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

April 18, 2022

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 THE PROCESS INTEGRATED CONTROL SYSTEM (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), March 23, 2021 (ADAMS Accession No. ML21095A235), and January 26, 2022 (ADAMS Package Accession No. ML22034A612), 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 licenseapplication covered by this RAI is Chapter 7, "Instrumentation and Control Systems."

It is requested that SHINE provide responses to the enclosed RAI within 30 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 301-415-2856, or by electronic mail at Michael.Balazik@nrc.gov.

Sincerely,

Signed by Balazik, Michael
on 04/18/22

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

SHINE Medical Technologies, LLC Docket No. 50-608

cc:

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

Nathan Schleifer, General Counsel
SHINE Technologies, LLC
3400 Innovation Court
Janesville, WI *53546*

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

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

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

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO THE NEUTRON FLUX DETECTION SYSTEM (EPID NO. L-2019-NEW-0004) DATED: APRIL 18, 2022

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ADAMS Accession No.: ML22088A166 **NRR-088**

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REQUEST FOR ADDITIONAL INFORMATION REGARDING

THE NEUTRON FLUX DETECTION SYSTEM

DESCRIBED IN OPERATING LICENSE APPLICATION

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, LLC

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), March 23, 2021 (ADAMS Accession No. ML21095A235), and January 26, 2022 (ADAMS Package Accession No. ML22034A612), 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 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 chapter of the SHINE operating license application covered by this RAI is Chapter 7, "Instrumentation and Control Systems."

The SHINE facility includes a process integrated control system (PICS) and the control console and display instrumentation to control and monitor facility systems and components. These include systems and components within the irradiation facility. PICS also provides control and monitoring of the systems and components in the radioisotope production facility (RPF). The functions of the PICS enable the operator to perform irradiation cycles, transfer target solution to and from the irradiation unit as well as throughout the RPF, and interface with the tritium purification system, processes in the supercell, waste handling operations, and the auxiliary systems. The PICS also monitors and controls nonsafety-related vendor provided instrumentation and control (I&C) systems. A portion of the PICS supports the main control board and operator workstations in the facility control room by receiving operator commands and collecting and transmitting facility information to the operators. Also, the main control board and operator workstations can assist operators in performance of normal operations or diverse actuations to the safety systems, if necessary. The NRC staff understands that PICS is designated as non-safety related because it's not credited in the accident analysis to prevent of

mitigate an accident event. However, the FSAR should provide reasonable assurance that (1) the facility can be operated within normal operating ranges without over-reliance of the target solution vessel reactivity protection system (TRPS) and engineered safety features actuation system (ESFAS) to routinely compensate for potential control errors, (2) that failure of any control or auxiliary system, or operator action, does not cause facility conditions more severe than those described in the accident analysis; and (3) that the PICS will prevent (automatically or manually) the TRPS or ESFAS from performing its intended safety function during an analyzed accident event. This includes an understanding of the design processes for demonstrating reliability and design quality. Therefore, consistent with NUREG-1537, Part 2, "Reactor Control System," the NRC staff evaluating that the FSAR has (1) analyzed the normal operating characteristics of the facility; (2) described the functions of the PICS and components designed to permit and support normal reactor operations; (3) confirmed that the PICS and its subsystems and components will give all necessary information to the operator or to automatic devices to maintain planned control for the full range of normal reactor operations; (4) the components and devices of the PICS are designed to sense all parameters necessary for facility operation with acceptable accuracy and reliability to transmit the information with high accuracy in a timely fashion; (5) control devices are designed for compatibility with the analyzed dynamic characteristics of the solution vessel; and (6) the design ensures sufficient interlocks, redundancy, and diversity of subsystems to avoid total loss of operating information and control, to limit hazards to personnel, and to ensure compatibility among operating subsystems and components in the event of single isolated malfunctions of equipment.

The NRC staff issued a RAI (ADAMS Accession No. ML20148M279), requesting information to describe how the proposed PICS meets its applicable Design Criteria. The responses to these RAIs were provided in (ADAMS Accession No. ML20255A026), and in the associated updated FSAR. The NRC staff requested this information to verify that there is reasonable assurance that the PICS is appropriately designed and will reliably provide adequate information for operation and control of the SHINE facility, and that applicable regulatory requirements are met.

Applicable Regulatory Requirements and Guidance Documents

The I&C systems, as described in the operating license application, are evaluated using the following regulations and guidance:

- Section 50.34, "Contents of applications; technical information," paragraph (b)(2) of 10 CFR, which requires a description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, 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.

- 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).

- 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).

Chapter 7 – Instrumentation and Control Systems

Process Integrated Control System

FSAR Section 1.3.3.1, "Principal Design Criteria," states:

> Principal design criteria for the facility are described in Section 3.1.

FSAR Section 3.1, "Design Criteria," includes a statement of the "SHINE safety criteria" and describes that the general facility design criteria are included in Table 3.1-3, "SHINE Design Criteria," and that design criteria specific to each system are include in the FSAR section for that system. Table 3.1-1, "Safety-Related Structures, Systems, and Components [(SSC)]," identifies the general facility design criteria applicable to each safety-related SSC. Table 3.1-2, "Nonsafety-Related Structures, Systems, and Components," identifies the general facility design criteria applicable to each nonsafety-related SSC. Both tables include a note that addresses SHINE Design Criteria 1-8 (i.e., the applicability of SHINE design criteria 1-8 is not addressed in the body of the table).

RAI 7-49 SHINE Design Criteria 1-8

Note 1 of SHINE FSAR Chapter 3, "Design of Structures, Systems, and Components," Table 3.1-2, "Nonsafety-Related Structures, Systems, and Components," states that "[t]he generally-applicable design criteria 1-8 from Table 3.1-3 are not specifically listed. See corresponding FSAR section(s) for detailed discussions of SSC design." SHINE FSAR Section 7.3.2.1, "SHINE Facility Design Criteria," and Table 3.1-2 specifies that SHINE Design Criteria 13 is applicable to PICS. However, it is not clear to the NRC staff whether SHINE Design Criteria 1-8 are applicable to the PICS.

Confirm whether SHINE Design Criteria 1-8 are applicable to the PICS. Update the SHINE FSAR to describe the relation of the PICS design bases to the applicable SHINE Design Criteria 1-8.

This information is necessary for the NRC staff to understand the relation of the design bases to the principal design criteria of facility, as required by 10 CFR 50.34.

RAI 7-50 SHINE Design Criteria 13 Applicability to FSAR Chapter 7.6

FSAR Chapter 7.6, "Control Console and Display Instruments," Section 7.6.1, "Description," includes descriptions of the control room, main control board, workstations, and other control room interface equipment. There is no listing of the "Control Console and Display Instruments," system in FSAR Tables 3.1-1 or 3.1-2. SHINE FSAR Section 7.6.2.1, "SHINE Facility Design Criteria," states: "There are no SHINE facility design criteria that are uniquely applicable to the control console and display instruments." SHINE FSAR Section 7.1.5, "Control Console and Displays," states, in part:

> The operator workstations and main control board are provided as the HSI subset of components for the FCR. These components are included as part of the PICS and are classified as nonsafety-related.

In addition to the PICS, it appears that SHINE Design Criterion 13 should also be applicable to its control console and display instruments (e.g., operator workstations and main control board) since these instruments are key in monitoring variables and systems important to safety. SHINE Design Criterion 13, "Instrumentation and controls," states:

> Instrumentation is provided to monitor variables and systems over their anticipated ranges for normal operation, for anticipated transients, and for postulated accidents as appropriate to ensure adequate safety, including those variables and systems that can affect the fission process, the integrity of the primary system boundary, the primary confinement and its associated systems, and the process confinement boundary and its associated systems. Appropriate controls are provided to maintain these variables and systems within prescribed operating ranges.

To ensure the underlying principles are met for SHINE Design Criterion 13 are satisfied for the control console and display instruments and to verify that appropriate controls are provided to maintain variables and systems within prescribed operating ranges, provide the following:

1. Identify any facility variables to be monitored and displayed for the control room operators that are important to the safe operation of the facility in addition to those already identified in Table 7.4-1 and Table 7.5-1 in the FSAR.

2. Identify if any of the variables to be monitored and displayed will be used by the control room operators to perform manual protective actions that are credited in the safety analyses.

This information is necessary for the NRC staff to understand the relation of the design bases to the principal design criteria of facility, as required by 10 CFR 50.34.

RAI 7-51 Equipment Qualification

NUREG-1537, Part 2, Section 7.3 states, in part, that "[t]he RCS should be designed for reliable operation in the normal range of environmental conditions anticipated within the facility."

SHINE FSAR Section 7.3.3.3, "Operating Conditions," describes that the PICS is designed to operate under normal environmental and radiological conditions, which are defined in SHINE FSAR Table 7.2-1, "Design Radiation Environments," through Table 7.2-6, "Primary Cooling Room Interior Design Environmental Parameters."

Describe how SHINE will ensure PICS and its components meet the SHINE defined environmental and radiological conditions for the areas where they would

be installed.

The information requested is necessary to support the following evaluation finding in NUREG-1537, Part 2, Section 7.3:

> The RCS should be designed for reliable operation in the normal range of environmental conditions anticipated within the facility.

RAI 7-52 SHINE Design Criteria 37

SHINE FSAR Chapter 3.1 contains Shine Design Criterion 37 which states:

> Criterion 37 - Criticality control Criticality in the facility is prevented by physical systems or processes and the use of administrative controls. Use of geometrically safe configurations is preferred. Control of criticality adheres to the double contingency principle.
>
> A criticality accident alarm system to detect and alert facility personnel of an inadvertent criticality is provided.

SHINE FSAR Tables 3.1-1 and 3.1-2 state that SHINE Design Criterion 37 applies to the following systems:

- Engineered safety features actuation system (ESFAS)
- Hot cell fire detection and suppression system (HCFD)
- Iodine and xenon purification and packaging (IXP)
- Molybdenum extraction and purification system (MEPS)
- Radioactive drain system (RDS)
- Radioactive liquid waste storage (RLWS)
- Target solution preparation system (TSPS)
- Target solution staging system (TSSS)
- Uranium receipt and storage system (URSS)
- Vacuum transfer system (VTS)
- Criticality accident alarm system (CAAS)
- Facility fire detection and suppression system (FFPS)
- Quality control and analytical testing laboratories (LABS)
- Solid radioactive waste packaging (SRWP)

The double contingency principle can be defined as:

> Process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Provide the following and update the PICS section of the FSAR, as appropriate:

1. Clarify and identify the portions of the systems that conform to the double contingency principle and that are monitored or controlled by PICS.

2. If the PICS is used to meet the double contingency principle or its failure could adversely affect the ability to meet the double contingency principle, describe (or reference other FSAR section that contain that description) how the associated I&C (including appropriate portions of the PICS system) implements (or supports compliance with) the double contingency principle.

3. If the PICS is used to achieve the double contingency principle, describe the technical specification limiting conditions for operations to ensure sufficient operable I&C equipment to ensure the double contingency principle is met in each instance.

4. If the PICS is used to achieve the double contingency principle, or if an PICS failure could challenge the double contingency principle, then describe the associated algorithms and implementing equipment.

RAI 7-53 Facility Operating permissive

FSAR Chapter 7 does not describe the effect of the facility operating permissive on the PICS or associated controlled systems.

Clarify the functional effect of the facility operating permissive on the PICS and associated controlled systems.

This description is necessary for the NRC staff to understand the interlocks to limit personnel hazards or prevent damage to systems during the full range of normal operations, as required by 10 CFR 50.34.