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

May 23, 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 2 (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 "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 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 NRC staff's understanding of the supplement. As such, the audit will begin on May 24, 2022, with additional audit sessions to be scheduled to discuss the remaining questions. Additional audit sessions may also be scheduled to support the continued review of the application supplement.

Following completion of the audit, the NRC staff 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 staff 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 05/23/22

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:
As stated

cc w/enclosure: See next page

cc:

Jeff Bartelme
Licensing Manager
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 Ave 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 REGULATORY AUDIT RELATED TO PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT, SESSION 2 (EPID NO. L-2019-NEW-0004) DATED: MAY 23, 2022

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REGULATORY AUDIT PLAN

RELATED TO PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT

SESSION 2

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 NRC 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* (10 CFR) 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 in the areas of the SHINE Safety Analysis, Chapter 9, "Auxiliary Systems," and Chapter 11, "Radiation Protection Program and Waste Management." This information will supplement the licensing review to understand and confirm the changes/modifications SHINE is making, and if there is any impact to the design criteria in the final safety analysis report (FSAR). Therefore, any additional information identified from the audit that is needed to address a regulatory finding may also be documented in the audit report.

Enclosure

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

Audit Team

The NRC staff participating in this audit will be:

- Michael Balazik (NRR/DANU)
- Zachary Gran (NRR/DRA)
- Gordon Curran (NRR/DSS)
- Nageswara (Rao) Karipineni (NRR/DSS)
- Mike Call (NMSS/DFM)

Audit Team Logistics

The virtual audit will begin on May 24, 2022, with additional audit sessions to be scheduled to discuss the remaining questions. 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, the 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: Beginning on May 24, 2022

SHINE Safety Analysis

1. Explain how the current proposed phased approach to construction and operations is consistent with the commitment to maintain the SHINE safety analysis (SSA) and the commitment in technical specification (TSs) 5.5.4, "Configuration Management," to follow 10 CFR 70.72, "Facility changes and change process" (as modified to use appropriate regulatory citations and terminology for SHINE), such that the SSA and the safety program derived from it are consistent with the as-built and as-operated facility at any given time.

2. Explain how the SSA, with its supplement, reflects (or will reflect) and is (or will be) an analysis that is applicable to the as-built and as-operated facility in each phase, including consideration of the following:

   - differences in the facility's systems, operations, and configurations,
   - impacts to accident sequences (likelihoods, consequences, new sequences),
   - impacts to safety controls (new controls, different configurations/roles of controls, different reliability management measures, non-safety related controls becoming safety related controls),
   - examples for the preceding include: Phases 1 and 2 – no material staging building (MATB) and no radioactive liquid waste immobilization system (RLWI) selective removal process; isolations for iodine and xenon purification and packaging (IXP) hot cell; valves (and dampers) in installed systems that lead to connections to uninstalled systems, and
   - multiple concurrent analyses for the same accident sequence depending on the phase (e.g., FRI-2 and FRI-23; FRI-10 and FRI-22; 13b.2.7-A and 13b.2.7-C; 13a2.1.12-O and 13a2.1.12-U; 13a2.1.12-Q and 13a2.1.12-T).

3. Clarify and explain how the SSA supplement and safety analysis report (SAR) supplement are consistent with regard to the description and evaluation of accident sequences and safety controls, including:

   - valves and other (system interface) isolation mechanisms; many more discussed in the SAR supplement than the SSA supplement (e.g., IXP, radiological ventilation zone 1 exhaust subsystem (RVZ1e) isolation outside irradiation unit (IU) cells, RVZ1e – IXP cryotrap interface, radiological ventilation zone 2 (RVZ2) – tritium purification system (, RVZ2 – IXP, RLWI selective removal process connections),
   - possibly new valves on some system connections/interfaces (e.g., RVZ1e outside the cooling room for connections to IU specific primary closed loop cooling system ; radioisotope process facility cooling system to neutron driver assembly system cooling cabinet interfaces),
   - RLWI selective removal part (e.g., Section 13b.1.1),
   - specific administrative controls (SAC), description including minimized lift height (e.g., Section 13a2.1.12), and
   - meaning of statements that no new accident sequences were identified that result in radiological release (or chemical release) (e.g., Sections 13b.2, 13b.3) versus. new/revised accident sequences and new safety controls.

4. Clarify how the TSs address phased approach, including the new safety controls, and how changing from different phases will not necessitate changes to TSs. If the TSs address all safety-related structures, systems, and components needed to prevent accidents, with accident sequences and controls changing from phase to phase (added, removed, changed configuration), it would seem the TSs would also need to change from phase to phase.

5. Explain how heavy load drops were re-evaluated for the phased approach and how the SSA supplement and SAR supplement both address these events. It is unclear why the SSA supplement does not identify and evaluate more accident sequences involving heavy load drops (either revised accident sequences from the SSA or new sequences versus what is in the SSA). Examples include drops onto operating IU cells (13a2.1.12-P), open IU cells after having operated (13a2.1.12-O), and open or operating target solution vessel off-gas system (TOGS) cells.

6. Clarify or describe the following with respect to the accident sequences, safety controls, and their reliability management measures identified and evaluated in the SSA supplement:

    - management measures for engineered controls (Table 2): any added information on maintenance (type, frequency), any surveillances/monitoring,
    - management measures: appropriate measures listed in accident sequences (e.g., FRI-22 and FRI-23; 13a2.1.4-K, 13b.2.4-X; lockout/tagout; material handling system (MHS)-AEC-01; 13a2.1.4-K),
    - safety control descriptions (e.g., PHASED-PEC-01, 13b.2.4-X),
    - meaning and impact of possibility/practicality of control on its failure probability index number (FPIN) (e.g., PHASED-SAC-03, 13b.2.7-C),
    - valve as passive engineering control (PEC), not active engineering control (AEC) (e.g., 13a2.1.4-K accident cause),
    - redundant AEC (e.g., 13a2.1.12-T crane – depends on how meet single failure proof; possible impact on SSA accident sequences (e.g., 13a2.1.12-P)),
    - frequency increase differences FRI-22 vs. FRI-10 versus heavy load drop accidents' frequency increase, and
    - FRI-23, SAC with a FPIN=-2 (should get -1 per SSA method).

Chapter 9, "Auxiliary Systems"

7. With respect to the heating ventilation and air conditioning system balancing to maintain the ventilation zone pressures and flows, with RVZ1e and possibly RVZ2e exhausting a relatively smaller quantity of air, while RVZ2s is supplying close to full design quantity. Describe or explain the capability of RVZ2s to operate at a much less than full flow during early phases of startup, particularly in Phase 1.

8. The MHS description provided in Subsection 9b.7.2 of the FSAR is not affected by phased startup operations. During Phase 1 through Phase 3, the IXP hot cell is not operational. Installation of the IXP during Phases 3 & 4 will require heavy lifts that may travel in vicinity of systems containing critical components or impact radiation-controlled systems during construction.

To ensure safe handling during construction, the NRC staff needs additional details of the following:

a. Section 9b.7.2 of the FSAR indicates the MHS description in the FSAR is not affected by phased startup operations. Section 13b.1.2.3 of the FSAR provides discussion of accident sequence of a heavy load drop onto the RLWI shielded enclosure or supercell during phased startup operations to account for an increased likelihood of the initiating event as a result of on-going installation activities. The licensee indicates this scenario is prevented by the credited controls currently in place and application of applicable guidance from NUREG-0612, "Control of Heavy Loads at Nuclear Power Plants: Resolution of Generic Technical Activity A-36," for control of heavy loads in the SHINE facility. Section 13b.1.2.3 also indicates, "Because these scenarios have preventative measures in place, there are no radiological consequences." With use of the non-single failure proof radioisotope production facility crane, provide additional details about how the controlled range of crane motion (i.e., interlocks and stops) would function during the phased construction installation activities to continue preventing the limiting release scenarios.

b. Section 9b.7.2 of the FSAR indicates the MHS description in the FSAR is not affected by phased startup operations. With the use of a single failure proof crane in the irradiation facility (IF), load drop is minimized. The SHINE request for additional information (RAI) response dated March 23, 2021, indicates special lifting devices are not used or defined. With lack of discussion of special lifting devices, the use of redundant slings or slings with twice the load rating is not provided. The RAI response does commit to ensuring that applicable lifting devices have redundant load paths or double the normal factors of safety, consistent with the guidance of Section 5.1.6 of NUREG-0612. Similar to the above, provide additional details about how sling use within the IF would be controlled during the phase construction installation activities to continue preventing the limiting release scenarios.

9. The solid radioactive waste packaging system description provided in Subsection 9b.7.5 of the FSAR is not affected by phased startup operations, except that the MATB is not available during Phase 1 and Phase 2. The MATB will not be compete and the solid waste drums will be stored in the radiologically controlled area (RCA), instead of MATB, prior to shipment. Additional storage may be needed within the RCA for material that would otherwise be stored in the MATB. With the MATB unavailable during Phase 1 & 2, additional waste barrels may need to be stored within the RCA area. Clarify the quantity and location of waste storage within the RCA.

Chapter 11, "Radiation Protection Program and Waste Management"

10. Section 20.1101, "Radiation protection programs," paragraph (b) of 10 CFR 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)."

In review of the information contained in the phase approach supplement FSAR Section 11.1.1, “Radiation Sources,” the applicant states, in part:

> During Phase 1, with IUs 1 and 2 operating, the dose rate in IU cell 3 and primary cooling room 3 is expected to be between 5 and 100 millirem per hour (mrem/hr), while the dose rate in the remaining cells (i.e., IU cells 4 through 8, TOGS cells 3 through 8, and primary cooling rooms 4 through 8) is expected to be less than 5 mrem/hr. During Phase 2, with IUs 1 through 5 operating, the dose rate in IU cell 6 and TOGS cell 6 is expected to be between 5 and 100 mrem/hr, while the dose rate in the remaining cells (i.e., IU cells 7 and 8, TOGS cells 7 and 8, and primary cooling rooms 6 through 8) is expected to be less than 5 mrem/hr. The probable dose rates within operating IU cells, TOGS cells, and cooling rooms during Phase 1 and Phase 2 are as provided in Figure 11.1-1 of the FSAR. The probable dose rates within the irradiation facility (IF) during Phase 3 and Phase 4 are as provided in Figure 11.1-1 of the FSAR.

In review of the above FSAR information, considering information shared during Advisory Committee on Reactor Safeguards meetings, and in review of calculational files made available during SHINE audits, the NRC staff is seeking to understand the general dose rates expected during phased operations to verify that SHINE is meeting the requirements contained in 10 CFR 20.1101(b) and adequately controlling doses to occupational workers.

It is the NRC staff’s understanding that the startup times for Phase 1 and 2 operations would be at or around the same time so the NRC staff would not expect changes to the expected dose in the areas in and around cells 1-5 during operation and would typically follow the dose map provided in FSAR Figure 11.1-1. If this assumption is incorrect, the NRC staff would seek information on the dose rates expected in cell 3 from cell 2 operations like the requests below.

As seen in the referenced FSAR text above, the stated dose rates for work performed in cell 6 from cell 5 operations is between 5-100 mrem/hr. The NRC staff finds that this is a broad range of doses and may not align with some of the information reviewed during previous audits. The NRC staff is looking for SHINE to provide an explanation and evaluation of what workers would expect as typical dose rates for work in cell 6 during phase operations. The NRC staff is looking for SHINE to establish expected dose rates workers would receive while performing work in cell 6 during cell 5 operations.

If the stated 5-100 mrem/hr dose rate estimates are correct, how does SHINE ensure that workers will maintain doses ALARA, consistent with the requirements contained in 10 CFR 20.1101(b)? The NRC staff seeks to understand the types of work that will be performed in the cell 6 area during cell 5 operations and how long the work in these areas will take with the understanding that the dose rates could be anywhere between 5-100 mrem/hr.

11. FSAR Section 11.1.1 states, in part:

> Figure 11.1-1 of the FSAR provides probable radiation area designations within the supercell assuming each hot cell is operational. During Phase 1 through Phase 3, the iodine and xenon purification and packaging (IXP) hot cell is not operational. The dose rate in the IXP hot cell is expected to be between 5 and 100 mrem/hr during Phase 1

> through Phase 3. The probable dose rates during Phase 4 are as provided in Figure 11.1-1 of the FSAR.

FSAR Section 4b.1 “Facility and Process Description,” states, in part:

> The production facility biological shield (PFBS) hot cells (supercell), including the IXP hot cell, is installed prior to Phase 1, however the IXP system is not installed in the IXP hot cell until Phase 4. The supercell confinement boundary is isolated from the IXP hot cell and the IXP hot cell drain to radioactive drain system (RDS) is plugged during Phase 1 through Phase 3.

For the discussion pertaining to the supercell and hot cells, the NRC staff seeks to understand what types of work are expected to occur within the supercell and IXP hot cell during the phased approach. Are the described dose rate estimates provided to indicate that there is expected work within the hot cell during operations? Are there any dose concerns related to the IXP system installation during Phase 4?