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

August 14, 2020

Gregory Piefer, Ph.D.
Chief Executive Officer
SHINE Medical Technologies, LLC
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC REGULATORY AUDIT RE: ACCIDENT ANALYSIS AND CRITICALITY SAFETY PROGRAM DESCRIBED IN OPERATING LICENSE APPLICATION (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), and March 27, 2020 (ADAMS Accession No. ML20105A295), 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* Part 50, "Domestic Licensing of Production and Utilization Facilities."

To support its review of the accident analysis and criticality safety program described in SHINE's operating license application, the NRC staff will conduct a virtual regulatory audit from August 17 to August 21, 2020, to gain a better understanding of the application. The audit may include review of documentation and discussions with SHINE personnel and management. The enclosed audit plan provides additional details of the objective and scope of the audit. To facilitate an efficient audit, please provide ready access to necessary documentation in the SHINE electronic reading room.

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) 415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Sincerely,

/RA/

Steven T. Lynch, 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: See next page

cc:

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, LLC
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Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC REGULATORY AUDIT RE: ACCIDENT ANALYISS AND CRITICALITY SAFETY SYSTEMS DESCRIBED IN OPERATING LICENSE APPLICATION (EPID NO. L-2019-NEW-0004) DATED: AUGUST 14, 2020

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REGULATORY AUDIT PLAN

REGARDING ACCIDENT ANALYIS AND CRITICALITY SAFETY PROGRAM DESCRIBED IN

OPERATING LICENSE APPLICATION

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

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), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), and March 27, 2020 (ADAMS Accession No. ML20105A295). This regulatory audit is intended to assist the NRC staff in its review of the accident analysis and criticality safety program described in the SHINE final safety analysis report (FSAR), submitted as part of SHINE's operating license application.

Regulatory Bases for the Audit

The purpose of this audit is to support the NRC staff's review of the licensee's accident analysis and criticality safety program, described in the Chapters 13, "Accident Analysis," and 6, "Engineered Safety Features," respectively, of the SHINE FSAR in accordance with the applicable regulatory requirements of Title 10 of the *Code of Federal Regulations* 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 for the Audit

The NRC staff will review the SHINE FSAR, technical specification (TS) requirements, and supporting reference documentation related to the SHINE accident analysis and criticality safety program. This audit will provide information necessary to continue the NRC staff's evaluation of the SHINE operating license application. In addition, the regulatory audit may identify additional information that will be required to be docketed to support the basis of the licensing decision and will allow NRC staff to more efficiently gain insights on the operating license application. To support this audit, the NRC staff will review documentation uploaded to SHINE's electronic reading room and participate in teleconference and video conference discussions with the applicant.

Information Needed for the Audit

SHINE should be prepared to support the NRC staff by having a copy of SHINE's FSAR and TSs readily available. Additionally, the licensee should be prepared to provide supporting documents and reports, calculations, and computer code verification to support the analysis documented in the FSAR, bases for TSs, or rationale for any required plans and procedures, as necessary.

Audit Team

The NRC staff performing this audit will be:

- Steven Lynch (Senior Project Manager)
- David Tiktinsky (Senior Project Manager)
- Elijah Dickson (Reactor Scientist)
- April Smith (Reliability and Risk Analyst)
- Michael Salay (Reactor Systems Engineer)
- Jeremy Munson (Nuclear Process Engineer)
- James Hammelman (Senior Chemical Process Engineer)
- Michael Smith (Health Physicist)
- William Rautzen (Health Physicist)
- Jason White (Physical Scientist/Meteorologist)
- Kevin Quinlan (Physical Scientist/Meteorologist)

Audit Team Logistics

The virtual audit will initiate on August 17, 2020, and continue through August 21, 2020, as needed, until NRC staff has an adequate understanding of the issues to be addressed to facilitate the continued review of the operating license application. Audit activities may be conducted as teleconference and video conference supported activities, as appropriate and efficient to the gathering of information by the NRC staff. The audit period may be reduced or extended, dependent on the NRC staff and licensee progress in addressing audit topics and questions. Additional audit activities may be planned in advance, as necessary, to support the understanding of information necessary to facilitate the continued review of the operating license application.

Deliverables

At the completion of the regulatory audit the NRC staff will issue requests for additional information within 30 days after the audit and issue a regulatory audit summary within 90 days after the audit. The regulatory audit summary will include the documents reviewed and the audit activities performed.

Audit Topics and Questions

The topics and questions for discussion during the regulatory audit are primarily based on the regulatory audit topics provided to SHINE via electronic mail on June 17, 2020 (ADAMS Package No. ML20226A251). The NRC staff provides the following clarifications related to citations of regulatory guidance related to these regulatory audit topics:

Audit Topic 3 – Atmospheric Dispersion Models for the Purposes of Assessing Offsite Radiological Consequences of Postulated Design Basis Accidents

Regulatory Guide 2.2, "Development of Technical Specifications for Experiments in Research Reactors," as it pertains to the development of TSs, is based on crediting natural consequence-limiting features such as atmospheric dilution, provided each such feature is specifically identified and conservatively justified by specific testing, physical data, or well-established physical mechanisms. This regulatory guide is included as a reference since specific use of 95th-percentile atmospheric dilution factors for design basis accidents is not discussed in NUREG-1537. This regulatory guide provides a brief discussion of the assumptions related to atmospheric dilution for design basis accident analysis in which "they should not be less conservative than those used in the analysis of design basis accidents," inferring the use of 95th-percentile atmospheric dilution factors for performing accident analyses.

Audit Topic 6 – Nuclear Criticality Safety Administrative Controls, Part 1

With respect to the development of TSs, American National Standards Institute/American Nuclear Society Standard 15.1, "The Development of Technical Specifications for Research Reactors," does not address approaches for incorporating nuclear criticality safety programs in a licensee's TS administrative controls. The NRC staff is including a reference to NUREGs 1430 through 1434, as they contain examples of standard TSs for Administrative Controls for other Part 50 licensees, including nuclear power reactors. These NUREGs include descriptions of procedures, programs and manuals, and reporting requirements for program management features within licensee-controlled documents. Section 5, "Administrative Controls," Subsection, "Programs and Manuals," of NUREGs-1430 through 1434 provides a list of licensee programs to be established, implemented and maintained, including descriptions of methodologies and parameters to be applied; how licensee-initiated changes are to be carried out; identification of approving officials; and applicable reporting requirements.

In developing nuclear criticality safety program administrative TS controls, SHINE may find it useful to consult the examples of approaches to addressing administrative TS controls described above to implement the SHINE nuclear criticality safety program.

Proposed Audit Schedule

Monday, August 17, 2020

10:00 AM	Entrance meeting, introductions, project status, overview of reference material
10:30 AM	Audit of reference materials
12:00 PM	Break for lunch
1:00 PM	Resume audit of reference materials
4:00 PM	Daily summary
5:00 PM	End for the day

Tuesday, August 18, 2020

8:00 AM	Resume audit of reference materials
12:00 PM	Break for lunch
1:00 PM	Audit topic discussions
4:45 PM	Daily summary
5:00 PM	End for the day

Wednesday, August 19, 2020

8:00 AM	Resume audit of reference material
12:00 PM	Break for lunch
1:00 PM	Resume audit topic discussions
4:45 PM	Daily summary
5:00 PM	End for the day

Thursday, August 20, 2020

8:00 AM	Resume audit of reference material
12:00 PM	Break for lunch
1:00 PM	Resume audit of reference material
4:30 PM	Daily summary
5:00 PM	End for the day

Friday, August 21, 2020

8:00 AM	Resume audit of reference material
12:00 PM	Break for lunch
1:00 PM	Follow-up discussions of audit topics and reference material, as needed
4:30 PM	Exit meeting[1]
5:00 PM	Conclude audit

[1] If follow-up discussions are not needed, the exit meeting may be conducted earlier.