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

July 27, 2022

Dr. Gregory Piefer
Chief Executive Officer
SHINE Technologies, LLC
3400 Innovation Court
Janesville, WI 53546

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR CONFIRMATORY INFORMATION RELATED TO RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System Accession No. ML19211C044), as supplemented, SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." By letter date January 27, 2022 (ML22027A353), SHINE submitted a supplement to the operating license application describing the impacts of phased startup operations. The phased startup operations application supplement describes new or different information from the full facility system descriptions and analyses provided in the final safety analysis report (FSAR) resulting from the SHINE phased approach to initial facility startup and operations.

During the NRC staff's review of SHINE's operating license application, as supplemented, questions have arisen for which confirmatory information is needed. The enclosed request for confirmatory information (RCI) identifies information needed for the NRC staff to continue its review of the SHINE FSAR, submitted in connection with the operating license application, and prepare a safety evaluation report. The specific technical area of the SHINE operating license application covered by this RCI is Chapter 11, "Radiation Protection Program and Waste Management."

It is requested that SHINE provide responses to the enclosed RCI within 30 days from the date of this letter. To facilitate a timely and complete response to the enclosed RCI, the NRC staff is available to meet with SHINE to clarify the scope of information and level of detail expected to be included in the RCI response. SHINE may coordinate the scheduling and agendas for any such meetings with the responsible project manager assigned to this project.

In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with

10 CFR 73.21, “Protection of Safeguards Information: Performance Requirements.” Following receipt of the confirmatory information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE’s operating license application, additional RCIs for other chapters and technical areas may be developed. The NRC staff will transmit any further questions to SHINE under separate correspondence.

If SHINE has any questions, or needs additional time to respond to this request, please contact me at 301-415-2856, or by email to Michael.Balazik@nrc.gov.

Sincerely,

Signed by Balazik, Michael
on 07/27/22

Michael Balazik, Project Manager
Non-Power Production and Utilization Facility
Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Docket No. 50-608
Construction Permit No. CPMIF-001

Enclosure:
As stated

cc: See next page

cc:

Jeff Bartelme, Director of Licensing
SHINE Technologies, LLC
3400 Innovation Court
Janesville, WI 53546

Nathan Schleifer, General Counsel
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Christopher Landers, Director
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Mark Paulson, Supervisor
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Wisconsin Department of Health Services
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Madison, WI 53701-2659

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

Mark Freitag
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Janesville, WI 53546

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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR CONFIRMATORY INFORMATION RELATED TO RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT (EPID NO. L-2019-NEW-0004) DATED: JULY 27, 2022

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ADAMS Accession Number: ML22206A208 **NRR-106**

OFFICE	NRR/DANU/PM	NRR/DANU/LA	NRR/DANU/BC	NRR/DANU/PM
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DATE	7/25/2022	7/26/2022	7/26/2022	7/27/2022

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REQUEST FOR CONFIRMATORY INFORMATION

REGARDING OPERATING LICENSE APPLICATION FOR

SHINE MEDICAL TECHNOLOGIES, LLC

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

By letter dated July 17, 2019 (Agencywide Documents Access and Management System Accession No. ML19211C044), as supplemented, SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." By letter date January 27, 2022 (ML22027A353), SHINE submitted a supplement to the operating license application describing the impacts of phased startup operations. The phased startup operations application supplement describes new or different information from the full facility system descriptions and analyses provided in the final safety analysis report (FSAR) resulting from the SHINE phased approach to initial facility startup and operations.

During the NRC staff's review of the SHINE operating license application, and the review of the supplement for phased startup operations, questions have arisen for which confirmatory information is needed. This request for confirmatory information (RCI) identifies information needed for the NRC staff to continue its review of the SHINE FSAR, submitted as part of the operating license application, and prepare a safety evaluation report. Specific chapters and technical areas of the SHINE operating license application covered by this RCI include the following:

- Chapter 11, "Radiation Protection Program and Waste Management"

Applicable Regulatory Requirements and Guidance Documents

Paragraph (b) of 10 CFR 20.1101, "Radiation protection programs," states: "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)."

RCI 11-1 By letter dated, May 23, 2022 (ML22094A114), the NRC staff issued audit questions to SHINE related to phased startup and operations approach. The NRC staff was seeking to better understand the radiation environments that workers would be exposed to when working in an empty irradiation unit (IU) cell adjacent to an operating IU cell to ensure occupational doses were ALARA. During a review of information made available during the audit, SHINE provided information in response to the NRC staff audit questions 10 and 11.

1. Confirm that the radiological dose estimates are as follows:

    a. The average dose rate in an empty IU cell adjacent to an operating IU cell is approximately 15 millirem per hour (mrem/hr) below the normal light water pool height and less than 5 mrem/hr above the light water pool height. The dose rate in the empty IU cell is approximately 60 mrem/hr at the height of the target solution vessel near the south wall.

    b. The maximum dose rate in an adjacent target solution vessel off-gas system cell is expected to be approximately 60 mrem/hr.

    c. The maximum dose rate in an adjacent primary cooling room is expected to be approximately 5 mrem/hr.

    d. During installation of the iodine and xenon purification and packaging system components, the adjacent cell can be operating, and the dose rate is expected to be approximately 5 mrem/hr.

2. Confirm that radiation protection surveys, and ALARA work planning practices will be implemented to maintain occupational doses ALARA.