemnity. Because NWMI PSAR Chapter 15.0 does not separate or distinguish between financial information related to 10 CFR Part 50 or 10 CFR Part 70 activities at the RPF, the staff's review evaluates the information provided for the entire RPF; however, as noted above, the staff conclusions are limited to whether NWMI satisfied the 10 CFR Part 50 requirements for the issuance of a construction permit.

Because NWMI proposes to construct a production facility and not a utilization facility, it does not have fuel cycle costs. However, the RPF will process LEU dissolved from irradiated targets. Therefore, the staff considered the cost of the LEU for the RPF in its first year of operation as part of this review.

The staff reviewed NWMI PSAR Section 15.1, "Financial Ability to Construct a Facility," against the applicable regulatory requirements at 10 CFR 50.33, "Contents of applications; general information," using regulatory guidance and standards to assess the sufficiency of the FQ of NWMI related to the construction of the proposed RPF. As part of this review, the staff evaluated information and discussions of NWMI's FQ, with special attention to the financial ability of the applicant to cover costs of construction. Areas of review for this section included estimates of construction costs, estimates of costs associated with the LEU used for targets, and the sources of funds to cover these costs. NWMI provided additional information related to its FQs to operate and decommission the NWMI RPF. This additional information is not required by 10 CFR 50.33(f)(1) for a construction permit applicant and is thus outside the scope of the FQs required for issuing a construction permit. Therefore, such information will be evaluated after NWMI submits an operating license (OL) application.

The staff reviewed NWMI PSAR Section 15.4, “Foreign Ownership, Control, or Domination,” against the applicable regulatory requirements at 10 CFR 50.38, “Ineligibility of certain applicants,” using regulatory guidance and standards to assess the sufficiency of NWMI’s application.

The staff reviewed NWMI PSAR Section 15.5, “Nuclear Insurance and Indemnity,” against the applicable regulatory requirements at 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements,” using regulatory guidance and standards to assess the sufficiency of NWMI’s application.

15.2 Summary of Application

NWMI PSAR Section 15.1 presents information related to NWMI’s financial ability to construct its proposed RPF, including the basis for NWMI’s conclusion that it possesses, or has reasonable assurance of obtaining, the funds necessary to cover estimated construction costs and related LEU costs. This section also provides budgetary estimates based on the preliminary design of the proposed NWMI RPF and states that NWMI has received committed sources of financing, including equity and debt, for a portion of its project.

NWMI PSAR Section 15.2, “Financial Ability to Safely Operate a Facility,” presents the basis for NWMI’s conclusion that it possesses, or has reasonable assurance of obtaining, the funds necessary to cover estimated operating costs for the period of the operating license. NWMI is anticipating to request an operating license with a period of 30 years. NWMI provides estimates for the total annual operating costs and expected revenues for each of the first 5 years of operation of the RPF from 2018 through 2022.

NWMI PSAR Section 15.3, “Financial Ability to Safely Decommission a Facility,” presents information indicating NWMI proposes to demonstrate how reasonable assurance will be provided that funds will be available to decommission the RPF.

NWMI PSAR Section 15.4, “Foreign Ownership, Control, or Domination,” presents information regarding the makeup of NWMI, from shareholders to board members.

NWMI PSAR Section 15.5, “Nuclear Insurance and Indemnity,” presents information indicating that NWMI is covered by the insurance and financial protection requirements of the Price-Anderson Act, pursuant to Section 170 of the Atomic Energy Act (AEA) of 1954, as amended.

15.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 15.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of NWMI’s FQ for the issuance of a construction permit under 10 CFR Part 50.

15.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of NWMI’s FQ are as follows:

- 10 CFR 50.33, “Contents of applications; general information.”
- 10 CFR 50.38, “Ineligibility of certain applicants.”

- 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR Part 50, Appendix C, “A Guide for the Financial Data and Related Information Required to Establish Financial Qualifications for Construction Permits and Combined Licenses.”

15.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI’s construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with 10 CFR regulatory requirements, the staff used:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996 (Reference 8).
- 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 (Reference 9).
- “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 (Reference 10).
- “Final Interim Staff Guidance [ISG] 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 (Reference 11).

15.4 Review Procedures, Technical Evaluation, and Evaluation Findings

In order to demonstrate FQ, an applicant for a construction permit must submit estimates of the total construction costs of the RPF and related fuel cycle costs, must indicate the source(s) of funds to cover these costs, must demonstrate that the applicant is not ineligible to apply for a construction permit because of FOCD, and must address financial protection and indemnity. The staff performed an evaluation of the financial information presented in NWMI PSAR Chapter 15.0 to assess the sufficiency of NWMI’s FQ for the issuance of a construction permit against these requirements. The sufficiency of NWMI’s FQ information is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 15.3, “Regulatory Basis and Acceptance Criteria,” of this SER. The results of this technical evaluation are summarized in SER Section 15.5, “Summary and Conclusions.”

15.4.1 Financial Ability to Construct a Facility

The staff evaluated the sufficiency of NWMI's financial ability to cover construction costs of the RPF and related fuel cycle costs (i.e., LEU material costs), as described in NWMI PSAR 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.

Consistent with the review procedures of NUREG-1537, Part 2, Section 15.1, the staff evaluated the applicant's estimates of construction cost, including plant equipment and LEU material costs. The estimates provided in the PSAR are based on NWMI's proposed design of the RPF completed in May 2015.

Pursuant to 10 CFR 50.33(f)(1) and 10 CFR Part 50, Appendix C, Section I.A.1, "Estimate of construction costs," the applicant outlined the projected costs for the construction of the proposed medical isotope production facility.

According to the application, the estimate covers all components of the project, including engineering and construction equipment, materials, and labor. NWMI incorporated data from similar projects and a preliminary RPF time-cycle logistical study that includes data for labor requirements, materials, operations, and maintenance as the bases of the cost estimate. The estimate also used inputs based the project schedule and site conditions. Based on a detailed review of the cost to construct the facility and the supporting bases and assumptions, the staff finds that the applicant provided the total construction and LEU costs, as required by 50.33(f)(1), and a reasonable basis for the applicant's cost estimate.

As required by 10 CFR 50.33(f)(1) and (f)(4), the applicant must indicate the source(s) of funds to cover estimated constructions costs and LEU (or special nuclear material) costs and, as a newly-formed entity, describe (a) its legal and financial relationships with its stockholders or owners, and (b) the stockholders' or owners' financial ability to meet any contractual obligations incurred or proposed to be incurred. As described in NWMI's PSAR Section 15.1, and General Information section of Part 1 of its application (Reference 67), NWMI is a limited liability corporation and a newly-formed entity that has established a wholly owned subsidiary for the RPF (which includes the production facility). Consistent with guidance in 10 CFR Part 50, Appendix C, II.A.2, "Source of construction funds," NWMI expects the source of funds for 100 percent of the construction costs to be debt financing. The applicant's reliance on debt financing through an established subsidiary is consistent with, and satisfies the criteria provided in 10 CFR Part 50, "Appendix C - A Guide for the Financial Data and Related Information Required To Establish Financial Qualifications for Construction Permits and Combined Licenses," II. "Applicants Which Are Newly Formed Entities." In addition, the applicant's ability to obtain equity financing and commitments for initial research and development, preliminary design, regulatory, and permitting cost projections, supports the conclusion that NWMI, through its subsidiary, has reasonable assurance of obtaining the funds necessary to cover estimated construction costs for this project.

Based on its review, the staff finds that the level of detail provided in the NWMI PSAR on NWMI's FQ for construction is reasonable and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 15.1, and the ISG Augmenting NUREG-1537, Part 2, Section 15.1, allowing the staff to make the following findings: (1) the applicant supplied

financial information regarding construction and related fuel cycle costs (i.e., LEU material costs) and the source of funds to cover these costs; and (2) there is reasonable assurance of the applicant obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs (i.e., LEU material costs).

Therefore, the staff concludes that NWMI's FQ for construction, as described in NWMI PSAR Section 15.1, meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

15.4.2 Financial Ability to Operate a Facility

In NWMI PSAR Section 15.2, the applicant addressed its financial ability to operate the proposed NWMI RPF. As stated above, areas of review for FQ for a construction permit are estimates of construction and related fuel cycle costs and the sources of funds to cover these costs as required by 10 CFR 50.33(f)(1). The information NWMI provided related to its financial ability to operate the proposed NWMI RPF is outside the scope of FQs necessary for issuing a construction permit and, therefore, will be evaluated after NWMI submits an OL application.

15.4.3 Financial Ability to Decommission a Facility

In NWMI PSAR Section 15.3, the applicant addressed its financial ability to decommission the proposed NWMI RPF. As stated above, areas of review for FQ for a construction permit are estimates of construction and related fuel cycle costs and the sources of funds to cover these costs as required by 10 CFR 50.33(f)(1). The information NWMI provided related to its financial ability to decommission the proposed NWMI RPF is outside the scope of the FQs necessary for issuing a construction permit and, therefore, will be evaluated after NWMI submits an OL application.

15.4.4 Foreign Ownership, Control, or Domination

The staff evaluated the sufficiency of NWMI's description of FOCD considerations, as presented in NWMI PSAR Section 15.4, using the regulations at 10 CFR 50.33(d) and 10 CFR 50.38 and guidance and acceptance criteria from Section 15.4, "Foreign Ownership, Control, or Domination (FOCD)," of the ISG Augmenting NUREG-1537, Parts 1 and 2. As stated in 10 CFR 50.38, any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, shall be ineligible to apply for and obtain a license.

Consistent with 10 CFR 50.33(d) and 10 CFR 50.38, along with the guidance in the ISG Augmenting NUREG-1537, the staff confirmed whether the application included a statement as to whether the applicant is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

The NWMI PSAR states that NWMI is a limited liability company formed under the laws of the state of Oregon with its headquarters located in Corvallis, Oregon. NWMI intends to construct and operate the NWMI RPF in Columbia, Missouri, at Discovery Ridge Research Park, which is owned and managed by the University of Missouri - Columbia. NWMI business operations are

managed under the direction of a Board of Managers, consisting of six managers and two executive officers, as well as through the officers of NWMI.[1] All managers and officers are citizens of the United States.

Furthermore, NWMI states that it is not owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. In addition, NWMI is not acting as an agent or representative of another person in filing the construction permit application.

Based on its review, the staff finds that the level of detail provided in the NWMI PSAR on FOCD considerations is reasonable and satisfies the requirements of 10 CFR 50.33(d) and 10 CFR 50.38. Specifically, the staff finds that NWMI is not a citizen, national, or agent of a foreign country, or any corporation, or other entity, which the staff knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

Therefore, the staff concludes that NWMI's FOCD considerations, as described in NWMI PSAR Section 15.4, meet the applicable regulatory requirements and guidance for the issuance of a construction permit for the production facility in accordance with 10 CFR Part 50.

15.4.5 Nuclear Insurance and Indemnity

The staff evaluated the sufficiency of NWMI's nuclear insurance and indemnity considerations, as described in NWMI PSAR 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.

Section 170, "Indemnification and Limitation of Liability," of the AEA, as implemented in the regulations of 10 CFR Part 140, requires that a construction permit is conditioned such that an operating license will not be issued by the Commission unless NWMI submits proof of financial protection and executes an indemnity agreement.

As stated above, areas of review for FQ for a construction permit are estimates of construction and related fuel cycle costs and the sources of funds to cover these costs as required by 10 CFR 50.33(f)(1). At this time, NWMI has not requested a license to operate a 10 CFR Part 50 facility. The staff will evaluate information NWMI provides related to nuclear insurance and indemnity with respect to its 10 CFR Part 50 facility if NWMI submits an OL application.

15.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of NWMI FQ, as described in Chapter 15.0 of the NWMI PSAR, and finds that: (1) NWMI supplied financial information for construction and related LEU material costs, (2) there is reasonable assurance that NWMI can obtain the funds necessary to cover estimated construction and related LEU material costs, and (3) the financial status of the applicant regarding construction and related LEU material costs is in accordance with the requirements of 10 CFR 50 33(a) and (f) and Appendix C of 10 CFR Part 50. Therefore, NWMI meets all applicable regulatory requirements and acceptance criteria in NUREG-1537 and the ISG augmenting NUREG-1537. The staff also

[1] The names and addresses of the members of the NWMI Board of Managers are included in Part 2 of the construction permit application (Agencywide Documents Access and Management System Accession No. ML15210A112).

finds that NWMI is not subject to FOCD, as required by 10 CFR 50.38, and that NWMI provided sufficient information regarding nuclear indemnity and insurance for the purposes of a construction permit where no materials license is held.

Therefore, as required by 10 CFR 50.40(b), the staff concludes that NWMI demonstrated the requisite FQ to engage in the proposed activities for the issuance of a construction permit for a production facility in accordance with the regulations in 10 CFR Part 50.

16 OTHER LICENSE CONDITIONS

Northwest Medical Isotopes, LLC (NWMI or the applicant) Preliminary Safety Analysis Report (PSAR) Chapter 16.0, "Other License Considerations," states that the NWMI Radioisotope Production Facility (RPF) "will only use new and appropriately qualified components and systems…." Additionally, NWMI states that the NWMI RPF will "not include equipment or facilities associated with direct medical administration of radioisotopes or other radiation-based therapies."

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) evaluated the descriptions and discussions of the NWMI production facility in the PSAR and finds that the preliminary design of the NWMI production facility does not include prior use components, and that the NWMI production facility will not be used for direct medical therapy. The staff concludes that an evaluation using the guidelines of "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" (Reference 11), for other license considerations is not required because:

(1) All equipment to be installed in the NWMI production facility will be new and purpose-built. No prior use components will be used in the construction of the NWMI production facility or support systems; and

(2) The NWMI production facility will not contain equipment or facilities associated with the direct medical administration of radioisotopes or other radiation-based therapies.

17 DECOMMISSIONING AND POSSESSION-ONLY LICENSE AMENDMENTS

Northwest Medical Isotopes, LLC (NWMI or the applicant) preliminary safety analysis report (PSAR) Chapter 17.0, "Decommissioning and Possession-Only License Amendments," states that decommissioning information is not required for a construction permit application. As such, the NWMI PSAR does not include a decommissioning plan or report.

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) evaluated this PSAR chapter and finds that Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.33, "Contents of applications; general information," paragraph (k) requires an applicant for an operating license for a production facility to submit a decommissioning report, but does not require an applicant for a construction permit for a production facility to submit a decommissioning report. Because the NWMI application seeks a construction permit for a production facility, and because NWMI is not seeking a possession-only license amendment, the staff concludes that no decommissioning information needs to be provided in the PSAR or evaluated for the issuance of a construction permit for a production facility under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

18 HIGHLY ENRICHED TO LOW-ENRICHED URANIUM CONVERSION

Northwest Medical Isotopes, LLC (NWMI or the applicant) preliminary safety analysis report (PSAR) Chapter 18.0, "Highly Enriched to Low-Enriched Uranium Conversion," states that the conversion from highly enriched to low-enriched uranium (LEU) is not applicable to the proposed NWMI Radioisotope Production Facility.

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) evaluated the descriptions and discussions of the NWMI production facility in the PSAR and finds that the preliminary design of the NWMI production facility does not utilize highly enriched uranium. As stated in PSAR Chapter 1.0, "The Facility," the NWMI production facility will only utilize LEU as target material. Therefore, the staff concludes that an evaluation using the guidelines of "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" (Reference 11), for uranium conversion is not required.

APPENDIX A
POST CONSTRUCTION PERMIT ACTIVITIES – CONSTRUCTION PERMIT CONDITIONS AND FINAL SAFETY ANALYSIS REPORT COMMITMENTS

A.1 Construction Permit Conditions

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) has determined that additional information is needed to address certain matters related to nuclear criticality safety in the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit application. The staff has also determined that a construction permit needs to be conditioned to require that NWMI will implement its quality assurance program during construction and perform a site-specific geotechnical investigation prior to the beginning of construction. Therefore, the staff recommends that, should the application be granted, the construction permit include the conditions set forth below. Additional details on the basis for each of these conditions appears in Chapter 2, "Site Characteristics," Chapter 6, "Engineered Safety Features," and Chapter 12, "Conduct of Operations," of the NWMI construction permit safety evaluation report (SER).

Proposed Permit Condition	SER Section	Description
3.D	6.4.5	Prior to the completion of construction, NWMI shall ensure that all nuclear processes are evaluated to be subcritical under all normal and credible abnormal conditions. This determination shall be done for each area as described in Section 6.3.1.1 of the NWMI preliminary safety analysis report (PSAR) prior to each area being completed, and shall be done consistent with the Upper Subcritical Limit (USL) established in Revision 2 of NWMI's Validation Report. NWMI shall submit periodic reports to the NRC, at intervals not to exceed 6 months from the date of the construction permit, summarizing any changes or indicate no change to the criticality safety evaluations as a result of the revised USL. This condition terminates once NWMI submits its Final Safety Analysis Report (FSAR).
3.E	6.4.5	Prior to the completion of construction, NWMI shall submit periodic reports to the NRC, at intervals not to exceed 6 months from the date of the construction permit, and these reports shall: Provide the technical basis for the design of the Criticality Accident Alarm System or notify the NRC of no change. Demonstrate detector coverage as defined in the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 70.24(a). This condition terminates once NWMI submits its FSAR.

Proposed Permit Condition	SER Section	Description
3.F	12.4.8	NWMI shall implement the quality assurance program described, pursuant to 10 CFR 50.34(a)(7), in Revision 3 of the NWMI PSAR, including revisions to the quality assurance program in accordance with the provisions below. NWMI may make a change to its previously accepted quality assurance program description included in Revision 3 of the NWMI PSAR, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the PSAR quality assurance program description that do not reduce the commitments must be submitted to the NRC within 90 days. Changes to the PSAR quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval before implementation, as follows: Changes made to the previously accepted quality assurance program description must be submitted as specified in 10 CFR 50.4. The submittal of a change to the PSAR quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the PSAR quality assurance program description commitments previously accepted by the NRC. The letter need not provide the basis for changes that correct spelling, punctuation, or editorial items. A copy of the forwarding letter identifying the changes must be maintained as a facility record for three years. Changes to the quality assurance program description included in the NWMI PSAR shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

Proposed Permit Condition	SER Section	Description
3.G	2.4.5	Prior to the beginning of construction, NWMI shall (a) complete a geotechnical investigation to identify any potential voids that may adversely impact stability of subsurface materials and foundation, soil and rock characteristics, and liquefaction potential at the site and (b) submit the results of this investigation, including any design changes made to the facility based on the findings of the investigation, in a report to the NRC. This condition terminates once NWMI submits the results of the geotechnical investigation in either this report or as part of its final safety analysis report, whichever occurs first.

A.2 Regulatory Commitments Identified in Responses to Requests for Additional Information

In responses to requests for additional information, the applicant identified elements of design, analysis, and administration that require additional research and development or correction. The staff determined that resolution of these items is not necessary for the issuance of a construction permit, but the applicant should ensure that these items are fully addressed in the final safety analysis report (FSAR) supporting an NWMI operating license application. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of an NWMI operating license application.

The following regulatory commitments, as identified in NWMI's responses to requests for additional information (RAIs), are the responsibility of the applicant, and have not yet been fulfilled:

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
3.1-1A	April 25, 2016 ML16123A119	The specific Radioisotope Production Facility (RPF) design codes, standards, and other referenced documents, including exceptions or exemptions to the identified requirements, will be finalized in the RPF final design and provided to the U.S. Nuclear Regulatory Commission (NRC) in late 2016. In addition, the codes, standards, and referenced documents for the RPF safety structures, systems, and components (SSCs) that are needed to demonstrate compliance with regulatory requirements will be identified and committed to in the Operating License Application.
3.1-1B	April 25, 2016 ML16123A119	The codes, standards, and referenced documents for the RPF SSCs that are needed to demonstrate compliance with regulatory requirements will be identified and committed to in the Operating License Application. If there are specific exceptions to code requirements, NWMI will identify the exceptions as part of the Operating License Application submittal.
6.3-1	April 25, 2016 ML16123A119	The intent of Section 6.3 of the Construction Permit Application (CPA) (NWMI-2013-021) is to demonstrate an understanding of a nuclear criticality safety (NCS) program by describing aspects of the program. The discussion was not meant to imply that the program would be implemented in its entirety for the CPA. The program will be fully developed as part of the Operating License Application activities.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
6.3-5	April 25, 2016 ML16123A119	To ensure the criticality accident alarm system (CAAS) coverage is adequate for the facility final design, NWMI will conduct a coverage analysis using the minimum accident of concern that produces a detector response when the dose rate at the detector is equivalent to 20 rad/minute (min) at 2 meters (m) from the reacting material. Using the source from the minimum accident of concern, NWMI will conduct one-dimensional deterministic computations, when practical, to evaluate CAAS coverage. For areas of the facility where the use of one-dimensional deterministic computations is not practical, NWMI will use 3D Monte Carlo analysis to determine adequate CAAS coverage. NWMI is designing the CAAS in accordance with American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.3, *Criticality Accident Alarm System.*
13.1-1	April 25, 2016 ML16123A119	NWMI intends to prevent the occurrence of a criticality accident regardless of whether it results in a high radiation dose. In the Operating License Application, NWMI will clearly state our intent to prevent the occurrence of a criticality accident regardless of whether the event results in a high radiation dose.
G-3	November 28, 2016 ML16344A053	The accident analyses in the final safety analysis report (FSAR), as part of the Operating License Application, will be consistent with the requirements of 10 CFR 70.61.
2.5-6b	November 28, 2016 ML16344A053	Additional information on the seismic requirements and evaluations of the RPF and associated items relied on for safety (IROFS) will be provided in the FSAR as part of the Operating License Application
3.2-1	November 28, 2016 ML16344A053	During the structural analysis, unknown loads will have a conservative value assumed and marked with "(HOLD)." As the design matures, the actual values will be inserted in the analysis and the HOLDs removed. Final design media cannot be issued if there are HOLDs identified. The facility live loads will be established during the completion of the final facility design and provided in the FSAR as part of the Operating License Application.
3.2-3	November 28, 2016 ML16344A053	The density of all interconnections (e.g., heating, ventilation, and air conditioning (HVAC) ductwork, conduits, cable trays, and piping) between equipment will be conservatively estimated and included in the final design for dead load for fixtures attached to ceilings or anchored to floors in the RPF. This information will be provided in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
3.3-2	November 28, 2016 ML16344A053	Selection of specific fire suppression systems for facility locations will be guided by the recommendations offered in relevant industry standards (e.g., National Fire Protection Association (NFPA) 801, *Standard for Fire Protection for Facilities Handling Radioactive Materials*) and will depend on the level of fire hazards at those locations, as determined from the final facility and process systems designs. These final detailed designs will include any facility design elements and sensitive equipment protection measures deemed necessary for addressing the maximum inadvertent rate and duration of water discharges from the fire protection systems. The final comprehensive facility design, along with commitments to design codes, standards, and other referenced documents (including any exceptions or exemptions to the identified requirements), will be identified and provided in the FSAR as part of the Operating License Application
3.4-2a	November 28, 2016 ML16344A053	The composition of soil in which the RPF is embedded will be included in the soil-structure-interaction analysis as part of the building response analysis. This information will be provided in the FSAR as part of Operating License Application.
3.4-4a	November 28, 2016 ML16344A053	Design of IROFS will consider seismic loads in all three directions using a combination of square-root-of-the-sum-of-squared or [100]/40/40 methodologies. The [100]/40/40 methodology will be used in the development of the final RPF design and in the FSAR as part of the Operating License Application.
3.4-4b	November 28, 2016 ML16344A053	Design of IROFS will consider seismic loads in all three directions using a combination of square-root-of-the-sum-of-squared or [100]/40/40 methodologies. The [100]/40/40 methodology will be used in the development of the final RPF design and in the FSAR as part of the Operating License Application.
3.4-8a	November 28, 2016 ML16344A053	The capacity of the standard support design for overhead fixtures mounted above RPF IROFS will be checked to ensure that the supports can withstand the seismic loads derived from the floor spectra (e.g., remain stable during and after postulated earthquake effects) of the attachment floor slab. This information will be provided in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
3.4-8b	November 28, 2016 ML16344A053	The RPF seismic design will include a check to ensure that pounding or sway impact will not occur between adjacent fixtures (e.g., rattle space). Estimates of the maximum displacement of any fixture can be derived from the appropriate floor response spectrum and an estimate of the fixture's lowest response frequency. This information will be provided in the FSAR as part of the Operating License Operation.
3.4-9	November 28, 2016 ML16344A053	Seismic instrumentation for the RPF site is not an IROFS; it provides no safety-related function and is therefore not "safety-related." Although the seismic recorders have no safety function, they must be designed to withstand any credible level of shaking to ensure that the ground motion would be recorded in the highly unlikely event of an earthquake. This capability requires verification of adequate capacity from the manufacturer (e.g., prior shake table tests of their product line), provision of adequate anchorage (e.g. manufacturer-provided anchor specifications to ensure accurate recordings), and a check for seismic interaction hazards such as water spray or falling fixtures. With these design features, the instrumentation would be treated as if it were safety-related Quality Level (QL)-2. Additional information on seismic [instrumentation] will be provided in the FSAR as part of the Operating License Application.
3.5-8	November 28, 2016 ML16344A053	Each of the hot cells will have manipulators that will be used to perform maintenance within the hot cells. Equipment within the hot cells will also be positioned on skids for ease of removal and replacement if necessary. If maintenance cannot be performed by the in-cell manipulators, the cover blocks can be removed and the required equipment replaced. For the tank hot cell, a portable manipulator can be moved to different locations [within] the tank hot cell to perform maintenance. The design philosophy that will be incorporated in the FSAR as part of the Operating License Application will use remote handling for as much maintenance as possible within the hot cells. In [addition], the ventilation and changes in building configuration will be designed to maintain zones and barriers consistent with defense-in-depth, redundancy, and independence to protect workers and the public.
3.5-9e	November 28, 2016 ML16344A053	The quantities or concentrations of fissionable material used in the criticality analyses for all areas or process equipment are provided in each individual criticality calculation or criticality safety evaluation. The single process batch to subcritical limit will be presented in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
5.1-2	November 28, 2016 ML16344A053	The target load per week described in PSAR Section 5.1.1 will be changed to 12 University of Missouri Research Reactor (MURR) targets per week in the FSAR as part of the Operating License Application. The modification will include update of NWMI-2015-CALC-022, *Maximum Vessel Heat Load, Temperature, and Pressure Estimates*, with a more detailed analysis and revision of PSAR Section 5.1.1, Figure 5-2.
6.3-9	November 28, 2016 ML16344A053	The validation report NWMI-2014-RPT-006, *MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross Sections*, was generated prior to any calculations being performed for the NWMI RPF process. The intention was to provide as broad a base of coverage within each area of applicability (AoA) parameter range as possible. The H/X range was extended below a value of 8 based on a data trending analysis performed in the validation report. Subsequent to publishing the validation report, analyses have been performed for all NWMI processes show[ing] that the extrapolation is no longer necessary. Therefore, the AoA for H/X will be changed to include values from 8 to 1,400.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
6.3-10a	November 28, 2016 ML16344A053	Section 5.1 of the validation report NWMI-2014-RPT-006, including Figures 5, 6, and 7, evaluates trends in important validation parameters. The calculation methodology should have a method bias that has neither dependence on a characteristic nor is a smooth function of a parameter. If a trend in a parameter exists, the bias will vary as a function of that trend over the parameter range. If no trend in the Parameter exists, then the bias will be constant over the parameter range. Figure 5 groups individual experiments into sets that correspond to common moderators that include water, graphite, carbon fluoride (CF_2), hydrogen bound in uranium trihydride (UH_3), and no moderator. When the calculation results for these experiment sets are graphed, some of the experimental results lie below a k_{eff} of 1.0. Figure 5 does not represent a bias calculation; it is an evaluation to determine if a trend exists in the moderator parameter that would suggest the method bias (calculated in Section 5.3 of the validation report) has a dependence on moderation. In the Section 5.1.5 discussion of conclusions regarding the trending evaluation depicted in Figure 5, rather than stating the evaluation demonstrates no significant bias with the various moderators, the statement should read, "the evaluation demonstrates no significant trend with respect to moderation that would influence the method bias." Similarly, for Figure 6, the intent is to determine if a trend exists in the reflector parameter that would suggest the method bias (calculated in Section 5.3) has a dependence on reflection. The Section 5.1.6 discussion will be modified to "the evaluation demonstrates no significant trend with respect to reflection that would influence the method bias." For Figure 7, the intent is to determine if a trend exists with respect to chemical form that would suggest the method bias has a dependence on chemical form. Section 5.1.7 will be modified to "the evaluation demonstrates no significant trend with respect to chemical form that would influence the method bias." The method bias is developed in Section 5.3, and all of the experiment sets included in Figures 5 through 7 are evaluated there for the method bias calculation.
6.3-10b	November 28, 2016 ML16344A053	The validation area of applicability in the validation report NWMI-2014-RPT-006 will be changed to include only certain chemical forms.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
6.3-11a	November 28, 2016 ML16344A053	Subsequent to publishing the validation report NWMI-2014-RPT-006, analyses have been performed for all RPF processes and it can now be concluded that some of the chemical forms and the moderating, reflecting, and absorbing materials listed in the AoA are not necessary to support the NWMI calculations. Therefore, the AoA will be changed to include only certain chemical forms. The moderating materials will be changed to include no moderator and water. The reflecting materials will be changed to include no reflector, water, concrete, polyethylene, and paraffin, and the absorber materials will be changed to include aluminum, steel, stainless steel, polyethylene, and paraffin.
6.3-11b	November 28, 2016 ML16344A053	For systems that have compounds, elements, or nuclides that fall outside the validation AoA in the validation report NWMI-2014-RPT-006, an increased margin of subcriticality (MoS) may be warranted, depending on the specific problem being analyzed. The analyst will document any extrapolation beyond the validation AoA in the calculation and justify whether an increase to the MoS is or is not required.
6.3-12a	November 28, 2016 ML16344A053	Subsequent to the issue of the validation report NWMI-2014-RPT-006, criticality safety calculations have been performed. Each calculation documentation includes an evaluation of the validation AoA. For systems that are outside the validation AoA, an increased MoS may be warranted, depending on the specific problem being analyzed. The analyst will document any extrapolation beyond the validation AoA in the calculation and justify whether an increase to the MoS is or is not required.
6.3-12b	November 28, 2016 ML16344A053	For systems that are outside the validation AoA, an increased MoS may be warranted, depending on the specific problem being analyzed. The analyst will document any extrapolation beyond the validation AoA in the calculation and justify whether an increase to the MoS is or is not required.
6.3-14b	November 28, 2016 ML16344A053	The current design of the hot cell uranium purification equipment does not include passive backflow design features, as the analyzed controls are considered to be adequate. Consideration will be given to providing passive backflow controls for criticality safety, and will be provided in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
6.3-16	November 28, 2016 ML16344A053	As stated in Section 4.2.4 of NWMI-2015-CSE-008, *NWMI Preliminary Criticality Safety Evaluation*, criticality in each of these systems will be prevented by incorporation of safe-geometry intermediate day tanks in the liquid systems that are physically isolated from any larger-geometry tanks with an air break, such that backflow of uranium to an unsafe geometry is physically impossible. The current wording of the control CSE-08-PDF12 in NWMI-2015-CSE-008 does not reflect the actual design and will be revised to clarify that the control consists of a safe-geometry intermediate day tank that is physically isolated from any larger geometry tank with an air break.
7.1-1	November 28, 2016 ML16344A053	The instrument and control (I&C) systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, preliminary design of the RPF I&C systems (e.g., details regarding the design bases, technical aspects, safety, philosophy, and objective for all I&C components that monitor and control RPF processes or systems) was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the final safety analysis report (FSAR) as part of the Operating License Application.
7.1-2	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C subsystems (including types of parameters monitored, number of channels designed to monitor each parameter, and actuation logic) was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
7.1-3	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C subsystems, including specific details on human-machine interface (HMI), was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.
7.2-1a	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing all of the equipment and major RPF I&C components (e.g., block, logic and schematic diagrams, software flow diagram, and description of how system operational and support requirements and operator interface requirements are met) was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.
7.2-1b	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing the detailed methodology and acceptance criteria used to establish trip or actuation setpoints or interlock functions was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
7.2-2	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing the detailed methodology and operation of the integrated facility process control (FPC) system as it relates to engineered safety features (ESF) managing, monitoring, and actuation was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.
7.2-3	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing the detailed methodology and operation of the integrated I&C systems was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application. When the final RPF design is complete, PSAR Chapter 7.0, Table 7-2, will be expanded to provide a cross-reference to the specific section of each I&C section and how the system is suitable for performing the functions stated for each design basis applicability item.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
7.3-1	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing how the key parameters are monitored to ensure adequate criticality control (e.g., instruments to detect deviations from nominal concentrations and quantities, status of software development procedures) was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.
7.4-1	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing the functionality and operation required of the ESFs was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.
9.1-5	November 28, 2016 ML16344A053	The need for heating, ventilation, and air conditioning (HVAC) space temperature control in Zone I will be evaluated and determined during the final design phase by performing a heat balance on the Zone I ventilation system. The maximum heat load on the ventilation system is anticipated to be dominated by heat losses from equipment in the Zone I ventilated areas (rather than decay heat) when operating at the maximum uranium throughput. Temperature control will also be evaluated for a loss of ventilation scenario. Results of the evaluation (including space temperature control systems that may be identified by the heat balance) will be described in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
9.3-1	November 28, 2016 ML16344A053	Hot cell fire suppression systems have been commercially available for years and include product designs compliant with NFPA and other relevant industry standards. Selection of the specific hot cell enclosure fire suppression system will be finalized during the final RPF design, along with commitments to design codes, standards, and other referenced documents, including any exceptions or exemptions to the identified requirements. These final designs and commitments will be identified and provided in the FSAR as part of the Operating License Application. Selection of the specific hot cell enclosure fire suppression system and its discharged fire suppressant handling systems will be finalized in the RPF and hot cell final detailed designs, along with commitments to relevant design codes and standards. These final designs and commitments will be identified and provided in the FSAR as part of the Operating License Application.
9.3-2	November 28, 2016 ML16344A053	Commitments to specific building and/or fire codes (e.g., NFPA 801) will be finalized and identified in the RPF final detailed design, both for facility construction and for fire protection program maintenance. This final detailed facility design and the relevant commitments to codes and standards will be identified and provided in the FSAR as part of the Operating License Application.
9.3-3	November 28, 2016 ML16344A053	The fire detection systems selected for the RPF's fire-protected areas, and the corresponding test and maintenance programs, will be included in the final RPF detailed designs, along with commitments to design codes, standards, and other referenced documents, including any exceptions or exemptions to the identified requirements. The final designs, test and maintenance programs, and standards commitments will be identified and provided in the FSAR as part of the Operating License Application.
9.3-4	November 28, 2016 ML16344A053	High efficiency particulate air (HEPA) filter fire protection will be included in the final RPF detailed designs, along with commitments to the relevant design codes, standards, and other referenced documents, including any exceptions or exemptions to the identified requirements. The final fire protection system designs, test and maintenance programs, and standards commitments will be identified and provided in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
9.3-5a	November 28, 2016 ML16344A053	Once finalized, the detailed design of the facility and its systems (including the final designs for fire protection and the final list of key safety systems and components to address severe accidents), along with the management programs to maintain their reliability, will be identified and provided in the FSAR as part of the Operating License Application.
9.3-5b	November 28, 2016 ML16344A053	Once finalized, the detailed design of the facility and its systems (including the final designs for fire protection and the final list of key safety systems and components to address severe accidents), along with the management programs to maintain their reliability, will be identified and provided in the FSAR as part of the Operating License Application.
9.3-6	November 28, 2016 ML16344A053	The combustible loading analysis results and the administrative program to control combustibles within the RPF will be finalized and provided along with the final detailed design information in the FSAR as part of the Operating License Application.
11.1-1a	November 28, 2016 ML16344A053	The calculations of airborne release in PSAR Section 11.1.1.1.2, “Release of Airborne Radionuclides,” are based on the processing of eight targets at MURR. This section will be updated in the FSAR as part of the Operating License Application. NWMI stated during the August 23, 2017, Advisory Committee on Reactor Safeguards (ACRS) subcommittee meeting that routine radioactive release calculations for the maximum amount of targets their license allows them to process would be performed for the operating license application.
11.1-1b	November 28, 2016 ML16344A053	PSAR Section 11.1.1.1.2 operating conditions were slightly more conservative than those described in PSAR Section 4.1.2.1. PSAR Sections 4.1.2.1 and 11.1.1.1.2 operating conditions will be aligned in the FSAR as part of the Operating License Application.
11.1-2a	November 28, 2016 ML16344A053	The dose rates in PSAR Chapter 11.0, Table 11-5, were either based on actual shielding calculations or were the goals/endpoints of the shielding analysis. This table will be updated in the FSAR as part of the Operating License Application when the final shielding design and calculations are completed. Areas identified as controlled access areas, restricted areas, radiation areas, and high radiation areas will be designated based definitions provided in 10 CFR 20, "Standards for Protection Against Radiation," and the predicted doses rates presented by the shielding analysis. Although the Radiation Protection Plan has not yet been developed (i.e., this plan will be supplied with the Operating License Application), dosimetry is anticipated to be required in any restricted area.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
11.1-3a	November 28, 2016 ML16344A053	Portal survey monitoring will be in-place at the exit from the restricted area into the administrative area. The specifics on the type and instrument used will be described in the FSAR as part of the Operating License Application and will either be a control that allows standing passive detection or hand and foot monitors.
11.1-6	November 28, 2016 ML16344A053	PSAR Section 11.1.2, Table 11-5, provides estimated dose rates based on the RPF design. Although a dose rate of zero may not be achievable in the controlled areas, this is the goal. As stated in PSAR Section 11.1.5.5.2, an area monitoring program will be established in the controlled area to demonstrate compliance with public exposure limits in the FSAR as part of the Operating License Application.
11.1-7	November 28, 2016 ML16344A053	Details on the area monitoring program will be provided in the FSAR as part of the Operating License Application. Area monitoring is anticipated to comprise a combination of passive (e.g., thermo-luminescent dosimeter (TLD) or optically-stimulated luminescence (OSL) monitors changed out monthly or quarterly) and active (e.g., energy-compensated Geiger-Mueller (G-M) detector systems with local and remote monitoring capability) monitoring systems located at points in the controlled area that would provide reasonable assurance that radiation areas are not present in the controlled area. The selection of specific instrumentation, range of detection, and alert/alarm setpoints will be consistent with the intent to detect radiation areas where they should not be and alert personnel to this changing condition.
11.2-1b	November 28, 2016 ML16344A053	An official charter describing the authority, duties, and responsibilities of personnel in the waste management organization will be described in the FSAR as part of the Operating License Application.
11.2-5a	November 28, 2016 ML16344A053	The estimates for the laboratory facilities or facility support waste volume projections in PSAR Chapter 19.0, Table 19-13, have no definitive basis and will be further defined in the NWMI Operating License Application.
11.3-1a	November 28, 2016 ML16344A053	Details of how the Irradiated Target Receipt Area will transition between ventilation Zones II and III during operating/maintenance activities will be provided in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
11.3-2a	November 28, 2016 ML16344A053	The RPF preliminary design of ventilation and containment systems was developed to ensure the sufficiency of the principal design criteria, design bases, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. The final facility design of the ventilation and confinement system will be described in the FSAR as part of the Operating License Application.
11.3-2b	November 28, 2016 ML16344A053	The RPF preliminary design of ventilation and containment systems was developed to ensure the sufficiency of the principal design criteria, design bases, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. The final facility design of the ventilation and confinement system will be described in the FSAR as part of the Operating License Application.
11.3-3	November 28, 2016 ML16344A053	The detailed ventilation system criteria, including minimum flow velocity at openings in each zone, maximum differential pressure across filters, and types of filters to be used (e.g. HEPA, high-efficiency gas adsorption [HEGA]), will be provided in the FSAR as part of the Operating License Application.
13.2-4	November 28, 2016 ML16344A053	The third accident scenario in PSAR Section 13.2.2 is a spill of molybdenum-99 (^{99}Mo) product during container loading operations. This scenario will be reevaluated in the Operating [License] Application. The current scenario assumes three to four times the curie content of a shipping cask and does not take in to account the inner container that would also reduce or eliminate the spill. Operating staff dose estimates and worker stay time (if needed) for accident scenarios will be provided in the FSAR as part of the Operating [License] Application.
13.2-5	November 28, 2016 ML16344A053	Loss of power was identified as an initiating event in numerous RPF accident sequences. NWMI concluded that no additional radiological accidents were present beyond what was identified in the hazard analysis and the quantitative risk analysis. No additional IROFS were identified from loss of power. The summary of radiological consequences from the analysis of other accidents where loss of power was an initiator will be provided in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
13.2-6	November 28, 2016 ML16344A053	Dose consequences were not determined for the RPF natural phenomena events. Using integrated safety analysis (ISA) methodology and since the IROFS and RPF processing areas are designed to withstand design-basis events (DBEs) (highly unlikely events), off-site dose calculation[s] were not completed for the Construction Permit Application. The worker dose estimates for a seismic event during target cask unloading will be developed and provided in the FSAR as part of the Operating License Application.
13.2-8b	November 28, 2016 ML16344A053	The process hazard analysis (PHA) tables for the RPF molybdenum system and waste handling will be updated for hazards associated with the molybdenum resin as part of the ongoing ISA process and will be reflected in the [Operating License Application]. Hazards/accidents will include changing temperature, flow and acid conditions, and their impacts on the anion resin.
13.2-9a	November 28, 2016 ML16344A053	The technical specification[s] will define modes and limiting conditions for operation (and maintenance). As suggested in the RAI, maintenance activities (e.g., removing a cover block to replace a piece of failed equipment) could change the configuration of the facility. For these situations, limits on operations activities or acceptable inventories will be defined and implemented.
13.2-9b	November 28, 2016 ML16344A053	The technical specification[s] will define modes and limiting conditions for operation (and maintenance). As suggested in the RAI, maintenance activities (e.g., removing a cover block to replace a piece of failed equipment) could change the configuration of the facility. For these situations, limits on operations activities or acceptable inventories will be defined and implemented.
13.2-10	November 28, 2016 ML16344A053	General RPF design features intended to prevent/mitigate a nitric acid fume release include RPF building containment and nitric acid storage tank construction and venting. Specific features will be addressed in the FSAR as part of the Operating License Application.
13.3-1b	November 28, 2016 ML16344A053	Detailed RPF accident scenarios for chemical hazards will be developed, analyzed, and documented in the FSAR as part of the Operating License Application
13.3-2	November 28, 2016 ML16344A053	Specific chemical safety accidents will be developed, analyzed, and documented in the FSAR as part of the Operating License Application, along with identification of relevant technical specifications.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
14.0-1	November 28, 2016 ML16344A053	Technical specifications on items involved with preventing release of radioactive materials routinely or in the event of an accident are planned for inclusion in sections that address limiting conditions of operation and surveillance/maintenance in the FSAR as part of the Operating License Application.
12A-3	April 28, 2017 ML17128A065	The individuals who fill the 24-hour on-shift staff positions designated and trained to perform the initial responsibilities of the Emergency Director, Emergency Coordinator, Radiation Safety Officer, and Radiological Assessment Team, until these positions are filled by responding emergency personnel, will be developed and submitted as part of the NWMI Operating License Application.
12A-8	April 28, 2017 ML17128A065	Effluent monitors used to project dose rates and radiological effluent releases and any associated setpoints for such systems will be identified in the NWMI Operating License Application. The manufacturer, detection methodology, and (therefore) instrument setpoints will also be identified in the Operating License Application.
12A-9b	April 28, 2017 ML17128A065	PSAR Chapter 12.0, Appendix A, Table A-1, will be amended such that the emergency action levels (EALs) for each emergency class are consistent with that found in ANSI/ANS 15.16.
12A-9c	April 28, 2017 ML17128A065	PSAR Chapter 12.0, Appendix A, Table A-1, will be amended such that the EALs for each emergency class are consistent with that found in ANSI/ANS 15.16.
6.3-17a	April 28, 2017 ML17128A067	For systems that are outside the validation AoA, an increased MoS may be warranted, depending on the specific problem being analyzed. The analyst will document any extrapolation beyond the validation AoA in the calculation and justify whether an increase to the MoS is or is not required.
6.3-17b	April 28, 2017 ML17128A067	NWMI will continue to develop its computer code validation described in NWMI-2014-RPT-006 prior to the facility final design phase and submission of the Operating License Application.
9.7-4a	April 28, 2017 ML17128A067	The PSAR, Table 3-3, calls out Regulatory Guide 3.10, *Liquid Waste Treatment System Design Guide for Plutonium Processing and Fuel Fabrication Plants,* as an appropriate design guide. As part of final design, NWMI will evaluate the need for use of Regulatory Guide 1.143, *Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants.*

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
6.3-19	September 28, 2017	Prior to end of construction and with the submittal of the Operating License Application, NWMI will ensure that all processes containing SNM within the RPF are evaluated to be subcritical under all normal and credible abnormal conditions. The evaluation will be done consistent with the upper subcritical limit (USL) as established in NWMI-2014-RPT-006, *MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections* (Revision 2). Parameters available for nuclear criticality safety (NCS) controls include mass, geometry, density, enrichment, reflection, moderation, concentration, interaction, absorption, volume, heterogeneity, physicochemical form, and process variables. Of these parameters, NWMI will use controls for mass, geometry, moderation, volume, and interaction. NWMI commits to evaluate controlled parameters at the associated safety limits (or more conservatively) and to evaluate parameters that are not controlled at the most reactive credible values. In addition, NWMI acknowledges that the use of a single NCS control to maintain the values of two or more controlled parameters constitutes only one component necessary to meet the double-contingency principle. NWMI will make every effort to use passive engineered controls, in particular, passive engineered geometry control. In addition, NWMI will strive to use NCS controls over reliance on the natural and credible course of events and will use control of two or more parameters over multiple controls on a single parameter, where possible. If the RPF operations rely on two or more controls on a single parameter, NWMI commits to using diverse over-redundant means of control.

A.3 Fulfilled Regulatory Commitments Identified in Responses to Requests for Additional Information

NWMI has fulfilled the following regulatory commitments initially identified in responses to RAIs, as verified by the staff:

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.5-1	April 25, 2016 ML16123A119	The Chapter 3.0 bullet in question, located in both referenced sections, Sections 3.5.1.3.1 and 3.5.2.2: • Ensure the potential for an inadvertent criticality accident is not credible will be changed to delete the "not credible" language.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
6.3-6A	April 25, 2016 ML16123A119	NWMI will provide analysis for CAAS coverage in all areas where special nuclear material (SNM) is handled, processed, or stored. PSAR Section 3.5.2.7.7 will be revised to be consistent with this approach.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
6.4-1	April 25, 2016 ML16123A119	NWMI commits to the following standards and guides: • ANSI/ANS-8.1, *Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors* - NCS practices, including administrative practices, technical practices, and validation of a calculational method • ANSI/ANS-8.3, *Criticality Accident Alarm System* - CAAS placement analysis and procedure development; the standard is used as modified by NRC Regulatory Guide 3.71, *Nuclear Criticality* • *Safety Standards for Fuels and Material Facilities* • ANSI/ANS-8.19, *Administrative Practices for Nuclear Criticality Safety* - NWMI NCS program	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 6, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
		development as it applies to organization, administration, roles, and responsibilities • ANSI/ANS-8.20, *Nuclear Criticality Safety Training* - NCS staff and contractor qualification and training procedure development • ANSI/ANS-8.24, *Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations* - Validation of a calculational method • NUREG-1520, *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility* - Guidance for meeting 10 CFR 70.61, “Performance Requirements" • NUREG/CR-4604, *Statistical Methods for Nuclear Material Management* - Guidance for normality testing of the data from critical experiment calculations • NUREG/CR-6698, *Guide for Validation of Nuclear Criticality Safety Calculational Methodology* - Guidance for validation of a calculational method Chapters 3.0 and 6.0 of the CPA (NWMI-2013-021) will be verified and/or modified to reflect these commitments.	

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
G-3	November 28, 2016 ML16344A053	Based on the response to RAI G-3, PSAR Section 13.2, "Analysis of Accidents with Radiological and Criticality Safety Consequences" will be revised to be consistent with the requirements of 10 CFR 70.61, and the maximum hypothetical accident (MHA) discussion in PSAR Section 13.2.1 will be deleted.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).
G-4	November 28, 2016 ML16344A053	SSCs will be designed to protect against both high and [intermediate] consequences. PSAR Section 3.5.1.3.1 described both the high and the [intermediate] consequence performance requirements from 10 CFR 70.61. To eliminate confusion and ensure completeness, these bullets were removed from PSAR Section 3.5.1.3, and the 10 CFR 70.61 performance requirements are referenced.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
2.2-1a	November 28, 2016 ML16344A053	Information related to aircraft crash impact frequencies will be added to PSAR Section 2.2.2.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).
2.2-1b	November 28, 2016 ML16344A053	PSAR Section 2.2.2.1 had a typographical error. 10.4 km (6.5 mi) is the correct distance from the Columbia Regional Airport to the RPF site, based on Google Earth measurements, and 10.4 km (6.5 mi) is the distance used in the associated calculations. The stated distance of 10.5 km will be changed to 10.4 km (6.5 mi) in PSAR Section 2.2.2.1.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
2.3-1	November 28, 2016 ML16344A053	The boundary of the "controlled area" described in PSAR Chapters 11.0 and 13.0 is the same as the "exclusion area boundary." PSAR Chapters 2.0, 11.0, and 13.0 will be updated to use the same terminology when referring to the "exclusion area boundary."	Partially incorporated into PSAR Chapter 2, Revision 2, Chapter 11, Revision 1, and Chapter 13, Revision 2 (ML17221A370). PSAR Chapter 13, page 13-52, uses “controlled area or exclusion area boundary,” without being clear that these are the same thing.
2.3-2a	November 28, 2016 ML16344A053	The seasonal and annual frequencies of tornadoes, thunderstorms, [lightning], and hail will be added to PSAR Section 2.3.1.7.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).
2.3-2b	November 28, 2016 ML16344A053	A table of winter weather events since 1996 in Boone County, Missouri will be added to PSAR Section 3.2.5.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370). NWMI added the information to PSAR Section 2.3.1.7 instead of PSAR Section 3.2.5.
2.5-4	November 28, 2016 ML16344A053	PSAR Chapter 2.0, Table 2-28, will be revised to incorporate earthquakes since 2002 with a magnitude over 3.0.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370). Table 2-28 was renumbered to Table 2-41.
2.5-5	November 28, 2016 ML16344A053	The 2009 International Building Code (IBC) reference callouts in PSAR Chapter 2.0 will be changed to 2012.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).
2.5-8	November 28, 2016 ML16344A053	Reference to the Boone County site as being soil Class D in PSAR Chapter 2.0, Section 2.5.6 will be changed to Class C.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.2-2	November 28, 2016 ML16344A053	The PSAR, including Section 3.2.4.2 and all appropriate supporting documentation, will be modified to state that Regulatory Guide 1.76, *Design Basis Tornado and Tornado Missiles for Nuclear Power Plants,* will be the basis for tornado wind loads and wind-generated missiles.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
3.3-1	November 28, 2016 ML16344A053	PSAR Sections 3.3.1 and 3.3.1.1 will be modified to point to PSAR Section 2.4.3 (instead of PSAR section 2.5.3) for flood information.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
3.4-2a	November 28, 2016 ML16344A053	Table 3-22 will be deleted from PSAR Section [3.4.1.1]. In addition, Regulatory Guide 1.60 will be added to PSAR Section 3.4.1.1 for the determination of the RPF design response spectra. The seismic soil classification for the RPF site is Class C. Thus, the reference to the Boone County site as being soil Class D in PSAR Section 2.5.6 will be changed to Class C. PSAR Section 2.5.6 will be modified to reflect the above information.	Incorporated into PSAR Chapter 2, Revision 2, and Chapter 3, Revision 2 (ML17221A370).
3.4-3	November 28, 2016 ML16344A053	Table 3-22 will be deleted from PSAR Section [3.4.1.1]. In addition, Regulatory Guide 1.60 will be added to PSAR Section 3.4.1.1 for the determination of the RPF design response spectra. The seismic soil classification for the RPF site is Class C. Thus, the reference to the Boone County site as being soil Class D in PSAR Section 2.5.6 will be changed to Class C. PSAR Section 2.5.6 will be modified to reflect the above information.	Incorporated into PSAR Chapter 2, Revision 2, and Chapter 3, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.5-2	November 28, 2016 ML16344A053	NWMI is using the 10 CFR 70.61 performance requirement for subcriticality. PSAR Section 3.5.1.3 was revised to reflect this, the bullets listing criteria for safety-related SSCs were removed, and 10 CFR 70.61 performance requirements/criteria are referenced.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
3.5-3a	November 28, 2016 ML16344A053	NWMI has revised its Quality Assurance (QA) Plan to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was modified to reflect the changes in the quality level definitions.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370).
3.5-3b	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2.	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
3.5-3c	November 28, 2016 ML16344A053	PSAR Chapter 3.0, Table 3-25, has been modified to match the changes in the NWMI QA Plan.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370). Table 3-25 has been renumbered to Table 3-24.
3.5-3d	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was modified to reflect the changes in the quality level definitions.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370).
3.5-4a	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Chapter 3.0, Table 3-25, was updated to reflect the changes in the quality level definitions.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). Table 3-25 has been renumbered to Table 3-24.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.5-4b	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was revised to change the definition of non-safety-related SSCs, and PSAR Chapter 3.0, Table 3-25, was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of non-safety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.
3.5-4c	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was revised to change the definitions and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). Table 3-25 has been renumbered to Table 3-24.
3.5-5a	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 has been revised to charge the definition of non-safety-related SSCs, and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of non-safety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.
3.5-5b	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 has been revised to charge the definition of non-safety-related SSCs, and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of non-safety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.5-5c	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 has been revised to charge the definition of non-safety-related SSCs, and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of non-safety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.
3.5-5d	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 has been revised to charge the definition of non-safety-related SSCs, and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of non-safety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.
3.5-6	November 28, 2016 ML16344A053	The first sentence in PSAR section 3.5.2, which pointed to PSAR Section 3.4.1 will be changed to PSAR Section 3.5.1.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
7.1-3	November 28, 2016 ML16344A053	To be consistent in the PSAR, terms like "operator interface displays" and "operator interface terminals" will be replaced with the single term, HMI (e.g., pages 7-i, 7-iv, 7-4, 7-15, 7-17, 7-18, 7-20, and 7-21).	Partially incorporated into PSAR Chapter 7, Revision 2 (ML17221A370). “Operator interface workstations” used 4 times in Table 7-2 (pages 7-18 and 7-21). “Two or three operator interface stations or HMIs” used on page 7-46 without making clear that these are the same thing.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
7.2-2	November 28, 2016 ML16344A053	PSAR Section 7.1 states, "Engineered safety feature (ESF) systems will operate independently from the FPC system or BMS [building management system]." This sentence will be amended in future versions of the PSAR to say, "Engineered safety feature (ESF) systems will operate upon actuation of an alarm setpoint reached for a specific monitoring instrument/device. For redundancy, this will be in addition to the FPC system or BMS ability [to] actuate ESF as needed." By amending this sentence, the descriptions in PSAR Sections 7.2.4.2.2 and 7.2.4.2.6 will be consistent with Section 7.1.	Incorporated into PSAR Chapter 7, Revision 2 (ML17221A370).
8.2-1	November 28, 2016 ML16344A053	PSAR Section 8.1.2 and 8.2 values for uninterruptable power supply (UPS) operation time were changed to 120 minutes to reflect the design basis in PSAR Section 3.5.2.7.9.	Incorporated into PSAR Chapter 8, Revision 2 (ML17221A370).
8.2-2	November 28, 2016 ML16344A053	The column headings in Table 8-1 of PSAR Chapter 8.0 were changed from "... power requirement" to "...peak power load" to be consistent with the description preceding the table. PSAR Section 8.2.2 will be modified to reflect the peak power of 1,178.6 kW (1,585 hp), as determined from Table 8-1.	Partially incorporated into PSAR Chapter 8, Revision 2 (ML17221A370). Section 8.2.2 was updated, however, Section 8.2 still reflects previous value of 1,000 kW.
9.1-1	November 28, 2016 ML16344A053	PSAR Section 9.1 will be modified to clarify terminology and to correct the apparent discrepancies noted in RAI 9.1-1. The bulleted items in PSAR Section 9.1 will be deleted, and the design basis description in Section 9.1.1 will be modified to cross-reference to PSAR Section 3.5.2.7.12 and to PSAR Chapter 6.0. References to "ventilation system" in PSAR Section 9.1 will be amended to read "facility ventilation system."	Partially incorporated into PSAR Chapter 9, Revision 1 (ML17193A418). Section 9.1.1 references PSAR Section 3.5.7.2, not 3.5.2.7.12 (there is no 3.5.7.2). Not all references to “ventilation system” corrected.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
9.1-2	November 28, 2016 ML16344A053	PSAR Section 9.1 will be modified to clarify terminology and to correct the apparent discrepancies noted in RAI 9.1-2. The bulleted items in PSAR Section 9.1 will be deleted. The design basis description in PSAR Section 9.1.1 will be modified to cross-reference to PSAR Section 3.5.2.7.11 and to PSAR Chapter 6.0. References to "offgas treatment system" in PSAR Section 9.1 will be amended to read "process vessel ventilation system."	Partially incorporated into PSAR Chapter 9, Revision 1 (ML17193A418). Section 9.1.1 references PSAR Section 3.5.7.2, not 3.5.2.7.11 (there is no 3.5.7.2). Not all references to “offgas treatment system” corrected.
9.1-3	November 28, 2016 ML16344A053	PSAR Section 9.1 will be modified to clarify terminology and to correct the apparent discrepancies noted in RAI 9.1-3. The bulleted items in PSAR Section 9.1 will be deleted, and the design basis description in PSAR Section 9.1.1 will be modified to cross-reference to PSAR Section 3.5.2.5.12 and to PSAR Chapter 6.0. References to "ventilation system" in PSAR Section 9.1 will be amended to read "facility ventilation system." The supply air is a subsystem of the facility ventilation system. PSAR Section 3.5.2.7.23, "Supply Air System," will be eliminated and appropriate design basis values moved to PSAR Section 3.5.2.7.12, "Facility Ventilation."	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 9, Revision 1 (ML17221A370 and ML17193A418). Section 9.1.1 references PSAR Section 3.5.7.2, not 3.5.2.7.12 (there is no 3.5.7.2). Not all references to “ventilation system” corrected.
9.1-4	November 28, 2016 ML16344A053	The bulleted items in PSAR Section 9.1 will be deleted, and the design basis description in PSAR Section 9.1.1 will be modified to cross-reference to PSAR Section 3.5.2.7.12 and Chapter 6.0.	Partially incorporated into PSAR Chapter 9, Revision 1 (ML17193A418). Section 9.1.1 references PSAR Section 3.5.7.2, not 3.5.2.7.12 (there is no 3.5.7.2).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
9.4-1	November 28, 2016 ML16344A053	PSAR Section 9.4.1 will be modified, and the sentence, "Additional information on the communications system design basis is provided in PSAR Chapter 3.0.," will be deleted, in order to address the information gap regarding the communication system design basis.	Incorporated into PSAR Chapter 9, Revision 1 (ML17193A418).
9.7-1a	November 28, 2016 ML16344A053	PSAR Sections 3.5.2.7 and 9.7 will be aligned with each other to enhance clarity and resolve discrepancies. The design basis bullets in PSAR Section 9.7.1.1 will be deleted, and the design basis description in PSAR Section 9.7.1 will be modified to cross-reference to the appropriate subsection of PSAR Section 3.5.2.7. Subsequent information in PSAR Section 9.7 will focus on the description of systems and components that satisfy the design basis functions.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 9, Revision 1 (ML17221A370 and ML17193A418). Section 9.7.1 references PSAR Section 3.5.2.7, not a subsection of 3.5.2.7, and it is not clear which subsection(s) are applicable.
9.7-1b	November 28, 2016 ML16344A053	The design basis description in PSAR Section 9.7.1 will be modified to cross-reference to the appropriate subsection of PSAR Section 3.5. Subsequent information in PSAR Section 9.7 will focus on the description of systems and components that satisfy the design basis functions.	Partially incorporated into PSAR Chapter 9, Revision 1 (ML17193A418). Section 9.7.1 references PSAR Section 3.5.2.7, not a subsection of 3.5.2.7, and it is not clear which subsection(s) are applicable.
9.7-2	November 28, 2016 ML16344A053	PSAR Sections 3.5.2.7 and 9.7 will be revised to enhance clarity and resolve discrepancies. The RPF system and subsystem designations will be used to align the utility systems. The design basis bullets in PSAR Section 9.7.1.1 will be deleted.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 9, Revision 1 (ML17221A370 and ML17193A418).
11.1-5	November 28, 2016 ML16344A053	The MHA is being deleted from the PSAR, consistent with the response to RAI G-3.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).

11.2-1a	November 28, 2016 ML16344A053	The Waste Management Lead (not the Radiation Protection Manager) has responsibility for oversight, handling, and disposal of radioactive wastes. PSAR Section 11.1.2.1.3 will be modified to delete "overseeing handling and disposal of radioactive wastes" from the description of the responsibilities of the Radiation Protection Manager; this information will be added to PSAR Section 11.2.1.3.2. Radioactive waste management responsibilities within the NWMI management structure include: • Implements waste management policy • Develops waste management procedures for the processing, packaging, and shipment of radioactive waste from the facility • Processes, packages, and ships radioactive waste from the facility • Provides technical input to the design of equipment and processes • Provides technical input to the waste management training program • Establishes and maintains contractual relationships with waste disposal sites and radioactive waste carriers • Maintains working knowledge of the waste acceptance criteria, standards, guides, and codes with respect to waste disposal • Conducts self-assessments of waste management practices and compliance with procedures in accordance with the waste management self-assessment program	Incorporated into PSAR Chapter 11, Revision 1 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
		These responsibilities will be added to PSAR Section 11.2.1.3.2.	
11.2-5a	November 28, 2016 ML16344A053	The estimated facility support waste values in Table 19-13 will be added to PSAR Chapter 11.0, Table 11-6.	Incorporated into PSAR Chapter 11, Revision 1 (ML17221A370).
12C.2.2-1	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was modified to reflect the changes in quality level definitions.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370).
13.2-2	November 28, 2016 ML16344A053	The MHA discussion in PSAR Section 13.2.1 will be removed from the PSAR, consistent with the response to RAI G-3.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).
13.2-3	November 28, 2016 ML16344A053	The data in Figure 13-2 of PSAR Section 13.2.1 is in units of total effective dose equivalent (TEDE). The labels on the figure will be corrected.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).
13.2-4	November 28, 2016 ML16344A053	In the Construction Permit Application, NWMI originally used both the Radiological Assessment System for Consequence Analysis (RASCAL) and Radiological Safety Analysis Code (RSAC) to model off-site accident consequences. Since the submission of the application, NWMI has selected RSAC for off-site accident consequence modeling. For the liquid spills and spray accident in PSAR Section 13.2.2, NWMI has rerun the off-site dose calculations using RSAC. The nearest permanent resident (432 m [0.27 mi] away) unmitigated dose estimate is 300 mrem, while the maximum receptor location (1,100 m [0.68 mi] away) has a TEDE of 1.8 rem.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
13.2-7	November 28, 2016 ML16344A053	RSAC has been selected as the model platform for all accident release and dose calculations for the RPF. The accidents described in PSAR Section 13.2.2.2 have been reevaluated using RSAC (instead of RASCAL). The maximum dose to the public occurs at a distance of 1,100 m (0.68 mi).	Partially incorporated into PSAR Chapter 13, Revision 2 (ML17221A370). The uranium separations feed spray release accident is still only evaluated using RASCAL, not RSAC. NWMI states in PSAR Section 13.2.2.7.2 that the uranium feed modeling will be rerun using RSAC as part of the operating license application.

<table>
<tr>
<td>14.0-1</td>
<td>November 28, 2016
ML16344A053</td>
<td>The variables or conditions in the table below are probable subjects of technical specifications based on their involvement with preventing release of radioactive materials routinely or in the event of an accident. This table will be added to the PSAR Chapter 14.0.
<table>
<tr><th>Item or variable</th><th>Reason</th></tr>
<tr><td>Uranium mass limits on batches, samples, and approved containers[a]</td><td>Criticality control</td></tr>
<tr><td>Spacing requirements on targets and containers with SNM[a]</td><td>Criticality control</td></tr>
<tr><td>Floor and sump designs[a]</td><td>Criticality control</td></tr>
<tr><td>Hot cell liquid confinement[a]</td><td>Criticality control</td></tr>
<tr><td>Process tank size and spacing[a]</td><td>Criticality control</td></tr>
<tr><td>Evaporator condensate monitor</td><td>Criticality control</td></tr>
<tr><td>Criticality monitoring system</td><td>Criticality control</td></tr>
<tr><td>In-line uranium content monitoring</td><td>Criticality control</td></tr>
<tr><td>Air pressure differential between zones[a]</td><td>Control of airborne RAM</td></tr>
<tr><td>Ventilation system filtration[a]</td><td>Control of airborne RAM</td></tr>
<tr><td>Process offgas subsystem</td><td>Control of airborne RAM</td></tr>
</table>
</td>
<td>Incorporated into PSAR Chapter 14, Revision 1 (ML17221A370).</td>
</tr>
</table>

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
		Primary offgas relief system — Control of airborne RAM **Hot cell shield thickness and integrity**[a] — Occupation and general public dose reduction **Hot cell secondary confinement boundary**[a] — Control of airborne RAM **Double-wall piping** — Control of liquid RAM/criticality control **Process closed heating and cooling loops** — Control of both airborne and liquid RAM **System backflow prevention devices** — Control of liquid RAM/criticality control **Stack height**[a] — Control of airborne RAM **Area radiation monitoring system** — Occupation and general public dose reduction [a] Items that will significantly influence the final design. RAM = radioactive material, SNM = special nuclear material	
12A-1a	April 28, 2017 ML17128A065	A legible figure of the proposed Northwest Medical Isotopes, LLC (NWMI) Radioisotope Production Facility (RPF) will replace Figure A-3 in NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility,* Chapter 12.0, "Conduct of Operations," Appendix A, "Emergency Response Plan."	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
12A-2b	April 28, 2017 ML17128A065	The listing of the Missouri Office of Emergency Coordination as the primary contact for radiological emergencies is in error. The Missouri Office of Emergency Coordination will be replaced with the Missouri State Emergency Management Agency in Section A3.1.2 of PSAR Chapter 12.0, Appendix A.	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
12A-2c	April 28, 2017 ML17128A065	The Missouri State Emergency Management Agency has responsibility for the State's formal radiological emergency preparedness program. Sections A3.1.2 and A3.3.3 of PSAR Chapter 12.0, Appendix A, will be updated to include the responsibility of this agency.	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
12A-4	April 28, 2017 ML17128A065	The following sentence will be added to the first paragraphs of PSAR Chapter 12.0, Appendix A, Sections A4.2 and A4.3, "The appropriate off-site agency described in Section A3.1 (depending on the nature of the emergency), should be notified within 15 minutes of the emergency being declared. Notification shall be made to the NRC Operations Center as soon as is reasonably possible, but no later than one hour after the declared emergency."	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
12A-5	April 28, 2017 ML17128A065	The eighth bullet under the responsibilities of the Emergency Director will be deleted in PSAR Chapter 12.0, Appendix A, Section A3.3.2. Authorization for reentry after an evacuation will rest with the Emergency Coordinator only.	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
12A-6a	April 28, 2017 ML17128A065	In PSAR Chapter 12.0, Appendix A, Section A3.3.1, a second paragraph will be added to read, "The Safety, Security and Emergency Preparedness Manager will have organizational responsibility for maintenance and implementation of an emergency preparedness program, including this plan, for facility equipment and personnel, including the scheduling and performance of equipment maintenance, personnel training, coordination with off-site support organizations, and drills associated with the emergency plan." The last three bullets in Section A3.3.2 under the responsibilities of the Emergency Coordinator will be deleted. The first item in Section A10.1 will be amended to read, "Initial and annual retraining will be conducted for emergency response personnel to maintain the ability to perform their assigned functions during an emergency event." The third item in Section A10.1 will be amended to read, "Training will also include, as appropriate, information on the use of protective equipment, protective clothing, and monitoring devices used in emergency response relevant to the personnel listed above. Initial training on the emergency plan should nominally take two hours and annual retraining should take one hour to perform."	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).

12A-7	April 28, 2017 ML17128A065	Item one of PSAR Chapter 12.0, Appendix A, Section A10.2, will be amended to read, "Annual on-site emergency drills will be conducted as action drills, with each required emergency measure being executed as realistically as is reasonably possible. Drills should be conducted such that: • Qualified individuals for each position in the emergency response organization demonstrate task-related knowledge through periodic participation. • Emergency drills demonstrate that resources are effective and used to control the site, mitigate further damage, control radiological releases, perform required on-site activities under simulated radiation or airborne and other emergency conditions, accurately assess the facility's status during an accident, and initiate recovery. • Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue, and other similar events. • Emergency drills demonstrate that on-site communications effectively support emergency response activities. • Emergency drills demonstrate that the emergency public information organization disseminates accurate,	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
		reliable, timely, and understandable information." The following will be added to Section A10.4.2(1.), "The ability to communicat[e] with off-site responding agencies shall be checked quarterly."	
12A-9a	April 28, 2017 ML17128A065	The PSAR, Chapter 13.0, as amended, shows that the maximum dose to the general public will not reach the emergency action levels defined for a Site Area Emergency or a General Emergency. Therefore, PSAR Chapter 12.0, Appendix A, Section A4.4 and A4.5, will be amended to read, "This class of emergency is not credible for the [RPF] because the doses predicted in Chapter 13.0 do not exceed the action levels specified for this emergency in ANSI/ANS 15.16, *Emergency Planning for Research Reactors."* The references to these two emergency classification[s] will also be removed from PSAR Chapter 12.0, Appendix A, Table A-1.	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
3.5-10d	April 28, 2017 ML17128A067	There is an error in PSAR Table 3-25. Since part of the process steam system, the in-cell secondary steam loops, has criticality controls, the system should be assigned as QL-1, not QL-2.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370). Table3-25 has been renumbered to Table 3-24.
9.7-3a	April 28, 2017 ML17128A067	The PSAR, Section 9.7.2, was rewritten to address the items listed in RAI 9.7-3a. The operational processing capabilities align with the PSAR, Section 4.1.2.1, "Process Design Basis."	Incorporated into PSAR Chapter 9, Revision 1 (ML17193A418).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
9.7-3b	April 28, 2017 ML17128A067	The PSAR, Section 9.7.2, was rewritten to address key elements of these requests for additional information (RAI). The inputs to the high-dose waste collection tank are batch transfers. The inputs must be sampled before transferring to the non-criticality safe, high-dose waste collection tank. The high-dose collection tank can be "isolated" (i.e., no incoming waste, agitated, and sampled when needed). Similarly, the high-dose concentrate tank is filled in a batch manner from the high-dose waste concentrator, agitated, and sampled prior to transfer to the solidification process.	Incorporated into PSAR Chapter 9, Revision 1 (ML17193A418).
9.7-4b	April 28, 2017 ML17128A067	The PSAR, Section 9.7.2, was rewritten to address key elements of these requests for additional information (RAI). The inputs to the high-dose waste collection tank are batch transfers. The inputs must be sampled before transferring to the non-criticality safe, high-dose waste collection tank. The high-dose collection tank can be "isolated" (i.e., no incoming waste, agitated, and sampled when needed). Similarly, the high-dose concentrate tank is filled in a batch manner from the high-dose waste concentrator, agitated, and sampled prior to transfer to the solidification process.	Incorporated into PSAR Chapter 9, Revision 1 (ML17193A418).

A.4 Regulatory Commitments Identified Through Meeting with the Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee

Following meetings on June 19, July 11, August 22 – 23, and September 21, 2017, with the Advisory Committee on Reactor Safeguards (ACRS) Northwest Medical Isotopes Subcommittee, NWMI identified elements of design, analysis, and administration that require additional information to fully address the comments of the ACRS Northwest Medical Isotopes Subcommittee members. NWMI listed these items in its letters dated September 18, 2017 (Reference 63), and September 28, 2017 (Reference 65). The staff determined that the resolution of these items is not necessary for the issuance of a construction permit, but that the applicant should ensure that these items are fully addressed in the FSAR supporting an NWMI operating license application. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of an NWMI operating license application.

The following regulatory commitments, as identified by NWMI, are the responsibility of the applicant, and have not yet been fulfilled:

Date and ADAMS Accession Number for Correspondence	Description
September 18, 2017 ML17265A048	NWMI will provide an evaluation of the effects of high frequency spectral accelerations (i.e., > 10 hertz) on high-frequency sensitive structures, systems, and components during seismic events (e.g., electrical relays, instrumentation) in its FSAR.
September 18, 2017 ML17265A048	NWMI will provide details on the final grading of site, ensuring that stormwater from localized downpours will be directed around and away from the Radioisotope Production Facility (RPF), in its FSAR.
September 18, 2017 ML17265A048	NWMI will provide a final hazards analysis (FHA) for its facility as part of its FSAR. This FHA will re-examine those accident sequences that were screened out of the preliminary hazards analysis, ensuring that the FHA properly accounts for the accident sequences relevant to the final design of the facility.
September 18, 2017 ML17265A048	NWMI will provide an evaluation of the potential impacts of a uranium fire in the target manufacturing facility licensed under 10 CFR Part 70 on the RPF.
September 18, 2017 ML17265A048	NWMI will provide an evaluation the possible effects of damaged electrical equipment and resulting in possible unexpected effects of interaction between otherwise unrelated, independent, and separate circuits.
September 28, 2017 ML17283A108	NWMI will determine during RPF final design whether facility operations will use an on-site dedicated fire water supply and/or use the City of Columbia fire water supply.

Date and ADAMS Accession Number for Correspondence	Description
September 28, 2017 ML17283A108	NWMI will resolve the discrepancy in the maximum estimated precipitation for the 24-hour and 48-hour period during the RPF final design and provide the information in the operating license application.
September 28, 2017 ML17283A108	NWMI will reexamine and ensure the accuracy of its estimates for aircraft take-offs and landings at the Columbia Regional Airport and for the surrounding heliports.
September 28, 2017 ML17283A108	NWMI will provide its strategy for addressing an extended shutdown of the NWMI production facility.
September 28, 2017 ML17283A108	NWMI will further assess the need for an independent control room as part of our RPF final design.

A.5 Ongoing Research and Development

The provisions of 10 CFR 50.34(a)(8) allow for ongoing research and development to confirm the adequacy of the design of structures, systems, and components (SSCs) to resolve safety questions prior to the completion of construction. In accordance with 10 CFR 50.34(a)(8), and as described in NWMI PSAR Section 1.3.4, "Experimental Facilities and Capabilities," and in NWMI's response to RAI 13.1-2, NWMI has identified ongoing research and development activities, as described below. The staff is tracking these activities and will verify their resolution prior to the completion of construction.

Reference	Date and ADAMS Accession Number for Correspondence	Description
PSAR, Chapter 1	September 8, 2017 ML1717257A022	NWMI will be performing testing to validate the acceptable operating conditions for material and target solution compatibility at MURR and the Department of Energy (DOE) national laboratories. Selected materials will be examined following irradiation testing at fluence levels expected in the operation of the target solution vessel for a 30-year lifetime. The testing will include specific work involving irradiation in a corrosive environment to examine the effects on the properties of selected raw materials and welded samples in an as-received and as-fabricated state.
Response to RAI 13.1-2a	November 28, 2016 ML16344A053	Laboratory resin tests are being completed to determine the interactions between solutions and resin as a function of temperature. The results from these tests will help define necessary hazard and accident controls.
Response to RAI 13.1-2b	November 28, 2016 ML16344A053	Tests are being performed to confirm whether a pressure relief system is feasible to design for an ion exchange column operating at approximately 45 lb/in^2 gauge and the uranium separation process approach will continue, or if a design change to the system or implementation of additional controls/process parameters to reduce the likelihood of a reaction or change of separation technology is required.
Response to RAI 13.1-2c	November 28, 2016 ML16344A053	Tests are being performed to evaluate the release of diamylamylphosphonate (DAAP) from the ion exchange column media during operation. Swollen media beads have the potential to release DAAP from the media skeleton to other process vessels. Release of DAAP is considered an issue from both a thermal/radiolytic decomposition perspective (e.g., in concentrators) and represents a potential criticality issue if DAAP were to collect as a separate phase in a non-geometrically favorable vessel.

APPENDIX B
REFERENCES

1. Letter NWMI-LTR-2015-003, from Northwest Medical Isotopes, LLC, "Re: NRC Project No. 0803 - Northwest Medical Isotopes, LLC, Submittal Part 1 Construction Permit Application For A Radioisotope Production Facility - Withdrawal of Part 1 Application Submitted On November 7, 2014 and Resubmittal of Application," dated February 5, 2015, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15086A262, ADAMS Package No. ML15086A261.

2. Letter NWMI-LTR-2015-006, from Northwest Medical Isotopes, LLC, "Re: NRC Project No. 0803 - Northwest Medical Isotopes, LLC, Submittal Part 2 Construction Permit Application for a Radioisotope Production Facility," dated July 20, 2015, ADAMS Accession No. ML15210A114.

3. Northwest Medical Isotopes, LLC, "NRC Project No. 0803 - Northwest Medical Isotopes, LLC, Submittal Part 2 Construction Permit Application for a Radioisotope Production Facility," dated July 20, 2015, ADAMS Package Accession No. ML15210A182.

4. Letter NWMI-LTR-007 from Northwest Medical Isotopes, LLC, "Re: Request For Exemption To Submit A Construction Permit Application In Two Parts As Described In 10 CFR 2.101 By Northwest Medical Isotopes, LLC," dated August 9, 2013, ADAMS Accession No. ML13227A295.

5. Letter from U.S. Nuclear Regulatory Commission (S. Lynch), to Northwest Medical Isotopes, LLC, "Acceptance Letter for Northwest Medical Isotopes, LLC Regarding Request for Exemption from the Requirements of 10 CFR 2.101(a)," dated August 22, 2013, ADAMS Accession No. ML13238A034.

6. Letter from U.S. Nuclear Regulatory Commission, to Northwest Medical Isotopes, LLC, "Northwest Medical Isotopes, LLC – Acceptance For Docketing of Part One of The Application For Construction Permit (TAC No. MF6135)," dated June 1, 2015, ADAMS Accession No. ML15125A048.

7. Letter from U.S. Nuclear Regulatory Commission, to Northwest Medical Isotopes, LLC, "Northwest Medical Isotopes, LLC – Acceptance for Docketing of Part Two of The Application for A Production Facility Construction Permit (TAC No. MF6138)," dated December 24, 2015, ADAMS Accession No. ML15341A112.

8. NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," February 1996, ADAMS Accession No. ML042430055.

9. NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," February 1996, ADAMS Accession No. ML042430048.

10. "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," October 17, 2012, ADAMS Accession No. ML12156A069.

11. "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," October 17, 2012, ADAMS Accession No. ML12156A075.

12. Letter from U.S. Nuclear Regulatory Commission, to Northwest Medical Isotopes, LLC, "Northwest Medical Isotopes, LLC. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF6135 and MF6138) and NRC Staff Review Schedule," dated March 28, 2016, ADAMS Accession No. ML16056A122.

13. Letter from U.S. Nuclear Regulatory Commission, to Northwest Medical Isotopes, LLC, "Northwest Medical Isotopes, LLC - Request for Additional Information Regarding Application for Construction Permit (TAC No. MF6138)," dated September 29, 2016, ADAMS Accession No. ML16236A013.

14. Letter from U.S. Nuclear Regulatory Commission, to Northwest Medical Isotopes, LLC, "Northwest Medical Isotopes, LLC – Request for Additional Information for Construction Permit Application Regarding Emergency Response Plan (TAC No. MF6138)," dated January 25, 2017, ADAMS Accession No. ML17013A584.

15. Letter from U.S. Nuclear Regulatory Commission, to Northwest Medical Isotopes, LLC, "Northwest Medical Isotopes, LLC – Request For Additional Information Regarding Application For Construction Permit (TAC No. MF6138)," dated March 29, 2017, ADAMS Accession No. ML17069A408.

16. Letter NWMI-LTR-2016-006 from Northwest Medical Isotopes, LLC, to U.S. Nuclear Regulatory Commission, "RE: Docket No. 50-609. Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Environmental Request for Additional information - Letter Dated March 28, 2016," dated April 25, 2016, ADAMS Accession No. ML16123A119.

17. Letter NWMI-LTR-2016-012, from Northwest Medical Isotopes, LLC, "RE: Docket No. 50-609, Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Regarding the Preliminary Safety Analysis Report Request for Additional information (Letter dated September 29, 2016) (TAC No. MF6138)," dated November 28, 2016, ADAMS Accession No. ML16344A052, ADAMS Package No. ML16344A049.

18. NWMI-LTR-2017-001, from Northwest Medical Isotopes, LLC, "RE: Docket No. 50-609, Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Environmental Request for Additional information - Letter Dated January 25, 2017," dated March 6, 2017, ADAMS Accession No. ML17093A661

19. Letter NWMI-LTR-2017-002, from Northwest Medical Isotopes, LLC, "RE: Docket No. 50-609, Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Environmental Request for Additional information - Letter Dated January 25, 2017," dated April 28, 2017, ADAMS Accession No. ML17128A065.

20. Letter NWMI-LTR-2017-003, from Northwest Medical Isotopes, LLC, “RE: Docket No. 50-609, Northwest Medical Isotopes, LLC Response to the U.S. Nuclear Regulatory Commission Regarding the Northwest Medical Isotopes, LLC - Request for Additional Information Regarding Application for Construction Permit (Letter dated March 29, 2017) (TAC No. MF6138),” dated April 28, 2017, ADAMS Accession No. ML17128A066, ADAMS Package No. ML17128A053.

21. Advisory Committee on Reactor Safeguards, Northwest Medical Isotopes Subcommittee, “Transcript of Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee Meeting - July 11, 2017,” dated July 11, 2017, ADAMS Accession No. ML17208A865.

22. U.S. Nuclear Regulatory Commission, NUREG-2209, “Final Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility,” dated May 31, 2017, ADAMS Accession No. ML17130A862.

23. Nuclear Waste Policy Act of 1982, Public Law No. 97-425, 96 Stat. 2201, January 7, 1983.

24. U.S. Nuclear Regulatory Commission, NUREG-1520, Revision 1, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” May 2010, ADAMS Accession No. ML101390110.

25. International Atomic Energy Agency, “Consideration of External Events in the Design of Nuclear Facilities other than Nuclear Power Plants, with Emphasis on Earthquakes,” IAEA-TECDOC-1347, March 2003.

26. U.S. Nuclear Regulatory Commission, Regulatory Guide 0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [light-water reactor] Edition,” March 9, 2010, ADAMS Accession No.ML100331298.

27. U.S. Department of Energy, “Accident Analysis for Aircraft Crash into Hazardous Facilities,” DOE-STD-3014-96, October 1996, Reaffirmed May 2006.

28. Terracon, 2011, Preliminary Geotechnical Engineering Report Discovery Ridge-Certified Site Program Lots 2, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 18, Trabue, Hansen & Hinshaw, Inc. and Terracon Project No. 09105094.1, February 11, 2011.

29. American Society of Civil Engineers. “Minimum Design Loads and Associated Criteria for Buildings and Other Structures,” ASCE/SEI 7-16, 2016 Edition, Reston, VA.

30. ANSI/ANS-8.1-2014, “Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors,” American Nuclear Society, La Grange Park, Illinois, U.S.A.

31. Attachment 3 to Letter NWMI-LTR-2016-012, from Northwest Medical Isotopes, LLC, “Response to the U.S. Nuclear Regulatory Commission Request for Additional Information Regarding the Preliminary Safety Analysis Report and Environmental Review of the Northwest Medical Isotopes, LLC Construction Permit Application Docket No. 50-609 Dated: September 29, 2016 (Document No. NWMI-2016-RAI-004, November 2016) Public Version,” dated November 28, 2016, ADAMS Accession No. ML16344A053.

32. U.S. Nuclear Regulatory Commission, Regulatory Guide 3.71, Revision 2, “Nuclear Criticality Safety Standards for Fuels and Material Facilities,” December 2010, ADAMS Accession No. ML103210345.

33. ANSI/ANS-8.3-1997 (Reaffirmed in 2012), “Criticality Accident Alarm System,” American Nuclear Society, La Grange Park, Illinois, U.S.A.

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35. ANSI/ANS-8.10-2015, “Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement,” American Nuclear Society, La Grange Park, Illinois, U.S.A.

36. ANSI/ANS-8.19-2014, “Administrative Practices for Nuclear Criticality Safety,” American Nuclear Society, La Grange Park, Illinois, U.S.A.

37 ANSI/ANS-8.20-1991 (Reaffirmed in 2015), “Nuclear Criticality Safety Training,” American Nuclear Society, La Grange Park, Illinois, U.S.A.

38. ANSI/ANS-8.22-1997 (Reaffirmed in 2016), “Nuclear Criticality Safety Based on Limiting and Controlling Moderators,” American Nuclear Society, La Grange Park, Illinois, U.S.A.

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43. ANSI/ANS-15.1-2007 (Reaffirmed in 2013), “The Development of Technical Specifications for Research Reactors.”

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APPENDIX C
PRINCIPAL CONTRIBUTORS

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Atchison, John	6, 13	Mechanical Engineering and Accident Analysis
Balazik, Michael	1, 14	Project Management
Barss, Daniel	12	Emergency Preparedness
Bland, J. Stewart	9, 11	Waste Management
Dusaniwskyj, Michael	15	Financial Qualifications
Helvenston, Edward	11	Radiation Protection
Gitnick, Mary T.		Project Management
Hammelman, James	13	Chemical Safety
Hofer, Gregory	3	Mechanical Engineering
Lynch, Steven	1, 14	Project Management
McIlvaine, James	9, 11	Waste Management
Marschke, Stephen	2	Environmental Engineering
Munson, Clifford	2	Seismic
Naquin, Tyrone	11	Radiation Protection
Odar, Enver	2	Seismic
Ramirez, Annie	12	Quality Assurance
Semmes, Mollie	9	Fire Protection
Servatius, James	5, 7	Mechanical and Instrumentation and Controls
Smith, April	13	Accident Analysis
Tiktinsky, David	4	Project Management
Tripp, Christopher	6	Criticality Safety

APPENDIX D
REPORT BY THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

November 6, 2017

The Honorable Kristine L. Svinicki
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: REPORT ON THE SAFETY ASPECTS OF THE CONSTRUCTION PERMIT APPLICATION FOR NORTHWEST MEDICAL ISOTOPES, LLC, RADIOISOTOPE PRODUCTION FACILITY

Dear Chairman Svinicki:

During the 648th meeting of the Advisory Committee on Reactor Safeguards (ACRS), November 2-3, 2017, we completed our review of the construction permit application for the Northwest Medical Isotopes, LLC (NWMI) radioisotope production facility. We reviewed the preliminary safety analysis report submitted by NWMI and the draft final safety evaluation report prepared by the NRC staff. Our Subcommittee on NWMI reviewed this matter during meetings on June 19, July 11, August 22 and 23, and September 21, 2017. During these reviews, we had the benefit of discussions with representatives of the staff and NWMI. We also had the benefit of the referenced documents. This report fulfills the requirement of Section 182b of the Atomic Energy Act of 1954, as amended, that the ACRS shall review each application under Section 103 or Section 104b for a construction permit or an operating license for a facility.

RECOMMENDATIONS

NWMI has submitted a preliminary design for a facility that addresses hazards associated with the extraction of ^{99}Mo from irradiated targets and the fabrication of targets for irradiation.

- Once the design is finalized, the proposed facility can be constructed and licensed for operation with adequate protection of the public health and safety and no undue risk to the environment.

- A construction permit for the proposed radioisotope production facility can be issued to NWMI.

BACKGROUND

NWMI was organized to be a supplier of the radioisotope ^{99}Mo for use in medical procedures. NWMI proposes to construct a facility to extract ^{99}Mo from irradiated urania targets enriched initially with slightly less than 20% ^{235}U. Irradiation of these targets will take place at research reactors in Oregon, Missouri, and possibly other places.

The extraction facility NWMI proposes will be located on a 7.4 acre site within the Discovery Ridge Research Park in Columbia, Missouri near the University of Missouri. This site is about 125 miles east of Kansas City and about 125 miles west of St. Louis. There is a regional airport within 6 miles of the facility and there are nearby heliports.

The proposed facility will be used to

- receive irradiated targets from the irradiation facilities, disassemble these targets, and acid dissolve the irradiated Urania,
- extract ^{99}Mo from solution by ion exchange and prepare the purified isotope for shipment,
- recover enriched uranium from solution and fabricate irradiation targets for shipment to research reactors, and
- store, handle and ship radioactive waste.

Targets will be irradiated at the research reactors for very short periods (~150 hours), so burnup will be quite modest. Dissolution of the irradiated material in nitric acid will be facile. Gaseous effluent produced during dissolution will include hydrogen, radioactive noble gases (Xe, Kr), and gaseous iodine radioisotopes. Noble gases will be retained on carbon absorber beds. Iodine will be retained in silver-modified zeolites.

The isotope ^{99}Mo will be extracted from the solution by ion exchange. No 'red oil' issues are expected to arise.

Target fabrication is based on a process that produces small urania particles. Valence adjustment is to be done by high temperature reduction in hydrogen. Episodically, enriched uranium metal will be received at the facility, dissolved, and used to augment the inventory of recycled target material.

DISCUSSION

Internal hazards posed by the proposed facility include:

- Criticality events, especially in solutions
- Fire
- Venting of radiotoxic vapors and gases from the facility
- Pipe and tank ruptures

Most of the proposed systems in the facility will be criticality safe by geometry. Otherwise, well established, double-contingency criticality safety practices have been adopted and conservatively applied. During the course of our review, NWMI reduced its upper subcritical limit and this change may lead to changes in facility systems and structures in the finalized design.

Fire is recognized as a threat to the facility. Strategies to detect, suppress, and extinguish fires have been defined. Selection of a strategy will be a part of the final design.

The facility is to have four nested ventilation zones. This is a widely accepted configuration to limit the possibility of inadvertent, uncontrolled release of radiotoxic gases, vapors, and particles. Ventilation flows will be to a 75-foot stack. HEPA filters will be used to mitigate particulate contamination in the ventilation flows.

Pipes and tanks in the facility are to be within lined cells and pathways to retain and collect any spilled solutions. Adequate allowances have been made for foaming in dissolution tanks.

External threats to the facility include natural events and man-made hazards. Measures to limit the probability of damage by high winds, wind-driven missiles, and external floods will be made in the final facility design. The proposed facility can be constructed to withstand expected seismic loads. Some additional attention will need to be given to high frequency (>10 Hz) seismic motions that do not threaten the structural integrity of the facility, but may affect internal systems.

Aircraft impact probabilities will be reassessed as a part of the final design to show that either these probabilities are sufficiently low or that the facility is sufficiently protected from aircraft impact. Threats to the facility posed by other man-made, external hazards such as highway traffic and nearby pipelines will be reassessed during the final design of the facility.

We conclude based on our review of the documents submitted by the applicant and our review of the staff safety evaluation report that the applicant has demonstrated adequate knowledge of the potential hazards and possible accidents at the proposed facility. They have sufficient knowledge of the requirements for adequate safety of the facility. The proposed quality assurance plan submitted by NWMI for the facility construction is sound and in compliance with the pertinent requirements. Furthermore, the applicant and the staff have documented topics that arose during the staff review and our review of the construction permit application that will receive particular consideration during design finalization.
A finalized design of the proposed facility can be constructed and subsequently licensed for operation with adequate protection of the public health and safety and no undue risk to the environment. A construction permit can be issued to NWMI.

Sincerely,

/RA/

Dennis C. Bley, Chairman

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(12-2010)
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(See instructions on the reverse)

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Division of Licensing Projects
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-000

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above", if contractor, provide NRC Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address.)

Same as 8 above.

10. SUPPLEMENTARY NOTES

M. Balazik

11. ABSTRACT (200 words or less)

This safety evaluation report (SER) documents the results of the safety review conducted by the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) on the Northwest Medical Isotopes, LLC (NWMI or the applicant) application to obtain a construction permit for a production facility (NWMI production facility or facility) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," to be constructed in Columbia, Missouri. Subject to 10 CFR Part 50, the proposed production facility would receive irradiated special nuclear material (SNM), and process the SNM to produce the medical radioisotope molybdenum-99. The production facility would be part of a larger facility, which the staff refers to as the radioisotope production facility (RPF), and which would also include target fabrication activities conducted under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." Although the staff reviewed NWMI's entire application, including information related to the 10 CFR Part 70 activities, to understand the interfaces between the 10 CFR Part 50 and 10 CFR Part 70 portions of the RPF, the staff findings in this SER are limited to those required for licensing a production facility under 10 CFR Part 50.This SER presents the results of the staff's review of the NWMI construction permit application as updated on September 8, 2017, and as supplemented by the applicant's responses to requests for additional information (RAIs).

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

Northwest Medical Isotopes, NWMI, construction permit, safety evaluation report, medical production facility, radioisotope production facility, production facility.

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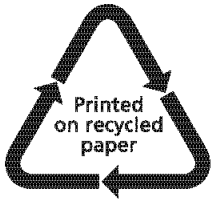

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Safety Evaluation Report
Northwest Medical Isotopes, LLC Construction Permit
Application for a Radioisotope Production Facility

May 2020