

ENVIRONMENTAL SITE AUDIT NEEDS LIST

The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the SHINE Medical Technologies, LLC (SHINE) Supplement to Environmental Report-Operating License Stage.

Please be prepared to discuss the following issues and make available the requested information during the environmental site audit.

Presentation(s)

The Environmental Report (ER) supplement identifies changes in the isotope production process (e.g., removal of the uranium (UREX) and thermal denitration processes) and facility change layouts. During the audit, the staff requests that the applicant provide an overview presentation of the radioisotope production process that highlights the changes in the production process and changes in facility layout. Include the following in the presentation:

1. a conceptual view (similar to Figure 2-4 in SHINE Construction Permit (CP) Final Environmental Impact Statement, NUREG-2183) of the proposed SHINE facility that depicts the changes in the facility layout and new buildings/structures.
2. updated publicly available versions of conceptual graphics for the SHINE Device (similar to Figure 2-5 in NUREG-2183) and a representative irradiation unit (similar to Figure 2-6 in NUREG-2183).
3. a revised SHINE radioisotope production system flow diagram that describes the overall isotope production process (similar to Figure 2-7 in NUREG-2183).

Proposed Action (PA)

Information Needs:

- PA-1 Describe the process and methodology used to identify any new information that has become available since issuance of NUREG-2183.
- PA-2 The ER supplement states that additional information about the frequency of radiological waste shipments is described in Final Safety Analysis Report (FSAR) Chapter 11. Chapter 11 of the FSAR however does not provide the frequency of radioactive waste shipments or deliveries to the proposed SHINE facility. Are there changes in the monthly inbound and outbound shipments during facility operations from what is discussed in the NUREG-2183 (Section 4.10.2)? If so, provide the monthly inbound truck deliveries, outbound medical radioisotope product shipments, and outbound radioactive and non-radioactive waste shipments estimated during operations.
- PA-3 10 CFR 51.45(d) states that the ER "shall describe the status of compliance" of Federal permits, licenses and approvals that must be obtained in connection with the proposed action. The ER supplement states that no additional permit or approvals have been identified since the issuance of NUREG-2183. However, the ER supplement does not provide any updates or changes that describe the status of compliance related to permits or approvals since issuance of

NUREG-2183. Provide a status update of the permits and approvals listed in Table B-4 of NUREG-2183. In addition, provide a copy of State of Wisconsin radioactive materials license (license number 105-2083-01) for Building One.

PA-4 Are there changes in the 8,200 6-day Ci of Mo-99 week SHINE expects to produce? If so, quantify the changes.

PA-5 The ER supplement identifies that the building designs have been refined resulting in a smaller total buildings footprint but similar overall total footprint. Provide the footprints of the following buildings and features:

- Storage building
- Material staffing building
- Resource building
- Nitrogen purge system structure
- Administration Building
- Parking lots
- Roads
- Stormwater features
- Building One

PA-6 Has SHINE identified any changes in the estimated workforce, shipments, waste types and quantities, or fuel consumption for decommissioning of the proposed SHINE facility? If so, quantify the changes.

Meeting/Break-out Discussion:

Provide a subject matter expert to resolve or clarify potential outstanding data or questions arising from the responses provided above.

Tour:

No tour requested

Land Use and Visual

Information Needs:

None required.

Meeting:

None required.

Tour:

None required.

Air Quality and Noise (AQN)

Information Needs:

- AQN-1 NUREG-2183 identifies six fuel combustion emission sources for the facility: one emergency diesel generator, four natural-gas-fired heaters to heat four buildings (the diesel generator building, the waste staging and shipping building, support facility building, and the administration building) and one natural gas boiler to meet heating requirements for the Production Facility Building. Section 2.7 of the ER supplement states that: 1.) SHINE will maintain a standby natural gas generator instead of the diesel generator identified in the CP ER; 2.) the heating system design for the facility has also changed and will include three 50-percent capacity natural gas fired heating boilers; and 3.) fuel combustion emissions sources from the facility will include the standby natural gas fired generator and the facility heating system. It is unclear if the change in the heating system design discussed in the ER supplement is referring to the entire SHINE medical radioisotope production facility (comprised of the main production facility, storage building, material staging building, resource building, and administration building) or specifically to the Main Production Facility (formerly the production facility building).
- a.) Will the three natural gas fired heating boilers identified in the ER supplement provide heating solely for the Main Production Facility?
 - b.) In addition to the three natural gas fired heating boilers identified in the ER supplement, will the SHINE facility heating system also consist of four natural gas-fired heaters? Are there changes in the number, design, or estimated use of natural-gas fired heaters from the four identified in the CP ER and NUREG-2183 as a result of building design refinements and new structures that would result in an increase in air emissions from what is presented in the NUREG-2183? If so, quantify the increase in air emissions.
 - c.) Provide an estimate of the total amount of natural gas the facility would use annually from the facility combustion sources.
- AQN-2 Provide for review the calculations that support the natural gas generator emissions presented in Table 2-3 of the ER supplement.
- AQN-3 Table 2-2 of the ER supplement identifies the types and quantities of radionuclides that will be released as gaseous effluents generated by operation of the facility. NUREG-2183 identifies that nitrogen oxides (approximately 3 tons per year) would be emitted from the radioisotope production process as a result of the use of nitric acid in the target solution vessels and in the thermal denitration process. As noted in the ER supplement, changes in the isotope production process include the removal of the UREX and thermal denitration processes. Clarify if as a result of the process design changes, NO_x will be emitted as a result of radioisotope production process. If so, provide the estimated amount of NO_x.
- AQN-4 The CP ER and NUREG-2183 indicate that up to 468 medical shipments associated with the proposed action would occur each year with most being transported by air. Section 4.2 of the ER supplement states that outgoing shipments of product from the Southern Wisconsin Regional Airport (SWRA) are

not expected to significantly increase the number of flights per year or noticeably increase the noise levels from the SWRA. Is there a change in the previously estimated 468 medical shipments per year that would result in an increase in shipments transported by air and therefore an increase in air traffic?

Meeting/Break-out Discussion:

Provide a subject matter expert to discuss the air quality and noise portions of the ER. This meeting will be used as needed to resolve or clarify outstanding data or questions arising from the responses provided above.

Tour:

None required.

Geologic Environment

Information Needs:

None required.

Meeting/Break-out Discussion:

None required.

Tour:

None required.

Water Resources (WR)

Information Needs:

- WR-1 Provide a revised water flow/water balance diagram that shows the expected average daily makeup inputs and contributions from facility processes to the sanitary sewer, in accordance with the description in ER Section 2.3.
- WR-2 For the CP, SHINE's ER described the facility as having "zero liquid discharge from the radiologically controlled area (RCA)." The ER supplement now indicates that "radioactive liquid discharges ... to the sanitary sewer are made in accordance with 10 CFR § 20.2003, 10 CFR § 20.2007, and Janesville City Ordinance 13.16" (ER sections 2.3, 4.13). The ER further indicates details are provided in FSAR Chapter 11. The FSAR variously states that "there are no piped liquid effluent pathways from the RCA to the sanitary sewer" (e.g., FSAR 11.1.4.1, 11.1.7.2, 11.2.3) and that "liquid effluent is not routinely discharged from the RCA...." FSAR Section 11.1.4.1 stated that "liquid effluent releases are collected and sampled prior to release." FSAR Sections 11.1.7.2 and 11.2.3 further indicate that "radioactive liquid discharges ... to the sanitary sewer are infrequent...." However, neither the ER supplement nor the FSAR clearly identify the radioactive liquid waste streams that could be disposed of via the sanitary sewer, and this specificity does not appear to be provided in FSAR Table 11.2-1, "Estimated Annual Waste Stream Summary." Clarify and provide a description of the possible sources and characteristics, including frequency of discharge and expected concentrations or activity levels, of radiological constituents that may be disposed of via the sanitary sewer.

Meeting/Break-out Discussion:

Provide a subject matter expert to discuss radioactive liquid effluents as may be necessary to resolve or clarify questions with respect to WR-2.

Tour:

As described in Cumulative Impacts below.

Ecological Resources

Information Needs:

None required.

Meeting/Break-out Discussion:

None required.

Tour:

None required.

Special Status Species and Habitats (SSS)

Information Needs:

- SSS-1 The ER identifies the northern long-eared bat (*Myotis septentrionalis*) as potentially occurring near the SHINE site but does not evaluate the potential effects of the proposed action on this species. Provide an evaluation of the potential effects on this species. Specifically, consider the risk of bat collisions with facility structures, elevated noise levels, and any other relevant impacts that northern long-eared bats could experience during operation or decommissioning of the SHINE facility. Confirm that there are no trees on the SHINE site greater than 3 inches in diameter at breast height that would be cleared or otherwise affected by the proposed action.
- SSS-2 The ER does not consider the federally listed whooping crane (*Grus americana*) or prairie bush-clover (*Lespedeza leptostachya*), both of which the U.S. Fish and Wildlife Service identifies as potentially occurring near the SHINE site in the Service's official list of species transmitted to the NRC on August 21, 2019 (ADAMS Accession Number [ML19233A174](#)). Provide an evaluation of the potential effects on these species. Specifically concerning the whooping crane, evaluate the risk of collisions with facility structures, elevated noise levels, and any other relevant impacts that whooping cranes could experience during operation or decommissioning of the SHINE facility. Specifically concerning the prairie bush-clover, evaluate the potential impacts of landscape maintenance, herbicide application, and any other relevant impacts that prairie bush-clover could experience during operation or decommissioning of the SHINE facility.
- SSS-3 The ER considers the federally listed eastern massasauga (*Sistrurus catenatus*), rusty patched bumblebee (*Bombus affinis*), and upland sandpiper (*Bartramia longicauda*). The U.S. Fish and Wildlife Service did not identify these species as occurring in the action area in its official species list referenced in the above

request. Explain why the ER includes these species. Is there additional information specific to these species for which the NRC staff should be aware?

SSS-4 Provide a copy of the following ER reference:

USFWS, 2018. The Information, Planning, and Consultation System (IPaC System) Resource List, Fish and Wildlife Service, Website: <https://ecos.fws.gov/ipac/>, Date accessed: June 27, 2018.

NOTE: For the above reference, provide the list of species obtained from the database.

SSS-5 Provide a copy of the following ER reference:

WDNR, 2018. Endangered Resources Review (ERR #12-020 (renewed), Proposed SHINE Medial Technologies Industrial Development – Renewed 7/17/18, Rock County, WI (T02N R12E S24), Wisconsin Department of Natural Resources, received July 17, 2018.

Meeting/Break-out Discussion:

None required.

Tour:

None required.

Historic and Cultural Resources (HC)

Information Needs:

HC-1 Have any historic and cultural resources been discovered during the course of excavation activities associated construction of the SHINE facility? If so, what if any action was taken to document the find(s)?

Meeting/Break-out Discussion:

None required.

Tour:

None required.

Socioeconomic Impacts

Information Needs:

None required.

Meeting/Break-out Discussion:

None required.

Tour:

None required.

Human Health

Information Needs:

None required.

Meeting/Break-out Discussion:

None required.

Tour:

None required.

Waste Management (WM)

Information Needs:

WM-1 Describe how SHINE proposes to reduce radiological and non-radiological waste generation to the maximum extent possible, including Greater-Than-Class-C waste generation.

WM-2 Provide process flow diagrams for the waste treatment and disposal pathways.

Other info needs are covered in Water Resources.

Meeting/Break-out Discussion:

Provide a subject matter expert to discuss the facility's waste management systems to provide an overview of waste processing systems, specifically, how the facility handles waste including waste minimization. In addition, discuss Building One's storage, usage, and release of radioactive and non-radioactive waste materials and possible release pathways for effluents and wastes.

Tour:

As described in Cumulative Impacts below.

Transportation (TR)

Information Needs:

TR – 1 Have any additional level of service analyses addressing potential traffic delays in the immediate vicinity of the SHINE facility been conducted subsequent to those referenced in NUREG-2183?

Meeting/Break-out Discussion:

None Required.

Tour:

None Required.

Accidents

Information Needs:
None required.

Meeting/Break-out Discussion:
None required.

Tour:
None required.

Environmental Justice

Information Needs:
None required.

Meeting/Break-out Discussion:
None required.

Tour:
None required.

Cumulative Impacts (CI)

Information Needs:

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| CI-1 | Provide the name, description, location, and status of any additional past, present, or reasonably foreseeable projects or actions that SHINE has identified since the ER supplement was prepared. |
| CI-2 | Section 3.8 of the ER supplement notes that Building One “stores, uses, and releases radioactive material...” in accordance with a state permit. Describe the current status of the facility and its expected role over the course of the proposed SHINE facility operating period. Characterize and quantify any gaseous and liquid effluents generated by facility operations, including concentrations and activity levels, as well as any radiological waste materials. In addition, identify the disposal paths for any such effluents and wastes. |

Meeting/Break-out Discussion:

A break-out discussion would only be necessary to clarify information learned on-site during the audit.

Tour:

A general tour of Building One with subject matter experts familiar with building and process operations.

Cost Benefit (CB)

Information Need:

CB-1 Is there any updated information to support the cost benefit analysis in NUREG-2183 (Section 5.4 – Cost Benefit Comparison – in particular, updates to Table 5-17 and the information presented on page 5-103)? If so, please provide a summary of the updated information.

Meeting/Break-out Discussion:

None required.

Tour:

None required.