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

August 24, 2022

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC REGULATORY AUDIT RELATED TO PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT, SESSION 1 (EPID NO. L-2022-NEW-0004)

Dear Dr. Piefer:

The U.S. Nuclear Regulatory Commission (NRC) staff has prepared an audit plan related to the review of the SHINE Medical Technologies, LLC (SHINE) "Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement," dated January 27, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22027A354). The enclosed audit plan provides the regulatory basis for the audit, describes the scope of the audit, identifies the audit team, and provides a listing of audit questions.

The audit will be conducted virtually, and its purpose is to confirm the staff's understanding of the supplement. As such, the audit will be held on August 25, 2022, from 11:00am to 12:00pm. Additional audit sessions may be scheduled to support the continued review of the application supplement.

Following completion of the audit, the NRC will provide an audit summary. The summary will include a description of any information identified during the audit that will need to be docketed to supplement the application and allow the NRC to continue its review.

If you have any questions, please contact me at (301) 415-1053, or by electronic mail at Holly.Cruz@nrc.gov.

Sincerely,

Signed by Cruz, Holly
on 08/24/22

Holly D. Cruz, Senior 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:
Audit Plan

cc w/encl: See next page

cc:

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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC REGULATORY AUDIT RELATED TO PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT, SESSION 1 (EPID NO. L-2022-NEW-0004)
DATED: AUGUST 24, 2022

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ADAMS Accession No.: ML22061A212 **NRR-106**

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REGULATORY AUDIT PLAN

RELATED TO PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT

SESSION 1

SHINE MEDICAL TECHNOLOGIES, LLC

DOCKET NO. 50-608

Background

The U.S. Nuclear Regulatory Commission (NRC) staff is continuing its review of the SHINE Medical Technologies, LLC (SHINE) operating license application, submitted by letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), in addition to the SHINE "Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement," dated January 27, 2022 (ADAMS Accession No. ML22027A354). The purpose of this audit is to confirm the staff's understanding of the supplement.

Regulatory Audit Bases

The licensee's phased startup operations application supplement is being reviewed in accordance with the applicable regulatory requirements of Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities." and applicable guidance provided in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Part 1, "Format and Content," and Part 2, "Standard Review Plan and Acceptance Criteria," (ADAMS Accession Nos. ML042430055 and ML042430048, respectively).

Regulatory Scope

The scope of this audit addresses the licensee's phased startup operations application supplement. With respect to the instrumentation and control systems review, the phased startup operations application supplement focuses on disabling inputs for various systems. This information will supplement the licensing review to understand and confirm the changes/ modifications SHINE is making to the Highly Integrated Protection System (HIPS) platform and associated inputs, if there is any impact to the design criteria in the Final Safety Analysis Report (FSAR), how operators will maintain a current understanding of the engineered safety feature actuation system (ESFAS), the tritium purification system (TPS), and the target solution vessel (TSV) reactivity protection system (TRPS) configuration and expected system response during successive stages of phased construction, and how securing displays/removing signals will prevent operator distractions. Additionally, this information will provide a better understanding of crane operator training, and the SHINE Safety Analysis. Therefore, any additional information identified from the audit that is needed to address a regulatory finding may also be documented in the audit report.

Desired Outcomes for the Audit

The desired outcomes of the audit are to: (1) gain a better understanding of information underlying the phased startup operations application supplement; (2) identify specific information that will require docketing to support the basis of the licensing or regulatory decision; and (3) identify a closure path for the audit questions provided in this audit plan.

Information and Material necessary for the Regulatory Audit

SHINE will need to provide design documentation, as noted below, in the electronic reading room to support the audit. The staff anticipates SHINE identifying additional documents that may address open technical items.

- HIPS programmable logic regression analysis performed for changes that had previously been tested and independently verified and validated, and
- Revisions to TECRPT-2018-0028, “HIPS Platform Application Specific Action Item Report for TRPS and ESFAS,” resulting from modifications to HIPS platform for accommodating the phased approach.

Audit Team

The NRC staff participating in this audit will be:

- Dinesh Taneja (NRR/DEX) – Instrumentation and Controls (I&C), Audit Team Leader
- Michael Waters (NRR/DEX)
- Michael Balazik (NRR/DANU)
- Jesse Seymour (NRR/DRO) – Human Factors
- Mike Call (NMSS/DFM)
- Gordon Curran (NRR/DSS)

Audit Team Logistics

The virtual audit will be held on August 25, 2022, from 11:00am to 12:00pm. This audit session will address the topics and questions as identified below. Should an additional audit session be needed, it will be scheduled accordingly. Additional audit sessions may be planned in advance, as new items are identified, to support the understanding of information necessary to facilitate the continued review of the application supplement.

Deliverables

At the completion of the regulatory audit, NRC staff will prepare a regulatory audit report, which will be issued within 60 days after the audit. New audit plans (including distinct entrance and exit discussions) will be issued as new items are identified.

Audit Session Questions: August 25, 2022, from 11:00am to 12:00pm.

1. With respect to the instrumentation and control systems review, the phased startup operations application supplement focuses on disabling inputs for various systems (such as HIPS equipment). **Item 1 resolved in Audit 2. Closed.** SHINE confirmed there are no impacts to the design criteria in the FSAR.

    - Provide an overview of the changes/modifications SHINE is making to the platform for disabling the selected portions.
    - Provide an overview of the techniques used to disable the inputs.
    - Confirm there are no impacts to the design criteria in the FSAR. Describe how SHINE performed these evaluations.
    - To assist in the staff's understanding, please explain why this is the most nonintrusive approach.

2. Describe/clarify how it will be ensured that operators maintain a current understanding of the ESFAS, TPS and TRPS configurations and expected system response during successive stages of phased construction.

3. SHINE states that control consoles and displays associated with equipment that has not yet been installed will have the ability to have their displays secured/signals removed to avoid creating operator distractions. Clarify/discuss how this will be implemented and managed.

4. Clarify/discuss what is meant by "providing indication" for components that are disabled/disconnected via the process integrated control system and describe any measures to ensure that operators use those indications correctly during different operational phases.

5. How will it be ensured that crane operators are trained to reliably implement any specific administrative controls associated with crane operations during continued construction due to the phased startup approach?

6. Confirm that enabling/disabling of inputs to the instrumentation and control systems from the facility process systems at each phase has no impact on the portions of the facility already in operation. Explain how that was evaluated. For example, it is not clear that inadvertent disabling of inputs for a system already in operation is not a credible event when personnel are performing actions to enable inputs for a newly installed system. If it is credible, then it could lead to impacts on the operating systems either from responses (or lack thereof) from the instrumentation and control systems or operator actions that rely on those inputs.