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United States Nuclear Regulatory Commission
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NUREG-2183
Supplement 1

Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility

Draft Report for Comment

Office of Nuclear Material Safety and Safeguards

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Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility

Draft Report for Comment

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Office of Nuclear Material Safety and Safeguards

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For any questions about the material in this report, please contact: Lance Rakovan, Senior Environmental Project Manager, at 301-415-2589 or by email at Lance.Rakovan@nrc.gov.

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COVER SHEET

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Cooperating Agency: U.S. Department of Energy, National Nuclear Security Administration

Title: *Environmental Impact Statement Supplement Related to the Operating License for the SHINE Medical Isotope Production Facility, Draft Report*

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ABSTRACT

In 2015, the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy, National Nuclear Security Administration (DOE-NNSA) issued NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility" (NRC 2015), which discussed the environmental impacts of constructing, operating, and decommissioning the SHINE Medical Isotope Production Facility (SHINE facility) in Janesville, Wisconsin. In 2016, at the conclusion of its safety and environmental reviews, the NRC issued a construction permit for the SHINE facility (NRC 2016). In July 2019, SHINE Medical Technologies, LLC (SHINE) submitted to the NRC an application for an operating license for the SHINE facility.

When a final environmental impact statement (FEIS) has been prepared in connection with the issuance of a construction permit for a facility, the NRC is required to prepare a supplement to the FEIS in connection with any issuance of an operating license for that facility in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 51.95(b). This supplement updates the prior environmental review and only covers matters that differ from those or that reflect significant new information relative to that discussed in the FEIS. Accordingly, in response to SHINE's operating license application, the NRC and the DOE-NNSA staff have considered whether there is any new information with respect to the environment or the environmental impacts of the SHINE facility, including information that is different from that considered in NUREG-2183. The NRC staff did not identify any information that presents a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility.

After weighing the environmental, economic, technical, and other benefits against environmental and other costs, the NRC staff's preliminary recommendation, unless safety issues mandate otherwise, is that the operating license be issued as proposed. The NRC staff based its recommendation on the following:

- the application, including SHINE's supplemental environmental report;
- consultation with Federal, State, Tribal, and local agencies;
- the staff's independent review; and
- the consideration of public comments.

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In 2015, the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy, National Nuclear Security Administration (DOE-NNSA) issued NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility" (NRC 2015), which discussed the environmental impacts of constructing, operating, and decommissioning the SHINE Medical Isotope Production Facility (SHINE facility) in Janesville, Wisconsin. In 2016, at the conclusion of its safety and environmental reviews, the NRC issued a construction permit for the SHINE facility (NRC 2016). In July 2019, SHINE Medical Technologies, LLC (SHINE, the applicant) submitted to the NRC an application for an operating license for the SHINE facility.

When a final environmental impact statement (FEIS) has been prepared in connection with the issuance of a construction permit for a facility, the NRC is required to prepare a supplement to the FEIS in connection with any issuance of an operating license for that facility in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 51.95(b). This supplement updates the prior environmental review and only covers matters that differ from those or that reflect significant new information relative to that discussed in the FEIS. Accordingly, in response to SHINE's operating license application, the NRC and the DOE-NNSA staff have considered whether there is any new information with respect to the environment or the environmental impacts of the SHINE facility, including information that is different from that considered in NUREG-2183 (NRC 2015, herein referred to as the FEIS). The NRC staff did not identify any information that presents a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility.

The SHINE facility is composed of an irradiation facility and a radioisotope production facility. The irradiation facility would consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as a utilization facility, as defined in 10 CFR 50.2. The radioisotope production facility would consist of hot cell structures, licensed collectively as one production facility, as defined in 10 CFR 50.2.

Upon acceptance of SHINE's operating license application, the NRC commenced its environmental review process in accordance with 10 CFR Part 51 by publishing in the *Federal Register* (84 FR 65424; November 27, 2019) a notice of intent to prepare a supplement to the FEIS and to conduct a scoping process. In preparation of this supplement, the NRC staff did the following:

- conducted a public scoping meeting in Janesville, Wisconsin;
- conducted a site audit;
- reviewed SHINE's application, including SHINE's supplemental environmental report;
- consulted with Federal, State, Tribal, and local agencies;
- conducted a review in accordance with 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; and Part 2, "Guidelines for Preparing and Reviewing

Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria" (NRC 2012); and

- considered the public comments received (see NRC's Scoping Summary Report for more information (NRC 2020c)).

PROPOSED FEDERAL ACTION

The NRC's proposed Federal action is to decide whether to issue an operating license to SHINE under the provisions of 10 CFR Part 50, to operate the SHINE facility for a period of 30 years. If licensed, the SHINE facility would produce radioisotopes including molybdenum-99 (Mo-99), iodine-131 (I-131), and xenon-133 (Xe-133). Operation of the SHINE facility for Mo-99 production will be accomplished in a phased manner. The phased approach will consist of four phases of process equipment installation and operation. SHINE will operate the equipment in the completed phases of the facility while process equipment installation continues for the other phases (SHINE 2022d).

The DOE-NNSA provided financial assistance for the SHINE project pursuant to the American Medical Isotopes Production Act of 2012, including, but not limited to, certain research and development and equipment procurement costs. The DOE-NNSA has not provided financial assistance for the construction or operation of the SHINE facility. If the DOE-NNSA decides to provide financial assistance for the construction or operation of the SHINE facility in the future, at that time the DOE-NNSA would review that proposal against this supplement to the FEIS and other documentation related to the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 et seq.) (NEPA), to determine if additional NEPA analysis is warranted.

PURPOSE AND NEED FOR ACTION

The purpose and need for the proposed Federal action (issuance of an operating license) is to provide an option for medical radioisotope production that could help meet the need for a domestic source of Mo-99. The decision to produce radioisotopes is at the discretion of the applicant. The NRC does not have a role in making the decision about whether a particular facility should be constructed and operated, unless there are findings in the safety review required by the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), or findings in the environmental analysis under NEPA that would cause the NRC to not issue the operating license. If the facility is licensed to operate, SHINE's bounding production of Mo-99 at a 125 kilowatts (kW) power level is up to 8,200 6-day curies (Ci) (3.034×10^{14} becquerels [Bq]). Additionally, SHINE expects to produce 2,000 Ci (7.4×10^{13} Bq) of Xe-133 and 2,000 Ci (7.4×10^{13} Bq) of I-131 per week (SHINE 2021a, 2021c).

ENVIRONMENTAL IMPACTS OF SHINE FACILITY OPERATIONS

In connection with SHINE's operating license application, the NRC is required to prepare a supplement to the FEIS (NRC 2015) in accordance with 10 CFR 51.95(b). The purpose of this supplement is to evaluate the environmental impacts of the SHINE facility, particularly with respect to any changes in the facility design, the radioisotope production process, or the environment, since the publication of the FEIS. This supplement updates information and only covers matters that differ from the FEIS or that reflect significant new information. The environmental impacts from the proposed action are designated as being SMALL, MODERATE, or LARGE.

The NRC staff considered the environmental impacts associated with alternatives to constructing the SHINE facility in Chapter 5 of the FEIS. At the conclusion of its safety and environmental reviews, the NRC issued a construction permit to SHINE on February 29, 2016. In October 2019, SHINE commenced NRC-authorized construction of the SHINE facility, consisting of the SHINE irradiation facility and radioisotope production facility, as described in the FEIS. The NRC staff considered other alternative technologies in the FEIS. No other alternative technologies are considered in this supplement.

After reviewing new and potentially significant information, the NRC staff concludes that issuing an operating license for the SHINE facility would have SMALL impacts on all resource areas and would not have impacts beyond those discussed in the FEIS. Consistent with its regulations in 10 CFR 51.95(b), the NRC staff updated the environmental review documented in the FEIS regarding SHINE's construction permit application. In this supplement, the staff discusses the new or differing information that it identified and explains that this new information does not present a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility. However, based on its subsequent review of changes in baseline environmental conditions, traffic attributable to changes in operations of the SHINE facility, and new traffic studies submitted by SHINE to the State of Wisconsin, the NRC staff determined that traffic volumes are not expected to exceed those presented in the FEIS and, thus, that the related impact determination in the FEIS should be revised. Therefore, in this supplement, the NRC staff determined that impacts on transportation infrastructure during SHINE facility operations would likely be SMALL, rather than the FEIS determination of SMALL to MODERATE.

PRELIMINARY RECOMMENDATION

After weighing the environmental, economic, technical, and other benefits against environmental and other costs, the NRC staff's preliminary recommendation, unless safety issues mandate otherwise, is that the operating license be issued as proposed. The NRC staff based its recommendation on the following:

- the application, including SHINE's supplemental environmental report;
- consultation with Federal, State, Tribal, and local agencies;
- the staff's independent review; and
- the consideration of public comments.

ABBREVIATIONS AND ACRONYMS

ac	acre(s)
ADAMS	Agencywide Documents Access and Management System
AEGL	Acute Exposure Guideline Levels
ALARA	As Low As is Reasonably Achievable
ALOHA	Areal Locations of Hazardous Atmospheres
APE	Area of Potential Effect
Bq	becquerels
BTU	British thermal units
CAS	continuous air sampler
CFR	*Code of Federal Regulations*
Ci	curies
CO	carbon monoxide
CO_2	carbon dioxide
CP	construction permit
CWA	Clean Water Act
dBA	A-weighted decibel(s)
DOE	U.S. Department of Energy
DOE-NNSA	U.S. Department of Energy – National Nuclear Security Administration
DOT	U.S. Department of Transportation
DQO	data quality objective
ECOS	Environmental Conservation Online System
EIS	environmental impact statement
EPA	U.S. Environmental Protection Agency
ER	environmental report
ERPG	Emergency Response Planning Guidelines
ESA	Endangered Species Act of 1973
FDA	Food and Drug Administration
FE	Federally endangered
FEIS	final environmental impact statement
FR	*Federal Register*
FSAR	final safety analysis report
FT	Federally threatened
ft	foot (feet)
ft^2	square foot (feet)

FWS	U.S. Fish and Wildlife Service
gal	gallon(s)
gpd	gallons per day
GTCC	greater-than-Class C
ha	hectare(s)
hr	hour(s)
IF	Irradiation Facility
km	kilometer(s)
kW	kilowatt(s)
kWh	kilowatt-hour(s)
L	liter(s)
LEU	low-enriched uranium
Lpd	liter(s) per day
m	meter(s)
m^2	square meter(s)
mg/L	milligram(s) per liter
mgd	million gallon(s) per day
MHA	maximum hypothetical accident
mi	mile
min	minute
MOA	Memorandum of Agreement
mrem	millirem
mSv	millisievert(s)
NEPA	National Environmental Policy Act of 1969
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NNSA	National Nuclear Security Administration
NO_x	nitrogen oxide
NPDES	National Pollutant Discharge Elimination System
NPUF	Non-power production or utilization facilities
NRC	U.S. Nuclear Regulatory Commission
PAC	Protective Action Criteria
PAG	Protection Action Guides

PM	particulate matter
PNNL	Pacific Northwest National Laboratory
RCA	radiologically controlled area
REMP	Radiological Environmental Monitoring Program
ROI	region of interest
RPF	radioisotope production facility
SER	Safety evaluation report
SHINE	SHINE Medical Technologies, LLC
SHPO	State Historic Preservation Office(r)
SO_2	sulfur dioxide
TEDE	total effective dose equivalent
TEEL	Temporary Emergency Exposure Limit
TIA	Traffic Impact Analysis
TOGS	Target Solution Vessel Off-Gas System
TPS	Tritium Purification System
U.S.	United States
U.S.C.	United States Code
UREX	uranium extraction
WAC	Wisconsin Administrative Code
WDNR	Wisconsin Department of Natural Resources
WHS	Wisconsin Historical Society
WI	Wisconsin
WisDOT	Wisconsin Department of Transportation

1 INTRODUCTION

In 2015, the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy, National Nuclear Security Administration (DOE-NNSA) issued NUREG-2183, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility” (NRC 2015), which discussed the environmental impacts of constructing, operating, and decommissioning the SHINE Medical Isotope Production Facility (SHINE facility) in Janesville, Wisconsin. In 2016, at the conclusion of its safety and environmental reviews, the NRC issued a construction permit for the SHINE facility (NRC 2016). In July 2019, SHINE Medical Technologies, LLC (SHINE, the applicant) submitted to the NRC an application for an operating license for the SHINE facility.

When a final environmental impact statement (FEIS) has been prepared in connection with the issuance of a construction permit for a facility, the NRC is required to prepare a supplement to the FEIS in connection with any issuance of an operating license for that facility in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 51.95(b). This supplement updates the prior environmental review and only covers matters that differ from those or that reflect significant new information relative to that discussed in NUREG-2183 (herein referred to as the FEIS). The NRC staff did not identify any information that presents a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility.

1.1 Background

By letter dated July 17, 2019, as most recently supplemented by a letter dated January 25, 2022, SHINE submitted to the NRC an application for an operating license under 10 CFR Part 50 for the SHINE facility. In accordance with 10 CFR 51.53(b), SHINE submitted a supplement to its construction permit (CP) environmental report (ER) as part of the operating license application (SHINE 2019, 2022b, 2022d). The Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), authorizes the NRC to issue operating permits for production and utilization facilities. The SHINE facility is composed of an irradiation facility and a radioisotope production facility. The irradiation facility would consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as a utilization facility, as defined in 10 CFR 50.2. The radioisotope production facility would consist of hot cell structures, licensed collectively as one production facility, as defined in 10 CFR 50.2.

To issue an operating license, the NRC is required to consider the environmental impacts of the proposed action under the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 et seq.). The NRC’s environmental protection regulations that implement NEPA are located in 10 CFR Part 51. In connection with the issuance of a construction permit (CP) to SHINE in 2016, the NRC prepared the FEIS (NUREG-2183, NRC 2015). In response to SHINE’s operating license application, the NRC is required to prepare a supplement to the FEIS in accordance with 10 CFR 51.95(b). The supplement only covers matters that differ from those or that reflect significant new information relative to that discussed in the FEIS. Significant new information is information that is both new and significant, presenting a seriously different picture of the environmental impacts of the SHINE facility.

1.2 Proposed Federal Action

The NRC's proposed Federal action is to decide whether to issue an operating license to SHINE under the provisions of 10 CFR Part 50, to operate the SHINE facility for a period of 30 years. If licensed, the SHINE facility would produce radioisotopes including molybdenum-99 (Mo-99), iodine-131 (I-131), and xenon-133 (Xe-133). Operation of the SHINE facility for Mo-99 production will be accomplished in a phased manner. The phased approach will consist of four phases of process equipment installation and operation. SHINE will operate the equipment in the completed phases of the facility while process equipment installation continues for the other phases (SHINE 2022d).

The DOE-NNSA provided financial assistance for the SHINE project pursuant to the American Medical Isotopes Production Act of 2012, including, but not limited to, certain research and development and equipment procurement costs. The DOE-NNSA has not provided financial assistance for the construction or operation of the SHINE facility. If the DOE-NNSA decides to provide financial assistance for the construction or operation of the SHINE facility in the future, at that time the DOE-NNSA would review that proposal against this supplement to the FEIS and other documentation related to NEPA to determine if additional NEPA analysis is warranted.

1.3 Purpose and Need for the Proposed Federal Action

The purpose and need for the proposed Federal action (issuance of an operating license) is to provide an option for medical radioisotope production that could help meet the need for a domestic source of Mo-99. The U.S. accounts for approximately half of the world's Mo-99 demand and relies primarily on foreign sources for its supply. Mo-99's decay product, technetium-99m (metastable) (Tc-99m), is used in over 40,000 medical procedures a day in the U.S. (DOE undated). Since the publication of the FEIS, NorthStar Medical Radioisotopes (NorthStar) became the first commercial U.S. Tc-99m producer since 1989. In 2018, the U.S. Food and Drug Administration (FDA) approved NorthStar's RadioGenix system, a Tc-99m generator platform and non-uranium-based Mo-99 production process (FDA 2018). In support of this action, in February 2018, the NRC staff issued 10 CFR Part 35 licensing guidance for medical use applicants and licensees possessing the NorthStar RadioGenix System. NorthStar then began commercial production of Tc-99m after the October 2018 issuance of an NRC safety evaluation report for its generator. NorthStar's targets, which contain molybdenum-98 (Mo-98), are irradiated at the University of Missouri-Columbia Research Reactor. Mo-99 produced from these irradiated targets is then placed in the NorthStar RadioGenix System to produce Tc-99m (NRC 2018). Also, after the issuance of the FEIS, the DOE-NNSA competitively awarded two new cost-shared cooperative agreements to SHINE in 2019 and 2021.

The decision to produce radioisotopes is at the discretion of the applicant. The NRC does not have a role in making the decision about whether a particular facility should be constructed and operated, unless there are findings in the safety review required by the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), or findings in the environmental analysis under NEPA that would cause the NRC to not issue the operating license. If the facility is licensed to operate, SHINE's bounding production of Mo-99 at a 125 kilowatts (kW) power level is up to 8,200 6-day curies (Ci) (3.034×10^{14} becquerels [Bq]). Additionally, SHINE expects to produce 2,000 Ci (7.4×10^{13} Bq) of Xe-133 and 2,000 Ci (7.4×10^{13} Bq) of I-131 per week (SHINE 2020a, 2021c).

1.4 U.S. Nuclear Regulatory Commission Environmental Review

On July 17, 2019, SHINE submitted its application for an operating license for the SHINE facility (SHINE 2019). At the conclusion of the acceptance review, the NRC published a Notice for Acceptance for Docketing in the *Federal Register* (FR) (84 FR 55187) on October 24, 2019. The NRC issued a notice of intent to prepare a supplement to the FEIS (NRC 2015) and conduct a scoping process (84 FR 65424) on November 27, 2019. This notice initiated a 45-day scoping period.

The NRC staff conducted a public scoping meeting in Janesville, Wisconsin, on December 12, 2019. All comments received during the scoping process are documented in the NRC's scoping summary report (NRC 2020c).

In February 2020, the NRC staff conducted a site audit to identify information that differs from or reflects significant new information relative to that discussed in the FEIS. During the site audit, the NRC staff met with SHINE personnel, reviewed specific documentation, and toured the site. A summary of the NRC staff's site audit was issued in March 2020 (NRC 2020b).

After the scoping period and site audit, the NRC staff documented its findings in this draft supplement to the FEIS. This supplement updates the prior environmental review and only covers matters that differ from those or that reflect significant new information relative to what was discussed in the FEIS. The NRC staff did not identify any information that presents a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility. The NRC staff will issue the draft supplement for public comment and, based on the information gathered during the public comment period, the NRC staff will amend the supplement, as necessary, and will then publish the final supplement.

To guide its assessment of environmental impacts of the proposed action, the NRC established three levels of significance for potential impacts: SMALL, MODERATE, and LARGE, as defined and explained in Section 1.4 of the FEIS.

1.5 Cooperating Agency

On December 1, 2014, and February 3, 2015, the NRC and the DOE-NNSA signed a Memorandum of Agreement (MOA) about the review of the SHINE CP application (DOE and NRC 2015). The NRC and the DOE-NNSA decided to develop an MOA to make the most effective and efficient use of Federal resources when reviewing SHINE's proposed facility consistent with the American Medical Isotopes Production Act (42 U.S.C. 2065). The goal of the agreement was to develop one environmental impact statement (EIS) that serves both the NRC licensing process and the DOE-NNSA funding process. After receiving SHINE's operating license application, the NRC and the DOE-NNSA developed and executed an updated MOA for the operating license application review. The MOA, signed on June 18, 2020 (NRC and DOE 2020), designates the NRC as the lead Federal agency and the DOE-NNSA as a cooperating agency in developing the supplement to the FEIS.

1.6 Evaluation of Significant New Information

In accordance with 10 CFR 51.95(b), this supplement updates the environmental review documented in the FEIS regarding SHINE's CP application. It discusses the new or differing information that the NRC staff identified from such sources as the applicant's ER, as supplemented, comments provided during the scoping process, and desktop reviews, including potential changes in the facility design, facility operations, regulatory environment, or affected environment. The NRC staff evaluated this information to determine whether it presents a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility as compared to the FEIS. Based on this review, the staff concluded that there is no significant new information with respect to the environmental impacts of the SHINE facility. The staff did not reassess the impacts of construction that have already occurred.

1.7 Status of Compliance

SHINE is responsible for complying with applicable NRC regulations and other Federal, State, and local requirements. APPENDIX A to this supplement includes a list of the permits and licenses that Federal, State, and local authorities must issue to SHINE before SHINE can commence operations at the proposed facility.

1.8 Consultation and Correspondence

The Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.), and the National Historic Preservation Act of 1966, as amended (NHPA) (54 U.S.C. 300101 et seq.), require Federal agencies to consult with applicable State and Federal agencies and Tribes before taking an action that may affect endangered species or historic properties. A chronological list of all correspondence sent and received during the environmental review for this supplement to the FEIS is provided in APPENDIX B .

1.9 Other Relevant NEPA Reviews

By letter dated April 29, 2021, as supplemented on August 20, 2021, and December 2, 2021, SHINE applied for an amendment to Construction Permit No. CPMIF-001 for the SHINE facility to allow for the receipt and possession of certain radioactive materials to be installed during facility construction (SHINE 2021d, 2021e, 2021h). The radioactive materials described in SHINE's application are byproduct and source materials required for the continued construction of the SHINE facility and would be installed in the facility's tritium purification system and subcritical assembly systems.

The NRC staff conducted a safety and environmental review of SHINE's license amendment request. Pursuant to 10 CFR 51.21, "Criteria for and Identification of Licensing and Regulatory Actions Requiring Environmental Assessments," 10 CFR 51.32, "Finding of No Significant Impact," and 10 CFR 51.35, "Requirement to Publish Finding of No Significant Impact; Limitation on Commission Action," an environmental assessment and finding of no significant impact regarding the license amendment request was published in the *Federal Register* on November 29, 2021 (86 FR 67737). At the conclusion of the safety and environmental reviews, the NRC issued Amendment No. 2 to Construction Permit No. CPMIF-001 for the SHINE facility on December 2, 2021 (NRC 2021).

2 PROPOSED FEDERAL ACTION

This section focuses on changes in the configuration and operation of the SHINE facility as compared to the FEIS.

2.1 Site Location, Layout, Design Changes and Construction

Section 2.1 of the FEIS describes the SHINE facility site location and proposed buildings. SHINE would operate on land annexed by the City of Janesville, Wisconsin, which is located approximately 4 miles (mi) (6.4 kilometers [km]) south of the city center of Janesville, 13 mi (21 km) north of the Wisconsin-Illinois border, and 63 mi (101 km) west of Lake Michigan. The site encompasses approximately 91 acres (ac) (37 hectares [ha]) bordered by U.S. Highway 51 and the Southern Wisconsin Regional Airport to the west. In May 2019, SHINE commenced site-preparation work and NRC-authorized construction of the SHINE facility started in October 2019. The following discussion presents new information regarding the SHINE facility layout (Figure 2-1) and building and operating characteristics.

Figure 2-1 Conceptual Layout of the SHINE Facility (Modified from SHINE 2020a)

Since the issuance of the FEIS, SHINE has indicated that it no longer intends to construct an administration building. Instead, administrative functions supporting Mo-99 production would be performed in a new corporate headquarters building constructed adjacent to the SHINE facility site (SHINE 2021a). The SHINE facility would be composed of four buildings with associated support structures (e.g., nitrogen purge system structure, storage tanks) and other engineered features (e.g., parking lots, paved entrance roads, stormwater features). The four buildings (see Figure 2-1) in which SHINE would conduct the majority of its operations are as follows:

- main production facility;
- storage building;
- material staging building; and
- resource building.

SHINE has refined the design of the main buildings, which resulted in a smaller total footprint and reduced excavation depth for these four main buildings (see Table 2-1). Collectively, these four buildings would cover approximately 80,000 square feet (ft^2) (7,400 square meters [m^2]). The largest building would be the main production facility, comprising the SHINE irradiation facility and radioisotope production facility, which would extend approximately 213 feet (ft) (64 meters [m]) in length and 158 ft (48 m) in width, and would have an estimated height of 58 ft (18 m) above grade. The tallest exhaust vent stack would be approximately 67 ft (20 m) above grade. The main buildings, support structures, and other engineered features would result in a total estimated facility footprint of approximately 350,000 ft^2 (32,000 m^2).

Construction and operation of the SHINE facility will be accomplished in a phased manner (SHINE 2022d). The phased approach will consist of four phases of process equipment installation and operation. Phases 1–3 will bring the eight irradiation units online for full Mo-99 production capability and Phase 4 will add I-131 and Xe-133 production capability (SHINE 2022b). The four phases involve the following activities (SHINE 2021b, SHINE 2021f):

- Phase 1: (1) the completion of the entire main production facility structure and the nitrogen purge system structure and the storage building and resource building, (2) the installation of irradiation units 1 and 2 and all associated auxiliary and support systems, and (3) the completion of the radioisotope production facility (RPF) and the installation of tritium purification system (TPS) train A. The function of the TPS is to separate the deuterium-tritium gas mixture from the neutron driver assembly system into pure deuterium and tritium gas streams that support the control of the deuterium-tritium fusion reaction, as well as to remove other impurities from the gas mixture. Upon completion of Phase 1, the SHINE facility would be capable of commencing production of Mo-99 using irradiation units 1 and 2 and TPS train A.
- Phase 2: (1) the installation of irradiation units 3, 4, and 5 and all associated auxiliary and support systems and (2) the installation of TPS train B. Upon completion of Phase 2, the SHINE facility would be capable of producing additional Mo-99 using irradiation units 3, 4, and 5 and TPS train B.
- Phase 3: (1) the installation of irradiation units 6, 7, and 8 and all associated auxiliary and support systems and (2) the installation of TPS train C. Upon completion of Phase 3, the SHINE facility would be capable of producing additional Mo-99 using irradiation units 6, 7, and 8 and TPS train C. Phase 3 would also include the installation of radioactive liquid waste immobilization system selective removal components and the material staging building.
- Phase 4: the installation of iodine and xenon purification and packaging components.

Table 2-1 SHINE Facility Building and Operating Characteristics

Category	2015 FEIS	Updated Facility Building and Operating Characteristics
Total Main Buildings Footprint	91,000 ft^2	80,000 ft^2
Total Facility Footprint	350,000 ft^2	350,000 ft^2
Permanently Disturbed Area	26 ac	18 ac
Total Materials Excavated	278,000 cubic yards	58,000 cubic yards
Excavation Depth of Main Production Facility Building (below grade)	40 ft	30 ft

Category	2015 FEIS	Updated Facility Building and Operating Characteristics
Highest Point: Tallest Exhaust Vent Stack (above grade)	66 ft	67 ft
Water Use	6,073 gallons per day	10,400 gallons per day
Sanitary Wastewater	5,850 gallons per day	8,830 gallons per day
Power Requirements (annually)	17.5 million kilowatt-hours	28 million kilowatt-hours
Natural Gas Consumption (annually)	62,000 million British thermal units	12,800 million British thermal units
Workforce	150 workers	Up to 200 workers
Radioactive Waste Shipments	25.6 per year	18 per year
Nonradioactive Waste Shipments	1 per month	5 per month
Inbound Truck Deliveries	36 per month	36 per month
Outbound Truck Deliveries	39 per month	39 per month

Note: Estimated values in the table are rounded.
Source: SHINE 2020a, 2020b, 2021a, 2022d.

2.2 Facility Operations

Section 2.3 of the FEIS provides a description of SHINE facility operations. The following discussion presents new information regarding SHINE facility operations. As discussed above, operation of the SHINE facility for Mo-99 production will be accomplished in a phased manner (SHINE 2022d). The phased approach will consist of four phases of process equipment installation and operation. SHINE will operate the equipment in the completed phases of the facility while process equipment installation continues for the other phases (SHINE 2022d). During this period of phased installation and operation, construction personnel and operational personnel will be onsite simultaneously and personnel onsite will not exceed 451 workers (SHINE 2022d). Upon completion of this period, operational activities would require an average of 200 workers and a monthly average of 36 inbound truck deliveries and 39 outbound medical radioisotope product shipments (SHINE 2020a). Facility operations would also require an average of 18 radioactive waste shipments per year and 5 nonradioactive waste shipments per month (SHINE 2020a).

2.2.1 Proposed Technology and Radioisotope Production Process

As discussed in Section 2.3.1 of the FEIS, the SHINE facility would consist of an irradiation facility and RPF. The irradiation facility would consist of eight accelerator-driven subcritical operating assemblies, and the RPF would consist of hot cell structures for the processing of irradiated material. Figure 2-2 depicts a conceptual model of an irradiation unit showing the ion accelerator configured above the subcritical operating assembly. As discussed in Section 2.3.2 of the FEIS, SHINE's overall radioisotope production process can be divided into four primary stages: neutron production, radioisotope production through uranium fissions, radioisotope extraction and purification, and packing and distribution (see Figure 2-3). The following discussion presents new information regarding the production process.

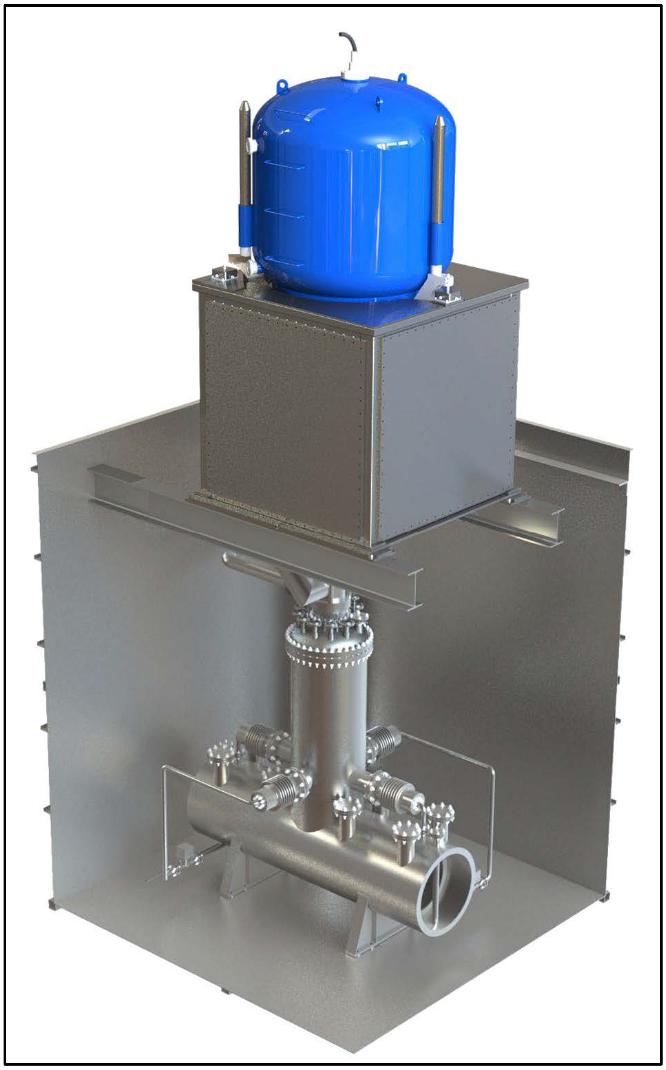

Figure 2-2 SHINE Irradiation Unit (Source: SHINE 2020a)

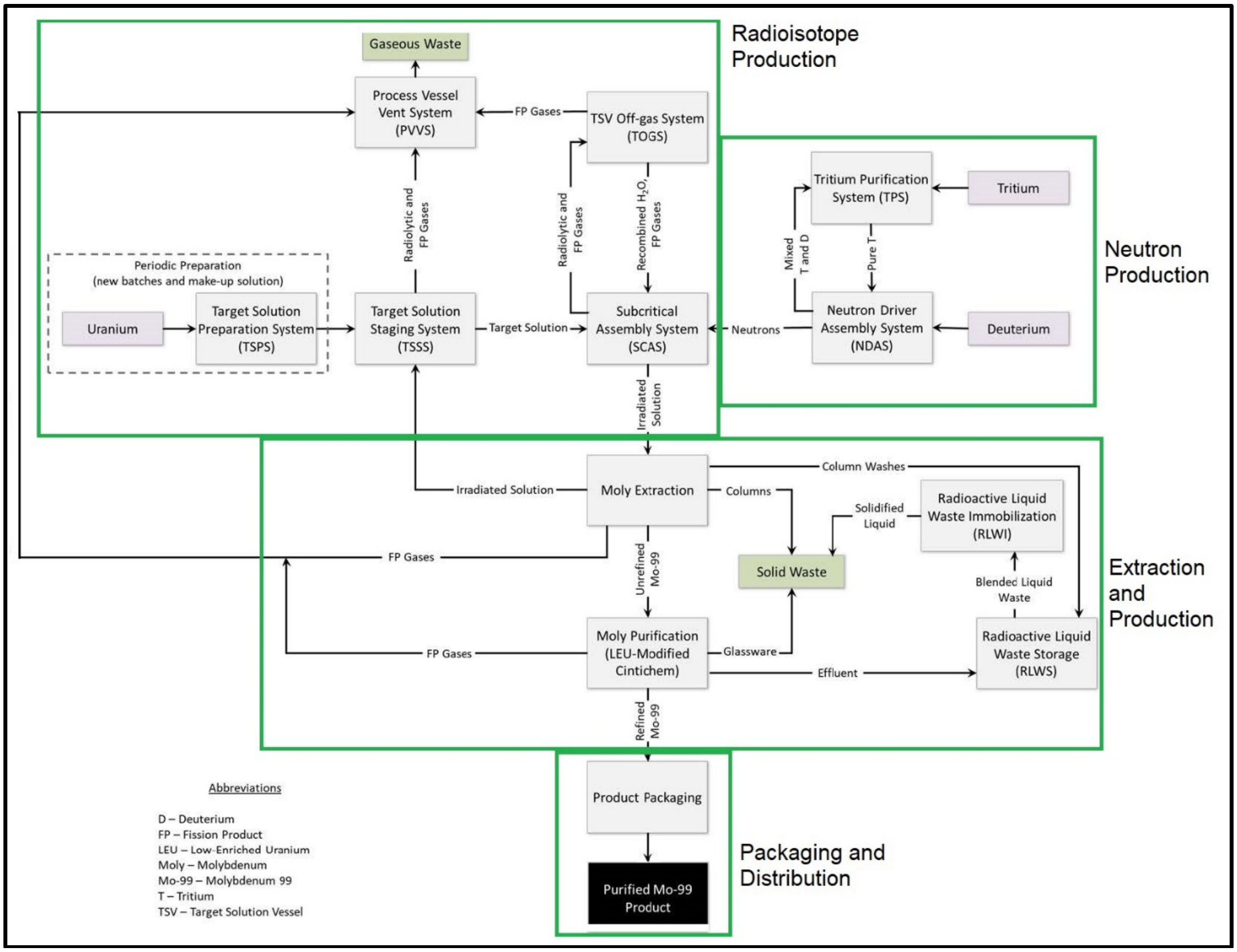

Figure 2-3 Radioisotope Production Process (Modified from SHINE 2020a)

Although the overall radioisotope production process remains the same as that discussed in Section 2.3.2 of the FEIS, SHINE refined and revised some of the processing details. Specifically, target solution preparation will no longer consist of dissolving uranium metal in nitric acid or using a thermal denitration system to generate uranium oxide. Rather, the updated process would use either uranium metal and/or uranium oxide. The uranium metal would be oxidized to uranium oxide thermally in an oxidation furnace. Uranium oxide would then be dissolved in a sulfuric acid solution to convert the uranium oxide to uranyl sulfate. Irradiated target solution would be recycled once the Mo-99 is separated from the target solution. SHINE determined that the uranium extraction (UREX) target solution cleanup process (a solvent extraction process to isolate uranium from fission products and transuranics) would no longer be necessary and removed this processing step. The NRC staff evaluates the new information related to the radioisotope production process in Chapter 3 of this supplement to the FEIS.

During operations, SHINE would receive low-enriched uranium (LEU) metal and/or uranium oxide for target material from the DOE-NNSA's Y-12 National Security Complex in Oak Ridge, Tennessee. In December 2021, SHINE executed uranium lease and take-back contracts with the DOE-NNSA and the DOE-Environmental Management (DOE-EM) (SHINE 2022c). The uranium lease and take-back actions are covered under a supplemental analysis: DOE/EIS-0279-SA-05 and DOE/EIS-0387-SA-02 (DOE-NNSA 2016). The DOE would determine if additional NEPA reviews for the take-back of SHINE's radioactive waste would be necessary.

2.2.2 Power Requirements

Section 2.4 of the FEIS describes the power requirements of the SHINE facility. Alliant Energy would supply electrical power to the SHINE facility. The following discussion presents new information regarding power requirements. Each irradiation unit is projected to use 145 kW (SHINE 2022d). When fully operational, the SHINE facility would annually consume approximately 28 million kilowatt-hours (kWh) of electricity (SHINE 2022d), rather than the estimated 17.5 million kWh discussed in the FEIS.

The emergency electrical power systems for the SHINE facility would consist of an uninterruptible electrical power supply system to power the safety-related equipment required to ensure and maintain safe facility shutdown. The uninterruptible electrical power supply system would consist of two independent 125-volt direct-current battery system trains along with the associated chargers, inverters, and distribution systems (SHINE 2021c). In contrast to the information presented in the FEIS, SHINE would maintain and test a standby natural-gas-driven generator, rather than a diesel generator. The standby natural-gas-driven generator would provide alternate power to the uninterruptible electrical power supply system. The generator would operate approximately 25 hours per year and consume approximately 200 million British thermal units (BTU) of natural gas annually (SHINE 2022d).

2.3 Water Use, Treatment, and Discharges

Section 2.5 of the FEIS describes water use, water treatment, and wastewater discharge management for the SHINE facility. As described in the FEIS, the City of Janesville municipal water system would supply water to support operational needs, including potable and sanitary use, heating and cooling makeup, process makeup, and fire suppression. All wastewater generated outside the radiologically controlled area (RCA) would be discharged directly to the City of Janesville sanitary sewer system in accordance with Janesville City Ordinance 13.16 (NRC 2015). The following discussion presents new information regarding these operational considerations.

The City of Janesville completed the construction of utility extensions, including for water and sewer, to the SHINE facility site in 2017 (SHINE 2020a). SHINE now projects that total average daily water use for facility operations would be about 10,360 gallons per day (gpd) (39,200 liters per day [Lpd]), rather than the estimated 6,073 gpd (23,000 Lpd) discussed in the FEIS (SHINE 2022d). The SHINE facility would be operated with a water-based fire-protection system. However, redesign of the fire-protection system has eliminated the need for the dedicated water tank that was referenced in Sections 2.1, 2.5.1, and 4.4.2.2 of the FEIS (SHINE 2022d, NRC 2015).

With respect to water treatment, SHINE redesigned the SHINE facility's primary closed-loop cooling system to operate without the need for corrosion-inhibiting chemicals to maintain appropriate water chemistry. Boiler water chemistry would be maintained by premixing the makeup water with manufacturer-recommended additives. In addition, the facility's process chilled water system would be treated with propylene glycol as necessary to support system function during winter conditions (SHINE 2022d).

SHINE also revised the projected sources of wastewater from the facility. While there would still be no liquid waste discharges from the RCA or from facility process systems directly to the sanitary sewer as described in the FEIS, the potential exists for infrequent discharge of liquid wastes containing radiological constituents from various sources. These discharges would include condensate from the radiological ventilation zone 2 recirculation subsystem air-handling units and small quantities of liquid discharges from any of the process cooling and heating systems (SHINE 2020a). SHINE personnel would collect and containerize these liquid wastes at their points of generation. Prior to release to the sanitary sewer, the liquid wastes would be sampled and analyzed to ensure that they meet NRC release criteria (10 CFR 20.2003 and 10 CFR 20.007) and the City of Janesville's sewer use requirements (SHINE 2020a, 2022d). Similarly, water collected from quality control and analytical testing laboratory sinks would be containerized, sampled, and analyzed to ensure that it meets disposal criteria prior to being discharged to the sanitary sewer. Liquid wastes that do not meet acceptance limits would be disposed of offsite as low-level radioactive waste. SHINE estimates that discharges of these waste streams would total less than 40 gallons (gal) (151 liters [L]) per week (SHINE 2020a).

SHINE expects that there would be no need to periodically flush water from the facility's closed-loop cooling-water systems, so no water from these systems would be periodically discharged to the City of Janesville sanitary sewer system, as was previously described in the FEIS (SHINE 2022d). In total, SHINE now estimates that total average wastewater flow to the sanitary sewer system would be 8,830 gpd (33,400 Lpd) (SHINE 2020a), compared to the estimate of 5,850 gpd (22,145 Lpd) discussed in the FEIS. The NRC staff evaluates the new information related to operational water use and the quality and quantity of SHINE's wastewater discharges in Chapter 3 of this supplement to the FEIS.

2.4 Cooling and Heating Dissipation Systems

Section 2.6 of the FEIS discusses the main production facility cooling system and the SHINE facility's heating systems. The purpose of the cooling systems is to remove heat from the target solution and dissipate it to the environment (SHINE 2021c). The following discussion presents new information regarding the operational characteristics of these systems.

The cooling system would consist of a primary closed-loop cooling system that provides forced convection cooling to remove heat from the subcritical assembly and rejects the heat to the radioisotope process facility cooling system, an intermediate chilled water loop. The intermediate chilled water loop is a closed-loop forced liquid cooling system that recirculates cooling water and rejects heat to the process chilled water system. The chilled water system is a closed-loop chilled water loop that rejects heat to the atmosphere by use of air-cooled chillers (SHINE 2021c).

The facility heating system for the main production facility would consist of three natural-gas-fired heating boilers. Three natural-gas-fired heaters (one per building) would provide heat for the storage building, resource building, and the material staging building (SHINE 2020a, 2021a). The NRC staff evaluates the new information related to facility cooling and heating systems in Chapter 3 of this supplement to the FEIS.

2.5 Storage, Treatment, and Transportation of Radioactive and Nonradioactive Waste

Section 2.7 of the FEIS discusses the storage, treatment, and transportation of waste as a result of constructing, operating, and decommissioning the SHINE facility. The following provides a general description of the SHINE facility waste management system along with new information regarding the waste management system.

2.5.1 Radioactive Wastes

SHINE does not anticipate any long-term storage of radioactive and nonradioactive materials, such as medical radioisotope products, target solution, reagents, or waste resulting from the following activities:

- neutron generator operation;
- target solution preparation;
- the target solution vessel waste gas removal system;
- Mo-99 recovery system operation;
- target solution cleanup;
- radioisotope production and purification processes;
- liquid radioactive waste volume reduction; and
- maintenance.

SHINE would treat and temporarily store the solid radioactive and nonradioactive waste generated as part of the radioisotope production process within the facility until it could ship the waste offsite for disposal. Subpart K and Appendix G of 10 CFR Part 20 (NRC) and 49 CFR Part 172 (U.S. Department of Transportation [DOT]) include regulations to protect public health and safety during transportation of radioactive fuel, radioactive wastes, and medical radioisotopes.

As discussed in Section 2.3.2 of the FEIS, SHINE's overall radioisotope production process can be divided into four primary stages: neutron production, radioisotope production through uranium fissions, radioisotope extraction and purification, and packing and distribution (see Figure 2-3 of this supplement to the FEIS). The overall radioisotope production process remains the same as that discussed in Section 2.2.1 of this supplement to the FEIS; however, SHINE refined and revised some of the processing details. Facility and production design changes resulted in the removal of the UREX and thermal denitration process (i.e., target solution cleanup), and SHINE modified the liquid radioactive waste handling systems for process optimization. Removal of the UREX and thermal denitration processes resulted in changes in the RPF design, effluent releases, and waste systems (SHINE 2022d).

The information below briefly describes the generation, storage, and waste management activities, waste minimization and pollution measures, and transportation of radioactive and nonradioactive waste. Additional information can be found in Sections 2.7 and 4.9 of the FEIS.

2.5.1.1 Gaseous Waste

Radioactive effluents from the radioisotope production process include both particulates and gas. The gaseous radioactive effluents would be routed through two separate, but connected, ventilation systems: the target solution vessel system and the process vessel vent system. The SHINE ventilation system design minimizes the potential spread of radioactive contamination within the facility and by controlling the amount of radioactive effluents released into the environment. SHINE uses high-efficiency particulate filters and carbon bed filters to treat gaseous radioactive effluents to reduce their radioactivity before they are released through a vent stack in the main production facility. Table 2-2 lists the quantity of radionuclides that SHINE estimates the facility would release annually.

Table 2-2 SHINE Facility Gaseous Radioactive Effluents

Effluent	FEIS Rate (Ci/yr)	Updated Rate (Ci/yr)
Krypton-85 (Kr-85)	< 120	170[(a)]
Iodine-131 (I-131)	< 1.5	< 0.1
Xenon-133 (Xe-133)	< 17,000	7800
Tritium (H-3)	< 4,400	73

Source: SHINE 2022d.
(a) This updated rate includes both Kr-85 and Kr-85m

Section 4.9 in the FEIS describes the monitoring of gaseous effluents and radioactive waste. The NRC staff evaluated the new information related to radioactive effluents in Chapter 3 of this supplement.

2.5.1.2 Other Liquid and Solid Waste

Operation of the SHINE facility would generate radioactive waste ranging from Class A to greater-than-Class C wastes, as discussed in Section 2.7.1.2 of the FEIS. Radioactive waste is generally considered to be any item or substance which is no longer of use to the facility and which contains radioactivity above the established natural background radioactivity. The wastes generated by the SHINE facility are not spent nuclear fuel, high-level waste, or byproduct material as defined in paragraphs (2), (3) and (4) of the definition of byproduct material set forth in 10 CFR 20.1003. Therefore, the radioactive wastes generated by the SHINE facility are all classified as low-level waste. The low-level waste generated by the SHINE facility during operation is expected to be classified as Class A, Class B, or Class C waste.[1]

The neutron multipliers are designed for the life of the facility and will be disposed of as greater-than-Class C (GTCC) waste during decommissioning. For the purposes of transportation, packaged wastes may be categorized as low specific activity, requiring Type A packaging, or requiring Type B packaging (SHINE 2021c).

Radiation protection program requirements and the As Low As is Reasonably Achievable (ALARA) program apply to radioactive waste management, including, but not limited to, control of materials, monitoring and surveys, RCA access control, contamination control, and personnel monitoring. The material staging building would be used for interim storage of wastes for decay and for preparation for shipment. Wastes would not be stored for more than 5 years. The material staging building design evaluated the shielding provided by the building to ensure that 10 CFR Part 20 site dose limits are met and that ALARA principles are followed (SHINE 2020b, 2021c).

[1] The NRC classifies low-level waste in 10 CFR 61.55 as Class A waste (contains short-lived radionuclides at relatively low concentrations), Class B waste (has higher half-lives and concentrations of radionuclides than Class A wastes), Class C waste (has higher half-lives and concentrations of radionuclides than Class A wastes), or greater-than-Class C (GTCC) waste, depending on the types and concentrations of radionuclides in the waste. Class B wastes have higher half-lives and concentrations of radionuclides and must meet more rigorous requirements with regard to their form to ensure stability after disposal (e.g., by adding chemical stabilizing agents). Class C wastes must meet even more rigorous requirements and require additional measures at a disposal facility to protect against inadvertent intrusion. GTCC wastes contain radionuclides at concentrations that are higher than that allowed for Class C wastes and that are not generally acceptable for near-surface disposal methods.

After liquid radioactive waste is treated, solidified, and packaged, it would be temporarily stored onsite only long enough for radioactive decay before offsite disposal shipment and for efficient frequency of disposal shipments. Any radioactive liquid discharges to the sanitary sewer would be infrequent and made in accordance with the release criteria in 10 CFR 20.2003, 10 CFR 20.2007, and Janesville City Ordinance 40-170. Prior to discharge, the collected liquid would be sampled, analyzed, and verified to meet the criteria for release to the sanitary sewer from the listed State and Federal regulations. Liquids meeting these criteria would be transferred outside of the RCA in portable containers and released to the sanitary sewer (SHINE 2021c, 2022d).

SHINE also revised the projected sources and volume of wastewater generated during facility operations, as previously described in Section 2.3 of this supplement to the FEIS. When transporting waste, SHINE must adhere to the applicable regulatory packaging and transportation requirements for radioactive material in 10 CFR Parts 20 and 71 (NRC), the State of Wisconsin's Administrative Code, and 49 CFR Parts 172 and 173 (DOT). These regulations help ensure safety on public roadways. Additional information can be found in Section 2.7 of the FEIS.

2.5.2 Nonradioactive Waste

The SHINE facility would generate nonradioactive waste as part of routine operation, maintenance, cleaning, and decommissioning activities. As discussed in Section 2.5.3 of this supplement to the FEIS, no significant production of nonradioactive waste is expected during normal operations of the SHINE facility. The NRC staff did not identify any significant new information with respect to nonradioactive solid or liquid waste since the issuance of the FEIS. Although SHINE revised the projected number of nonradioactive waste shipments at the facility from 12 to 60 shipments per year, this revision does not reflect a substantial change in the amount of nonradioactive waste generated. Section 3.10 of this supplement to the FEIS discusses the impact of factors including the revised projected number of nonradioactive waste shipments on the transportation affected environment.

2.5.3 Waste Minimization and Pollution Prevention Program

SHINE procedures would ensure the proper operation of the waste systems. Waste minimization is a key element of SHINE's Radiological Waste Management Program. SHINE's implementing procedures address the following:

- responsibilities for waste minimization and pollution prevention;
- employee training and education on general environmental activities and hazards regarding the facility, operations, pollution prevention, waste minimization requirements, goals, and accomplishments;
- setting goals for reducing the volume or radioactivity in each waste stream;
- sorting and compaction to reduce the volume of solid waste;
- segregation of nonradiological and radiological wastes to reduce the volume of radiological waste due to contamination;
- process controls that minimize generation of wastes;
- periodic assessments to identify opportunities to reduce or eliminate the generation of wastes; and

- recognition of employees for efforts made to improve waste minimization and environmental conditions (SHINE 2020a).

No GTCC waste is generated during normal operations. The neutron multipliers are designed for the life of the SHINE facility and would be GTCC waste at the end of their life. SHINE has executed a lease and take-back contract with DOE (SHINE 2020a). During decommissioning, the DOE would take title to and be responsible for the final disposition of the neutron multipliers (SHINE 2020a).

No significant production of nonradioactive waste is expected during normal operations.

2.6 Facility Decommissioning

Section 2.8 of the FEIS discusses decommissioning of the SHINE facility. As part of the operating license application, SHINE updated its decommissioning cost and its method that would be used to provide funds for decommissioning (SHINE 2021c). SHINE estimates that the facility would be decommissioned over a period of 24 months and would require a peak workforce of approximately 26 workers (see Table 2-1). Decommissioning of the SHINE facility would generate radioactive waste from NRC Class A to GTCC waste. SHINE estimates that approximately 18 truck deliveries and 22 offsite waste shipments would, on average, be required each month during decommissioning. An estimate of waste quantities and Class type is provided in Table 2-3.

Table 2-3 SHINE Facility Decommissioning Characteristics

	FEIS	Updated Characteristics
Employees	261	26
Duration	6 months	2 years
Waste Shipments (monthly)	191	22
Inbound Shipments (monthly)	72	18

Source: SHINE 2020a and 2020b.

Table 2-4 Waste Type and Quantities[a] During Decommissioning of the SHINE Facility

Waste Type	Weight (pounds)	Volume (cubic feet)
Nonradiological Construction and Demolition Waste	1,802,000	--[b]
Class A Components	489,879	26,361
Class A Concrete	2,641,200	36,542
Class A Liquids	1,468,791	23,528
Class B/C Components	141,200	5,528
Low-Level Mixed Waste	1,377	22
Greater-than-Class C	20,800	40

(a) Quantities presented are totals over the 24-month decommissioning phase (Source: SHINE 2020a).
(b) The volume will vary depending upon the density of the various substances and packaging material.

2.7 Alternatives and Cost-Benefit

2.7.1 Alternatives

The NRC considered the environmental impacts associated with alternatives to construction of the SHINE facility in Chapter 5 of the FEIS. The NRC considered the following alternatives to construction, operations, and decommissioning of the SHINE facility at the proposed site in Janesville, Wisconsin:

- the no-action alternative;
- construction, operations, and decommissioning of the SHINE facility at the Chippewa Falls site (Alternative Site No. 1);
- construction, operations, and decommissioning of the SHINE facility at the Stevens Point site (Alternative Site No. 2); and
- construction, operations, and decommissioning of a linear-accelerator-based facility at the SHINE site (alternative technology).

At the conclusion of the NRC's safety and environmental reviews, the NRC issued a CP to SHINE on February 29, 2016 (NRC 2016). NRC-authorized construction of the SHINE facility commenced in October 2019 consisting of the eight subcritical operating assemblies (irradiation units) and RPF, as described in the CP FEIS. Since the issuance of the CP, SHINE has refined its design in the operating license application. No other alternative technologies are considered in this supplement.

2.7.2 Cost-Benefit

Section 5.4 of the FEIS described the potential impacts of operating the proposed SHINE facility and aggregated them into expected costs and benefits. This section updates the analysis of potential societal benefits of the proposed action and costs presented in the FEIS. FEIS Table 5-17 identified the costs and benefits associated with constructing, operating, and decommissioning the proposed SHINE facility.

For this review, only information that is new or differs from the description of environmental impacts presented in the FEIS is summarized below. Based on the review of available information, the NRC staff did not identify any significant new information that would present a seriously different picture of the proposed action or its impacts from that stated in the FEIS.

Table 2-5 Benefits of Constructing, Operating, and Decommissioning the SHINE Facility

Benefit Category	Description	Impact Assessment
Domestic Production of Molybdenum-99	SHINE would produce a domestic supply of molybdenum-99. Additionally, SHINE would also produce iodine-131 (I-131) and xenon-133 (Xe-133).[a]	_
Use of Low-enriched Uranium Target Solution	No change from the FEIS.	_

Benefit Category	Description	Impact Assessment
Tax Revenues	Tax increment finance agreement for the first 10 years of the project, allows SHINE to make payments in lieu of taxes of $1,300,000 per year. SHINE would also pay property taxes during this 10-year period that are estimated to be $42,500 per year based on the assessed value of the property before improvements.	–
Local Economy	No change from the FEIS.	–

(a) Since publication of the FEIS, NorthStar Medical Radioisotopes (NorthStar) became the first commercial U.S. technetium-99m (Tc-99m) producer since 1989.

Source: SHINE 2020a.

Table 2-6 Costs of Constructing, Operating, and Decommissioning the SHINE Facility

Cost Category	Description	Impact Assessment
Land Use	Building footprint reduced from 26 to 18 ac and the stack height increased to 67 from 66 ft.	SMALL
Visual Resources	Minor increase in stack height to 67 from 66 ft.	SMALL
Air Quality	SHINE has eliminated the use of nitric acid as a uranium solvent and the thermal denitration process. Therefore, there would be no significant nitrogen oxide emissions from radioisotope production. Air emissions during SHINE facility operations would primarily consist of (1) fuel combustion associated with isotope production and facility heating and (2) vehicular traffic. Onsite combustion sources include a natural gas standby generator, three natural-gas-fired boilers, and three natural gas heaters.	SMALL
Noise	The increase in traffic from 150 workers to 200 workers would not result in noticeable increased noise levels.	SMALL
Geologic Environment	Reductions in the maximum depth of excavation to complete facility construction along with reductions in the area of land disturbance and volume of earthwork would further reduce impacts on soils and geologic resources.	SMALL
Water Resources	Facility water use would increase from approximately 6,100 to 10,400 gpd, but the increase would not strain the groundwater production capacity of the City of Janesville Water Utility. Sanitary wastewater discharge would increase from about 5,800 to 8,800 gpd. Sources of wastewater to the sanitary sewer would be managed at the point of generation, including analysis, prior to discharge to ensure that NRC release criteria for radiological constituents as well as City of Janesville's sewer use permit requirements are met.	SMALL
Ecological Resources	Building footprint reduced from 26 to 18 ac. Impacts remain limited to former agricultural land with no disturbance to aquatic or naturally vegetated terrestrial habitats.	SMALL
Historic and Cultural Resources	No change from the FEIS.	SMALL

Cost Category	Description	Impact Assessment
Socioeconomics	The projected increase in jobs from 150 to 200 generated during SHINE facility operation is still less than 1 percent of the currently available labor force in Janesville and Rock County.	SMALL
Human Health	Due to changes in the RPF, calculated radiation dose to members of the public is reduced from approximately 9.0 millirem (mrem) (0.09 milli-sieverts [mSv]) to 4.6 mrem (0.046 mSv). New information is presented in regard to SHINE’s radiological environmental monitoring program (REMP), its radiation protection program, and its ALARA program.	SMALL
Waste Management	The liquid radioactive waste handling systems have been modified to account for the removal of the UREX process and associated systems, and to optimize processing.	SMALL
Transportation	Based on (1) small changes in baseline traffic conditions, (2) small changes in projected traffic attributable to operations of the SHINE facility, and (3) new traffic studies submitted by SHINE to the State of Wisconsin, the NRC has determined that impacts on the transportation infrastructure during operations would likely be minimal.	SMALL
Accidents	Due to changes in the RPF, new information is presented for radiological and chemical accidents. SHINE’s calculated radiation dose for the maximum hypothetical accident is now 727 millirem (mrem) (7.27 milli-sieverts [mSv]), which, while an increase from 82.0 mrem (0.82 mSv) in the FEIS, is still within the U.S. Environmental Protection Agency early-phase Protective Action Guides limit of 1 rem (0.01 Sv) total effective dose equivalent. Regarding chemical accidents, SHINE performed a hazardous chemical consequence assessment that demonstrates that no chemical consequence exceeds DOE Protective Action Criteria limits at the site boundary or the nearest residence, which is an impact reduction from the FEIS, where one chemical of concern (nitric acid) was identified as having the potential to exceed these limits. Further, the NRC is conducting an independent review of the potential dose to the public from radiological and chemical accidents in the NRC’s safety evaluation report.	SMALL
Environmental Justice	The percentage of minority populations in the City of Janesville remained unchanged from the previous review, the information about minority populations living near the SHINE facility does not significantly differ from the information described in the FEIS. The percentages of low-income populations and families in the City of Janesville and Rock County decreased from the previous review, the information on low-income populations living near the SHINE facility does not significantly differ from what was described in the FEIS.	Minority and low-income populations would not be expected to experience any high and adverse effects

Source: SHINE 2020a, SHINE 2022d.

The financial costs related to the construction, operation, and decommissioning of the proposed SHINE facility are described in Section 5.4 of the FEIS and in Chapter 15 of the final safety analysis report (FSAR) (SHINE 2020b, SHINE 2021c). In the FEIS, the NRC determined that SHINE had obtained the funding needed to cover estimated construction and fuel cycle costs in accordance with 10 CFR 50.33(f)(1). Since the issuance of the FEIS, additional publicly disclosed financial commitments include the following:

- capital investment from Deerfield Management Company, L.P.: $150 million;
- capital investment from Oaktree Capital Management, L.P.: $50 million;
- Series B equity financing raised: $30 million;
- additional cost shared cooperative agreements with the DOE-NNSA: $50 million; and
- City of Janesville loan package: $1.5 million (SHINE 2020a, DOE-NNSA 2021).

SHINE's updated operational cost estimates that are provided in Section 15.2 of the FSAR include the total annual operating costs for the first 5 years (SHINE 2021c). SHINE expects the revenue, primarily from the sale of Mo-99 and other radioisotopes, to exceed operating costs. To date, SHINE has entered into contracts with GE Healthcare; Lantheus Medical Imaging, Inc.; and HTA Co., Ltd to sell Mo-99. SHINE reduced its cost estimate for decommissioning of the facility from $60,000,000 to $51,000,000 (SHINE 2020a, 2021c).

3 AFFECTED ENVIRONMENT AND ENVIRONMENTAL CONSEQUENCES

This supplement evaluates the same environmental resource areas that were considered in the FEIS. Consistent with its regulations in 10 CFR 51.95(b), the NRC staff considered whether there is any significant new information with respect to the environmental impacts of the SHINE facility, including information that is different than that considered in the FEIS. As described in the following sections, the new information identified by the staff would have no effect on resource areas or conditions such as the geologic environment, human health, historic and cultural resources, and socioeconomics. For the remaining resource areas, the NRC staff provides a resource-specific assessment of information that differs from or that reflects new information relative to that discussed in the FEIS. Based on this review, the NRC staff concludes that the impacts of SHINE facility construction, operations, and decommissioning are either less than or bounded by the analysis of impacts presented in the FEIS. The NRC staff has further determined that SHINE's phased approach to construction and operation (see Section 2.1) would have no differing impacts for any resource area compared to the sum of the impacts evaluated in the FEIS. Therefore, the staff identified no significant new information that would present a seriously different picture of environmental impacts from that depicted in the FEIS.

3.1 Land Use and Visual Resources

Section 4.1 of the FEIS discusses the land use and visual resource impacts of the proposed SHINE facility. Since publication of the FEIS, SHINE refined the layout of the major structures within the boundaries of the 91-ac site, thereby reducing the footprint of permanent land disturbance from 26 ac to 18 ac (SHINE 2022d). The height of the exhaust stack, the tallest structure onsite, increased to 67 ft from 66 ft (SHINE 2020b). Aerial photography and information provided by SHINE (SHINE 2020b) indicate that additional light industrial development, including a Dollar General Distribution Center (completed in 2017) and Building One (a demonstration facility containing radioactive materials, completed in 2018), occurred near the site since the FEIS was published. Also, SHINE began building its Headquarters Building and Therapeutics Facility in 2021, at a location approximately 0.25 mi (0.4 km) north of the site. Construction of the Headquarters Building was completed and its use and occupancy began in August 2021 (See Table 3-6 in Section 3.14 for more information about new and expanded facilities in the surrounding area.)

The reduced footprint of disturbance and slightly greater exhaust stack height would not substantially alter the overall aesthetic properties of the proposed facilities. The presence of the other new facilities rendered the surrounding area more industrial in character, making operation of the proposed SHINE facilities even more compatible with surrounding land uses. The NRC staff therefore concludes that impacts on land use and visual resources from the operation of the SHINE facility would remain SMALL.

3.2 Air Quality and Noise

3.2.1 Air Quality

Section 3.2 of the FEIS provides a general description of the climate of the region, meteorological conditions, and regional air quality. Since publication of the FEIS, the U.S. Environmental Protection Agency (EPA) updated the primary and secondary national ambient air quality standard for ozone (8-hour average concentration) to 0.070 parts per million (EPA 2020a). Since publication of the FEIS, the EPA has published 2017 national emissions inventory data. Table 3-1 presents the 2017 annual emissions of criteria air pollutants for Rock County. The NRC staff identified no other new or differing information that would warrant revision of the description of the meteorology and regional air quality affected environment.

Table 3-1 Rock County Annual Air Emissions Inventory

Category	CO	NO_x	SO_2	PM_{10}	$PM_{2.5}$	VOC	CO_2
2017 Annual Rock County[(a)] Emissions (tons)	20,170	4,330	64	5,710	1,710	6,195	1,790,630
Estimated Annual Emissions During Operation of the SHINE Facility (tons/year)[(b)]	65	11	0.3	1.0	<1.0	1.5	17,300
Percent of Rock County Air Emissions	0.3	0.2	0.4	0.02	0.05	0.02	1.0

N/A = not available; CO = carbon dioxide; CO_2 = carbon dioxide; NOx = nitrogen oxides; PM-10 = particulate matter less than 10 microns in diameter; SO_2 = sulfur dioxide; VOC= volatile organic compounds.

(a) Source: EPA 2020b

(b) Total emissions from natural gas standby generator, three natural-gas-fired boilers, three natural gas heaters, and worker vehicle emissions. Emissions for the three natural-gas-fired boilers and three natural gas heaters are from FEIS Table 4-5 (NRC 2015). Worker vehicle emissions were revised from FEIS Table 4-7 (NRC 2015) to reflect a 25 percent increase in workforce. Emissions for the natural gas standby generator are from SHINE 2022d.

Section 4.2.2.1 of the FEIS discusses air emissions and air quality impacts as a result of operation of the SHINE facility. The following discussion presents new information regarding the air quality impacts.

As discussed in Section 2.2.1 of this supplement, the isotope production process has eliminated the use of nitric acid as a uranium solvent and the thermal denitration process. Therefore, no significant nitrogen oxide air emissions would be released as part of radioisotope production. Air emissions from operating the SHINE facility would be predominantly from the fuel combustion associated with processing and facility heating and vehicular traffic from workers commuting to and from the facility. Facility onsite combustion sources would include a natural gas standby generator, three natural-gas-fired boilers, and three natural gas heaters (SHINE 2020a, 2021a).

The natural gas standby generator would be used intermittently for testing, approximately 25 hours per year (SHINE 2022d). The heating system for the main production facility building would now consist of three natural-gas-fired heating boilers, and the heating system for the storage building, resource building, and the material staging building would consist of one natural gas heater per building (SHINE 2020a, 2021a). As noted in Table 2-1 of this supplement, the main production facility building, storage building, resource building, and the material staging building footprints would be smaller than what was considered in the FEIS. As a result of the smaller building footprints, the annual natural gas consumption of the natural boiler and three natural gas heaters would be less than what was considered in the FEIS, and the air emissions presented in Table 4-5 of the FEIS would be bounding. SHINE estimates the total annual natural gas usage of the natural gas standby generator, three natural-gas-fired boilers, and three natural gas heaters to be 12,300,000 scf (12,800 million BTU), and as noted in Table 2-1 of this supplement, estimated annual gas consumption would be lower than what was considered in the FEIS.

Air emissions would also result from workforce vehicles. SHINE estimates an increase of 50 workers from what was considered in the FEIS (SHINE 2022d). Therefore, approximately 200 passenger vehicles would commute to and from the SHINE facility on a daily basis and would represent a 25 percent increase in vehicle emissions.

Table 3-1 presents total air emissions during operation of the SHINE facility from combustion sources and work vehicles. The total estimated air emissions from onsite combustion sources and from worker vehicles would be well below 100 tons/year for each criteria air pollutant and would represent 1 percent or less of Rock County air emissions (EPA 2020a). Therefore, the NRC staff concludes air emissions from related activities during operations would have little potential to significantly affect air quality or interfere with plans to achieve compliance with National Ambient Air Quality Standards, and the air quality impacts from operations would remain SMALL.

3.2.2 Noise

Section 3.2.3 of the FEIS discusses the baseline noise conditions in the vicinity of the SHINE site. Since publication of the FEIS, development in the vicinity of site has resulted in additional vehicular noise. The Dollar General Distribution Center is located approximately 0.25 mi (0.4 km) from the SHINE site. Access to the Dollar General Distribution Center is via Innovation Drive, which is accessed through Prairie Street. Increases in noise levels as a result of additional vehicular noise primarily occur along Highway 11 and Prairie Street. Adjacent to and south of the SHINE site is Building One—a demonstration facility that houses radioactive material. Construction of Building One was completed in 2018 and approximately up to 15 employees currently occupy the building (SHINE 2020a). Additional vehicular noise along U.S. Highway 51 as a result of 15 employees relative to average daily peak volumes along the highway (549-696) is not noticeable. The NRC staff did not identify additional development within the noise region of influence that could affect changes in baseline noise conditions.

Section 4.2.2.2 of the FEIS discusses noise impacts resulting from operation of the SHINE facility. In the FEIS, NRC staff considered the noise impacts of 150 worker vehicles and estimated that an additional 150 vehicles would result in an increase of 1 A-weighted decibel (dBA). SHINE estimates that operational activities would require 200 workers (SHINE 2022d). Sound levels increase at a rate of 3 dBA per doubling of traffic volumes and an increase of 3 dBA is barely noticeable (FHWA 2018; IDoT 2015). As presented in Section 3.10.1of this supplement, average annual traffic counts along U.S. Highway 51 ranges between 8,100 and 8,600 and average daily peak volumes range from 549 and 696. The conservative assumption that all SHINE worker vehicles travel along U.S. Highway 51 at the same time would not result in a doubling of traffic volumes. Therefore, the increase in traffic from 200 workers would not result in noticeable increased noise levels.

The Southern Wisconsin Regional Airport currently operates approximately 144 flights per day, 52,452 flights per year (FAA 2020). Each year, up to 520 medical shipments (including I-131 and Xe-133) associated with operations of the SHINE facility would occur, most of them being transported by air (SHINE 2020a). Therefore, the NRC staff does not anticipate a noticeable increase in flight operations or an appreciable increase in noise above current airport operations as a result of medical shipments. The NRC staff concludes noise impacts as a result of operation of the SHINE facility would remain SMALL.

3.3 Geologic Environment

The NRC staff identified no differing or new information that would warrant revision of the description of the affected environment and environmental impacts contained in Sections 3.3 and 4.3, respectively, of the FEIS. The NRC staff now projects total construction impacts on geology and soils would be less than those projected in the FEIS. As summarized in Section 2.1 and detailed in Table 2-1, the impacts would likely be smaller due to a reduction in the maximum depth of excavation necessary to complete facility construction and a reduction in the volume of earthwork and excavation associated with a smaller facility footprint. The NRC staff concludes that the impacts on the geologic environment from the operation of the proposed SHINE facility would remain SMALL.

3.4 Water Resources

3.4.1 Surface Water

Section 3.4.1 of the FEIS describes the surface water resources of the SHINE site and vicinity, including the surface water hydrology of the Rock River, local watershed and drainages, surface water quality, and surface water use (NRC 2015). The NRC staff did not identify any new or differing information that would warrant revision of the description of the surface water affected environment in the FEIS.

Section 4.4.1.2 of the FEIS evaluates the potential environmental impacts of SHINE facility operations on surface water quality and use, including wastewater generation and disposal. The following discussion evaluates new information regarding projected impacts on surface water resources from SHINE facility operations.

As stated in Section 4.4.1.2 of the FEIS and referenced in Section 2.3 of this supplement, all wastewater generated outside the RCA would be discharged directly to the City of Janesville sanitary sewer. In support of facility operations, SHINE identified the potential for infrequent small volumes of liquid wastes containing radiological constituents to be discharged to the sanitary sewer. Facility personnel would properly manage any such waste streams at the point of generation and would analyze them prior to their being discharged to ensure that the liquids meet NRC release criteria and the City of Janesville's sewer use requirements. The NRC staff finds that this operational change would have no substantial effect on the quality of liquid effluent introduced to the City of Janesville's sanitary sewer and no effect on surface water quality.

Compared to the information presented in the FEIS, SHINE has increased its estimate of the volume of sanitary wastewater requiring discharge to the sanitary sewer during facility operations. This change is mainly attributable to the maturation of SHINE's facility design relative to the conceptual design considered at the construction permit stage. SHINE now projects that the total average daily wastewater flow would be approximately 8,830 gpd (33,400 Lpd) (see Section 2.3). This is a 51 percent increase over the estimate presented in the FEIS. Nonetheless, this change would have a negligible impact on the operation of the City of Janesville wastewater treatment plant and no impact on the receiving surface water quality of the Rock River that receives treated effluent from the treatment plant. This is because the quality of the sanitary effluent that would be discharged from the SHINE facility has not substantially changed, as it would predominantly consist of sanitary wastewater with only minor contributions from facility processes. In addition, the total volume of sanitary wastewater that would be discharged from the SHINE facility to the treatment plant would be small by volume compared to the treatment plant's currently available (excess) average treatment capacity of at least 6.8 million gpd (mgd) (25.7 million liters per day (mLd) (SHINE 2022d). Therefore, the NRC staff concludes that the impacts on surface water hydrology, quality, and use from the operation of the proposed SHINE facility would remain SMALL.

3.4.2 Groundwater

Section 3.4.2 of the FEIS describes the groundwater resources of the SHINE site and vicinity including the hydrogeology of the site and Rock County region, groundwater quality of the region's aquifers, well yields, and regional groundwater use. The NRC staff identified no differing or new information that would warrant revision of the description of the groundwater-affected environment.

Section 4.4.2.2 of the FEIS evaluates the potential environmental impacts of SHINE facility operations on groundwater hydrology, groundwater quality, and groundwater use (NRC 2015). The following discussion evaluates new information regarding projected impacts on groundwater resources from SHINE facility operations.

The SHINE facility site is served by municipal water supplied by the City of Janesville Water Utility. As described in Section 3.4.2 and 4.4.2.1 of the FEIS, the City of Janesville uses groundwater as its source. Table 4-11 in Section 4.4.2.2 of the FEIS summarizes projected water requirements for SHINE facility operations. Since issuance of the FEIS, SHINE now projects that the total average daily water use to support facility operations would be 10,360 gpd (39,200 Lpd) (see Section 2.3). This change is mainly attributable to the maturation of SHINE's facility design relative to the conceptual design considered at the construction permit stage. This is a 71 percent increase over the estimate presented in the FEIS. The City of Janesville Water Utility continues to have a substantial surplus water supply, with excess capacity of 22 mgd (83 mLd) (City of Janesville 2020a; SHINE 2022d). Thus, SHINE's revised water demand remains a very small percentage (less than 0.1 percent) of the utility system's available (excess) capacity and would have no impact on the utility system or other system customers. Based on the preceding discussion, the NRC concludes that the impacts on groundwater resources from the operation of the proposed SHINE facility would remain SMALL.

3.5 <u>Ecological Resources</u>

As noted in Section 4.5.1 of the FEIS, the site consisted only of former agricultural land and developed land. Portions of the site have been subsequently disturbed to build SHINE facilities, and areas where agricultural use has terminated can be expected to support only ruderal (weedy) vegetation typical of unused farmland. The footprint of disturbance has changed from the 26 ac estimated in the FEIS to only 18 ac (SHINE 2022d). Impacts from further development activity would be limited to former agricultural land and would not disturb aquatic habitats, wetlands, or terrestrial habitats that do not have a history of recent agricultural use. The NRC staff identified no other new or differing or information that would warrant revision of the description of the ecological resources affected environment.

SHINE notes that the height of the stack, the tallest of the SHINE structures, would be 67 ft rather than 66 ft considered in the FEIS (SHINE 2022d). The increased stack height would not substantially alter the low potential for bird collisions. The applicant continues to acknowledge the potential for runoff containing sediments, contaminants from paved surfaces, and herbicides; and the applicant has therefore developed a stormwater management plan consisting of infiltration ponds and filtration grasses to prevent excessive runoff (SHINE 2022d). Routine best management practices would protect surrounding terrestrial and aquatic habitats from adverse effects associated with sedimentation or contamination. The assessment of projected decommissioning impacts presented in Section 4.5.3 of the FEIS remains unchanged (NRC 2015). Based on the preceding discussion, the NRC staff concludes that impacts on ecological resources from the operation of the proposed SHINE facility would remain SMALL.

3.6 Special Status Species and Habitats

In Section 3.5.4 of the FEIS, the NRC staff described the special status species and habitats potentially present near the SHINE site. The sections below summarize and update this information. The NRC staff identified no other new or differing or information that would warrant revision of the description of special status species and habitats.

3.6.1 Endangered Species Act: Federally Listed Species and Critical Habitats

As detailed in Section 3.5.4 of the FEIS, the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) jointly administer the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.). The Endangered Species Act of 1973 (ESA) “action area” includes areas affected directly or indirectly by the Federal action (50 CFR 402.02). The following sections describe the SHINE action area and the species and habitats that may occur in the action area under the FWS’s and the NMFS’s jurisdictions.

3.6.1.1 Action Area

Section 3.5.4.1 of the FEIS describes the ESA action area as the lands within the 91-ac (37-ha) SHINE site and the adjacent offsite area in which construction of the water main and sanitary sewer line would occur. The offsite area consists of a 0.62 ac (0.25 ha) area of agricultural land along U.S. Highway 51 near the northwestern boundary of the SHINE site affected by the City of Janesville’s construction of the site’s water and sewer line.

No natural surface water features occur on the SHINE site, and SHINE operations would not involve any surface water withdrawal, diversion, or discharge. During operations, SHINE would obtain water from the City of Janesville and would send all wastewater generated outside the RCA to the Janesville wastewater treatment plant.

Stormwater runoff drains to a series of catch basins and underground piping to two infiltration cells that reduce the amount total dissolved solids (SHINE 2022d). Any stormwater that does not drain to the catch basins flows over dense grassland, which serves as a filter for suspended solids, before leaving the site. Eventually, stormwater flows to an unnamed tributary to the Rock River that lies approximately 1 mi (1.6 km) southeast of the site.

3.6.1.2 Federally Listed Species and Critical Habitats under U.S. Fish and Wildlife Service Jurisdiction

As part of its operating license application review, the NRC staff submitted project information to the FWS’s Environmental Conservation Online System (ECOS) Information for Planning and Conservation system to obtain an updated list of species in accordance with 50 CFR 402.12(c). The FWS provided the NRC with a list of threatened and endangered species that may occur in the proposed action area (FWS 2019a) and subsequently provided additional information about these species in an email (FWS 2019b). The FWS’s ECOS list identified four species:

- northern long-eared bat (*Myotis septentrionalis*),
- whooping crane (*Grus americana*),
- eastern prairie fringed orchid (*Platanthera leucophaea*), and
- prairie bush-clover (*Lespedeza leptostachya*).

While the NRC staff evaluated the prairie bush-clover in its previous review, the NRC has not previously evaluated the northern long-eared bat, whooping crane, or eastern prairie fringe orchid for SHINE. In the sections below, the NRC analyzes the likelihood of occurrence and potential impacts on these species as well as whether any new information exists that would change the NRC's previous conclusion for the prairie bush-clover. No critical habitats are within the project area under review (FWS 2019a). Table 3-2 identifies the NRC staff's ESA effect determinations that resulted from the staff's analysis. As a result of this analysis, the staff determined that none of the four species are present in the action area due to habitat requirements, life history traits, or a combination of other factors.

Table 3-2 Effect Determinations for Federally Listed Species under U.S. Fish and Wildlife Service Jurisdiction

Species	Federal Status[(a)]	Potentially Present in the Action Area?	Effect Determination[(b)]
northern long-eared bat	FT	No	No effect
whooping crane	FE	No	No effect
eastern prairie fringed orchid	FT	No	No effect
prairie bush-clover	FT	No	No effect

(a) Under the Endangered Species Act, species may be designated as Federally endangered (FE) or Federally threatened (FT).

(b) The NRC staff makes its effect determinations for federally listed species in accordance with the language and definitions specified in the FWS and NMFS's Endangered Species Consultation Handbook (FWS and NMFS 1998).

3.6.1.2.1 Northern Long-Eared Bat (Myotis septentrionalis)

The northern long-eared bat is found across much of the eastern and north-central United States and all Canadian provinces from the Atlantic coast west to the southern Northwest Territories and eastern British Columbia. In Wisconsin, the Wisconsin Department of Natural Resources reports occurrences of the species in 33 counties across the state, including Rock County (WDNR 2019). Northern long-eared bats predominantly overwinter in hibernacula of various sizes that include underground caves and abandoned mines. In summer, northern long-eared bats typically roost individually or in colonies underneath bark or in cavities or crevices of both live trees and snags.

SHINE (2022d) reports no evidence of this species on the SHINE site. Prior to construction, the SHINE site was in agricultural use and did not contain any trees or caves. The closest acoustic survey conducted, which the Wisconsin Bat Program conducted in northern Janesville, did not find evidence of northern long-eared bats (SHINE 2020a). Even if northern long-eared bats were to roost nearby, individuals would be unlikely to fly across or otherwise use the SHINE site because the species prefers riparian and other edge habitats when foraging and migrating. Thus, the action area does not provide suitable habitat.

Because the action area does not provide suitable habitat and no occurrences of this species are known from the SHINE site or surrounding vicinity, the proposed action is very unlikely to result in impacts on this species. Thus, the risk of impacts such as mortality or injury from collisions with facility structures and vehicles; habitat loss, degradation, disturbance, or fragmentation, and associated effects; and behavioral changes resulting from noise or other site activities are extremely unlikely. For these reasons, the NRC staff concludes that the proposed action would have no effect on the northern long-eared bat.

3.6.1.2.2 Whooping Crane (Grus americana)

The only remaining naturally occurring whooping crane population winters on the Gulf Coast, primarily in Texas's Aransas National Wildlife Refuge, and breeds in Canada's Northwest Territories and Alberta, mainly in Wood Buffalo National Park. Between these locations, the individuals stop over within suitable habitat during migration. A reintroduced population also migrates from Florida to Wisconsin with the guidance of ultralight aircraft, and two other reintroduced populations in Florida and Louisiana are nonmigratory (Cornell 2020). Thus, the population in Wisconsin is considered a nonessential experimental population. For this reason, the Wisconsin Department of Natural Resources does not track whooping cranes in its Natural Heritage Inventory, and sightings in Wisconsin are not well documented.

Whooping cranes breed in shallow, grassy, mixed wetlands and winter within coastal marshes and estuaries. During migration, the species prefers wild shallow river flats and wetlands for stopover. Thus, the action area does not provide suitable habitat. SHINE (2022d) reports no evidence of this species on the SHINE site.

Because the action area does not provide suitable habitat and no occurrences of this species are known from the SHINE site or surrounding vicinity, the proposed action is very unlikely to result in impacts to this species. Thus, the risk of impacts such as mortality or injury from collisions with facility structures and vehicles; habitat loss, degradation, disturbance, or fragmentation, and associated effects; and behavioral changes resulting from noise or other site activities are extremely unlikely. For these reasons, the NRC staff concludes that the proposed action would have no effect on the whooping crane.

3.6.1.2.3 Eastern Prairie Fringed Orchid (Platanthera leucophaea)

The eastern prairie fringed orchid occurs in mesic prairies and wetlands in Illinois, Indiana, Iowa, Maine, Michigan, Missouri, Ohio, Oklahoma, Virginia, and Wisconsin. It requires full sun and little to no woody encroachment for successful growth.

In fall 2011, spring 2012, and summer 2012, SHINE (2013) performed pedestrian surveys of terrestrial plants to qualitatively characterize site flora. Surveyors did not identify the eastern prairie fringed orchid itself or suitable habitat for this species on the site. No additional surveys have been completed since that time. The action area, which was previously used for agriculture, was further disturbed during SHINE construction and remains unsuitable for the eastern prairie fringed orchid in its current state as an industrial use site. Based on this information, the NRC staff finds that this species is extremely unlikely to occur on the SHINE site and that the proposed action would have no effect on the eastern prairie fringed orchid.

*3.6.1.2.4 Prairie Bush-Clover (*Lespedeza leptostachya*)*

During its construction permit review, the NRC determined that prairie bush-clover does not occur on the SHINE site. The NRC has not identified any information during the current review that would change its previous conclusions with respect to this species. Therefore, the NRC staff concludes that the proposed action would have no effect on the prairie bush-clover.

3.6.1.3 Federally Listed Species and Critical Habitats under National Marine Fisheries Service Jurisdiction

No federally listed species or critical habitats under the NMFS's jurisdiction occur within the action area because the Rock River and the unnamed tributary do not contain any anadromous or marine species. Accordingly, the proposed action would have no effect on federally listed species or critical habitats under the NMFS's jurisdiction, and ESA Section 7 consultation with the NMFS is not required.

3.6.2 Magnuson–Stevens Act: Essential Fish Habitat

No essential fish habitat occurs near the SHINE site because the NMFS and regional Fishery Management Councils have not designated such habitat under the Magnuson–Stevens Fishery Conservation and Management Act, as amended (16 U.S.C. 1801 et seq.) within the Rock River or the unnamed tributary. Accordingly, the proposed action would have no effect on essential fish habitat, and essential fish habitat consultation with the NMFS is not required.

3.7 Historic and Cultural Resources

As detailed in Section 4.6 of the FEIS, the NRC is required under the National Historic Preservation Act of 1966, as amended (NHPA; 54 U.S.C. 300101 et seq.), to consider the effects of its undertaking on historic properties included in, or eligible for inclusion in, the National Register of Historic Places in the Area of Potential Effects (APE). The APE for operation of the SHINE facility is the 91-ac (37-ha) site and its immediate environs. The historic preservation review process (Section 106 of the NHPA) is outlined in regulations issued by the Advisory Council on Historic Preservation in 36 CFR Part 800.

In accordance with 36 CFR 800.8(c), on November 27, 2019, the NRC initiated consultations on the proposed action by writing to the Advisory Council on Historic Preservation and the State Historic Preservation Officer (SHPO), which in the State of Wisconsin is part of the Wisconsin Historical Society (WHS). The NRC similarly initiated consultation with the following 24 Federally recognized Tribes (see Appendix B):

- Citizen Potawatomi Nation
- Bad River Band of Lake Superior Chippewa Indians
- St. Croix Chippewa Indians of Wisconsin
- Menominee Indian Tribe of Wisconsin
- Flandreau Santee Sioux Tribe of South Dakota
- Iowa Tribe of Oklahoma
- Forest County Potawatomi Community
- Hannahville Indian Community
- Ho-Chunk Nation of Wisconsin
- Sac and Fox Nation

- Lower Sioux Indian Community
- Prairie Band of Potawatomi Nation
- Prairie Island Indian Community
- Santee Sioux Nation
- Sisseton-Wahpeton Oyate of the Lake Traverse Reservation
- Spirit Lake Tribe
- Upper Sioux Community
- Peoria Tribe of Indians of Oklahoma
- Winnebago Tribe of Nebraska
- Fort Belknap Indian Community of the Fort Belknap Reservation of Montana
- Lac du Flambeau Band of Lake Superior Chippewa Indians
- Little Traverse Bay Bands of Odawa Indians
- Miami Tribe of Oklahoma
- Osage Nation.

In its letters, the NRC staff provided information about the proposed action, defined the APE, and indicated that the NRC intends to comply with Section 106 through the NEPA process, pursuant to 36 CFR 800.8(c). The NRC invited participation in the identification and possible decisions concerning any historic properties and also invited participation in the scoping process.

In a response from the WHS dated December 10, 2019, the Wisconsin SHPO acknowledged that the APE has not changed since the FEIS review determined that no historic properties would be affected, and that they had no additional concerns or comments about the effect of the SHINE facility on historic cultural features in the project area (WHS 2019).

The NRC also received responses from the Winnebago Tribe of Nebraska and the Miami Tribe of Oklahoma. The Winnebago Tribe of Nebraska requested that NRC provide additional copies of maps included in the agency's November 27, 2019, correspondence showing the location of the SHINE site. The NRC staff provided this information to the Winnebago Tribe of Nebraska on January 24, 2020 (NRC and Winnebago 2020). The Miami Tribe of Oklahoma indicated that the Tribe is not currently aware of any existing documentation directly linking a specific Miami cultural or historic site to the SHINE site. However, because the SHINE site is within the aboriginal homelands of the Miami Tribe, they requested that they be consulted if any human remains, Native American cultural items, or archaeological evidence is discovered during any phase of the project (MTO 2020).

Accordingly, the NRC staff identified no new or differing information that would warrant revision of the description of the affected environment and no significant new information regarding environmental impacts contained in FEIS Sections 3.6 and 4.6, respectively. In addition, no historic or cultural resources have been discovered during the course of excavation activities associated with construction of the SHINE facility (SHINE 2020a). Although normal operation and maintenance of the SHINE facility could result in the inadvertent discovery of previously undiscovered cultural resources, SHINE would continue to follow the procedures specified in its cultural resource management plan to manage and protect any such resources, as discussed in Section 4.6.4 of the FEIS. Therefore, the NRC staff concludes that the impacts on historic and cultural resources from the operation of the proposed SHINE facility would remain SMALL.

3.8 Socioeconomics

The NRC staff identified no differing or new information that would warrant revising the description of the affected environment, and no significant new information regarding environmental impacts, contained in FEIS Sections 3.7 and 4.7, respectively. The projected 200 jobs generated during SHINE facility operation (see Section 2.1, Table 2-1) are still less than 1 percent of the currently available labor force in Janesville and Rock County; therefore, employment impacts would remain SMALL.

3.9 Human Health

Section 3.8 of the FEIS provides a general description of the regulatory requirements for operating the SHINE facility in regard to radiological and nonradiological human health. It also describes the human health impact pathways for both potential radiological and potential nonradiological hazards. The NRC staff identified no differing or significant new information related to the human health-affected environment beyond the information in the FEIS.

Section 4.8.2 of the FEIS discusses the human health impacts as a result of operation of the SHINE facility. The following discussion presents new information regarding radiological human health impacts resulting from operations of the SHINE facility.

As discussed in Section 2.7 of the FEIS, radioactive gaseous effluents containing krypton, xenon, iodine, and tritium would be released into the environment. The NRC staff expects radioactive gaseous effluents to be the only contributor to a radiation dose to members of the public because, as discussed in Section 3.9 of this supplement, no routine radioactive liquid effluents would be released, because there would be no piped effluent pathways from the RCA to the sanitary sewer. Radioactive liquid wastes would generally be solidified and shipped offsite for disposal. Any radioactive liquid discharges to the sanitary sewer would be infrequent and made in accordance with the release criteria in 10 CFR 20.2003, 10 CFR 20.2007, and Janesville City Ordinance 40-170 (City of Janesville 2020b). Prior to discharge, the collected liquid would be sampled, analyzed, and verified to meet the criteria for release to the sanitary sewer from the listed State and Federal regulations. Liquids meeting these criteria would be transferred outside of the RCA in portable containers and released to the sanitary sewer. Buildings containing radioactive material include shielding to minimize direct radiation outside the facility. Given this shielding, SHINE projected negligible direct radiation from the facility at the site boundary (SHINE 2020a, 2021c).

SHINE estimates that the maximum dose to a member of the public from radioactive gaseous effluents in the offsite environment would be approximately 4.6 mrem (0.046 mSv) (SHINE 2021c). This is less than the dose estimated in the FEIS and is attributed to the removal of the UREX and thermal denitration processes and the resultant changes in the RPF design, effluent releases, and waste systems, as described in Section 3.9 of this supplement. This dose is well below the annual dose limit of 100 mrem (1.0 mSv) in 10 CFR 20.1301(a)(1) and is well below the ALARA requirements in 10 CFR 20.1101(d) that impose a constraint of 10 mrem (0.1 mSv) on the annual dose from radioactive gaseous effluents (SHINE 2021c).

3.9.1 Description of the Radiation Control Program

SHINE established a radiation protection program for protection of the radiological health and safety of workers and members of the public during facility operations. The objectives of the program are to prevent acute radiation injuries (non-stochastic or deterministic effects) and to limit the potential risks of probabilistic (stochastic) effects (which may result from chronic exposure) to otherwise acceptable levels. The SHINE radiation protection program was developed and would be implemented commensurate with the risks posed by a medical isotope facility. The program contains the SHINE management policy statement to maintain occupational and public radiation exposures that are ALARA (SHINE 2021c).

SHINE developed its radiation protection program to meet the requirements of 10 CFR Part 20, Subpart B, “Radiation Protection Programs,” and to be consistent with the guidance provided in Regulatory Guide 8.2, Revision 1, “Administrative Practices in Radiation Surveys and Monitoring” (NRC 2011), and ANSI/ANS 15.11-2016, “Radiation Protection at Research Reactor Facilities” (ANSI/ANS 2016). To achieve occupational doses to onsite personnel and doses to members of the public that are ALARA, SHINE’s radiation protection program includes, but is not limited to, the following:

- written procedures, policies, and practices to safely implement and carry out all necessary activities of the radiation control program;
- defined roles and personnel responsibilities for implementing and carrying out the radiation control program, from key management personnel to onsite workers;
- periodic assessments of work practices and internal/external doses received to evaluate the program’s effectiveness;
- radiation work plans, radiation protection training, and the use of personal protective equipment to limit radiation exposure;
- facility and equipment design and engineering controls to limit access, work times, and radiation exposure;
- the use of radiation dosimetry devices to determine external radiation dose and appropriate calculational methodologies to determine internal radiation dose;
- the use of calibrated radiation detection and measurement instruments to perform functions such as radiation surveys, contamination surveys, package surveys, sealed source leak tests, air sampling measurements, effluent release measurements, and dose rate measurements; and
- recordkeeping of radiation protection records to develop trend analysis to keep staff and management informed regarding radiation protection matters and for reporting required information to regulatory agencies (SHINE 2021c).

SHINE considered NRC guidance provided in Regulatory Guides 8.2 (NRC 2011), 8.13 (NRC 1999), and 8.29 (NRC 1996) in the design and implementation of the SHINE ALARA program. The stated objective of the program is to make every reasonable effort to maintain exposure to radiation as far below the limits of 10 CFR 20.1201 for occupational workers and 10 CFR 20.1301 for members of the public as is practical. The radiation protection program summarized above documents the policies, procedures, and practices that are implemented to ensure the ALARA goal is met (SHINE 2021c).

3.9.2 Description of the Radiological Environmental Monitoring Program

SHINE would maintain a REMP as another method of demonstrating compliance with the requirements of 10 CFR 20.1302, “Compliance with Dose Limits for Individual Members of the Public.” The REMP would be used to verify the effectiveness of facility measures that 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 (SHINE 2021c).

SHINE also considered NRC guidance provided in Regulatory Guide 4.1, "Radiological Environmental Monitoring for Nuclear Power Plants" (NRC 2009) and Table 3.12-1 of NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors" (NRC 1991), when developing the REMP for its facility (SHINE 2020b). In addition, SHINE used the data quality objectives (DQOs) process, which is a scientific systematic planning method for determining the type, quantity, and quality of data needed to reach defensible decisions or make credible estimates. SHINE developed the DQOs according to the EPA's Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA 2006) (SHINE 2021c).

3.9.2.1 Direct Radiation Monitoring

SHINE will measure direct exposure to gamma- and beta-emitting radionuclides released through the stack of their production facility at various receptor locations using environmental dosimeters. The dosimeters measure direct radiation from radiation sources contained within the SHINE main production facility, from sources within the material staging building, from radioactivity in the airborne effluent, and from deposition of airborne radioactivity onto the ground.

SHINE considered NRC guidance in NUREG-1301 (NRC 1991) when determining the number of environmental dosimeters and their placement locations. Given that guidance and taking into account the facility size, SHINE determined that it would monitor direct radiation at 24 separate dosimeter locations. SHINE determined the locations of the environmental dosimeters to provide annual direct dose information at onsite locations that are expected to have occupancy and at property line locations, which ensure all directions are monitored. The property line locations would include the direction of the theoretical Maximally Exposed Individual and the direction of the nearest occupied structure. Three of the dosimeters would be stationed offsite at special interest areas and one dosimeter would be located a significant distance from the SHINE facility to represent background dose. SHINE stated that at least one location would include a paired dosimeter so that data quality can be determined. Figure 3-1 shows the location of the onsite and property line environmental dosimeters. SHINE would contract with a laboratory to process the results from the environmental dosimeters and generate reports containing those values each quarter. Background radiation based on results from the baseline environmental survey would be subtracted from the dosimeter results (SHINE 2021c).

3.9.2.2 Air Sampling

SHINE considered NRC guidance provided in Table 3.12-1 of NUREG-1301 (NRC 1991) and the DQO (EPA 2006) process when establishing locations for airborne sample acquisition, sampling frequency, and type of sample analysis. Airborne sampling is done to identify and quantify particulates and radioiodine in airborne effluents. SHINE would perform air sampling monthly using continuous air samplers (CASs), which include a radioiodine canister for iodine-131 (I-131) analysis and a particulate sampler, which is analyzed for gross beta radioactivity.

To ensure all directions are monitored, SHINE would locate four CASs near the facility property line in the north, south, east, and west direction sectors. These CASs would be co-located with the environmental dosimeters labeled ED1, ED9, ED5, and ED13 in Figure 3-1. A control CAS would be located a sufficient distance from the SHINE facility to provide background information for airborne activity.

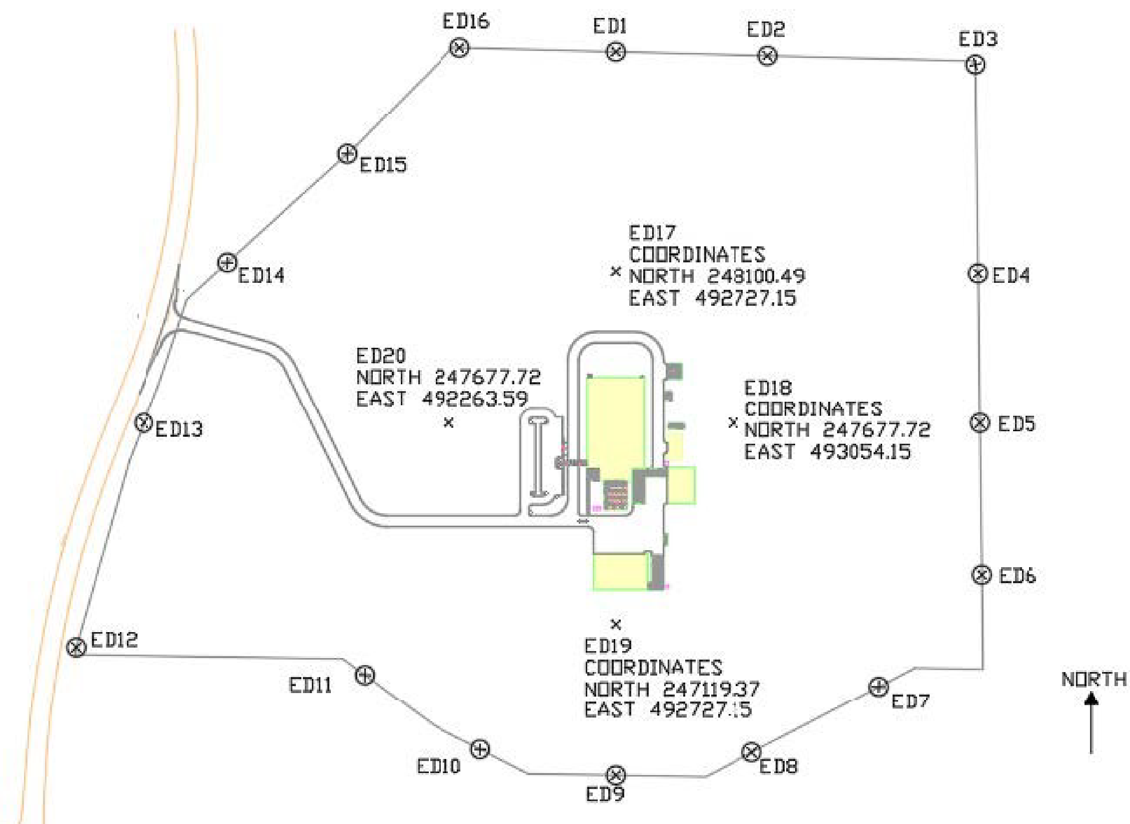

Figure 3-1 Environmental Dosimeter Locations (SHINE 2021c)

SHINE would use the air sampling data to validate its effluent monitoring and dose compliance data sets. Results would be compared to the radionuclide-specific values in 10 CFR Part 20, Appendix B, "Annual Limits on Intakes and Derived Air Concentrations of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage." A sum of the fractions approach would be used, wherein the isotopic values measured would be compared with their associated limits in 10 CFR Part 20, Appendix B. This would allow the calculation of dose due to iodine and particulate activities and would include both inhalation dose and cloud immersion dose. Background subtraction would be based on the results of the baseline environmental survey, and thus would provide a location-specific and statistically valid means of subtracting background (SHINE 2021c).

3.9.2.3 Groundwater Monitoring

Four test wells within the property boundary of the SHINE facility were used for monitoring groundwater in support of a hydrological assessment of the site. One test well is located north, one south, one east, and one west of the SHINE main production facility. The nearest drinking water source is a well located approximately a third of a mile (0.54 km) to the northwest of the facility. Measured local water table elevations for the site identify the groundwater gradient and indicate that the groundwater flow is to the west and to the south. Therefore, SHINE would sample the test wells to the west and the south quarterly for tritium and gamma-emitting isotopes (SHINE 2021c).

3.9.2.4 Preoperational Baseline Monitoring

Prior to commencement of operations, SHINE would complete preoperational baseline monitoring, which would serve to provide baseline data for evaluating the impact of operations at its facility. The preoperational monitoring would be conducted so that the preoperational radiological conditions are understood in sufficient detail to allow future reasonable, direct comparison with data collected after licensed operation of the facility. The collection of samples and analysis of data would follow the sampling and analyses schedules specified in the sections above for direct radiation monitoring, air sampling, and groundwater monitoring, and would continue into the operational phase of facility operation (SHINE 2021c).

3.9.2.5 Reports and Procedures

An annual report about the REMP would be provided to the NRC. The annual report would provide summarized results of environmental surveys performed outside the facility.

Environmental surveys conducted in support of the REMP would be performed in accordance with SHINE facility implementing procedures. Document control measures would be employed to ensure that changes to the REMP or implementing procedures are reviewed for adequacy, approved by authorized personnel, and are distributed to and used at the appropriate locations throughout the facility. Records of offsite environmental surveys would be retained in accordance with the SHINE records management program for the lifetime of the facility.

SHINE would conduct an annual environmental monitoring program review to examine the adequacy and effectiveness of the REMP. The program review would evaluate the need to expand (or reduce) the environmental monitoring program given the results of the environmental data and trends in environmental radioactivity. SHINE states that any reductions would be thoroughly evaluated and justified, given that environmental data indicating the absence of facility-related radioactivity are important. The review would confirm exposure pathways and sampling media and validate that the principal radionuclides being discharged are the same nuclides being analyzed in the environmental program.

Any adverse trends or anomalies identified during the conduct of the program, annual report preparation, or periodic reviews would be entered into the facility corrective action program for disposition. (SHINE 2021c)

As discussed in Section 4.8.2.2 of the FEIS, the NRC staff concluded that the nonradiological impacts from the proposed SHINE facility on workers and members of the public would be SMALL. The NRC staff is currently conducting an independent safety evaluation to verify that the radiological exposure to occupational workers and to members of the public would be below regulatory limits set in 10 CFR Part 20. The results of this evaluation will be documented in a separate safety evaluation report (SER), which will be publicly available. If the NRC staff concludes that the dose to workers and the public would be below the regulatory limits set in 10 CFR Part 20, the NRC staff concludes that the radiological human health impacts would be SMALL.

3.9.3 Radiological Impacts from Transportation

As described in Section 19.4.10 of the SHINE CP ER (SHINE 2015a), transportation of radioactive materials, both on public highways and by air, would occur in conjunction with operation of the SHINE facility. Radioactive materials transported to and from the SHINE facility site would include fresh LEU, unirradiated and irradiated LEU targets; purified Mo-99, I-131, and Xe-133 products; and take-back LEU. When transporting waste and other radioactive materials on public roads, SHINE or commercial carriers must comply with the applicable DOT regulations in 49 CFR Parts 172, 173, 177, and 397, as well as the NRC packaging requirements for radioactive material in 10 CFR Part 71. For transport of medical isotope products by air, the air carrier chosen by SHINE must also comply with additional DOT regulations in 49 CFR Part 175. While SHINE would ship most of the medical isotopes by air, transportation scenarios were based on land routes to conservatively estimate radiological doses because air shipments would expose a smaller public population and the resulting exposure time for the air crews would be shorter for each shipment (SHINE 2015a).

As discussed in Section 19.4.10 of the SHINE CP ER (SHINE 2015a), SHINE estimated the total incident-free dose to the general public from all public highway radioactive material transportation associated with the proposed SHINE facility including transportation of waste. In SHINE's CP transportation analysis, it was noted that the output of the version of the routing code TRAGIS applied in the CP analysis would have a different population count than an exposed population total based on the population densities. Thus, SHINE scaled the CP population doses based on the ratio between the two population totals.

During the operating license application review, the NRC found differences in the number of radiological waste shipments relative to the numbers provided in the CP ER (NRC 2020a; SHINE 2020a). SHINE updated its CP transportation analysis to account for adjustments to the number of radioactive waste shipments and to apply a conservative external radiation level (NRC 2020d, 2020e; SHINE 2020c). Radioactive waste shipments to the Energy Solutions facility in Clive, Utah, changed from 12 in the CP ER to 17, and shipments to Waste Control Specialists facility in Andrews, Texas, changed from 22 to 1. The number of annual medical isotope shipments of 52 remains unchanged. SHINE made a conservative external radiation level of 40 mrem/hour (0.4 mSv/hr) at 1 m from a shipment by assuming a point source based on the 49 CFR 173.441(b)(3) regulatory limit of 10 mrem/hr (0.1 mSv/hr) at any point 2 m (6.6 ft) from the outer lateral surfaces of the vehicle.

The revised dose to the workers (i.e., package handlers and transportation workers) for the radioactive material from the SHINE facility was determined to be approximately 27.3 person-rem/year (yr). SHINE is required to ensure that all worker occupational doses are within regulatory limits of 10 CFR Part 20 and are ALARA. The revised doses to members of the public along the highway transportation routes were assessed to be approximately 42.6 and 0.75 person-rem/yr based on unscaled and scaled populations, respectively. These total population doses are significantly less than 1 percent of the annual natural background dose (i.e., an individual annual dose of approximately 310 mrem/yr (3.1 mSv/yr)) for a scaled population of 221,594 provided in the CP ER (SHINE 2015b).

The NRC has previously evaluated the environmental impact of the transportation of radioactive materials on public roads and by air. The NRC concluded in 1977 that when radioactive material transportation is performed in compliance with all Federal regulations, the impact of such transportation is small (NRC 1977). The Commission determined that the environmental impacts, radiological and nonradiological, of normal (incident-free) transportation of radioactive materials and the risks and consequences of accidents involving radioactive material shipments in packages for which the NRC has issued design approvals meeting the performance standards of 10 CFR Part 71 were small (49 FR 9352). Regulations, shipping practices, and cask designs for transporting radioactive material have remained essentially unchanged since 1977. Although more recent NRC assessments of the safety of radioactive materials transportation have focused on nuclear power reactor spent fuel, rather than the types of radioactive materials that would be transported in conjunction with the proposed SHINE facility, these assessments have shown, through the use of more advanced calculation methodologies, that the impacts associated with transportation of nuclear power reactor spent fuel are smaller than originally thought in 1977 (NRC 2014). Because transportation performed in conjunction with operation of the SHINE facility would be conducted in compliance with DOT and NRC regulations and would have low radiological impacts on the public, the NRC staff concludes that the impacts from transportation of radioactive materials during operation would be SMALL.

3.9.4 Waste Management

Section 2.7 of the FEIS describes the storage, treatment, and transportation of radioactive and nonradioactive waste related to the SHINE facility. SHINE does not anticipate any long-term storage of radioactive and nonradioactive materials, such as medical radioisotope products, target solution, reagents, or resulting waste. However, operation of the SHINE facility would include temporary storage and generation of radioactive waste. Section 4.9 of the applicant's supplemental ER and request for additional information responses (SHINE 2019, 2021a, 2022d) updates the waste management information and a summary is presented in Section 2.5 of this supplement.

Section 2.5 of this supplement describes and evaluates the radiological waste management program, including administrative controls, waste processing systems, and types and quantities of radiological waste and radiological waste shipments at the SHINE facility and new information regarding waste management. Based on its review of the additional information, the NRC staff identified no differing or new information that would change the generation, storage, waste management activities, waste minimization and pollution measures, and transportation of radioactive and nonradioactive waste for waste systems. The NRC staff concludes that the potential impacts of the changes on waste management at the SHINE facility would not affect the conclusions reached in the previous FEIS and would remain SMALL.

3.10 Transportation

Section 3.9 of the FEIS describes the major road, rail, and air transportation features in the vicinity of the SHINE site. Section 4.10 of the FEIS describes the additional traffic during operation of the SHINE facility that would result from commuting employees, inbound material deliveries, outbound medical isotope product shipments, and outbound radioactive and nonradioactive waste shipments. The NRC staff identified differing or new information since the publication of NUREG-2183 (NRC 2015) that would change some aspects of the affected transportation environment and potential impacts associated with operation of the SHINE facility. Specifically, the Wisconsin Department of Transportation (WisDOT) published updated traffic counts for the road network serving the site, and SHINE revised the estimated shipment and worker traffic needed to support operation of the facility. In addition, SHINE conducted supplementary transportation studies to assess the potential impact of operating the RPF.

3.10.1 Changes in Baseline Average Annual Daily and Peak Hour Traffic Counts

Section 3.9, Table 3-21, of the FEIS presents average annual daily and peak hour traffic counts along road segments in the vicinity of the site based on data collected in 2010. Updated 2016 average annual daily traffic counts for these road segments are provided below in Table 3-3. Updated traffic counts and estimates generally indicate small changes from the 2010 data considered in the FEIS, without a discernable pattern of increases or decreases in traffic near the SHINE site (SHINE 2022d).

Table 3-3 Average Annual Daily Traffic Counts in the Vicinity of the SHINE Site

Traffic Count Location	Vehicles Per Day 2010	Vehicles Per Day 2016
U.S. Highway 51, south of State Trunk Highway 11	9,000	8,100
U.S. Highway 51, north of Town Line Road	9,400	8,600
State Trunk Highway 11, east of U.S. Highway 51	8,400	11,100
State Trunk Highway 11, west of U.S. Highway 51	4,500	5,100
State Trunk Highway 11, west of Interstate 39/90	12,400	12,800
Interstate 39/90, south of State Trunk Highway 11	45,700	47,400
Interstate 39/90, north of State Trunk Highway 11	50,400	53,500
Town Line Road, east of U.S. Highway 51	3,400	3,400

Sources: SHINE 2022d, WisDOT 2016a.

Estimated annual average peak and daily traffic totals in the vicinity of the site are provided in Table 3-4. These values also generally indicate small changes in increases or decreases in peak volumes, with peak annual average volumes along U.S. Highway 51 (accessing the site) ranging from 549 (midday peak) to 696 (PM peak).

Baseline traffic conditions may also be influenced by road improvements completed in the vicinity of the SHINE facility since publication of the FEIS. These include lane expansion along Prairie Street (County Highway G) south of State Trunk Highway 11, and redesign of the interchange between State Highway Trunk 11 and Interstate 39/90.

Table 3-4 Estimated Annual Average Peak and Daily Total Traffic Counts in the Vicinity of the Proposed Site

Count Site No.	Location	Year of Count	AM Peak	Midday Peak	PM Peak	Daily Total
531345	U.S. Highway 51, north of Happy Hollow	2010	667	679	746	8,977
	Road, Rock Township	2016	577	549	656	8,083
530104	U.S. Highway 51, 1.0 mi. (1.6 km) south	2010	693	(a)	802	(a)
	of SWRA	2016	597	575	696	8,558
531344	State Trunk Highway 11, east of	2010	659	509	703	8,411
		2016	795	642	830	11,075
531491	State Trunk Highway 11, between River	2010	368	263	382	4,465
	Road and U.S. Highway 51	2016	427	331	432	5,084
530215	U.S. Highway 51, 0.5 mi. (0.8 km) south	2010	537	753	401	9,628
	of Burbank Avenue, City of Janesville	2016	684	754	857	10,334

Count Site No.	Location	Year of Count	AM Peak	Midday Peak	PM Peak	Daily Total
531300	Townline Road, between County Highway G and the Interstate 39/90 overpass	2010 2016	58 (a)	66 (a)	96 (a)	1,102 (a)

(a) No information available
Sources: SHINE 2022d, WisDOT 2016b

3.10.2 Updated SHINE Commuter and Shipment Information

Updated SHINE facility operating characteristics that could impact the local transportation network are presented in Table 2-1 of this supplement.

These characteristics include the projected number of radioactive waste shipments, which decreased from 26.5 to 18 per year, and the projected number of nonradioactive waste shipments, which increased from 12 to 60 per year. Collectively, these changes would result in an increase of 3.3 waste shipments per month. Other inbound and outbound truck deliveries were projected to remain unchanged at 36 and 39 per month, respectively (SHINE 2020a).

In its supplemental ER, SHINE additionally estimated that the number of workers commuting to the site would increase from 150 to 200 and SHINE commissioned updated traffic studies (see Section 3.10.3) based on this higher bounding value (SHINE 2022d). However, SHINE subsequently indicated that it no longer intends to construct an administration building on the SHINE facility site, and that administrative activities supporting Mo-99 production will be performed elsewhere in a new corporate headquarters building (see Section 3.13.7). Accordingly, SHINE now expects that the number of workers accessing the SHINE facility site on a daily basis, via the connection to U.S. Highway 51, will be substantially less than the 200 workers assumed in the updated traffic studies (SHINE 2021a).

3.10.3 Updated Traffic Studies

Section 4.10.2 of the FEIS discusses transportation impacts as a result of operation of the SHINE facility. In the FEIS, the NRC staff determined that impacts on transportation during operations would be SMALL to MODERATE because previous traffic studies had suggested a slight degradation of service (i.e., traffic delays) could result at the intersection of westbound State Trunk Highway 11 onto southbound U.S. Highway 51 during the morning peak traffic hour. Since publication of the FEIS, two additional analyses have been completed that assess the potential traffic impacts that could result from operation of the SHINE facility.

First, SHINE commissioned a Traffic Impact Analysis (TIA) that included updated level of service analyses for the intersection of U.S. Highway 51 and State Trunk Highway 11, and for the intersection of U.S. Highway 51 and the SHINE facility (SHINE 2020a, 2022d). The purpose of the TIA was to identify the required improvements at the proposed access point to the facility, and to determine if impacts on the existing roadway network would require other infrastructure improvements. The study identified the existing traffic volumes and analyzed the existing conditions of the study at intersections during the weekday AM and PM peak hours. It also evaluated existing and potential 2020 traffic operations with and without the proposed development within the study area, and possible improvements that could be made at these intersections to accommodate the proposed development in the area. A supplemental level of service analysis for the intersection of State Trunk Highway 11 and County Highway G and for the intersection of U.S. Highway 51 and Town Line Road was also performed in association with the TIA (SHINE 2020a).

SHINE's initial traffic studies supporting the FEIS indicated that a slight degradation of service would occur at the intersection of U.S. Highway 51 and State Trunk Highway 11 during AM peak hours. In contrast, the updated level of service analyses indicated that all intersections would continue to have acceptable operations, that is, all study area intersections would operate at an acceptable level, with no degradation of service levels. The updated analyses further indicated that the impacts on the existing road network from construction and operation of the SHINE facility would be minimal and would not require mitigative measures.

Based on subsequent review of changes in baseline conditions, traffic attributable to changes in the operation of the SHINE facility, and new traffic studies submitted by SHINE to the State of Wisconsin, the NRC staff determined that traffic volumes are not expected to exceed those presented in the FEIS, and the earlier impact determination has been updated to indicate that impacts on the transportation infrastructure during operations would likely be SMALL.

3.11 Accidents

SHINE presented accident analyses related to the SHINE facility in two categories: those that involve nuclear processes or radiation and those that involve the handling and storage of hazardous chemicals. Hazard identification for a given postulated accident is performed by identifying the radiological or chemical hazards that have the potential to cause harm to the public, facility staff, or the environment. This includes physical process hazards (e.g., deflagration, fire, flooding) that could result in adverse effects on licensed materials. Radiological hazards include radiation sources from the SHINE processes (e.g., neutron driver, target solution vessel), fission products, activation products, and tritium. Fissile material hazards are also considered for postulated criticality accidents. Chemical hazards are identified that could affect licensed materials or the safe operation of the facility. Chemical effects considered include flammable, reactive, oxidation, and chemical incompatibility effects. The potential consequences are also identified for each postulated accident sequence and consist of radiological dose to the public or facility staff (i.e., control room operator), chemical dose to the public or facility staff (i.e., control room operator and RCA worker), criticality event, or no consequence of concern (SHINE 2021c).

3.11.1 Maximum Hypothetical Accident

This section discusses the potential offsite radiological consequences of the maximum hypothetical accident (MHA) and the controls to prevent or mitigate these potential consequences. The MHA is a conservative evaluation and represents the bounding consequences for fission-product-based design-basis accidents at the SHINE facility.

To demonstrate the protection of the public health and safety, SHINE compared the results of this analysis to the 1 rem (0.01 Sv) TEDE limit established by the EPA early-phase Protective Action Guides (PAGs) (EPA-400-R-92-001, "Manual of Protective Action Guides and Protective Actions For Nuclear Incidents," issued May 1992, and final revision EPA 400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents," issued January 2017). The purpose of the EPA PAGs is to support decisions about protective actions to provide reasonable assurance of adequate protection of the public from unnecessary exposure to radiation. The EPA PAGs are dose guidelines to support decisions that trigger protective actions such as staying indoors or evacuating to protect the public during a radiological incident. The PAG is defined as the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. Three principles considered in the development of the EPA PAGs are (1) prevent acute effects, (2) balance protection with other important factors and ensure that actions result in more benefit than harm, and (3) reduce risk of chronic effects. In the early phase of a nuclear incident, which may last hours to days, the EPA PAG recommends the protective actions of sheltering-in-place or evacuation of the public to avoid inhalation of gases or particulates in an atmospheric plume and to minimize external radiation exposures between 1 rem to 5 rem (0.01 to 0.05 Sv). So, if the projected dose to an individual from an incident is less than 1 rem (0.01 Sv), no protective action for the public is recommended.

SHINE identified the MHA for the SHINE facility as a failure of the Target Solution Vessel Off-Gas System pressure boundary resulting in a release of off-gas into the Target Solution Vessel Off-Gas System (TOGS) cell. This is a credible fission-product-based design-basis accident that bounds the radiological consequences to the public of all other credible fission-product-based accident scenarios. The appropriateness of this MHA will be documented by the NRC staff in a separate SER, which will be publicly available. SHINE provided a detailed description of this MHA in Section 13a2.2.7 of FSAR Chapter 13. A summary of the MHA is presented below.

In the MHA scenario, the initiating event is a break of the TOGS line downstream of the TOGS blower and subsequent release of noble gases and iodine into the TOGS cell. The nitrogen purge system actuates and pressurizes the TOGS cell through the leak in the TOGS pressure boundary. The radioactive material enters the gas space above the light-water pool and becomes confined by the primary confinement boundary. Some of the radioactive material is transported into the irradiation facility through minor leakage paths around penetrations in the confinement boundary. Detection of this airborne radiation in the radiological ventilation zone 1 exhaust subsystem (RVZ1e) actuates the primary confinement boundary isolation valves and an irradiation unit trip within 20 seconds of detection. After the isolation of the primary confinement boundary, leakage between the irradiation unit cell and the irradiation facility (IF) is driven primarily by pressure-driven flow caused by the nitrogen purge system. The irradiation unit cell sealing is a significant contributor to the function of the primary confinement boundary and will maintain its function under accident conditions. A sufficient time delay is provided by the holdup volume in RVZ1e to prevent radioactive gases from exiting through RVZ1e prior to the isolation of the primary confinement boundary. The radioactive material is then dispersed throughout the IF and exits the facility to the environment through building penetrations. The detection of high radiation in the RCA actuates the ventilation dampers between the RCA and the environment and minimizes the transport of the radioactive material to the environment. No operator actions are taken or required to reach a stabilized condition or to mitigate dose consequences. SHINE identified the safety controls to mitigate the severity of the MHA to be the primary confinement boundary, the ventilation radiation monitors, the nitrogen purge system, the ventilation isolation mechanisms, the holdup volume in the RVZ1e, and the evacuation of facility personnel in the immediate area within 10 minutes after receipt of electronic dosimeter or local radiation alarms. These safety controls will ensure that radioactive material is held up temporarily in the primary confinement boundary before any release from the building (SHINE 2021c).

The calculated dose for the MHA scenario is 727 mrem (7.27 mSv) to a maximally exposed member of the public (SHINE 2021c), which is within the EPA early-phase PAG limit of 1 rem (0.01 Sv) TEDE. The duration of the MHA is 30 days for the calculation of dose to the public. Because the assumptions of the MHA scenario are bounding, the doses calculated will likely not be exceeded by any other fission-product-based accident that may be considered to be credible.

SHINE also analyzed a release of the tritium inventory from the TPS as a design-basis accident. This analysis established bounding radiological conditions for a release of tritium due to a TPS process deflagration, release of tritium to the facility stack, and release of tritium from the tritium storage bed. SHINE stated that the initiating event is a seismic event that causes a break in the tritium piping and vessels such that the uncontrolled release of the entire tritium in-process inventory occurs within the tritium confinement boundary. SHINE assumed that the tritium confinement boundary remains intact and performs a mitigation function with respect to radionuclide transport from the TPS to the IF. The tritium confinement boundary components are designed to maintain their integrity under postulated accident conditions and are maintained in accordance with the facility configuration management and maintenance programs. Throughout this accident sequence, the leakage rate between each TPS glovebox and the TPS room is constant. After the TPS room ventilation is isolated, radiation transport is driven by air exchange between each TPS glovebox and the IF. Transport to the environment occurs through RCA boundary leakage paths. SHINE identified the safety controls to mitigate the severity of this accident to be the TPS room ventilation isolations, the glovebox pressure control and the vacuum/impurity treatment subsystem (VAC/ITS) ventilation isolations, the TPS confinement A/B/C tritium monitors, the tritium confinement boundary, the evacuation of facility personnel in the immediate area within 10 minutes after receipt of electronic dosimeter or local radiation alarms, and that the tritium release event recovery actions are completed within 10 days (SHINE 2021c).

The calculated dose for the postulated tritium inventory release design-basis accident is 798 mrem (7.98 mSv) to a maximally exposed member of the public (SHINE 2021c), which is within the EPA early-phase PAG limit of 1 rem (0.01 Sv) TEDE. The duration of the postulated tritium inventory release design-basis accident is 10 days for the calculation of dose to the public. Because the assumptions of this scenario are bounding, the doses calculated will likely not be exceeded by any other accident that may be considered to be credible.

As stated above, the MHA and the tritium release accident doses are less than 1 rem (0.01 Sv) TEDE. Further, as part of its separate safety review of the SHINE operating license application, the NRC staff is conducting a thorough, independent review of the potential dose to the public from the SHINE facility, which will be documented in the staff's SER. If the staff determines in its SER that the potential dose to the public from the SHINE facility is within the EPA early-phase PAG limit of 1 rem (0.01 Sv) TEDE, then the staff concludes that the impacts from potential radiological accidents would be SMALL.

3.11.2 Hazardous Chemical Accidents

SHINE evaluated the potential hazards of the chemicals proposed to be used at the SHINE facility. The analysis was performed for hazardous chemicals within the facility that interact with or are produced from licensed materials. These include chemicals that are licensed materials or contain licensed materials as precursor compounds, or substances that physically or chemically interact with licensed materials and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they endanger life or health. These include substances that are comingled with licensed material or that are produced by a reaction with licensed material. These do not include substances prior to process addition to licensed materials or after process separation from licensed materials. The analysis is therefore bounding for all hazardous chemicals produced from or comingled with licensed materials (SHINE 2021c).

To demonstrate the protection of the public health and safety for accidents involving chemical releases, SHINE used the quantitative acceptance limits taken from the Protective Action Criteria (PAC) values (DOE-NNSA 2018). The PAC values correspond to Acute Exposure Guideline Levels (AEGLs) in EPA guidance (EPA 2015), Emergency Response Planning Guidelines (ERPGs) (NOAA 2019), or Temporary Emergency Exposure Limit (TEEL) (DOE 2016) values for the chemicals. Two exceptions are applied to rhodium chloride and uranyl peroxide, which do not have published PAC values. For these chemicals, acceptance limits were developed using TEEL limits (DOE 2016; SHINE 2021c).

SHINE evaluated hazardous chemical releases from the SHINE facility using dispersion models and/or computer codes that are consistent with methodologies contained in NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook" (NUREG/CR-6410) (NRC 1998). SHINE used the ALOHA (Areal Locations of Hazardous Atmospheres) computer code (NOAA 2013) to model chemical releases and to perform consequence analysis for the public and the nearest residence (SHINE 2021c). ALOHA is widely used to support accident analysis and emergency response evaluations by government agencies, such as the EPA and the DOE. For input to this computer code, SHINE determined the material-at-risk present for each chemical in its inventory to be the largest quantity present in a single vessel or process location. These hazardous chemicals, with the exception of proprietary chemicals, are identified in Table 3-5. The material-at-risk is assumed to be the largest quantity of material that can be present for a single release event. Using this information, along with the necessary atmospheric parameters to run the ALOHA computer code, SHINE calculated the resulting chemical release concentrations for the maximum offsite individual at the site boundary and the nearest residence, 230 m (755 ft) and 788 m (2,585 ft), respectively (SHINE 2021c). This information is provided in Table 3-5.

Table 3-5 SHINE Hazardous Chemical Source Terms and Concentration Levels

Hazardous Chemical	Material-at-Risk (kg)	Source Term (mg)	PAC-1[(a)] (mg/m^3)	PAC-2[(a)] (mg/m^3)	PAC-3[(a)] (mg/m^3)	Site Boundary Concentration (230 m) (mg/m^3)	Nearest Residence Concentration (788 m) (mg/m^3)
Alpha-Benzoin Oxime	0.0688	1.38	0.49	5.4	32	1.30E-05	8.50E-07
Ammonium Hydroxide	0.1[(b)]	2490	13	140	840	2.89E-02	1.89E-03-
Ammonium Nitrate	2.77	55.37	6.7	73	440	5.22E-04	3.42E-05
Hydrochloric Acid	0.038[(b)]	1380	2.7	33	150	1.90E-02	1.24E-03
Hydrogen Peroxide	3.2	1380	14	70	140	2.24E-03	1.47E-04
Nitric Acid	2.7[(c)]	4820	0.41	62	240	7.91E-03	5.19E-04
Potassium Hexachloro-ruthenate	0.012	0.24	0.5	2	20	2.26E-06	1.48E-07
Potassium Permanganate	0.0727	1.45	8.6	14	150	1.37E-05	8.99E-07

Hazardous Chemical	Material-at-Risk (kg)	Source Term (mg)	PAC-1[a] (mg/m^3)	PAC-2[a] (mg/m^3)	PAC-3[a] (mg/m^3)	Site Boundary Concentration (230 m) (mg/m^3)	Nearest Residence Concentration (788 m) (mg/m^3)
Rhodium Chloride[d]	0.012	0.24	1.68	18.5	110	2.26E-06	1.48E-07
Silver Nitrate	0.012	0.24	0.05	0.9	5	2.26E-06	1.48E-07
Sodium Hydroxide	0.620	12.4	0.5	5	50	1.17E-04	7.67E-06
Sodium Iodide	0.012	0.24	13	140	860	2.26E-06	1.48E-07
Sodium Sulfite	0.478	9.55	11	120	710	9.01E-05	5.91E-06
Sulfuric Acid	78.0	1560	0.2	8.7	160	1.47E-02	9.65E-04
Uranium Metal[e]	7.8	0	0.6	5	30	0.00E+00	0.00E+00
Uranium Oxide	40.0	2400	0.68	10	30	2.26E-02	1.48E-03
Uranyl Peroxide[f]	6.84	13.68	0.94	10.4	62	1.29E-02	8.46E-04
Uranyl Sulfate[f]	191.2	235[g]/ 19120[g]	0.92	10.2	61	1.11E-02	7.25E-04

(a) PAC values are based on the U.S. Department of Energy's Protective Action Criteria Database (DOE-NNSA 2018), unless otherwise specified.
(b) The material-at-risk was increased to the minimum mass that ALOHA can model for a puddle release.
(c) Based on the largest-capacity subgrade waste tank.
(d) PAC values were not identified for rhodium chloride in the PAC Database (DOE-NNSA 2018). PAC values were developed from toxicity information found on the safety data sheet using the methodology from DOE-HDBK-1046-2016 (DOE 2016).
(e) Uranium metal is stored as solid pieces; therefore, there is no hazard associated with dropping solid metal pieces.
(f) PAC values were not identified for uranyl peroxide or uranyl sulfate in the PAC Database (DOE-NNSA 2018). For uranium compounds, the American Conference of Governmental Industrial Hygienist, short-term exposure limit is 0.6 mg/m^3, which is multiplied by a compound adjustment factor based on the methodology from DOE-HDBK-1046-2016 (DOE 2016) to obtain the TEEL-1 (PAC-1) value. PAC-2 and PAC-3 values were calculated based on the methodology from DOE-HDBK-1046-2016.
(g) The first source term value listed is for a two-minute release, while the second source term value corresponds to a full-tank release. For each receptor, the source term value that yields the most conservative result is used.
Source: SHINE 2021c

Emergency exposure limits are essential components of planning for the uncontrolled release of hazardous chemicals. These limits, combined with estimates of exposure, provide the information necessary to identify and evaluate accidents for the purpose of taking appropriate protective actions. During an emergency response to an uncontrolled release, these limits may be used to evaluate the severity of the event, to identify potential outcomes, and to decide what protective actions should be taken. In anticipation of an uncontrolled release, these limits may also be used to estimate the consequences of an uncontrolled release and to plan emergency responses (DOE 2016).

PAC (AEGLs and ERPGs) are defined as follows.

The AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours. Three levels—AEGL-1, AEGL-2, and AEGL-3—are used for each of five exposures periods (10 minutes, 30 minutes, 1 hour, 4 hours, and 8 hours) and are distinguished by varying degrees of severity of toxic effects. The DOE guidance, which SHINE followed, states that the 1-hour AEGL values should be used to assess the potential impacts associated with the accidental release of hazardous chemicals. The three AEGLs are defined as follows:

- AEGL-1 is the airborne concentration (expressed in ppm or milligrams per cubic meter [mg/m^3]) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure.
- AEGL-2 is the airborne concentration (expressed in ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting, and adverse health effects or an impaired ability to escape.
- AEGL-3 is the airborne concentration (expressed in ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening adverse health effects or death.

The three Emergency Response Planning Guidelines (ERPGs) are defined as follows:

- ERPG-1 is the maximum concentration in air below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing anything other than mild transient adverse health effects or perceiving a clearly defined objectionable odor.
- ERPG-2 is the maximum concentration in air below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health effects or symptoms that could impair their abilities to take protective action.
- ERPG-3 is the maximum concentration in air below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects.

SHINE performed a hazardous chemical consequence assessment to demonstrate that potential consequences are within acceptable limits. This assessment determined whether the release of hazardous chemicals from the SHINE facility could lead to exceeding the PAC values. SHINE performed the analysis for the public and the nearest residence as presented in Table 3-5 above. The acceptance limits established for chemical consequence are that the PAC-1 limit shall not be exceeded for members of the public. The results in Table 3-5 show that no chemical consequence exceeds PAC-1 limits at the site boundary or the nearest residence.

Given SHINE's analysis presented in this section, the NRC staff concludes that the impacts on members of the public from the potential uncontrolled release of hazardous chemicals under accident conditions would be minimal. Further, as part of its separate safety review of the SHINE operating license application, the staff is conducting a thorough, independent review of the health impacts on the public from a chemical accident, which will be documented in the staff's SER. If the staff determines in its SER that the potential dose to the public from the SHINE facility is within PAC-1 limits, then the staff concludes that the impacts from potential chemical accidents would be SMALL.

3.12 Environmental Justice

Section 4.12 of the FEIS describes the scope of the NRC's consideration of environmental justice issues, including the requirements of Executive Order (EO) 12898 "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (59 FR 7629).

The following discussion presents new information regarding the NRC staff's environmental justice impact analysis, including the evaluation of the potential for disproportionately high and adverse human health and environmental effects on minority and low-income populations that could result from operating the SHINE facility.

3.12.1 Minority Populations near the SHINE Facility

According to the U.S. Census Bureau's 2014–2018 American Community Survey 5-Year Estimates (USCB 2020), the minority population in the City of Janesville remained the same (12 percent); according to 2018 American Community Survey 1-Year Estimates, the minority population for all of Rock County, as a percent of the total population, had increased by 2.5 percent to about 17.5 percent. Because total and percent minority populations in the City of Janesville remained unchanged from the previous review, the information about minority populations living near the SHINE facility is not considered to be significant new information beyond that described in the FEIS.

3.12.2 Low-Income Populations Near the SHINE Facility

According to the U.S. Census Bureau's 2014–2018 American Community Survey 5-Year Estimates (USCB 2020), approximately 6,100 persons and 1,200 families (approximately 15 and 12 percent, respectively) residing within a 5 mi (8 km) radius of the SHINE facility were identified as living below the Federal poverty threshold. The 2018 Federal poverty threshold was $25,465 for a family of four.

According to the U.S. Census Bureau's 2018 American Community Survey Census 1-Year Estimates (USCB 2020), the median household income for Wisconsin was $60,773, and 11 percent of the State population and 7 percent of families were found to be living below the Federal poverty threshold. The City of Janesville and Rock County had lower median household income averages ($54,573 and $57,037) and slightly higher (or the same) percentages of persons (13 and 11 percent) and families (10 and 8 percent) living below the poverty level, respectively. Because the percentages of low-income populations and families in the City of Janesville and Rock County decreased from the previous review, the information on low-income populations living near the SHINE facility is not considered significant new information beyond that described in the FEIS.

3.12.3 Impact Analysis

Potential impacts to minority and low-income populations during operations would mostly consist of radiological and nonradiological human health and environmental (e.g., noise and traffic) effects. All people living near the industrial park would be exposed to the same environmental effects from SHINE facility operations, and any impacts would depend on the magnitude of the change in ambient environmental conditions. Potential human health impacts to minority and low-income populations from SHINE facility operations would mostly consist of radiological effects; however, radiation doses are expected to be well below regulatory limits. In addition, permitted nonradiological air emissions are required to be within regulatory standards.

Demographic information (i.e., race, ethnicity, income, and poverty data) for the City of Janesville and Rock County have not changed appreciably since publication of the FEIS. Based on this information and the analysis of human health and environmental impacts presented in this supplement, minority and low-income populations living near the industrial park would not experience disproportionately high and adverse human health and environmental effects during SHINE facility operations. Therefore, the environmental justice impact conclusions in the FEIS remain unchanged.

3.13 Cumulative Impacts

Section 4.13 of the FEIS considers the potential cumulative impacts of the construction, operation, and decommissioning of the potential SHINE facility. As detailed in the FEIS, cumulative impacts may result when the environmental effects associated with the proposed action are overlaid or added to temporary or permanent effects associated with other past, present, and reasonably foreseeable actions. The NRC staff considered new or differing information with respect to changes in the environment, new or revised projects or actions related to the operation of the SHINE facility, changes in the design of the SHINE facility, and proposed methods of SHINE facility operation that might substantively change the staff's previous cumulative impacts analysis.

In addition to refinements of the site layout of the SHINE facility and other operational design changes, the NRC staff identified and considered additional projects or updated information regarding projects identified in the FEIS relevant to the cumulative impacts analysis, as listed below in Table 3-6. Additional information regarding these past, present, and reasonably foreseeable projects and actions is presented in the SHINE's supplemental ER (Section 4.13) (SHINE 2022d).

For some resource areas, the NRC staff identified no differing or significant new information that would substantively change the cumulative impacts analysis for those resources, and the cumulative impacts analysis presented in the FEIS remains bounding relative to the scope and intensity of potential cumulative impacts. Consequently, the staff did not revise its cumulative impact analysis for the following resource areas: geologic environment, groundwater resources, socioeconomics, historic and cultural resources, and environmental justice. The following sections of this supplement update the cumulative impacts analysis presented in the FEIS.

Table 3-6 Past, Present, and Reasonably Foreseeable Projects and Other Actions Considered in the Cumulative Impacts Analysis

Project Name	Summary of Project	Location	Status
SHINE Building One	Demonstration and isotope production facility housing radioactive materials	0.25 mi. (0.4 km) south of the site	Existing operating facility; modifications to support lutetium-177 research and production, and Mo-99 chemical process optimization completed in 2021.
SHINE Headquarters and Therapeutics Facility	Co-located facilities supporting SHINE administrative and lutetium-177 production activities, respectively	0.25 mi. (0.4 km) north of the site	Construction of Headquarters Building completed in August 2021; Construction of Therapeutics Facility to be completed in 2022.
Dollar General Distribution Center	Distribution facility	0.25 mi. (0.4 km) northeast of the site	Existing operating facility
NaturPak Pet	Pet food processing plant	0.4 mi (0.6 km) northeast of the site	Existing operating facility
Alliant Energy Generation Facility	Power generation facility	3.2 mi. (5.1 km) south of site	Existing operating facility, completed expansion in 2020.
NorthStar Medical Radioisotopes	Medical radioisotope facility	7.7 mi (12.4 km) south of site	Existing operating facility
United Ethanol	Ethanol production plant	11 mi. (17.7 km) northeast of site	Existing operating facility

Sources: SHINE 2021a, 2022d.

3.13.1 Land Use and Visual Resources

Section 3.1 of this supplement describes and evaluates identified SHINE facility operational changes with respect to land use and visual resources. The NRC staff concludes that the potential impacts of these changes on land use and visual resources would remain SMALL. Section 4.13.1 of the FEIS concluded that the cumulative impacts on land use and visual resources would be SMALL and that conclusion remains accurate. The FEIS analysis recognized that the proposed SHINE facilities and other projects are situated in a predominantly agricultural landscape, but in a location where the land is zoned for industrial development and several new light industrial projects are proposed. The analysis recognized the ongoing trend toward increased urban development and more light industrial facilities in the area surrounding the SHINE site. Because the site and surrounding area is situated close to an existing urban area and an airport, and has already been zoned for industrial use, the cumulative land use and visual effects of building and operating the SHINE facilities along with other existing and contemplated industrial facilities would be minimal. The NRC staff concludes that the new information available now does not change the cumulative impact determination for land use and visual resources that was presented in the FEIS.

3.13.2 Air Quality and Noise

3.13.2.1 Air Quality

Section 3.2.1 of this supplement describes and evaluates identified SHINE facility operational changes with respect to air emissions and their effects on air quality. The NRC staff concludes that the potential impacts of these changes on air quality would remain SMALL. Section 4.13.2.1 of the FEIS concluded that cumulative impacts on air quality would be SMALL.

Based on the NRC's review of additional activities near the SHINE facility, the operational impacts of these facilities and associated vehicle air emissions, when combined with identified changes in the operation of the SHINE facility and associated emissions would not noticeably alter air quality. As discussed in Section 3.2.1 of this supplement, Rock County is designated attainment/unclassified with respect to National Ambient Air Quality Standards; therefore, emissions from these operational facilities have not contributed to a violation of the National Ambient Air Quality Standards. Construction of the Therapeutics Facility will generate air emissions from construction equipment engines, fugitive dust, and worker and delivery vehicles. Construction-related activities will be short term and intermittent. Operation of the SHINE Headquarters Building and the Therapeutics Facility will result in vehicular air emissions associated with employees commuting to and from the facilities, including a collective workforce of 150 personnel and a collective total of approximately 75 shipments per week (50 inbound/25 outbound) (SHINE 2021a). Air emission sources from Building One include natural-gas-fired heating/air conditioning units and vehicular emissions associated with 10 employees (SHINE 2020a, 2021a). Future projects could result in changes in present-day emissions within Rock County as a result of stationary sources and worker vehicle emissions. However, given the small number of reasonably foreseeable projects, the NRC staff does not anticipate that the increase in air emissions would be significant.

Therefore, the NRC staff concludes that this new information does not change the cumulative impact determination for air quality that was presented in the FEIS.

3.13.2.2 Noise

Section 3.2.2 of this supplement describes and evaluates SHINE facility operational changes and associated noise impacts. The NRC staff concludes that the potential impacts of these changes on noise would remain SMALL. Section 4.13.2.2 of the FEIS concluded that cumulative impacts on noise would be SMALL. The additional activities would primarily result in transportation-related noise from worker vehicles and delivery trucks accessing the facilities. The Dollar General Distribution Center is located approximately 0.25 mi (0.4 km) from the SHINE site. However, access to the Dollar General Distribution Center is via Innovation Drive, which is accessed through Prairie Street (County Highway G). Access to the NaturPak Pet packaging facility is also along Prairie Street. Therefore, increases as a result of additional vehicular noise primarily occur along Highway 11 and Prairie Street, rather than along Highway 51. Construction of the SHINE Therapeutics Facility will result in additional noise from onsite construction equipment use and vehicular noise along U.S. Highway 51 from worker vehicles and shipment deliveries (SHINE 2021a). However, construction activities will be short term and temporary and should not cause a noticeable increase in noise levels given current traffic volumes from nearby roads and noise levels from the airport. Operation of the SHINE Headquarters Building and the Therapeutics Facility will collectively involve noise associated with 150 worker vehicles and a collective total of approximately 75 shipments per week (SHINE 2021a). Approximately 10 employees will occupy Building One. However, given current traffic volumes along U.S. Highway 51 (see Section 3.10 above), additional vehicular noise from worker vehicles, deliveries, and shipments would not be noticeable.

Therefore, the NRC staff concludes that this new information does not change the cumulative impact determination for noise presented in the FEIS.

3.13.3 Water Resources

Sections 3.4.1 and 3.4.2 of this supplement describe and evaluate identified facility operational changes with respect to wastewater generation and water use and their effect on surface water and groundwater resources, respectively. The NRC staff concludes that the potential impacts of these changes on affected water resources would remain SMALL. In Section 4.13.3.4 of the FEIS, the NRC staff concluded that cumulative impacts on water resources would be SMALL.

In addition, the NRC staff reviewed the updated information about past, present, and reasonably foreseeable projects and activities summarized in Table 3-6. Based on the staff's review, the new and expanded projects, when combined with identified changes in wastewater generation and water use by the SHINE facility, would have a negligible incremental impact on surface water or groundwater resources. This is because, as supported by the staff's analysis presented in Sections 3.4.1 and 3.4.2 of this supplement, the area's wastewater treatment and water supply infrastructure have abundant excess capacity to accommodate local growth and industrial development without impacting water quality or availability. For example, Building One, adjacent to the SHINE facility site, has water demands that are comparable to those for SHINE facility operations. Similarly, sanitary wastewater discharges from Building One to the City of Janesville wastewater treatment plant total about 7,500 gpd (28,400 Lpd), which is comparable to but less than those estimated to occur during SHINE operations. There are no routine radiological liquid effluent discharges from Building One, including no radiological liquid effluent discharges due to lutetium-177 (Lu-177) production (SHINE 2020a, 2021a).

Construction of SHINE's Therapeutics Facility could have localized and temporary impacts onsite hydrology and water quality due to stormwater runoff. The builder's adherence to best management practices for soil erosion and sediment control would minimize the potential for offsite impacts. Once construction is completed, revegetation of the building site and the installation of permanent stormwater management systems would prevent any soil erosion and uncontrolled stormwater runoff.

The City of Janesville will provide water supply and sanitary sewer service to support operations at the Headquarters Building (completed in August 2021) and the Therapeutics Facility (to be completed in 2022). The NRC staff estimates that during operations water use and wastewater generation associated with these facilities would be similar to but less than those associated with Building One. This projection is based on the number of SHINE staff that are expected to work there and the activities that are planned to be conducted there. Liquid effluents generated and discharged to the City of Janesville sewer system from the facilities would be limited to sanitary wastewater. There are no planned radiological liquid effluent discharges associated with production activities in the Therapeutics Facility because all radiological wastes would be decayed in storage (SHINE 2021a).

In addition, new construction associated with the identified projects would be subject to State of Wisconsin-administered National Pollutant Discharge Elimination System (NPDES) requirements pursuant to Federal Clean Water Act requirements for water pollution control (33 U.S.C. 1251 et seq.). The NPDES program requires all facilities that discharge pollutants from any point source into waters of the U.S. to obtain an NPDES permit and requires industrial facilities and large land-disturbing activities and projects to obtain and comply with individual or general permits for the discharge of site stormwater. Furthermore, any such facilities would also be subject to municipal requirements for soil erosion and sediment control and stormwater management. Therefore, the NRC staff concludes that this new information does not change the cumulative impact determination for water resources that was presented in the FEIS.

3.13.4 Ecological Resources

Section 3.5 of this supplement describes and evaluates identified facility operational changes and their effect on ecological resources. The NRC staff concludes that the potential impacts of these changes on ecological resources would remain SMALL. In Section 4.13.3.4 of the FEIS, the NRC staff concluded that cumulative impacts on ecological resources would be MODERATE. That analysis recognized that the proposed SHINE facilities and other projects are situated in a predominantly agricultural landscape and would not substantially affect natural habitats. But the analysis also recognized past degradation of natural habitats in the surrounding landscape related to agricultural and urban development and the continued occurrence of agricultural runoff into streams and, therefore, concluded that the cumulative impacts on ecological resources would be MODERATE. However, it determined that the contribution of the proposed SHINE facilities and other industrial facilities in the surrounding area would be minimal. The new information presented in Section 3.5 regarding the effects on ecological resources subsequent to publication of the FEIS continues to indicate that the contribution from the SHINE facilities would be minimal. Therefore, the NRC staff concludes that this new information does not change the cumulative impact determination for ecological resources (MODERATE) that was presented in the FEIS.

3.13.5 Human Health

Section 3.9 of this supplement describes and evaluates identified facility operational changes and their effects on human health. The NRC staff concludes that the impacts from operations at the proposed SHINE facility remain SMALL. In Section 4.13.8 of the FEIS, the NRC staff concluded that cumulative impacts on human health would be MODERATE. For this evaluation of cumulative impacts, the NRC staff considers the impacts in the region of interest (ROI) associated with the operation of other facilities using radioactive and nonradioactive material in the recent past, present, and reasonably foreseeable future. The geographic ROI for the evaluation of cumulative effects on human health is that within a 5 mi (8 km) radius of the proposed SHINE facility. Within this ROI, there are no nuclear power plants that would contribute to radioactive or nonradioactive exposure.

Based on the NRC staff’s review of additional activities near the SHINE facility, the operational impacts of these facilities, when combined with identified changes in the operation of the SHINE facility, would not noticeably impact human health. Construction of the NorthStar Medical Radioisotopes facility in Beloit is complete and the facility commenced operation in 2018. No new or different information about NorthStar Medical Radioisotopes operations has been identified that would affect the conclusions reached in the FEIS. Building One and the Therapeutics Facility are the only newly identified facilities that use radioactive materials in the vicinity of the site since the issuance of the FEIS. Building One, located south of and adjacent to the SHINE facility site, will be used for isotope production of and research related to Lu-177 for the proposed Therapeutics Facility, chemical process development using depleted uranium, accelerator testing and operation, storage and testing of support equipment, and as an employee training facility. The Therapeutics Facility, located north of and adjacent to the SHINE facility site, will be used for the production of Lu-177 for commercial sale. Both Building One and the Therapeutics Facility will store and use radioactive material under a State of Wisconsin radioactive materials license (license number 105-2083-01). Operations at Building One and the Therapeutics Facility will comply with public dose limits set forth in Chapter DHS 157 of the Wisconsin Administrative Code (WAC 2018). To demonstrate that radioactive air emissions are ALARA, SHINE controls routine airborne effluent releases such that an individual member of the public likely to receive the highest dose does not receive a total effective dose equivalent in excess of 10 mrem/yr (0.1 mSv/yr) from air emissions. In addition, SHINE ensures that the maximally exposed member of the public does not exceed a dose of greater than 2 mrem (0.02 mSV) in any 1 hour and 100 mrem/yr (1 mSv/yr) from external sources (SHINE 2021a, 2021c).

As discussed in Section 4.8.2.2 of the FEIS (NRC 2015), the NRC staff concluded that the nonradiological impacts from the proposed SHINE facility to workers and members of the public would be SMALL. Given that the nonradiological impacts from the facilities listed in Table 3-6 would be within the regulatory limits of the State of Wisconsin and given the distance between the facilities and the proposed SHINE facility, the NRC staff concludes that the cumulative impact on workers and members of the public would be SMALL.

The NRC staff is currently conducting a thorough independent safety evaluation to verify that the radiological exposure to the members of the public would be below regulatory limits set in 10 CFR Part 20. If the NRC staff concludes that the cumulative dose to workers and the public would be below the regulatory limits set in 10 CFR Part 20, the NRC staff concludes that the cumulative radiological impacts do not change the cumulative impact determination for human health presented in the FEIS.

Under Radioactive Material License No. 105-2083-01 issued on January 6, 2021, by the State of Wisconsin, SHINE intends to produce Lu-177 for use in medical treatments (SHINE 2021a).

Section 3.9.3 of this supplement describes and evaluates the transportation of radioactive material from the SHINE facility. The production of Lu-177 will result in additional radioactive material shipments, in addition to those described in Section 3.9.3. As presented in SHINE 2021a, SHINE expects the following additional shipments of licensed nuclear material:

- approximately 100 annual shipments of licensed nuclear material to Building One,
- approximately 200 annual shipments of Lu-177 product from Building One,
- approximately 600 annual shipments of licensed nuclear material to the proposed Therapeutics Facility, and
- approximately 800 annual shipments of Lu-177 product from the proposed Therapeutics Facility.

The above shipments related to the production of Lu-177 would use Type A packages and Type B packages and would be shipped by non-exclusive use third-party carriers (i.e., commercial shipment carriers). These shipments would be made in accordance with the applicable NRC and DOT regulations.

Therefore, the NRC staff concludes that radiological exposures to workers and the public would be within applicable regulatory limits and that this new information does not change the cumulative impact determination for human health that was presented in Section 4.13.8 of the FEIS.

3.13.6 Waste Management

Section 3.9.4 of this supplement describes and evaluates identified facility operational changes and their effects on waste management. The NRC staff concludes that the potential impacts of these changes on waste management would remain SMALL. Section 4.13.0 of the FEIS discusses the cumulative impacts from the disposal of radioactive and nonradioactive waste within a 5 mi (8 km) radius from the proposed SHINE facility. Table 3-6 above lists additional projects since publication of the FEIS that are relevant to the cumulative impact analysis. Based on the NRC staff's review of additional activities near the SHINE facility, the operational impacts of these facilities, when combined with identified changes in the operation of the SHINE facility, would not noticeably impact waste management.

Building One and the Therapeutics Facility are the only newly identified facilities that use radioactive materials in the vicinity of the site since the issuance of the FEIS. Building One will be used for isotope production of and research related to Lu-177 for the proposed Therapeutics Facility, chemical process development using depleted uranium, accelerator testing and operation, storage and testing of support equipment, and as an employee training facility. The Therapeutics Facility will be used for the production of Lu-177 for commercial sale. Both Building One and the Therapeutics Facility will store and use radioactive material under a State of Wisconsin radioactive materials license (license number 105-2083-01).

As stated previously, under Radioactive Materials License No. 105-2083-01 issued on January 6, 2021, SHINE intends to produce Lu-177 for use in medical treatments (SHINE 2021a). There are no planned effluents of gaseous or liquid releases from Lu-177 production at Building One or the proposed Therapeutics Facility. The waste generated from the production of Lu-177 would consist of short half-life materials that are decayed in storage. Therefore, there is no planned radioactive waste from Lu-177 production at Building One or the Therapeutics Facility (SHINE 2021a).

Building One would contribute to radioactive and nonradioactive waste. Nonradioactive liquid effluents from Building One consist of plumbing wastewater (SHINE 2020a). Radioactive wastes generated in Building One consist primarily of tritium-contaminated solid wastes (e.g., used gloves, parts, and equipment) (SHINE 2020a). The facility may also generate solid wastes (e.g., discarded equipment) containing neutron-activation products generated from operation of the accelerator, or tritiated liquid wastes exceeding the limits for release to the sanitary sewer system. Radioactive wastes generated in Building One that must be disposed of are analyzed and quantified in accordance with approved procedures prior to being shipped offsite for disposal at a licensed commercial disposal facility. Total waste generated is anticipated to be approximately twelve 30 gal drums of Class A waste and less than 1 gal of mixed waste per year (SHINE 2020a, 2021a).

Based on this information provided by SHINE for Building One and the Therapeutics Facility, radioactive and nonradioactive waste quantities would not be significant and would be adequately managed for disposal. Therefore, the NRC staff concludes that the cumulative waste impacts do not change the cumulative impact determination that was presented in the FEIS.

3.13.7 Transportation

Section 3.10 of this supplement describes and evaluates identified facility operational changes and their effects on transportation infrastructure. Section 4.13.10 of the FEIS addresses the direct and indirect contributory effects from the construction, operation, and decommissioning of the SHINE facility when added to the effects from other past, present, and reasonably foreseeable future actions on transportation infrastructure. Since publication of the FEIS, baseline traffic conditions have changed, and SHINE has conducted additional transportation studies to assess the potential impact of operating and decommissioning the SHINE facility, as discussed in Section 3.10 of this supplement.

There has also been new commercial development in the immediate vicinity of the SHINE facility site that has, or will, add additional vehicular traffic to the associated local road network. As shown in Table 3-5, SHINE has constructed and is operating its Building One demonstration facility approximately 0.25 mi (0.4 km) south of the site along U.S. Highway 15 (SHINE 2020b). A new Dollar General Distribution Center is also now operating approximately 0.25 mi (0.4 km) northeast of the SHINE site, as is a new NaturPak Pet food processing plant approximately 0.4 mi (0.6 km) northeast of the site. Vehicular traffic access associated with the Dollar General and NaturPak facilities would be via Innovation Drive and Prairie Street (SHINE 2022d). In addition, construction of a new SHINE Headquarters Building approximately 0.25 mi (0.4 km) north of the site was completed in 2021, and final construction and operation of the adjacent SHINE Therapeutics Facility is expected in 2022. This construction will include an access road for limited employee movement between the SHINE facility and the Headquarters Building/Therapeutics Facility sites (SHINE 2021a).

SHINE expects Building One to operate with a workforce of up to 20 personnel and require approximately 50 shipments (40 inbound/10 outbound) per week. Additionally, SHINE expects the Headquarters Building and the Therapeutics Facility to operate with a collective workforce of 150 personnel and require a collective total of approximately 75 shipments per week (50 inbound/25 outbound) (SHINE 2021a). Some of the shipments supporting Building One and the Therapeutics Facility would include licensed nuclear material and Lu-177 product, as discussed in Section 3.13.5 of this supplement.

Whereas primary vehicular access to the SHINE facility and Building One are from U.S. Highway 15, primary vehicular access to the Headquarters Building and Therapeutics Facility would be via Innovation Drive and Prairie Street, which have undergone substantial improvements to support commercial development along this corridor and to enhance traffic flow with State Trunk Highway 11 (SHINE 2021a). Accordingly, the additional vehicular traffic associated with these new commercial operations are not expected to result in noticeable changes along U.S. Highway 51 and in the immediate vicinity of the SHINE facility (SHINE 2020a, 2021a). Therefore, based on the NRC staff's review of additional vehicular traffic attributable to new commercial development near the SHINE facility, in conjunction with the changes in baseline conditions and traffic attributable to changes in operations of the SHINE facility, traffic volumes are not expected to exceed those presented in the FEIS, and cumulative impacts on the transportation infrastructure would remain SMALL to MODERATE.

3.14 <u>Summary</u>

Cumulative impacts would range from SMALL to MODERATE depending on the resource area. Specifically, these cumulative impacts would be SMALL for all resource area components other than ecological resources and transportation. Based on the review of available information, the NRC staff concludes that this new information does not change the cumulative impact determinations presented in the FEIS.

4 CONCLUSIONS

This chapter presents the conclusions and recommendations of the environmental review of the SHINE facility, as supplemented herein.

Section 4.1 summarizes the impacts of the proposed action, Section 4.2 discusses unavoidable impacts from the proposed action, and Section 4.3 presents the NRC staff's conclusions and preliminary recommendation.

4.1 Environmental Impacts of the Proposed Action

Consistent with its regulations in 10 CFR 51.95(b), the NRC staff considered whether there is any differing or significant new information with respect to the environmental impacts of the SHINE facility considered in the FEIS. This supplement updates the prior environmental review and only covers matters that differ from those or that reflect significant new information relative to that discussed in the FEIS. The NRC staff did not identify any information that presents a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility. The NRC staff further concludes that issuing an operating license for the SHINE facility would have SMALL impacts on all resource areas and would not have impacts beyond those already discussed in the FEIS. Based on its subsequent review of changes in baseline environmental conditions, traffic attributable to changes in operation of the SHINE facility, and new traffic studies submitted by SHINE to the State of Wisconsin, the NRC staff determined that traffic volumes are not expected to exceed those presented in the FEIS and, thus, that the related impact determination in the FEIS should be revised accordingly to indicate that impacts on the transportation infrastructure during operations would likely be SMALL, rather than SMALL to MODERATE.

4.2 Resource Commitments

Section 102(2)(C)(ii) of NEPA (42 U.S.C. 4321 et seq.) requires that an EIS include information about any adverse environmental effect that cannot be avoided if the proposed action is implemented. Unavoidable adverse impacts are predicted adverse environmental impacts that cannot be avoided and that have no practical means of further mitigation. The NRC staff did not identify any unavoidable adverse environmental impacts, short-term uses of the environment, or irreversible and irretrievable commitments of resources beyond those presented in Table 6-2 of the FEIS.

4.3 Preliminary Recommendation

After weighing the environmental, economic, technical, and other benefits against environmental and other costs, the NRC staff's preliminary recommendation, unless safety issues mandate otherwise, is that the operating license be issued as proposed. The NRC staff based its recommendation on the following:

- the application, including SHINE's supplemental ER;
- consultation with Federal, State, Tribal, and local agencies;
- the staff's independent review; and
- the consideration of public comments.

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6 PREPARERS OF THIS SUPPLEMENT

Members of the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Material Safety and Safeguards prepared this supplement to NUREG-2183 with assistance from other NRC organizations and support from the U.S. Department of Energy (DOE) National Nuclear Security Administration (NNSA), and Pacific Northwest National Laboratory (PNNL). Table 6-1 below identifies each contributor's name, affiliation, and function or expertise.

Table 6-1 Past List of Preparers
(in alphabetical order)

Name	Affiliation	Education/Experience	Function of Expertise
Briana Arlene	NRC	Masters Certification, National Environmental Policy Act; B.S. Conservation Biology; 16 years of experience in ecological impact analysis, Endangered Species Act Section 7 consultations, and Essential Fish Habitat consultations	Special Status Species and Habitats
Phyllis Clark	NRC	M.S. Nuclear Engineering; M.B.A, Business Administration; B.S. Physics; 35 years of industry and Government experience including nuclear power plant and production reactor operations, systems engineering, reactor engineering, fuels engineering, criticality, power plant emergency response, and project management	Waste Management
Jennifer Davis	NRC	B.A. Historic Preservation and Classical Civilization (Archaeology); 5 years of archaeological fieldwork; 20 years of experience in NEPA compliance, project management, and cultural resources impact analysis and regulatory compliance	Environmental Project Manager, Cost-Benefit
Peyton Doub	NRC	M.S. Plant Physiology (Botany); B.S. Plant Sciences (Botany); Duke NEPA Certificate; Professional Wetland Scientist; Certified Environmental Professional; 30 years of experience in terrestrial and wetland ecology and NEPA	Land Use and Visual Resources, Ecological Resources
Robert Elliott	NRC	B.S. Marine Engineering; Licensed Professional Engineer; 29 years of Government experience including containment systems analysis, balance of plant analysis, evaluation of integrated plant operations/technical specifications, and project management, with 13 years of management experience	Branch Chief
Kevin Folk	NRC	M.S. Environmental Biology; B.A. Geoenvironmental Studies; 30 years of experience in NEPA compliance; geologic, hydrologic, and water quality impacts analysis; utility infrastructure analysis, environmental regulatory compliance; and water supply and wastewater discharge permitting	Geologic Environment, Water Resources

Name	Affiliation	Education/Experience	Function of Expertise
Robert Hoffman	NRC	B.S. Environmental Resource Management; 35 years of experience in NEPA compliance, environmental impact assessment, alternatives identification and development, and energy facility siting	Proposed Action, Historic and Cultural Resources, Cumulative Impacts, Decommissioning, Transportation
Nancy Martinez	NRC	B.S. Earth and Environmental Science; A.M. Earth and Planetary Science; 8 years of experience in environmental impact analysis	Backup Project Manager, Proposed Action, Meteorology, Air Quality, and Noise
Don Palmrose	NRC	B.S. Nuclear Engineering; M.S. Nuclear Engineering; Ph.D. Nuclear Engineering; 34 years of relevant experience	Transportation
William Rautzen	NRC	B.S. Health Physics; B.S. Industrial Hygiene; M.S. Health Physics; 8 years of experience in environmental impact analysis	Human Health, Accidents
Jeffrey Rikhoff	NRC	M.R.P. Regional Planning, M.S. Economic Development and Appropriate Technology; 38 years of combined industry and Government experience including 31 years of NEPA compliance, socioeconomics and environmental justice impact analyses, cultural resource impact assessments, consultations with American Indian Tribes, and comprehensive land use and development planning studies	Socioeconomics, Environmental Justice
	DOE-NNSA		
Amy Miller	DOE-NNSA	M.W.R. Master of Water Resources M.C.R.P. Master of Community and Regional Planning; NEPA Compliance Officer; 8 years of NEPA experience; 12 years in the environmental compliance field.	NEPA compliance
	DOE-NNSA		
	DOE-NNSA		
Kimberly Leigh	PNNL	B.S. Environmental Science; 22 years of experience in NEPA compliance and project management	Project Team Leader
Susan Ennor	PNNL	B.A. Journalism; 5 years of experience in corporate/organizational communications; 35 years of experience in science and technical communications	Editor

APPENDIX A

APPLICABLE LAWS, REGULATIONS, AND OTHER REQUIREMENTS

Section B.1 of Appendix B to the FEIS (NUREG-2183) discusses the Federal, State, and local requirements that may be applicable to operation of the SHINE facility. Table A-1 below lists new information on permits and licenses that SHINE Medical Technologies, LLC (SHINE) has or plans to obtain from Federal, State, and local authorities to construct and operate the SHINE facility.

Table A-1 Applicable Federal and State Laws, Regulations, and Requirements

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe of Receipts	Status
Permits and Approvals from Federal Agencies					
NRC	Atomic Energy Act 10 CFR 50.35 and 10 CFR 50.50	Construction Permit	Construction of the SHINE facility	2016	Issued February 2016
NRC	Atomic Energy Act 10 CFR 50.57	Operating License	Operation of the SHINE facility	2023	Application submitted July 2019
NRC	Atomic Energy Act 10 CFR Part 40	Source Material License	Possession, use, and transfer of radioactive source material	2023	Application submitted July 2019
NRC	Atomic Energy Act 10 CFR Part 30	By-Product Material License	Possession, use, and transfer of radioactive byproduct material	2023	Application submitted July 2019
NRC	Atomic Energy Act 10 CFR Part 70	Special Nuclear Material License	Receipt, possession, use, and transfer of special nuclear material	2023	Application submitted July 2019
FAA	Federal Aviation Act	Construction Notice FAA 7460-1	Construction of structures that could affect air navigation	2019-2022	FAA Form 7460-1 was submitted in April 2019 for the main production facility. A Determination of No Hazard to Air Navigation was received April 2019. SHINE submitted FAA Form 7460-1 for the nitrogen purge system structure, resource building, and storage building in March 2021 and a Determination of No Hazard to Air Navigation was received May 2021. SHINE will submit FAA Form 7460-1 for

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe of Receipts	Status
					the material staging building prior to commencing construction of the structure.
FAA		Construction Notice FAA Form 7460-2	Construction of structures that could affect air navigation	2022	SHINE intends to submit FAA Form 7460-2 within 5 days after the construction of each structure reaches its greatest height.
DOT	Hazardous Material Transportation Act, 49 CFR Part 107	Certificate of Registration	Transportation of hazardous materials	2023	SHINE intends to submit DOT Form F-5800.2 in 2023.
Permits and Approvals from State Agencies					
WDNR	Federal CWA; Wisconsin Statutes, Chapter 283; Wisconsin Administrative Code, Chapter NR 216	Construction Storm Water Discharge Permit	Discharge of stormwater runoff from the construction site	2018	SHINE received coverage under Wisconsin Pollutant Discharge Elimination System General Permit No. WI-S067831-05, Construction Site Storm Runoff, in October 2018.
WDNR	Federal CWA; Wisconsin Statutes, Chapter 283; Wisconsin Administrative Code, Chapter NR 216	Industrial Storm Water Discharge Permit	Discharge of stormwater runoff from the site during facility operation	2023	SHINE intends to submit a No Exposure Certification at least 14 working days before initiation of operations.
WDNR	Wisconsin Statutes, Chapters 280 and 281; Wisconsin Administrative Code, Chapter NR 809	Approval Letters	Construction by the City of Janesville of water and sanitary sewer extensions to the SHINE facility	2017	Approval was obtained by the City of Janesville prior to construction of utility extensions in 2017.
WDNR	Wisconsin Statutes, Chapter 291; Wisconsin Administrative Code,	Compliance with hazardous waste	Generation of hazardous waste	2023	SHINE intends to notify WDNR of Storage and Treatment Conditional Exemption (NR 666, Subchapter N) within 90 days of low-level mixed waste generation.

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe of Receipts	Status
	Chapter NR 660, 662, and/or 666	notification, record keeping, and reporting requirements			
Wisconsin Department of Safety and Professional Services	Wisconsin Statutes, Chapter 101; Wisconsin Administrative Code, Chapter SPS 341	Permit to operate	Obtain and maintain a valid permit to operate the boiler	2022	SHINE intends to submit a permit application prior to operation of the boiler.
Wisconsin Department of Safety and Professional Services	Wisconsin Statutes, Chapter 101; Wisconsin Administrative Code, Chapter SPS 361	Fire Sprinkler and Alarm Permit	Installation of suppression and alarm systems	2022	SHINE intends to submit the fire suppression and fire alarm plan for review in 2022.
Wisconsin DOT	Wisconsin Statutes, Chapter 85; Wisconsin Administrative Code, Chapter Trans 231	Permit for a temporary connection to State Trunk Highway	Construction of a temporary construction entrance from U.S. Highway 51	2019	SHINE submitted an application to work on highway right-of-way in March 2019. Permit issued in April 2019.
Wisconsin DOT	Wisconsin Statutes, Chapter 86; Wisconsin Administrative Code, Chapter Trans 231	Permit for a permanent connection to State Trunk Highway	Approval of a permanent connection to U.S. Highway 51	2022	SHINE intends to submit an application prior to commencing construction of a permanent connection in 2022.
Wisconsin DOT	Wisconsin Statutes, Chapter 85; Wisconsin Administrative Code, Chapter Trans 231	Right-of-Entry Permit	Construction by the City of Janesville of utility extensions across U.S. Highway 51	2017	Permit obtained by the City of Janesville prior to construction of utility extensions in 2017.

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe of Receipts	Status
Permits and Approvals from Local Agencies					
City of Janesville Community Development Department	City of Janesville Ordinance 42-273	Site Plan Approval (includes Building Site Permit for the Southern Wisconsin Regional Airport Overlay District)	Administrative approval of the site layout and plans for parking, lighting, landscaping, and similar local issues	2018	SHINE submitted the Site Plan and building elevations with approval obtained in 2018.
City of Janesville Community Development Department	City of Janesville Ordinance 32-103	Stormwater Plan Approval (may be included in Site Plan Approval)	Administrative approval of grading and drainage plans	2018	SHINE submitted the Stormwater Management Plan with the Site Plan that was approved in 2018.
City of Janesville Community Development Department	City of Janesville Ordinance 32-104	Erosion Control Permit (may be included in Site Plan Approval)	Administrative approval of erosion control plans	2018	SHINE submitted the Erosion Control Plan with the Site Plan with approval in 2018.
City of Janesville Community Development Department	City of Janesville Ordinances 40-31 and 40-75	Sanitary Sewer and Water Supply Facility Approvals	Administrative approval of construction, installation, and operation of connections to the municipal sewer and water supply systems	2020-2022	SHINE received approval of construction and installation of connections to municipal sewer and water supply systems in 2020. For operation, SHINE intends to provide baseline monitoring report to wastewater treatment plant at least 90 days before discharge in 2022.
City of Janesville Community	City of Janesville Ordinance 10-55	Plumbing Plan Approval	Installation of plumbing systems	2021-2022	SHINE received Plumbing Plan approval for the main production facility, resource building, and storage building in 2021.

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe of Receipts	Status
Development Department					SHINE intends to submit the Plumbing Plan for the material staging building in 2022.
City of Janesville Community Development Department	City of Janesville Ordinance 10-121	HVAC Plan Approval	Installation of HVAC systems	2021-2022	SHINE received HVAC approval for the main production facility, nitrogen purge system structure, resource building, and storage building in 2021. SHINE intends to submit the HVAC Plan for the material staging building in 2022.
City of Janesville Community Development Department	City of Janesville Ordinance 10-90	Electrical Permit	Building new electrical systems	2021 – 2022	SHINE received Electrical Plan approval for the main production facility, nitrogen purge system structure, resource building, and storage building in 2021. SHINE intends to submit the Electrical Plan for the material staging building in 2022.
City of Janesville Community Development Department	City of Janesville Ordinance 10-10	Building Permit	Construction of buildings	2019 – 2022	SHINE submitted the building plans for the main production facility, in phases, in 2019 and 2020. Building permits for the main production facility foundation issued in 2019. Building permit for the main production facility superstructure issued in 2020. Building permits for outbuilding are expected to be received in 2022.
City of Janesville Community Development Department	City of Janesville Ordinance 10-18	Occupancy Permit	Occupancy of completed buildings	2023	Each building would be inspected after construction to allow occupancy.
Rock County Highway Department	Wisconsin Statutes, Chapter 84; Rock County Utility Accommodation Policy 96.00	Permit to Construct, Maintain, and Operate Utilities within Highway Right-of-Way	Construction by the City of Janesville of utility extensions across County Trunk Highway G	2017	Permit issued by Rock County Highway Department to the City of Janesville prior to construction of utility extensions in 2017.

Source: SHINE 2022d

APPENDIX B

ENVIRONMENTAL REVIEW CORRESPONDENCE

Table B-1 through Table B-3 include chronological lists of correspondence related to the environmental review of SHINE Medical Technologies, LLC (SHINE) for an operating license for the SHINE Medical Isotope Production Facility in Janesville, Wisconsin. All documents, with the exception of those containing proprietary information, are available electronically from the Public Electronic Reading Room found on the Internet at the following web address: http://www.nrc.gov/reading-rm.html. From this website, the public can gain access to the U.S. Nuclear Regulatory Commission's (NRC's) Agency Document and Management System, which provides text and image files of the NRC's public documents. Table B-1 contains general correspondence related to the environmental review, Table B-2 and Table B-3 provide correspondence related to consultations under Federal laws for historic and cultural resources and biological resources. The NRC is responsible for conducting consultations under certain Federal laws, as appropriate, such as the National Historic Preservation Act (NHPA) of 1966, as amended (54 United States Code (U.S.C.) 300101 et seq.), and the Endangered Species Act (ESA) of 1973 (16 U.S.C. 1531 et seq.).

Table B-1 Environmental Review General Correspondence

Document Date	Sender	Recipient	Document Description	Accession Number
7/17/2019	SHINE	NRC	Application for an Operating License, Revision 0 of the Final Safety Analysis Report and Revision 3 of the Environmental Report-Operating License Stage	ML19211C143
9/5/2019	NRC	SHINE	Notice of Receipt and Availability of Operating License Application	ML19235A307
10/8/2019	NRC	SHINE	Operating License Application Acceptance Review Results	ML19276D409
10/31/2019	NRC	Hedberg Public Library	Maintenance of Reference Materials at the Hedberg Public Library for the Environmental Review of SHINE Operating License Application	ML19298B961
11/24/2019	NRC	SHINE	Notice of Intent to Prepare a Supplement to the Final Environmental Impact Statement and Conduct Scoping	ML19326B098
12/2/2019	NRC		Press Release-19-060 - NRC to Hold Public Meeting Seeking Comment on Environmental Review for SHINE Operating License	ML19336A196
12/5/2019	EPA	NRC	Scoping Comments re: SHINE Medical Technologies, LLC Operating License Review	ML20010D451
12/19/2019	NRC	SHINE	Environmental Site Audit Regarding SHINE Proposed Medical Isotope Production Facility (forwarding Audit Plan)	ML19353C687

Document Date	Sender	Recipient	Document Description	Accession Number
1/2/2020	NRC	SHINE	Notice of Opportunity for Hearing and Petition for Leave to Intervene	ML19324F962
1/9/2020	EPA	NRC	Response to Notice of Intent to Prepare Supplement to the Final Environmental Impact Statement	ML20010E604
1/16/2020	NRC	NRC	Memorandum: Summary of Public Scoping Meeting Conducted for the SHINE Operating License Application Review	ML20010D168
2/28/2020	NRC	SHINE	Request for Additional Information for Environmental Review of the SHINE Proposed Medical Isotope Production Facility Operating License Application	ML20052C761
3/12/2020	NRC	SHINE	Summary of the Environmental Site Audit Related to the Review of the Operating License Application for SHINE Proposed Medical Isotope Production Facility	ML20058A022
3/13/2020	SHINE	NRC	Response to Environmental Requests for Additional Information for SHINE Application and Supplement to Environmental Report-Operating License Stage, Revision 4	ML20073E880
3/31/2020	NRC	SHINE	Environmental Scoping Summary Report Regarding the SHINE Medical Technologies, LLC Operating License Application	ML20058C521
4/14/2020	NRC	SHINE	Supplemental Request for Additional Information for the Environmental Review of the SHINE Medical Technologies, LLC Operating License Application	ML20092L592
4/30/2020	NRC	SHINE	Operating License Application Technical Review Schedule	ML20114E315
5/8/2020	SHINE	NRC	Response to Supplemental Environmental Requests for Additional Information and Supplement to Environmental Report-Operating License Stage, Revision 5	ML20246G852
6/11/2020	SHINE	NRC	Revision 1 of SHINE Response to Request for Additional Information PA-7S	ML20163A047
6/16/2020	NRC	NRC	Memorandum: Summary of June 2, 2020, Public Meeting Conducted for SHINE Operating License Application Environmental Review	ML20162A000

Document Date	Sender	Recipient	Document Description	Accession Number
6/18/2020	NRC	NRC	Memorandum of Agreement between the U.S. Department of Energy and the NRC on the Environmental Review Related to the issuance of an Authorization to Operate SHINE Medical Isotope Production Facility	ML20099E354
12/18/2020	NRC	SHINE	Request for Additional Information for Environmental Review of the Proposed Medical Isotope Production Facility Operating License Application	ML20352A225
1/22/2021	SHINE	NRC	Response to Environmental Requests for Additional Information for SHINE Application and Supplement to Environmental Report-Operating License Stage	ML21022A027
1/27/2021	NRC	NRC	Memorandum: Summary of Public Meeting Conducted for the SHINE Medical Technologies, LLC Operating License Application Environmental Review	ML21019A159
2/26/21	SHINE	NRC	Overview of Phased Approach to Initial Facility Operations	ML21057A340
4/29/2021	SHINE	NRC	Request to Amend Construction Permit No. CPMIF-001	ML21119A165
6/8/2021	NRC	SHINE	Acceptance of the Application for a Construction Permit Amendment Related to the Receipt and Possession of Radioactive Materials	ML21158A070
8/20/2021	SHINE	NRC	Request to Amend Construction Permit Response to Request for Additional Information	ML21242A028
9/2/2021	SHINE	NRC	Schedule Update	ML21245A055
9/13/2021	NRC	SHINE	Notice of Consideration of Issuance of Amendment, Opportunity to Request Hearing, and Order of Imposing Procedures for Document Access	ML21245A217
11/16/2021	SHINE	NRC	Application for an Operating License Supplement No. 12, Submittal of Revision 7, to Supplement the Environmental Report	ML21320A066
12/2/2021	NRC	SHINE	Issuance of Amendment No. 2 to Construction Permit	ML21320A225
3/16/2022	SHINE	NRC	Operating License Application Supplement No. 19, Submittal of a Revision to the SHINE Supplement to the Environmental Report	ML22075A144

Table B-2 Environmental Review NHPA Section 106 Consultation Correspondence

Document Date	Sender	Recipient	Document Description	Accession Number
11/27/2019	NRC	Wisconsin Historical Society	Request for Scoping Comments and Initiate NHPA Section 106 Consultation Concerning the SHINE Technologies, LLC Application for an Operating License	ML19323E507
11/27/2019	NRC	Advisory Council on Historic Preservation	Request for Scoping Comments and Initiate NHPA Section 106 Consultation Concerning the SHINE Technologies, LLC Application for an Operating License	ML19323E288
11/27/2019	NRC	Multiple Tribal Officials	Request for Scoping Comments and Initiate NHPA Section 106 Consultation Concerning the SHINE Technologies, LLC Application for an Operating License	ML19325E112
12/10/2019	Wisconsin Historical Society	NRC	Scoping comments from Wisconsin Historical Society regarding WHS#: 12-0129 RO SHINE Medical Isotope Production Facility	ML20014D409
1/6/2020	Miami Tribe of Oklahoma	NRC	Scoping comments from Miami Tribe of Oklahoma on SHINE Operating License Application	ML20006G581
1/24/2020	NRC	Winnebago Tribe of Nebraska	Response to Winnebago Tribe of Nebraska SHINE Scoping Request	ML20031D557

Table B-3 Environmental Review Endangered Species Act Section 7 Consultation Correspondence

Document Date	Sender	Recipient	Document Description	Accession Number
8/21/2019	FWS	NRC	List of Threatened and Endangered Species for the SHINE Production Facility Operating License	ML19233A174
11/12/2019	NRC	FWS	Request for Federally Listed Species Information in connection with SHINE Production Facility Operating License in Janesville, Wisconsin	ML19325D154
11/21/2019	FWS	NRC	FWS to NRC, Reply to Request for Federally Listed Species Information in connection with SHINE Production Facility Operating License in Janesville, Wisconsin	ML19325D155

NRC FORM 335 (12-2010) NRCMD 3.7 U.S. NUCLEAR REGULATORY COMMISSION **BIBLIOGRAPHIC DATA SHEET** *(See instructions on the reverse)*	1. REPORT NUMBER (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.) **NUREG-2183 Supplement 1 Draft**
2. TITLE AND SUBTITLE **Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility** Draft Report for Comment	3. DATE REPORT PUBLISHED MONTH: **June** YEAR: **2022** 4. FIN OR GRANT NUMBER
5. AUTHOR(S) See Chapter 6	6. TYPE OF REPORT Technical 7. PERIOD COVERED (Inclusive Dates)

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

Division of Rulemaking, Environmental, and Financial Support
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

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 above

10. SUPPLEMENTARY NOTES

Docket No. 50-608

11. ABSTRACT (200 words or less)

In 2015, the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy, National Nuclear Security Administration (DOE-NNSA) issued NUREG-2183, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility” (NRC 2015), which discussed the environmental impacts of constructing, operating, and decommissioning the SHINE Medical Isotope Production Facility (SHINE facility) in Janesville, Wisconsin. In 2016, at the conclusion of its safety and environmental reviews, the NRC issued a construction permit for the SHINE facility (NRC 2016). In July 2019, SHINE Medical Technologies, LLC (SHINE) submitted to the NRC an application for an operating license for the SHINE facility.

When a final environmental impact statement (FEIS) has been prepared in connection with the issuance of a construction permit for a facility, the NRC is required to prepare a supplement to the final FEIS in connection with any issuance of an operating license for that facility in accordance with Title 10 of the Code of Federal Regulations (10 CFR) 51.95(b). This supplement updates the prior environmental review and only covers matters that differ from those or that reflect significant new information relative to that discussed in the final EIS. Accordingly, in response to SHINE’s operating license application, the NRC and DOE-NNSA staff have considered whether there is any new information with respect to the environment or the environmental impacts of the SHINE facility, including information that is different from that considered in NUREG-2183. The NRC staff did not identify any information that presents a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility.

After weighing the environmental, economic, technical, and other benefits against environmental and other costs, the NRC staff’s preliminary recommendation, unless safety issues mandate otherwise, is that the operating license be issued as proposed. The NRC staff based its recommendation on the following:

- the application, including SHINE’s supplemental environmental report;
- consultation with Federal, State, Tribal, and local agencies;
- the staff’s independent review; and
- the consideration of public comments.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)	13. AVAILABILITY STATEMENT
SHINE Medical Technologies, LLC (SHINE)	unlimited
SHINE Medical Isotope Production Facility (SHINE facility)	14. SECURITY CLASSIFICATION
SHINE	*(This Page)* unclassified
Final Environmental Impact Statement (FEIS)	*(This Report)* unclassified
National Environmental Policy Act (NEPA)	15. NUMBER OF PAGES
	16. PRICE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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NUREG-2183
Supplement 1, Draft

Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility

June 2022