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

March 21, 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 THE ELECTRICAL POWER SYSTEMS (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."

During the NRC staff's review of SHINE's operating license application, 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 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 RCI is Chapter 8, "Electrical Power Systems."

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 electronic mail at Michael.Balazik@nrc.gov.

Sincerely,

Signed by Balazik, Michael
on 03/21/22

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
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Janesville, WI 53546

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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
City Manager
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1326 Putnam Avenue
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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR CONFIRMATORY INFORMATION RELATED TO THE ELECTRICAL POWER SYSTEMS (EPID NO. L-2019-NEW-0004) DATED: MARCH 21, 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."

During the NRC staff's review of the SHINE operating license application, and the review of documents during the audit, 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 final safety analysis report (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 8, "Electrical Power Systems"

Applicable Regulatory Requirements and Guidance Documents

Section 50.34, "Contents of applications; technical information," paragraph (b) of 10 CFR states, in part, that "[t]he final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole." As part of presenting its design bases, SHINE has established the following principal design criteria relevant to its electrical power systems:

- Criterion 4 – Environmental and dynamic effects

  Safety-related [structures systems and components] (SSCs) are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility.

- Criterion 27 - Electric power systems

  An on-site electric power system and an off-site electric power system are provided to permit functioning of safety-related SSCs. The safety functions are to provide sufficient capacity and capability to assure that:

  1) target solution design limits and primary system boundary design limits are not exceeded as a result of anticipated transients, and

  2) confinement integrity and other vital functions are maintained in the event of postulated accidents.

  The on-site uninterruptible electric power supply and distribution system has sufficient independence, redundancy, and testability to perform its safety functions assuming a single failure.

  Provisions are included to minimize the probability of losing electric power from the uninterruptible power supply as a result of or coincident with, the loss of power from the off-site electric power system.

- Criterion 28 - Inspection and testing of electric power systems

  The safety-related electric power systems are designed to permit appropriate periodic inspection and testing of important areas and features, such as wiring, insulation, connections, and switchboards, to assess the continuity of the systems and the condition of their components. The systems are designed with a capability to test periodically:

  1) the operability and functional performance of the components of the systems, such as on-site power sources, relays, switches, and buses; and

  2) the operability of the systems as a whole and, under conditions as close to design as practical, the full operation sequence that brings the systems into operation, including operation of applicable portions of the protection system, and the transfer of power among the on-site and off-site power supplies.

Section 50.34(b)(2) of 10 CFR requires “a description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, with technical justification therefore, 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.”

Section 50.34(b)(2)(ii) of 10 CFR states, in part, that for facilities other than nuclear reactors, such items as the…electrical systems…shall be discussed insofar as they are pertinent.

RCI 8-11 FSAR Section 8a2.2, “Emergency Electrical Power Systems,” states, in part, “The UPSS [uninterruptable electric power supply system] consists of a 125-volt direct current (VDC) battery subsystem, inverters, bypass transformers, distribution panels, and other distribution equipment necessary to feed safety-related alternating current (AC) and direct current (DC) loads and select nonsafety-related AC and DC loads.” FSAR Section 8a2.2.1, “Uninterruptible Electrical Power

Supply System Design Basis," states, in part, that the UPSS "is designed, fabricated, erected, tested, operated, and maintained to quality standards commensurate with the importance of the safety functions to be performed." The onsite safety functions are to provide sufficient capacity and capability per Criterion 27.

The NRC staff finds that that the licensee does not provide a description in the FSAR of the safety classification of UPSS subcomponents, (e.g., cables, connectors, etc.,).

Confirm that the UPSS subcomponents used to support safety-related loads in FSAR Table 8a2.2-1, "UPSS Load List," are designated as safety-related. If the UPSS subcomponents are not safety-related, provide an explanation of how the subcomponents meets Criterion 27 for capability and demonstrate how the subcomponent will perform its safety function, (i.e., identify relevant standards).