



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

January 31, 2023

Ken Westlake  
U.S. Environmental Protection Agency  
Region 5  
77 W. Jackson Blvd.  
Chicago, IL 60604

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – NOTICE OF AVAILABILITY OF ENVIRONMENTAL IMPACT STATEMENT SUPPLEMENT RELATED TO THE OPERATING LICENSE FOR THE SHINE MEDICAL ISOTOPE PRODUCTION FACILITY (DOCKET NUMBER: 50-608)

Dear Ken Westlake:

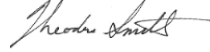
The U.S. Nuclear Regulatory Commission (NRC) staff has completed supplement 1 to NUREG-2183, "Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility," regarding the SHINE Medical Technologies, LLC (SHINE) operating license application for the SHINE Medical Isotope Production Facility (SHINE facility). Supplement 1 to NUREG-2183 is being issued in accordance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 et seq.) (NEPA), as part of the NRC's process to decide whether, under the provisions of title 10 of the *Code of Federal Regulations* part 50, to issue a license to SHINE to operate the SHINE facility for a period of 30 years. The U.S. Department of Energy, National Nuclear Security Administration (DOE-NNSA) participated in the environmental review as a cooperating agency. 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 supplement 1 to NUREG-2183 and other documentation related to NEPA to determine if additional NEPA analysis is warranted. Therefore, impact determinations made in supplement 1 to NUREG-2183 should only be attributed to the NRC.

Supplement 1 to NUREG-2183 will be submitted to the U.S. Environmental Protection Agency (EPA) via e-NEPA no later than February 3, 2023. In addition, copies are being distributed to interested Federal, State, tribal, and local agencies, industry organizations, interest groups, and members of the public. One electronic copy of supplement 1 to NUREG-2183 is enclosed with this letter. A copy of this document has also been made available at the Hedberg Public Library, 316 South Main Street, Janesville, WI 53545 and the NRC's Public Document Room, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852 and Agencywide Documents Access and Management System (ADAMS) ML23024A168. ADAMS is accessible on the NRC's website at <https://www.nrc.gov/reading-rm/adams.html>.

The NRC's responses to the EPA's comments provided by email dated August 17, 2022, ML22230B959, on the draft of supplement 1 to NUREG-2183 are also enclosed. These responses can also be found in appendix C of supplement 1 to NUREG-2183.

Should you have any questions, please contact Lance Rakovan, Senior Project Manager, by telephone at 301-415-2589 or via email at [Lance.Rakovan@nrc.gov](mailto:Lance.Rakovan@nrc.gov).

Sincerely,



Signed by Smith, Theodore  
on 01/31/23

Theodore B. Smith, Chief  
Environmental Review License Renewal Branch  
Division of Rulemaking, Environmental,  
and Financial Support  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 50-608

Enclosures:  
As stated

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DATED: January 31, 2023

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**ADAMS Accession No.: ML23024A168**

<b>OFFICE</b>	PM: ENRB/REFS	PM: NRR/DANU/UNPL	LA:REFS/ENRB	BC:ELRB/REFS
<b>NAME</b>	LRakovan	MBalazik	AWalker-Smith	TSmith
<b>DATE</b>	1/27/2023	1/27/2023	1/27/2023	1/31/2023

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**The U.S. Nuclear Regulatory Commission's Responses to the U.S. Environmental Protection Agency's Comments on the draft of Supplement 1 to NUREG-2183, "Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility"**

**Comment:** Following our review of the draft report, we offer the following comments concerning radioactive waste disposition and ensuring there is a clear waste disposition path for all materials generated during operation and decommissioning (i.e., facility cleanup and dismantlement)<sup>1</sup>.

Regarding Greater-than-Class-C (GTCC) waste generation and disposition, Section 2.5.3 (Waste Minimization and Pollution Prevention Program) of the Draft Report states: "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)."

Recommendations for the Final Report: Explicitly describe and reference the lease and take-back contract. EPA recommends the Final Report (1) provide the date the lease and take-back contract was signed, and (2) include the reasons for the contract, including that the contract is necessary since SHINE GTCC waste does not have a commercial waste disposal option available. In addition, we recommend that the Final Report discuss how NRC and SHINE would ensure the minimization of GTCC, Class B, and Class C radioactive waste generation and avoid generating waste without a clear treatment and disposal path. (4-1 [Kowal, Kathy])

**Comment:** Section 2.5.1.2 (Other Liquid and Solid Waste) of the Draft Report states: "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."

Recommendations for the Final Report: Briefly describe (1) how the low-level waste would be managed prior to shipment for off-site disposal, (2) the period of time that low-level waste would be stored on site prior to shipment, (3) the commercial waste disposition options that would be available and may be used, and (4) whether any potential Class B and C materials could be processed so they can be reclassified as Class A low-level waste. (4-2 [Kowal, Kathy])

**Comment:** Section 2.6 (Facility Decommissioning) of the Draft Report states that "Class B/C Components" and "Low-Level Mixed Waste" would be generated during decommissioning of the SHINE facility.

Recommendations for the Final Report: Clarify the classification of "Low-Level Mixed Waste" (i.e., whether it would be Class A, B, and/or C low-level waste), and discuss the anticipated Resource Conservation and Recovery Act hazardous waste components. (4-3 [Kowal, Kathy])

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<sup>1</sup> <https://www.energy.gov/nnsa/articles/doe-offices-and-shine-sign-first-ever-contracts-under-uranium-lease-and-take-back>

**Response:** *The NRC staff revised the supplement to the final environmental impact statement (FEIS) in response to these comments to include a high-level summary of the DOE's Uranium Lease and Take-Back Program with SHINE. The general topics regarding the management of low-level waste at the SHINE facility are mentioned in the section noted. Specific information is proprietary and thus is not detailed in this supplement to the FEIS. Low-level radioactive waste is classified as class A, class B, or class C (minor volumes are classified as greater than class C). Class A includes both dry active waste and processed waste. Classes B and C normally include processed waste and irradiated hardware. Low-level mixed waste contains both low-level radioactive (i.e., class A, class B, class C, or GTCC) and a nonradioactive hazardous (i.e., toxic) waste component. The silver-coated zeolite beds in the target solution vessel off-gas system may be either class B or class C waste including a toxic component and, therefore, are classified as low-level mixed waste.*

*Resource Conservation and Recovery Act waste regulations govern the disposal of solid and hazardous waste. The Wisconsin Department of Natural Resources regulates solid and hazardous waste in Wisconsin. This issue is discussed in section 2.7.2, "Nonradioactive Waste," of NUREG-2183, which states that "SHINE does not intend to treat or permanently store hazardous wastes on site.... SHINE would dispose of hazardous wastes generated at the facility at a licensed hazardous waste disposal site. Because SHINE will not store or treat hazardous wastes on site, it will not require a hazardous waste treatment or storage permit from the Wisconsin Department of Natural Resources, which has the permitting authority for hazardous wastes under Wisconsin Administrative Code 660." Section 2.7.3, "Waste Minimization and Pollution Prevention Program," of NUREG-2183 also describes SHINE's waste minimization program. Further, as described in section 4.9.2, "Nonradioactive Waste," of NUREG-2183, SHINE would implement waste management systems to control, handle, process, store, and transport nonradioactive waste generated during construction, operations, and decommissioning.*