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

December 23, 2021

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO RADIATION DAMAGE (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Package Accession No. ML20357A084), December 15, 2020 (ADAMS Package Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), 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."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report, 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 RAI is radiation damage.

It is requested that SHINE provide responses to the enclosed RAI within 45 days from the date of this letter. To facilitate a timely and complete response to the enclosed RAI, 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 RAI 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 additional 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 RAIs 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 301-415-0293, or by electronic mail at Molly-Kate.Gavello@nrc.gov.

Sincerely,

Molly-Kate Gavello Signed by Gavello, Molly-Kate on 12/23/21

Molly-Kate Gavello, 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:

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

Mark Freitag
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P.O. Box 5005
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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO RADIATION DAMAGE (EPID NO. L-2019-NEW-0004) DATED: DECEMBER 23, 2021

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ADAMS Accession Number: ML21355A360 **NRR-088**

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REQUEST FOR ADDITIONAL 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 (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Package Accession No. ML20357A084), December 15, 2020 (ADAMS Package Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), 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."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. This request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (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 RAI is radiation damage.

Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE operating license application, which describes the SHINE irradiation facility, including the irradiation units, and radioisotope production facility , using the applicable regulations, as well as the guidance contained in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048). The NRC staff is also using the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069), and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS

Accession No. ML12156A075). As applicable, additional guidance cited in SHINE's FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE operating license application.

For the purposes of this review, the term "reactor," as it appears in NUREG-1537, the ISG Augmenting NUREG-1537, and other relevant guidance can be interpreted to refer to SHINE's "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate within the context of the application and corresponding with the technology described by SHINE in its application. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to refer to SHINE's "target solution."

Chapter 4 – Irradiation Unit and Radioisotope Production Facility Description

The following regulatory requirement is applicable to RAIs 4a-15 through 4a-18:

> Paragraph (b)(2) of Section 50.34, "Contents of applications; technical information," of 10 CFR Part 50 requires, in part, that an FSAR include a description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

RAI 4a-15 The referenced embrittlement studies, "The Effects of Neutron Radiation on Structural Materials," and "Radiation Effects Design Handbook: Section 7," used for evaluating radiation damage in the SHINE target solution vessel (TSV) and the subcritical assembly support structure (SASS) use neutron fluence above 1 megaelectron volt (MeV) as a measure for radiation damage. However, the implicit correlation between fluence and displacement per atom in the radiation effects data may not be the same as the actual SHINE neutron spectrum because of the 14.1 MeV neutron source used in the SHINE irradiation units.

Provide a complete energy spectrum of neutrons expected in the limiting areas of the SHINE TSV and the SASS, including expected relative populations of thermal and fast neutrons that will contribute to radiation damage. The limiting areas depend on a combination of limiting local stresses during normal conditions and design basis events and the local radiation fluence. Provide spectrum diagrams, including comparison(s) to prototypical light water reactor spectrums, and accompanying descriptions demonstrating that the expected energy spectrums would not result in radiation damage, as supported by the referenced embrittlement studies.

This information is necessary for the NRC staff to determine the relevancy of the embrittlement studies used by SHINE to predict radiation damage in the SHINE TSV and SASS. Further, this information is necessary for the NRC staff to find that SHINE has included adequate descriptions and analyses of the structures, systems, and components of the facility to show that safety functions will be accomplished, consistent with the requirements of 10 CFR 50.34(b)(2).

RAI 4a-16 In SHINE FSAR Section 4a2.4.1.1, "Design Considerations," SHINE states, in part, the following:

> Radiation effects and corrosion testing has been performed at Oak Ridge National Laboratory (ORNL) to determine the characteristics of stainless steel for TSV relevant conditions. The results of the radiation effects testing, corrosion testing, and literature data were used as input for the final TSV design.

However, SHINE does not describe the types and results of the corrosion and irradiation testing performed by ORNL. Further, SHINE does not adequately demonstrate within the FSAR how the TSV and SASS will fulfill their design basis requirements over their intended lifetimes. Therefore:

a) Identify the types and results of the corrosion and irradiation testing performed at ORNL on the TSV and SASS materials and how these test results have been used to demonstrate the adequacy of the TSV and SASS components over the components' intended design lifetimes. Provide relevant references to studies and reports used to support the evaluation of the adequacy of these components.

b) Demonstrate that the design requirements will be maintained over the intended operating lifetimes of the TSV and SASS by evaluating the potential effects of material degradation due to the operating environment (i.e., operating temperature, cooling water chemistry, and radiation damage).

This information is necessary for the NRC staff to determine that SHINE has included adequate descriptions and analyses of the structures, systems, and components of the facility to show that safety functions will be accomplished, consistent with the requirements of 10 CFR 50.34(b)(2).

RAI 4a-17 SHINE FSAR Figure 4a2.7-1, "Target Solution Vessel Heat Transfer Surfaces," shows that cooling channel 3 (CC3) provides forced water to cool the TSV outer wall. FSAR Chapter 4a2.7.3.1, "General Characteristics," states, in part, that "(CC3) is the annular gap between the TSV and the SASS inner baffle." FSAR Figure 4a2.7-1 shows a gap/area between the SASS inner baffle and the SASS inner wall that could create stagnant water flow zones that may subsequently lead to degradation (e.g., cracking) of the inner baffle and inner wall components. However, the SHINE FSAR does not describe the impacts of such potential degradation on the ability of the primary closed loop cooling system (PCLS) and SASS to fulfill their design requirements over the intended service life.

Therefore, confirm whether stagnate flow zones are created in the area between the SASS inner baffle and SASS inner wall that may lead to degradation (e.g., cracking) of either component. If stagnate flow zones are created, demonstrate that the PCLS and SASS design requirements continue to be met over the intended service life of those components.

This information is necessary for the NRC staff to determine that SHINE has included adequate descriptions and analyses of the structures, systems, and components of the facility to show that safety functions will be accomplished, consistent with the requirements of 10 CFR 50.34(b)(2).

RAI 4a-18 Paragraph (b)(6)(iv) of 10 CFR 50.34 requires that an applicant's FSAR include information regarding the "[p]lans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components."

Section 4a2.4.1.5, "Chemical Interactions and Neutron Damage," of the SHINE FSAR states, in part, the following:

> The TSV, TSV dump tank, TOGS, and associated components act as the PSB and are safety-related. Surveillance and inspection capabilities for these structures, systems, and components (SSCs) are provided in order to assess mechanical integrity and verify corrosion rates are acceptable. The surveillance and inspection program ensures the integrity of the PSB components is not degraded below acceptable limits due to radiation damage, chemical damage, erosion, pressure pulses, or other deterioration.

However, SHINE does not describe the surveillance, testing, and inspection program(s) that will be implemented to monitor the integrity of the TSV and SASS over the design life.

Provide descriptions of the following aspects of surveillance, testing, and inspection program(s) that will be in place to monitor the integrity of the TSV and SASS over the design life:

- Surveillance Program: Describe the objectives of the surveillance program, identify the locations within the TSV containing surveillance specimens, and provide the bases for choosing these locations. Then, describe the surveillance program planned at each TSV surveillance location. This description should include the following information:
  - Type, size, number, and purpose of each unique specimen-type
  - Extraction and testing periodicity for each unique specimen type

- Testing and evaluation to be performed for each unique specimen type and the associated standards that will be used to govern the testing and evaluation.

- Inspection Program: Describe the objectives of the inspection programs for the TSV and SASS, identify the planned inspection locations within the TSV and SASS, and provide the bases for choosing these locations. Then, describe the inspection program planned at each TSV and SASS location. This description should include the following information:
  - Inspection method(s) and associated periodicity
  - Inspection coverage (i.e., surface area or volume)
  - Applicable codes and standards governing the inspection methods and the interpretation of inspection results

    - Accessibility constraints or challenges that may limit inspection coverage

- The intended use of results from both the surveillance and inspection programs to update the initial programs, if necessary, should also be described.

This information is necessary for the NRC staff to determine that SHINE has the appropriate program(s) in place to monitor the integrity of the TSV and SASS consistent with the requirements of 10 CFR 50.34(b)(6)(iv).