

SECTION 19.1

INTRODUCTION OF THE ENVIRONMENTAL REPORT

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Acronyms and Abbreviations

| <u>Acronym/Abbreviation</u> | <u>Definition</u> |
|-----------------------------|--|
| CFR | Code of Federal Regulations |
| COE | U.S. Army Corps of Engineers |
| CP | Construction Permit |
| DOE | U.S. Department of Energy |
| EA | Environmental Assessment |
| ER | Environmental Report |
| ERR | Endangered Resources Review |
| FAA | Federal Aviation Administration |
| FDA | U.S. Food and Drug Administration |
| FWS | U.S. Fish and Wildlife Service |
| HEU | highly enriched uranium |
| HFR | High Flux Reactor |
| I-131 | iodine-131 |
| IRE | Institut National des Radioéléments |
| LEU | low enriched uranium |
| Mo-99 | molybdenum-99 |
| NEPA | National Environmental Policy Act |
| NRC | U.S. Nuclear Regulatory Commission |
| NRCL | National Research Council |
| NRU | National Research Universal |
| NTP | Nuclear Technology Products Radioisotopes |
| OL | Operating License |
| SHINE | SHINE Medical Technologies, Inc. |
| SHPO | State Historic Preservation Office |
| SPCC | Spill Prevention, Control and Countermeasure |

Acronyms and Abbreviations (cont'd)

| <u>Acronym/Abbreviation</u> | <u>Definition</u> |
|-----------------------------|--------------------|
| Tc-99m | technetium-99m |
| U-235 | uranium-235 |
| WNN | World Nuclear News |
| Xe-133 | xenon-133 |

CHAPTER 19

19.1 INTRODUCTION OF THE ENVIRONMENTAL REPORT

In accordance with the provisions of Title 10 of the Code of Federal Regulations (CFR) Part 50 “Domestic Licensing of Production and Utilization Facilities,” and supporting guidance, SHINE Medical Technologies, Inc. (SHINE) is providing this Environmental Report (ER) in support of an application to construct and operate a radioisotope facility in Janesville, Wisconsin. SHINE is providing this comprehensive ER as required with its application. The ER provides information to the U.S. Nuclear Regulatory Commission (NRC) to facilitate preparation of an Environmental Assessment (EA) in accordance with the provisions of 10 CFR 51 Subpart A, National Environmental Policy Act – Regulations Implementing Section 102 (2). This chapter provides an introduction to the assessment of the environmental effects of construction, operation, and decommissioning of this facility on the site and surrounding areas.

This ER follows the content and organization of the Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, Chapter 19 (NRC, 2012). This ER supports the regulatory review that is performed by the NRC under 10 CFR 51. This regulation requires that environmental impacts from the project be evaluated and described in a concise, clear, and analytical manner. This ER describes the project, potential alternatives, and the methods and sources used in the environmental impact analysis.

This ER discusses the existing environment at the proposed Janesville, Wisconsin site (referred to throughout the ER as the SHINE site) and vicinity, and summarizes the environmental impacts of construction, operation, and decommissioning. In addition, this ER considers appropriate impact mitigation measures, and reviews alternative sites and technologies.

The SHINE facility produces molybdenum-99 (Mo-99), iodine-131 (I-131), and xenon-133 (Xe-133). The decay product of Mo-99, technetium-99m (Tc-99m), is used for diagnostic nuclear medicine procedures. The purpose and need for the proposed action is provided in Section 19.1.1 and a description of the proposed action is provided in Section 19.2.

19.1.1 PURPOSE AND NEED FOR THE PROPOSED ACTION

The proposed federal action is the issuance of a Construction Permit (CP) and Operating License (OL), under the provisions of 10 CFR 50, that would allow SHINE to construct and operate a radioisotope facility to produce Mo-99, I-131, and Xe-133. Further discussion of the proposed action is provided in Section 19.2.

Molybdenum-99

There is currently no domestic production of Mo-99 and its daughter isotope technetium-99m (Tc-99m). The U.S. is forced to import its entire supply of these isotopes, which are used in 80 percent of nuclear medicine procedures. Tc-99m is an essential ingredient in diagnostic radiopharmaceuticals used for:

- Bone scans
- Lung perfusion imaging
- Kidney scans and functional imaging
- Liver scans

- Sentinel lymph node localization
- Cardiac perfusion imaging
- Brain perfusion imaging
- Gall bladder function imaging
- Blood pool imaging
- Thyroid and salivary gland imaging
- Meckel's scans

Between 95 and 98 percent of the world's supply of Mo-99 is produced by just four organizations (NRCL, 2009):

- MDS Nordion (Canada).
- Covidien (Netherlands).
- Institut National des Radioéléments (IRE) (Belgium).
- Nuclear Technology Products Radioisotopes (Pty) Ltd. (NTP) (South Africa).

Two of these companies (MDS Nordion [approximately 60 percent of the U.S. supply] and Covidien [approximately 40 percent of U.S. supply]) supply nearly all of the Mo-99 used in the U.S. These two companies obtain the vast majority of their Mo-99 from two reactors (NRCL, 2009):

- National Research Universal (NRU) reactor in Chalk River, Ontario, Canada.
- High Flux Reactor (HFR) in Petten, the Netherlands.

The NRU reactor has been in operation since 1957 and HFR has been in operation since 1961. Due to the age of these reactors, disruption of the supply of Mo-99 is an ongoing concern.

The most recent disruptions of Mo-99 supply resulted from the shutdown of HFR from August 2008 to February 2009 and again from February 2010 to September 2010 for repairs. Concurrent with the HFR shutdown, the NRU reactor was also shut down for repairs from May 2009 to August 2010 (WNN, 2009; Fissile Material, 2010; MSNBC, 2010). While both reactors were shut down, there was an increase in production from other Mo-99 producers in Europe and South Africa; however, the U.S. experienced a shortage of Mo-99/Tc-99m, resulting in hospitals and clinics postponing or cancelling diagnostic imaging procedures (NRCL, 2009).

In addition to the age of the HFR and NRU reactors, there are three other supply reliability concerns:

- Increasing demand, both domestically and globally, for Mo-99.
- Increasing difficulty of transporting Mo-99 across international borders, especially by air, due to security concerns.
- The short half-life of Mo-99 (2.75 days) and Tc-99m (6.01 hours).

Because of these supply reliability concerns and national security concerns, U.S. government policy and law is to encourage the domestic production of Mo-99. The SHINE facility makes a significant contribution toward accomplishing these goals.

Current U.S. demand for Mo-99 is between 5000 and 7000 6-day curies per week, and this demand is projected to grow in the range of 3 to 10 percent per year (NRCL, 2009). The SHINE facility can produce up to 8200 6-day curies of Mo-99 per week.

The SHINE facility also helps achieve U.S. government nonproliferation objectives. Most of the world's production of Mo-99 is achieved by irradiating highly enriched uranium (HEU) targets in research and test reactors. The U.S. is the primary supplier of HEU for Mo-99 production. In 1992 Congress passed the Energy Policy Act of 1992 (U.S. Government, 1992). One of the nonproliferation objectives of the Energy Policy Act of 1992 was to create a strategy to phase out U.S. exports of HEU for radioisotope production. Based on this, the U.S. is encouraging Mo-99 producers to eliminate use of HEU in medical isotope production. The SHINE facility uses LEU (less than 20 percent enrichment) to produce Mo-99.

Iodine-131

There are two methods used to produce I-131: irradiation of tellerium-130 in a nuclear reactor, and generation as a by-product of the irradiation of uranium-235 (U-235) for Mo-99 production. Both methods are used to supply the U.S. I-131 is used for (NM, 2012):

- Radiation therapy.
- Radioactive labeling for diagnostic radiopharmaceuticals.

Currently, there is no commercial production of I-131 in the U.S. The U.S. supply of I-131 is provided by DRAXIMAGE (66 percent), Covidien (26 percent), and MDS Nordion (8 percent). These companies obtain their I-131 for U.S. consumption from two reactors (OECD, 2010):

- NRU reactor in Chalk River, Ontario, Canada.
- SAFARI-1, Pelindaba, South Africa.

The SAFARI-1 reactor has been in operation since 1965 (OECD, 2010). As discussed above for Mo-99, due to the ages of the reactors, disruption of the supply of I-131 is an ongoing concern.

Xenon-133

Xe-133 gas is produced as a by-product of the irradiation of U-235 for Mo-99 production. Xe-133 is used for (RxList, 2012):

- Lung imaging.
- Diagnostic evaluation of pulmonary function.
- Assessment of cerebral blood flow.

19.1.2 REGULATORY PROVISIONS, PERMITS, AND REQUIRED CONSULTATIONS

This section lists and summarizes the status of federal, state, local, and other permits and consultations required for the construction and operation of the proposed SHINE radioisotope facility. The applicable law, ordinance, or regulation that governs each permit and/or consultation is also identified.

Table 19.1.2-1 lists the permits and other approvals required for construction and operation of the SHINE facility. The table provides the following information for each permit or approval, as applicable:

- Name of the responsible regulatory agency
- Applicable law, ordinance, or regulation

- Name of the permit or approval
- Activity covered by the permit or approval
- Current status

Table 19.1.2-2 lists the consultations required for construction and operation of the SHINE facility. The table provides the following information for each consultation, as applicable:

- Name of the responsible regulatory agency
- Applicable law, ordinance, or regulation
- Required consultation
- Summary of any surveys required to complete the consultation
- Current status

In addition to the formal consultations listed in Table 19.1.2-2, SHINE has made informal contacts with the U.S. Nuclear Regulatory Commission, the National Nuclear Security Administration, the Bureau of Indian Affairs, the Wisconsin Department of Health Services, and the City of Janesville Community Development Department. The purpose of these informal consultations was to inform the agencies about the project and to coordinate project planning.

An on-site field delineation completed in accordance with U.S. Army Corps of Engineers (COE) guidance (COE, 2010) found no jurisdictional wetlands or waters of the United States on the SHINE site. Therefore, no permitting or consultation with the COE is expected to be required.

No potential administrative delays or other problems have been identified that would prevent any required agency consultations or approvals. The SHINE facility is designed and planned to comply with all applicable environmental quality standards and regulatory requirements. The facility also will comply with current Good Manufacturing Practices followed by the pharmaceutical industry.

**Table 19.1.2-1 Permits and Approvals Required for Construction and Operation
(Sheet 1 of 5)**

| Agency | Regulatory Authority | Permit or Approval | Activity Covered | Status |
|---------------------------------------|--|--|---|---|
| U.S. Nuclear Regulatory Commission | Atomic Energy Act 10 CFR 50.50 | Construction Permit | Construction of the SHINE facility | Addressed in this license application |
| | 10 CFR 50.57 | Operating License | Operation of the SHINE facility | Addressed in this license application |
| | 10 CFR 40 | Source Material License | Possession, use, and transfer of radioactive source material | Addressed in this license application |
| | 10 CFR 30 | By-Product Material License | Production, possession, and transfer of radioactive by-product material | Addressed in this license application |
| | 10 CFR 70 | Special Nuclear Material License | Receipt, possession, use, and transfer of special nuclear material | Addressed in this license application |
| | National Environmental Policy Act (NEPA) 10 CFR 51 | Environmental Assessment or Environmental Impact Statement in accordance with NEPA | Site approval for construction and operation of a radioisotope facility | Addressed in this license application |
| Federal Aviation Administration (FAA) | Federal Aviation Act 14 CFR 77 | Construction Notice | Construction of structures that potentially may impact air navigation | SHINE submitted structure evaluation requests on October 26, 2011. The FAA issued Determinations of No Hazard to Air Navigation on November 9 and 15, 2011. |
| U.S. Environmental Protection Agency | Resource Conservation and Recovery Act 40 CFR 261 and 262 | Acknowledgement of Notification of Hazardous Waste Activity | Generation of hazardous waste | Notification not yet submitted |
| | Clean Water Act 40 CFR 112, Appendix F | Spill Prevention, Control and Countermeasure (SPCC) Plans for Construction and Operation | Storage of oil during construction and operation | SPCC Plans not yet prepared |
| U.S. Department of Transportation | Hazardous Material Transportation Act 40 CFR 107 | Certificate of Registration | Transportation of hazardous materials | Registration application not yet submitted |

**Table 19.1.2-1 Permits and Approvals Required for Construction and Operation
(Sheet 2 of 5)**

| Agency | Regulatory Authority | Permit or Approval | Activity Covered | Status |
|---|---|--|--|---|
| Wisconsin Department of Natural Resources | Federal Clean Air Act | Air Pollution Control Construction Permit | Construction of an air pollution emission source that is not specifically exempted | Permit application not yet submitted |
| | Wisconsin Statutes Chapter 285 Wisconsin Administrative Code Chapter NR 406 | | | |
| | Federal Clean Air Act | Air Pollution Control Operation Permit | Operation of an air pollution emission source that is not specifically exempted | Permit application not yet submitted |
| | Wisconsin Statutes Chapter 285 Wisconsin Administrative Code Chapter NR 407 | | | |

**Table 19.1.2-1 Permits and Approvals Required for Construction and Operation
(Sheet 3 of 5)**

| Agency | Regulatory Authority | Permit or Approval | Activity Covered | Status |
|--|---|---|--|---|
| Wisconsin Department of Natural Resources, continued | Federal Clean Water Act | Construction Storm Water Discharge Permit | Discharge of storm water runoff from the construction site | Notice of Intent to be covered by general permit not yet submitted |
| | Wisconsin Statutes Chapter 283 Wisconsin Administrative Code Chapter NR 216 | | | |
| | Federal Clean Water Act | Industrial Storm Water Discharge Permit | Discharge of storm water runoff from the site during facility operation | Notice of Intent to be covered by general permit not yet submitted. The facility may be eligible for an industrial Storm Water Discharge Permit exclusion under Wisconsin Administrative Code NR 216.21(3) |
| | Wisconsin Statutes Chapter 283 Wisconsin Administrative Code Chapter NR 216 | | | |
| | 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 | Plans and specifications not yet submitted |
| | Wisconsin Statutes Chapter 291 Wisconsin Administrative Code Chapter NR 660, 662, and/or 666 | Compliance with hazardous waste notification, record keeping, and reporting requirements | Generation of hazardous waste | Notification not yet submitted; other requirements become applicable during operation |
| Wisconsin Department of Safety and Professional Services | Wisconsin Statutes Chapter 101 | Building Plan Review | Compliance with state building codes; required before a local building permit can be issued for a commercial building | Plans not yet submitted |
| | Wisconsin Administrative Code Chapters SPS 361 and 362 | | | |
| Wisconsin Department of Transportation | Wisconsin Statutes Chapter 85 | Permit for Connection to State Trunk Highway | Construction of driveway connection to U.S. Route 51 | Permit application not yet submitted |
| | Wisconsin Administrative Code Chapters Trans 231 | | | |

**Table 19.1.2-1 Permits and Approvals Required for Construction and Operation
(Sheet 4 of 5)**

| Agency | Regulatory Authority | Permit or Approval | Activity Covered | Status |
|--|--|---|---|--------------------------------------|
| Wisconsin Department of Transportation continued | Wisconsin Statutes Chapter 85 | Right of Entry Permit | Construction by the City of Janesville of utility extensions across U.S. Route 51 | Permit application not yet submitted |
| | Wisconsin Administrative Code Chapters Trans 231 | | | |
| | Wisconsin Statutes Chapter 114 | Variance from Height Limitation Zoning Ordinances | Construction of structures that exceed height limitations established for Southern Wisconsin Regional Airport | Plans not yet submitted for review |
| | Wisconsin Administrative Code Chapters Trans 56 | | | |
| City of Janesville Community Development Department | City of Janesville Ordinance 18.24.050.A | 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, etc. | Plans not yet submitted for review |
| | City of Janesville Ordinance 15.06.070 | Storm Water Plan Approval (may be included in Site Plan Approval) | Administrative approval of grading and drainage plans | Plans not yet submitted for review |
| | City of Janesville Ordinance 15.05.080 | Erosion Control Permit (may be included in Site Plan Approval) | Administrative approval of erosion control plans | Plans not yet submitted for review |
| | City of Janesville Ordinance 15.01.100.A | Building Permit | Construction of buildings | Permit application not yet submitted |
| | City of Janesville Ordinance 15.01.100.A | Plumbing Plan Approval | Installation of plumbing systems | Permit application not yet submitted |
| | City of Janesville Ordinance 15.04.010.A | HVAC Plan Approval | Installation of heating, ventilation, and air conditioning systems | Permit application not yet submitted |
| | City of Janesville Ordinance 8.32.010 | Fire Sprinkler and Alarm Permit | Installation of sprinkler and alarm systems | Permit application not yet submitted |
| | City of Janesville Ordinance 15.01.190.A | Occupancy Permit | Occupancy of completed buildings | Permit application not yet submitted |

**Table 19.1.2-1 Permits and Approvals Required for Construction and Operation
(Sheet 5 of 5)**

| Agency | Regulatory Authority | Permit or Approval | Activity Covered | Status |
|---|--|---|---|---|
| City of Janesville Community Development Department continued | City of Janesville Ordinance 13.16 | Sanitary Sewer and Water Supply Facility Approvals | Administrative approval of construction, installation, and operation of connections to the municipal sewer and water supply systems | Permit application not yet submitted |
| City of Janesville Plan Commission | City of Janesville Ordinance 18.24.040 | Conditional Use Permit (when the site property is annexed by the City, the property will automatically be zoned for industrial use) | Construction of multiple buildings on the same site | Permit application not yet submitted |
| 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 | Permit application not yet submitted |
| Note: No jurisdictional wetlands or waters of the United States have been identified on the SHINE site; therefore, authorization under Section 404 of the Clean Water Act is not expected to be required for construction or operation. | | | | |
| Sources for identification of permit requirements: City of Janesville, 2012; State of Wisconsin, 2012; Wisconsin Department of Natural Resources, 2012. | | | | |

**Table 19.1.2-2 Consultations Required for Construction and Operation
(Sheet 1 of 2)**

| Agency | Regulatory Authority | Required Consultation | Surveys Required | Status |
|---|---|--|-------------------------------|---|
| U.S. Fish and Wildlife Service (FWS) | Endangered Species Act, 16 USC 1536 | Consultation regarding potential to adversely impact protected species; concurrence with no adverse impact or consultation on appropriate mitigation measures | None | Consultation letter was submitted to the FWS on December 16, 2011; FWS issued a response on January 25, 2012, stating no further action required. |
| | Bald and Golden Eagle Protection Act, 16 USC 668-668c | Consultation regarding potential to adversely impact eagles; concurrence with no adverse impact or consultation on appropriate mitigation measures | None | Consultation letter and response as above. |
| Wisconsin State Historic Preservation Office (SHPO) | National Historic Preservation Act, Section 106 | Consultation regarding potential to adversely impact historic resources; concurrence with no adverse impact or consultation on appropriate mitigation measures | Phase I archaeological survey | Phase I survey was completed on December 15, 2011. Consultation letter was submitted to the SHPO on February 15, 2012; response was received on March 12, 2012 stating agreement with finding that no historic properties will be affected. |
| Wisconsin Department of Natural Resources | Wisconsin Statutes Chapter 29, Section 604 | Endangered Resources Review (ERR) to document recorded occurrence of protected species or rare natural habitats | None | Request for ERR was submitted on January 16, 2012; ERR response was issued on February 1, 2012, stating no further action required. |

**Table 19.1.2-2 Consultations Required for Construction and Operation
(Sheet 2 of 2)**

| Agency | Regulatory Authority | Required Consultation | Surveys Required | Status |
|--|--|--|------------------|---|
| <p>Native American Nations:</p> <ul style="list-style-type: none"> - Citizen Potawatomi Nation, Oklahoma - Flandreau Santee Sioux Tribe of South Dakota - Forest County Potawatomi Community, Wisconsin - Hannahville Indian Community, Michigan - Ho-Chunk Nation of Wisconsin - Lower Sioux Indian Community, Minnesota - Prairie Band of Potawatomi Nation, Kansas - Prairie Island Indian Community, Minnesota - Santee Sioux Nation, Nebraska - Sisseton-Wahpeton Oyate, South Dakota - Spirit Lake Tribe, North Dakota - Upper Sioux Community, Minnesota - Winnebago Tribe of Nebraska | <p>National Environmental Policy Act</p> <p>National Historic Preservation Act</p> <p>Native American Graves Protection and Repatriation Act</p> | <p>Consultation regarding protection of traditional Native American religious and cultural resources</p> | <p>None</p> | <p>Consultation letters were sent to the Native American tribes on July 26, 2012. The Winnebago Tribe of Nebraska responded on August 2, 2012, requesting notification if any burial sites are discovered. No other responses have been received.</p> |