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

December 7, 2022

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

SUBJECT: SHINE TECHNOLOGIES, LLC REGULATORY REPORT ON THE AUDIT OF CHAPTER 13, "ACCIDENT ANALYSIS AND CRITICALITY SAFETY," AS 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), SHINE Medical Technologies, LLC (SHINE) submitted its application for an operating license.

Enclosed is a report on the regulatory audit conducted by staff of the U.S. Nuclear Regulatory Commission (NRC) in connection with its review of the application, in addition to the review of chapter 13, "Accident Analysis and Criticality Safety," of the SHINE Medical Technologies, LLC operating license application. This regulatory audit was held to close technical gaps identified during the review of chapter 13.

The audit report does not make any licensing conclusions or findings, but it is part of the administrative record of the NRC staff's review of the application and may provide information supporting the NRC staff's safety evaluation. The audit followed the plan provided by letter dated August 14, 2020 (ADAMS Accession No. ML20226A419), unless otherwise noted in the enclosed report. This report constitutes the final report on the audit. The closure of the audit items are documented in the NRC staff safety evaluation.

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 12/07/22

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: See next page

cc:

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SUBJECT: SHINE TECHNOLOGIES, LLC REGULATORY REPORT ON THE AUDIT OF CHAPTER 13, “ACCIDENT ANALYSIS AND CRITICALITY SAFETY”, AS DESCRIBED IN OPERATING LICENSE APPLICATION (EPID NO. L-2019-NEW-0004) DATED: DECEMBER 7, 2022

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ADAMS Accession No.: ML22301A149 **NRR-106**

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REGULATORY AUDIT REPORT

REGARDING CHAPTER 13, "ACCIDENT ANALYSIS AND CRITICALITY SAFETY"

OPERATING LICENSE APPLICATION

SHINE TECHNOLOGIES, LLC

DOCKET NO. 50-608

Location:	Virtual
Dates:	August 17, 2020, from 10:00am to 5:00pm (Central Time) August 18, 2020, from 8:00am to 5:00pm (Central Time) August 19, 2020, from 8:00am to 5:00pm (Central Time) August 20, 2020, from 8:00am to 5:00pm (Central Time) August 21, 2020, from 8:00am to 5:00pm (Central Time)
Audit Team Members:	Eljiah Dickson (NRR/DRA) – Audit Team Leader Jeremy Munson (NRC/RII) – Technical Reviewer Michael Balazik (NRR/DANU), et.al.
Licensee Representatives:	Jeff Bartelme, SHINE Technologies, LLC (SHINE), et al.

Background

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), SHINE submitted its application for an operating license. This report summarizes the regulatory audit conducted by staff of the NRC on August 17, 2020 – August 21, 2020, and provides a closure path for each of the Audit Topics and Questions.

This audit was conducted in connection with the NRC staff's review of the application. The audit report does not make any licensing conclusions or findings, but it is part of the administrative record of the NRC staff's review of the application and may provide information supporting the NRC staff's safety evaluation. The audit followed the plan provided by letter dated August 14, 2020 (ADAMS Accession No. ML20226A419), unless otherwise noted in this report.

Regulatory Bases for the Audit

The purpose of the audit was to close technical gaps identified during the review of chapter 13, "Accident Analysis and Criticality Safety." The licensee's proposed accident analysis 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).

Audit Activities

The following activities were performed during the audit:

1. Entrance Meeting

At the entrance meeting on August 17, 2020, the NRC staff explained the scope and desired outcomes for the audit. The NRC staff stated that after completion of the audit, an audit report will be prepared and sent to SHINE.

2. Review of Audit Topics and Questions

This audit was held to: (1) gain a better understanding of information underlying the application in the area of the chapter 13, “Accident Analysis and Criticality Safety,” (2) identify specific information that will require docketing to support the basis of the licensing or regulatory decision; and (3) close open technical items or identify a closure path for the audit questions identified in this audit plan.

The audit addressed updates to the SHINE final safety analysis report (FSAR) in chapter 13, “Accident Analysis and Criticality Safety.” The audit also addressed additional information and FSAR revisions provided for other systems. Therefore, any additional information identified from the audit that is needed to address a regulatory finding has been documented in this audit report.

As discussed in the audit plan, the NRC staff conducted document reviews using the electronic reading room as part of the audit. The following list comprises the documents the NRC staff reviewed as a part of this audit. The NRC staff did not review any additional documents in the electronic reading room beyond those listed.

- CALC-2014-0022 Rev. 5, Peak Hydrogen Concentration Following TOGS Blower Failure
- CALC-2018-0003 Rev. 2, Target Solution Vessel Drain Rate
- CALC-2018-0010 Rev. 2, _Bounding Fission Product Inventories and Source Terms
- CALC-2018-0010_R2_Source1a-Target_Solution
- CALC-2018-0010_Rev. 2, Source1a-TOGS
- CALC-2018-0010_Rev. 2, Source1b-Target_Solution_No Extraction
- CALC-2018-0012 Rev. 0, MCNP5 Validation for Reactivity in Solution Systems for Shine Facility
- CALC-2018-0016 Rev. 1, Coefficients of Reactivity
- CALC-2018-0017 Rev. 3, Direct Dose Rates from Below Grade Sources
- CALC-2018-0034 Rev. 1, Direct Dose Rates from Irradiation Unit Cell Operations
- CALC-2018-0035 Rev. 3, Target Solution Vessel Fill System Design
- CALC-2018-0039 Rev. 1, Direct Dose Rates from Solidified Liquid Waste
- CALC-2018-0045 Rev. 1, Direct Dose Rates from the Target Solution Vessel Off-Gas System
- CALC-2018-0046 Rev. 2, Target Solution Vessel (TSV) Thermal Hydraulics
- CALC-2018-0048 Rev. 4a, Radiological Dose Calculations
- CALC-2018-0048 Rev. 5a, Radiological Dose Calculations
- CALC-2018-0048 Rev. 7, Radiological Dose Calculations
- CALC-2018-0048 Rev. 8, Radiological Dose Consequences

- CALC-2018-0049 Rev. 2, Chemical Dose Analysis
- CALC-2018-0050 Rev. 1, Direct Dose Rates from Supercell Operations
- CALC-2018-0063 Rev. 1, SHINE Facility Dose Rate Maps and Radiation Zoning
- CALC-2019-0004 Rev. 0A, Instrument Uncertainty Calculation – TSV Off Gas System Flow
- CALC-2019-0013 Rev. 1, Target Solution Vessel Transient Analysis
- CALC-2019-0045 Rev. 1, Instrument Uncertainty Calculation
- CALC-2020-0002 Rev. 0, MEPS Hot Water Loop Leak Dose Rate and PVVS Carbon Monoxide
- CALC-2020-0010 Rev. 0, Instrument Uncertainty Calculation – NFDS Power Range
- DCD-NDAS-0001 Rev. 6, Neutron Driver Assembly System
- DCD-NFDS-0001 Rev. 4, Neutron Flux Detection System Design Criteria Document
- DCD-PCLS-0001 Rev. 6, Primary Closed Loop Cooling System
- FAI-19-0035 Rev. 1, Leak Path Factor Analysis for the SHINE Facility
- NCS-CALC-2018-0002 Rev. 1, Criticality Safety - Annular Tank
- NCS-CALC-2018-0003 Rev. 1, Criticality Safety — General Piping
- NCS-CALC-2019-0001 Rev. 0, Criticality Safety- TSV Off-Gas System
- NCSE-2018-0002 Rev. 2, Nuclear Criticality Safety Evaluation of the Radioactive Liquid Waste
- NCSE-2018-0003 Rev. 2, Nuclear Criticality Safety Evaluation of the Molybdenum Extraction (2)
- NCSE-2018-0005 Rev. 0, Nuclear Criticality Safety Evaluation of the TSV Off-Gas System
- NCSE-2018-0007 Rev. 1, Nuclear Criticality Safety Evaluation of the Process Vessel Ventilation
- NCSE-2019-0001 Rev. 0, Nuclear Criticality Safety Evaluation of the Iodine Extraction
- TECRPT-2018-0034 Rev. 12 (ECI) Target Solution Vessel Reactivity Protection System Functional
- TECRPT-2018-0034 Rev. 13, Target Solution Vessel Reactivity Protection System Functional Requirements
- TECRPT-2019-0013 Rev. 1, Neutron Driver Operational Envelope and Startup Transients
- TECRPT-2020-0016 Rev. 0, SHINE Safety Analysis Summary Report
- TECRPT-2020-0016 Rev. 3, SHINE SSA
- TECRPT-2020-0016 Rev. 5, SHINE SSA
- TECRPT-2021-0048 Rev. 0, Phased Startup Supplement to the SHINE Safety Analysis

Table 13-1 lsists the NRC staff audited scenarios specific MARs or referenced source documents.

Table 13-1: Accident-Specific Materials-at-Risk

Scenario	Accident-Specific Material at Risk Source Document File or Activity
1a	CALC-2018-0010_R2_Source1b-Target_Solution_NoExtraction.xlsx[a]
3, 1b	CALC-2018-0010_R2_Source2-TOGS_Iodine.xlsx[a]
	CALC-2018-0010_R2_Source3and4-TOGS_KrXe_andDPs.xlsx[a]
5	4000 Ci Tritium [b]
6	32000 Ci Tritium [b]
7	200,000 Ci Tritium [b]
8	3000 Ci Tritium [b]
9a, 11	CALC-2018-0010_R2_Source1a-Target_Solution.xlsx[a]
9b	CALC-2018-0010_R2_Source7-ExtColmEluate.xlsx[a]
10	CALC-2018-0010_R2_Source12-PVVS_IodineRPF.xlsx[a]
12	CALC-2018-0010_R2_Source1a-Target_Solution.xlsx[a]
13	CALC-2018-0010_R2_Source3and4-TOGS_KrXe_andDPs.xlsx[a]
14	CALC-2018-0010_R2_Source1b-Target_Solution_NoExtraction.xlsx[a]

SHINE's evaluation of the transport of radioactive material is generally consistent with the methods described in NUREG/CR-6410 when developing leak path factors (LPFs). The LPF model yields the fraction of a given radionuclide that is released to the environment. To support this method, SHINE provided the analyses which identified the control volumes and leakage paths in the document Fauske & Associates, LLC document, entitled "FAI/19-0035 Rev. 1, ""Leak-Path Factor Analysis" for the SHINE facility which are further elaborated in SHINE calculation document CALC-2018-00486, Rev. 1, "Radiological Dose Consequences." The purpose of this analysis was to compute for the SHINE facility LPFs and where appropriate ARFs for each of the design-basis accident scenarios. The thirteen FAI/19-0035 scenarios were identified and presented as follows:

- Scenario 1: Failure of the primary system boundary (TSV (TSV) or connected piping), leading to target solution being released into the IU cell.
- Scenario 2: Failure of the dump tank leading to target solution being released into the IU cell light water pool.
- Scenario 3: Malfunction of the TOGS equipment leading to TOGS gas inventory being released into the TOGS cell.
- Scenario 4: Single neutron driver assembly system (NDAS) failure leading to a tritium release into the IU cell.
- Scenario 5: Multiple (8) NDAS failures leading to a tritium release into the IU cells.
- Scenario 6: Tritium release into the TPS room.
- Scenario 7: Tritium header release into the Irradiation Facility general area.
- Scenario 8: Malfunction of extraction or purification cell equipment leading to radioactive solution being released in the supercell.
- Scenario 9: PVVS guard bed fire leading to radioisotope release to the downstream PVVS components.

- Scenario 10: A pipe break in the RPF trench with freshly-irradiated target solution.
- Scenario 11: A hold tank leak or rupture in a tank vault immediately after exiting the supercell leading to target solution being released in a tank vault.
- Scenario 12: A fire in the final in-series PVVS delay bed leading to radioisotopes being released to the environment.
- Scenario 13: A spill of liquid waste in the RLWI leading to a spill of liquid waste in the RLWI skid.

Scenario 1 is subdivided into 1a and 1b representing a primary system boundary breach below the target solution line and a primary system boundary breach above the target solution line respectively.

Scenario 2 is equivalent to scenario 1a except that Scenario 2's break in the primary system boundary occurs farther from the surface of the pool. Because the light water pool is not credited for the removal of radionuclides, scenarios 1a and 2 are equivalent; therefore, there is no independent analysis of Scenario 2 in this calculation.

Scenarios 1-6 describe accidents that may take place in individual cells within the primary confinement. Analyzing a release in a single cell results in a conservative calculation of allowed radionuclide leakage from the cell. There is no limitation on the confinement leakage rate between the IU cell and the TOGS cell portions of the primary confinement.

Scenario 9 is subdivided into 9a and 9b representing a target solution spill and molybdenum eluate tank spill, respectively.

SHINE's identification of leak-path scenarios to model radionuclide transport through the facility is consistent with NUREG/CR-6410 which presents methodology to compute radiological consequences utilizing the five-factor formula.

SHINE utilized LPFs for each of the thirteen scenarios from those reported by Fauske & Associates in the FAI/19-0035 Rev. 1 report. (note: Eeach scenario numbers listed in to FAI/10-0035 calculation document do not numerical match the SHINE FSAR DBA scenarios). The LPF x ARFs time-dependent results are reported for noble gases, iodine, and non-volatiles from FAI/19-0035 Rev. 1 as follows:

- 3 malfunction of TOGS equipment.
- Table 6-5: Scenario 3 malfunction of TOGS equipment to the Irradiation Facility building.
- Table 6-6: Scenario 4 deflagration in the TOGS pressure boundary.
- Table 6-7: Scenario 4 deflagration in the TOGS pressure boundary to the Irradiation Facility building.
- Table 6-8: Scenario 5 single NDAS failure.
- Table 6-9: Scenario 5 single NDAS failure to the Irradiation Facility building.
- Table 7-1: Scenario 7 tritium release to TPS glove box.

- Table 7-2: Scenario 7 tritium release to TPS glove box to the Irritation Facility building.
- Table 7-3: Scenario 8 tritium header release.
- Table 8-1: Scenario 9 malfunction of cell equipment.
- Table 8-2: Scenario 9 malfunction of cell equipment to the Radioisotope Production Facility building.
- Table 9-1: Scenario 11 pipe break in the Radioisotope Production Facility trench.
- Table 9-2: Scenario 11 pipe break in the Radioisotope Production Facility trench to the Radioisotope Production Facility building.
- Table 9-3: Scenario 12 hold tank failure in the Radioisotope Production Facility trench.
- Table 9-4: Scenario 12 hold tank failure in the Radioisotope Production Facility trench to the Radioisotope Production Facility building.
- Table 9-5: Scenario 13 PVVS delay bed fire in the vault.

The LPF models is consistent with NUREG/CR-6410 which presents methodology to compute radiological consequences utilizing the five-factor formula.

For receptors at the site boundary, SHINE reports the bounding short-term 95th percentile atmospheric χ/Q values within Table 6.1-1 of Calc. No. 2012-03852, Revision 0, “Short-Term Diffusion Estimates for SHINE.”

For receptors within the control room, SHINE reports the bounding short-term 95th percentile atmospheric χ/Q values within CALC-2020-0018 Rev. 0, “Atmospheric Dispersion for Control Room Habitability Calculations."

3. Exit Briefing

An exit briefing was held on August 21, 2020. During this exit briefing, the audit team restated the purpose of the meeting, recapped the closure paths of the audit items, and highlighted areas where additional information may be warranted. It was noted that during the audit, SHINE had stated that it would provide supplemental information on the docket to address additional information needs identified by the NRC staff. Based on SHINE providing this supplemental information to address information needs identified by the NRC staff, the NRC staff considers the audit items provided in the audit plan closed. However, the NRC staff noted that it is still continuing its review of the SHINE operating license application, including the supplemental information, and that additional audits may be necessary. No disagreements with the audit