



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

February 28, 2020

Gregory Piefer, Ph.D.
Chief Executive Officer
SHINE Medical Technologies, LLC
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR ENVIRONMENTAL
REVIEW OF THE SHINE MEDICAL TECHNOLOGIES, LLC – PROPOSED
MEDICAL ISOTOPE PRODUCTION FACILITY OPERATING LICENSE
APPLICATION (DOCKET NUMBER: 50-608)

Dear Dr. Piefer:

The U.S. Nuclear Regulatory Commission (NRC) staff is reviewing the SHINE Medical Technologies, LLC (SHINE) application for an operating license for a proposed medical isotope production facility in Janesville, Wisconsin. As part of the environmental review, the NRC staff is developing a supplement to NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility," (Agencywide Documents Access and Management System Accession Number ML15288A046). The NRC staff has identified areas where additional information is needed to complete the environmental review. Enclosed is a list of environmental requests for additional information (RAIs).

These RAIs were discussed with Mr. Jeffrey Bartelme and a mutually agreeable date for the response is within 30 days from the date of this letter. If you have any questions, please contact me by telephone at 301-415-3835 or via e-mail at Jennifer.Davis@nrc.gov.

Sincerely,

/RA Robert Hoffman acting for/

Jennifer Davis, Senior Project Manager
Environmental Review New Reactors Branch
Division of Rulemaking, Environmental
and Financial Support
Office of Nuclear Material Safety
and Safeguards

Docket No. 50-608

Enclosures:
As stated

cc w/encl.

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ADAMS Accession Nos.: ML20052C761

*** via e-mail**

OFFICE	NMSS/REFS/ERMB	NMSS/REFS/ERLB	NMSS/REFS/ERNB
NAME	*AWalker-Smith	*RElliott	*RHoffman for JDavis
DATE	02/21/2020	02/28/2020	02/28/2020

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REQUEST FOR ADDITIONAL INFORMATION FOR ENVIRONMENTAL REVIEW OF THE
SHINE MEDICAL TECHNOLOGIES, LLC – PROPOSED MEDICAL ISOTOPE PRODUCTION
FACILITY OPERATING LICENSE APPLICATION (DOCKET NUMBER: 50-608)

Proposed Action (PA)

- PA-1 Describe the process and methodology used to identify any new information that has become available since issuance of NUREG-2183, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility” (Agencywide Documents Access and Management System Accession Number (ADAMS) [ML15288A046](#)).
- PA-2 The environmental report (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 Medical Technologies, LLC (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 Title 10 of the *Code of Federal Regulations* (10 CFR) Part 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.
- a.) Provide a status update of the permits and approvals listed in Table B-4 of NUREG-2183.
 - b.) Provide a copy of State of Wisconsin radioactive materials license (license number 105-2083-01) for Building One.
 - c.) Will uranium metal or uranium oxide be supplied by the Department of Energy, Y-12 National Security Complex? Has SHINE secured a lease and take-back contract with the Department of Energy?
- PA-4 Are there changes in the 8,200 6-day curies of molybdenum-99 (Mo-99) per week that 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 staging 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 following characteristics for decommissioning of the proposed SHINE facility:

- estimated workforce,
- shipments,
- waste types and quantities, or
- fuel consumption?

If so, quantify the changes and frequency, as applicable.

PA-7 The ER supplement states that the proposed action is the issuance of an Operating License, under the provisions of 10 CFR Part 50, that would allow SHINE to operate a radioisotope production facility to produce Mo-99, iodine-131 (I-131), and xenon-133 (Xe-133).

- a.) Clarify if the waste shipments, deliveries, medical radioisotope product shipments provided in response to PA-2 account for I-131 and Xe-133. If not, provide this information.
- b.) Provide how much I-131 and Xe-133 will be produced on a weekly basis.

PA-8 Provide the following that was presented to the U.S. Nuclear Regulatory Commission (NRC) staff during the SHINE environmental audit:

- a.) a conceptual view of the proposed SHINE facility and process (Overview Presentation Slide Nos. 3 and 10).
- b.) updated publicly available versions of conceptual graphics for the SHINE Device and a representative irradiation unit (Overview Presentation Slide No. 24).
- c.) a revised SHINE radioisotope production system flow diagram that describes the overall isotope production process (Overview Presentation Slide No. 12).

Air Quality and Noise (AQN)

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 construction permit (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 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, nitrogen oxide (NO_x) will be emitted as a result of radioisotope production process. If so, provide the estimated amount of NO_x.

AQN-3 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.

- a.) 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?
- b.) Clarify if the 468 medical shipments accounts for Mo-99, I-131, and Xe-133.

- AQN-4 Discuss if the SHINE facility will require an air permit from the Wisconsin Department of Natural Resources for operation of the following onsite air emission sources: natural gas generator, three natural gas fired heating boilers, and four natural gas heaters.

Water Resources (WR)

- 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 potential sources of radioactive liquid waste that could be disposed of via the sanitary sewer. No such listing appears 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 quantity (volume), frequency of discharge, and expected concentrations or activity levels, of radiological constituents that may be disposed of via the sanitary sewer. Specify how (1) any such liquids might be introduced into the sanitary sewer for disposal if "there are no piped liquid effluent pathways from the RCA to the sanitary sewer" as referenced above and (2) how SHINE will ensure that any and all radiological constituents will meet the regulatory standards (e.g., 10 CFR § 20.2003) specified above.

Special Status Species and Habitats (SSS)

- SSS-1 The ER supplement 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 supplement 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.

Historic and Cultural Resources (HC)

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)?

Waste Management (WM)

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.

Transportation (TR)

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? If so, please include a copy of these reports.

Cumulative Impacts (CI)

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 (including number of current employees) 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.

Cost Benefit (CB)

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). In addition, does SHINE have updated information regarding the

financial commitments listed on page 5-103 since the issuance of NUREG-2183 (see bulleted list)? If so, please provide the updated information.

cc w/encl.:

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

Christopher Landers
Director, Office of Conversion
National Nuclear Security
Administration, NA 23
U.S. Department of Energy
1000 Independence Ave SW
Washington, DC 20585

Mark Paulson
Supervisor
Radiation Protection Section
Wisconsin Department of Health
Services
P.O. Box 2659
Madison, WI 53701-2659

Shelley Warwick
Environmental Analysis Specialist-
South Team
Wisconsin Department of Natural
Resources
3911 Fish Hatchery Road
Fitchburg, WI 53711

Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
Dept of Materials Science
and Engineering
University of Maryland
4418 Stadium Drive
College Park, MD 20742-2115

Mark Freitag
City Manager
P.O. Box 5005
Janesville, WI 53547-5005

Field Office Supervisor
U.S. Fish and Wildlife Service
Ecological Services Field Office
2661 Scott Tower Drive
New Franken, WI 54229

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548