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

April 14, 2020

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

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

Dear Dr. Piefer:

By letter dated February 28, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20052C761), the U.S. Nuclear Regulatory Commission (NRC) staff issued requests for additional information related to the SHINE Medical Technologies, LLC's (SHINE) application for an operating license for its proposed Medical Isotope Production Facility in Janesville, Wisconsin. SHINE provided responses by letter dated March 13, 2020 (ADAMS Accession No. ML20073E880). The NRC staff has reviewed the information provided and determined that additional information is needed to complete its preparation of a supplemental environmental impact statement. Enclosed are the staff's supplemental requests for additional information.

These clarifications 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,

Jennifer A. Davis Digitally signed by Jennifer A. Davis
Date: 2020.04.14 13:59:02 -04'00'

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.: ML20092L592 *** via e-mail**

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

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 51.95(b), the NRC staff is preparing 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 (ADAMS) Accession Number ML15288A046) to reflect matters that differ from the final environmental impact statement or that reflect significant new information concerning matters discussed in the final environment impact statement. The following supplemental requests for additional information (RAIs) below are issued to SHINE Medical Technologies, LLC (SHINE) to support the NRC staff in identifying and documenting any changes in the proposed action or new and significant information relevant to environmental concerns in the preparation of a supplement to the final environmental impact statement in NUREG-2183 supporting the issuance of an operating license to SHINE. These questions supplement previous requests RAIs issued on February 28, 2020 ADAMS Accession No. ML20052C761.

PA-6S

In RAI PA-6, the NRC staff requested in part, that SHINE provide any changes in the number of shipments and the types/quantities of waste expected during decommissioning of the facility. SHINE's response to this RAI identified the outbound number of shipments; however, the number of inbound deliveries was not provided. NUREG-2183, identifies that 72 truck deliveries would be required each month.

Identify whether there are any changes in the number of estimated inbound truck deliveries as identified in NUREG-2183 during decommissioning.

PA-7S

In RAI PA-7, the NRC staff requested that SHINE clarify whether the number of medical radioisotope product shipments discussed in NUREG-2183 (468 shipments per year) accounted for shipments of iodine-131 (I-131) and xenon-133 (Xe-133) in addition to molybdenum-99 (Mo-99), and provide how much I-131 and Xe-133 would be produced on a weekly basis.

a.) SHINE's response to this RAI points to Final Safety Analysis Report (FSAR) Section 9b.5.1.1, "Byproduct Materials Extraction and Purification," for the quantities of Xe-133 and I-131 produced on a weekly basis; these values are redacted and proprietary and therefore cannot be disclosed in the supplement to NUREG-2183. The supplement is a public disclosure document intended to inform decision-makers and the public, as such, all references within the document must be publicly available.

    Provide non-proprietary bounding weekly quantities of Xe-133 and I-131 that will be produced (similar to the bounding production quantity of Xe-133 and I-131 discussed in Section 2.3.2.4 of NUREG-2183).

b.) SHINE's response to this RAI states that when accounting for I-131 and Xe-133, the total number of medical radioisotope product shipments will be 520 shipments per year, which is an increase in the number of medical radioisotope product shipments considered in NUREG-2183. The SHINE Construction Permit Environmental Report (CP ER) 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. According to the SHINE CP ER, the dose to the workers (i.e., package handlers and transportation workers) for the radioactive material from the SHINE facility was determined to be a total of 9.63 person-rem/year. The doses to members of the public along the highway transportation routes was assessed to be 0.350 person-rem per year.

i. Clarify whether the doses to workers and members of the public presented in the SHINE CP ER bound the additional shipments of Xe-133 and I-131. Update the transportation doses to workers and members of the public for all isotope shipments, as necessary.

ii. Discuss if the three types of medical radioisotope shipments have the same external radiation levels so that it is immaterial as to what isotope is in the truck shipment. SHINE's response to PA-2 and PA-7 informed the staff that SHINE was using Mo-99 shipments to bound the shipments for the I-131 and Xe-133 product shipments. To assess this, the staff needs to know if the external radiation levels for I-131 and Xe-133 packages are the same or lower than the external radiation levels for Mo-99 package shipments.

iii. Given the increased number of total product shipments accounting for the additional Xe-133 and I-131 shipments, the NRC staff is seeking clarification on information related to the analysis of truck shipments of all radioisotopes that served as a basis for impacts presented in the SHINE CP ER (52 truck shipments per year to Covidien and Lantheus Medical Imaging facility, respectively). Clarify the following:

1. Who are the customers for SHINE's Mo-99, Xe-133, and I-131 shipments and what are the anticipated shipment modes (e.g., air and truck) to be used for each customer?

2. How many truck shipments are now being assumed on an annual basis (e.g., SHINE CP ER assumed 52 truck shipments to two sites)? Is Covidien still a viable destination for the analysis of truck shipments?

3. Based on the above, are the total radiological doses of any revised truck shipment analysis still bounded by the SHINE CP ER transportation analysis of Section 19.4.10.1.3, "Incident-Free Radiological Doses"?

iv. In its response to RAI PA-2, SHINE states that the number of radiological waste shipments to support operations of the SHINE facility will be approximately 18 shipments per year, a decrease from the estimated 25.6 shipments year considered in NUREG-2183. With fewer shipments, clarify whether there is a change to the calculation in RADTRAN presented in Section 19.4.10.1.2, "Treatment and Packaging," of the SHINE CP ER. Discuss whether the radionuclide quantity and volume would now be larger per shipment due to a reduced number of shipments (i.e., describe any changes in the amounts of radioactive waste to be generated).

cc w/encl.:

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