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

April 7, 2021

Dr. Gregory Piefer, Chief Executive Officer
SHINE Medical Technologies, LLC
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – SUMMARY OF AUDIT RELATED TO GEOTECHNICAL TOPICS (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 Accession No. ML20357A084), and December 15, 2020 (ADAMS Accession No. ML21011A264), 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 enhance the review of geotechnical topics associated with the SHINE operating license application the NRC staff conducted a regulatory audit on March 16, 2021. A summary of the regulatory audit is enclosed.

If SHINE has any questions please contact me at 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Sincerely,

Steven T. Lynch

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
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

Nathan Schleifer
General Counsel
SHINE Medical Technologies, LLC
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

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 – SUMMARY OF AUDIT RELATED TO GEOTECHNICAL TOPICS (EPID NO. L-2019-NEW-0004) DATED: APRIL 7, 2021

DISTRIBUTION:
PUBLIC
DHardesty, NRR
SLynch, NRR
LTran, NRR
MBalazik, NRR
ZXi, NRR
AGhosh, NRR
JColaccino, NRR
NParker, NRR

ADAMS Accession No.: ML21089A334 **NRR-106**

OFFICE	NRR/DANU/PM	NRR/DANU/LA	NRR/DEX/BC	NRR/DANU/BC (A)	NRR/DANU/PM
NAME	SLynch	NParker	JColaccino	DHardesty	SLynch
DATE	4/2/2021	4/5/2021	4/5/2021	4/7/2021	4/7/2021

OFFICIAL RECORD COPY

OFFICE OF NUCLEAR REACTOR REGULATION

REGULATORY AUDIT SUMMARY

REGARDING GEOTECHNICAL TOPICS DESCRIBED IN

OPERATING LICENSE APPLICATION

SHINE MEDICAL TECHNOLOGIES, LLC

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

Location:	SHINE Medical Technologies, LLC, Janesville, Wisconsin
Audit Date:	March 16, 2021
Audit Team Members:	Steven Lynch, Senior Project Manager
	Zuhan Xi, Geotechnical Engineer
	Amitava Ghosh, Geotechnical Engineer
	Joseph Colaccino, Chief, Structural, Civil, and Geotechnical Engineering Branch
Licensee Representatives:	Jeff Bartelme, SHINE Director of Licensing
	Jim Costedio, SHINE Vice President of Regulatory Affairs and Quality
	Abbey Donahue, SHINE Structural Engineering Manager
	Marc Anderson, Sargent & Lundy
	Joshua Bickett, Sargent & Lundy
	Jonathan Dean, Sargent & Lundy
	David Nielson, Sargent & Lundy

1.0 BACKGROUND

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

Enclosure

(ADAMS Accession No. ML20357A084), and December 15, 2020 (ADAMS Accession No. ML21011A264), 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." This regulatory audit was intended to assist the NRC staff in its review of the geotechnical topics described in the SHINE final safety analysis report (FSAR), submitted as part of SHINE's operating license application.

This audit supported the NRC staff's review of the licensee's geotechnical topics program using the applicable 10 CFR requirements, as well as the guidance contained in 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), and 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). The NRC staff is also using the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069), and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A075). As applicable, additional guidance cited in SHINE's FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE operating license application.

The audit was conducted in accordance with the audit plan and associated topics (ADAMS Package No. ML21053A259).

2.0 AUDIT ACTIVITIES AND OBSERVATIONS

Entrance Briefing

The NRC staff discussed the goals and objectives of the audit at the entrance briefing, which focused on gaining a better understanding of SHINE geotechnical topics. In addition, it was discussed that the regulatory audit may identify additional information that would be required to be docketed to support the basis of the licensing decision and allow NRC staff to more efficiently gain insights on the operating license application. Further, the NRC staff indicated that the information gained from the audit review would assist the NRC staff to better focus any requests for additional information (RAIs) needed to support the review.

Review of Audit Information

SHINE made the documents listed in Table 1, "Audit Review Documents," available on its electronic reading room for NRC staff to review in preparation for the regulatory audit discussions. The documents included the evaluation of ultimate bearing capacity and allowable soil bearing capacity, as well as a calculation package for the structural design of the SHINE facility, including a detailed total settlement analysis and the predicted subgrade modulus of the site soils for the structural analysis.

Table 1, "Audit Review Documents"

Document No.	Title	Revision	Date
Golder Report #8 of Project No. 113-81051	Geotechnical Calculations, Bearing Capacity, and Settlement	1	08/03/2012
Sargent & Lundy Report CALC-2017-1000	SHINE Facility Structural Design	8	01/27/2021

Summary of Observations

The NRC staff reviewed the documents listed in Table 1 to verify information provided in SHINE's response to RAI 3.4-6, provided by letter dated December 15, 2020 (ADAMS Accession No. ML21011A264). Specifically, the NRC staff sought to confirm that the allowable soil bearing pressure is higher than the foundation contact pressures and that differential and total settlements are not beyond maximum allowable values. The NRC staff focused its audit review on the Golder Report #8, as well as Attachment P, "Evaluation of Soil Subgrade Modulus," and Attachment X, "DL and LL Diagram for Geotechnical Calculations," of Sargent & Lundy Report CALC-2017-1000.

The NRC staff examined the analyses and calculations in the reference documents and confirmed that that the soil properties used for the analysis are proper and conservative. For SHINE's bearing capacity evaluation, the NRC staff noted that the calculation method is widely accepted and used by the industry. The NRC staff acknowledged that the assumption of a small foundation size in the calculation leads to a conservative estimate of the bearing capacity. For SHINE's settlement calculation, the NRC staff noted that the total settlement was evaluated by three different recognized methods.

The NRC staff conducted a regulatory audit teleconference on March 16, 2021, with SHINE to better understand how the analyses and calculations provided in the electronic reading room support the information provided by SHINE in its response to RAI 3.4-6. The following topics were discussed during the teleconference:

- allowable soil bearing capacities, including the predicted maximum foundation contact pressure from structural response analyses;
- allowable settlement limits;
- settlement profile in consideration of loading variation over the mat foundation, rigidity of mat foundation, and subgrade soil material; and
- soil depth of influence used in settlement analysis.

Based on the review of the information provided to the NRC staff to review via the internet portal and the discussion at the audit teleconference on March 16, 2021, the NRC staff found that SHINE provided an evaluation of ultimate and allowable bearing capacities that is conservative and acceptable to support information provided in the FSAR and agreed upon revisions to the FSAR and RAI response.

Exit Briefing

On March 16, 2021, the NRC staff held an exit meeting with the licensee. No issues or concerns were identified by the licensee during the audit exit briefing. The NRC staff indicated the audit was concluded.

3.0 RESULTS OF REGULATORY AUDIT

During the regulatory audit, SHINE provided clarification and/or justification of the information provided in its response to RAI 3.4-6 and additional detail related to the NRC staff discussion topics. As a result of these discussions, SHINE agreed to revise its application materials as follows:

1) Clarify the net allowable static bearing pressure in FSAR Section 3.4.2.6.3.1, “Soil Parameters,” provide information on the predicted maximum foundation contact pressure from the structural response analyses under design loading conditions, and verify the maximum pressure that can be enveloped by the allowable soil bearing capacity.

2) Supplement the response to RAI 3.4-6 to include the information that the facility structure is designed to accommodate the potential differential and total settlements of the foundation of the facility structure and, consequently, that there are no allowable settlement limits.

Since SHINE agreed to voluntarily supplement the FSAR and the response to RAI 3.4-6, the NRC staff did not identify any outstanding issues following the conclusion of this regulatory audit.