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

March 23, 2022

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC REGULATORY AUDIT OF INSTRUMENTATION AND CONTROL SYSTEMS DESCRIBED IN OPERATING LICENSE APPLICATION, SESSION 2 (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

The U.S. Nuclear Regulatory Commission (NRC) staff has prepared an audit plan related to the review of Chapter 7, “Instrumentation and Control Systems,” of the SHINE operating license application. 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 is intended to close gaps identified during the technical review. As such, the audit will be held on March 28, 2022, from 1:00pm to 3:00pm and March 30, 2022, from 3:00pm to 5:00pm. Additional audit sessions may be scheduled to support the continued review of the operating license application.

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) 415-1217, or by electronic mail at Joshua.Borromeo@nrc.gov.

Sincerely,

Signed by Borromeo, Joshua
on 03/23/22

Joshua M. Borromeo, Chief
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 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 OF INSTRUMENTATION AND CONTROL SYSTEMS IN OPERATING LICENSE APPLICATION, SESSION 2 (EPID NO. L-2019-NEW-0004) DATED: MARCH 23, 2022

DISTRIBUTION:
PUBLIC
NParker, NRR
NCarte, NRR
DTaneja, NRR
MWaters, NRR
JColaccino, NRR
SAnderson, NRR
JBorromeo, NRR
MBalazik, NRR
MGavello, NRR
HCruz, NRR
DHardesty, NRR

ADAMS Accession No.: ML22075A331 **NRR-106**

OFFICE	NRR/DANU/PM	NRR/DANU/LA	NRR/DANU/BC
NAME	HCruz	NParker	JBorromeo
DATE	3/22/2022	3/22/2022	3/23/2022

OFFICIAL RECORD COPY

OFFICE OF NUCLEAR REACTOR REGULATION

REGULATORY AUDIT PLAN, SESSION 2

REGARDING CHAPTER 7, INSTRUMENTATION AND CONTROL SYSTEMS

OPERATING LICENSE APPLICATION

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 Chapter 7, "Instrumentation and Control Systems," of the SHINE final safety analysis report (FSAR) and responses to requests for additional information (RAI). This regulatory audit is intended to close technical gaps identified during the review of Chapter 7, as communicated periodically to SHINE in a Chapter 7 status tracker and documented in this plan.

Regulatory Audit Bases

The licensee's proposed instrumentation and control systems 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 updates to the SHINE FSAR and associated responses to RAIs on the highly integrated protection system (HIPS), target solution vessel (TSV) reactivity protection system (TRPS), engineered safety feature actuation system (ESFAS). Consistent with the regulatory basis specified in the system RAIs, this information will supplement the licensing review to understand and confirm how TRPS and ESFAS: (1) will perform its safety function including after a single failure and meeting requirements for environmental qualification, redundancy, diversity, and independence; (2) will have surveillance tests and intervals that give confidence that the equipment will reliably perform its safety function; and (3) has appropriate digital hardware and software verification and validation programs to provide confidence in design quality. The audit may also address additional information and FSAR revisions provided for other systems, such as the process integrated control system (PICS). 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 application in the area of instrumentation and control systems, (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 in the Audit Topics and Questions section of 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, and to resolve open technical items. The NRC staff anticipates SHINE identifying additional documents that may address open technical items.

- ESFAS and TRPS Design Documents (e.g., as referenced in response to RAI 7-10)

Audit Team

The NRC staff participating in this audit will be:

- Dinesh Taneja (NRR/DEX) – HIPS and ESFAS Lead, Audit Team Leader
- Norbert Carte (NRR/DEX) –TRPS Lead
- Michael Waters (NRR/DEX)
- Michael Balazik (NRR/DANU)
- Duane Hardesty (NRR/DANU)
- Jesse Seymour (NRR/DRO) – Human Factors
- Elijah Dickson (NRR/DRA) – Accident Analysis

Audit Team Logistics

The virtual audit will be held on March 28, 2022, from 1:00pm to 3:00pm and March 30, 2022, from 3:00pm to 5:00pm. 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 open technical items are identified, 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 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 open technical items are identified. Closure paths for each item will be captured in the Audit Topics and Questions section of this audit plan.

Audit Session 2: March 28, 2022, from 1:00pm to 3:00pm and March 30, 2022, from 3:00pm to 5:00pm.

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
7.2.5.1 HIPS Description		
- Equipment Interface Module (EIM)	**Open Technical Item- 7.2.5-05** FSAR Figures 7.4-1, Sheets 11 - 13, and Figures 7.5-1, Sheets 21 – 26 depicts 'Nonsafety Input Decode Logic' as a part of the actuation and priority logic (APL) circuit board within the EIM. This is not described in the HIPS Topical Report. **Describe this SHINE application-specific HIPS design feature.** This information is needed to understand how the HIPS differs from the version approved in the Topical Report in order to confirm that the functionality of the EIM and the adequacy of the TRPS and ESFS design to perform the functions necessary to ensure facility safety and its conformance to the design bases (see Section 7.4, NUREG-1537, Part 2).	
7.4.2.1.2 Protection System Functions	**Open Technical Item 7.4.2-08** The NRC staff cannot validate that selected TRPS equipment analytical limits (ALs) in Table 7.4-1 address and are consistent with the ALs used/assumed ALs in the accident analysis in Chapter 13. There does not appear to be ALs specified in the Chapter 13 accident scenarios. There appears to be values discussed in the Chapter 4 description of operations, but the NRC staff cannot make reasonable inferences in all cases on how Chapter 4 values correspond to Table 7.4-1. The NRC staff audited a table (SHINE Response to Topic Request 5B updated 07/02/2021) in the electronic reading room to support the Chapter 13 accident analysis but could not derive the relationship of values to the ALs specified in Table 7.4-1 and corresponding values in technical	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
	specification (TS) 3.2 (especially for flux and power limits, and setpoints). **Reference a table, crosswalk, or provide other method of clarification during the audit that demonstrates the applicability of Table 7.4-1 ALs to the specific ALs that are assumed in Chapter 13 accidents scenarios that rely upon TRPS and corresponding values in TS.** This information is needed to confirm proposed ALs, trip setpoints, time delays, accuracy requirements, and actuated equipment response to verify that the TRPS is consistent with the FSAR analyses and that this information is adequately included in the TSs (see Section 7.4, NUREG-1537). *For example:* - *The AL for High Source Range Neutron Flux in FSAR Table 7.4-1 is 2.52x.* - *FSAR Chapter 7.4.4.1.1 points to FSAR Chapter 13a2.1.2, Scenarios 5, 6, & 11, none of which include the AL.* - *Scenario 5 does not point to any other FSAR Section.* - *Scenario 6 points to 4a2.6.3 which does not contain the AL.* - *Scenario 11 does not point to any other FSAR Section.* *The only place that the 2.52x flux limit appears by words search in Chapter 4 is in 4a2.6.1.7. The 2.52x flux limit does not appear in Chapters 13. Furthermore, Chapters 7 & 13 do not appear to point to 4a2.6.1.7. The NRC staff does not want to make an incorrect inference in the applicability of the 2.52x flux limit and establish an incorrect licensing basis.*	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
7.4.2.1.6 Separation of Protection and Control Systems	**Open Technical Item 7.4.2-12** (a) The NRC staff cannot validate that all shared components have been identified and confirm that these instances address SHINE Design Criterion 18. The RAI 7-9(c) response (ADAMS Accession No. ML21272A344), and update to Section 7.4.2.1.6 of the FSAR states, in part: "Sensors with an output used to determine TRPS protective actions are safety-related and input directly to the TRPS. The TRPS provides these sensor inputs to the PICS through redundant outputs. After receiving the input from the TRPS, the PICS performs its control function, if one is associated with the input. The inputs to the TRPS that have both safety-related protection functions and nonsafety-related control functions are TSV off-gas system (TOGS) oxygen concentration (Subsection 7.4.4.1.10) and TOGS mainstream flow (Subsection 7.4.4.1.11). For each of these inputs, the nonsafety-related control function is based upon the median value of the inputs to the TRPS (Subsection 7.3.1.1.2). Since the median value is selected, a failure of a single input will not impact the control function." The use of a sensor that provides redundant output to both safety systems and controls is a shared component. Section 7.4.2.1.6 of the FSAR update also identifies two instances of shared components: (1) TOGS mainstream flow and (2) TOGS oxygen concentration.	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
	FSAR Chapter 5a2.2.3, "Instrumentation and Control," upon further review by NRC staff appears to identify another instance: "Temperature instrumentation is provided to ensure the cooling water supply temperature remains within allowable limits despite variations in TSV power. Output from the temperature instrumentation is used for controlling the flow of RPCS [radioisotope process facility cooling system] water through the PCLS [primary closed loop cooling system], heat exchanger to regulate the cooling water supply temperature at the SCAS cooling water inlet. … If the PCLS temperature or flowrate is outside allowable limits, the TRPS initiates an IU [irradiation unit] Cell Safety Actuation, resulting in a transfer of the target solution to the TSV dump tank where it is cooled by natural convection to the light water pool." FSAR Chapter 7.4.4.1.5, "High PCLS Temperature," also appears to describe how this same temperature instrumentation is used for protection against inappropriate cooling water supply temperature. **Clarify if this temperature instrumentation employs a shared component (e.g., sensor) between protection and control equipment. Identify any other instances of similar nature where protection and control functions share equipment (e.g., rely upon a common sensor for protection and controls), as appropriate.** **Also, describe the tritium or power density control during the initial part of Mode 2 (e.g., See TS Figure 3.1.6). It is not clear to the NRC staff how**	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
	separation of protection and control is addressed for this operation in protection of the low temperature power density safety limit curve in Figure 3.1.6. The NRC staff also recognizes that median signal select algorithm may be used to address sensor bypass and trip modes for shared equipment between protection and control functions. **(b) Describe the median signal select algorithm when one sensor is faulty, in trip, or in bypass. This description should also include the assumed behavior when a second sensor misbehaves.** This information is needed to understand the separation and independence of PICS and TRPS, verify the safe shutdown would not be compromised by a combination of the two systems, and confirm that a single random failure or malfunction in the TRPS or PICS could not prevent the TRPS from performing its intended function (see Section 7.4, NUREG-1537 Part 2). Note: Because this is also related to PICS functionality, the NRC staff is developing an RAI to understand the median signal select algorithm.	
7.4.2.2.6 Prioritization of Functions	**Open Technical item 7.4.2-13** The FSAR describes the manner of PICS control of certain components based on control through the APL as the normal means of control (see FSAR Chapter 7.3.1.3.11 & Figure 7.4-1 Sheets 11-13). However, 1) TECRPT-2019-0048, Revision 5, “TRPS System Design Description,” Figure 3-8, “Control of a Solenoid Valve by both TRPS and PICS” and (2) TECRPT-2019-0002, Revision 5, “Engineered Safety	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
	Features Actuation System Design Description," Figure 3-8, "Control of a Solenoid Valve by both ESFAS and PICS," depict and describe a different manner of PICS control of certain components (i.e., PICS directly controlling components without going through the APL as the normal means of control; and the use of PICS inputs to the APL to reset automatic actuation signals). **Explain the manner of PICS control of these components and confirm that Section 7.3.1.3.11 of the FSAR is accurate.** This information is needed to verify the relationship of TRPS and PICS control prioritization and understand how the PICS operation could not prevent the TRPS from performing its intended function in all operating configurations (see Section 7.4, NUREG-1537, Part 2).	
7.4.2.2.8 Setpoints	**Open Technical Item 7.4.2-14** The NRC staff is confirming how selected variables and functions listed in FSAR Chapter 7.4.4.1 support the analysis summarized in FSAR Chapter 13 in order to verify that the TRPS functions and setpoint protects against conditions exceeding analytical limits and remain within design basis conditions. However, the NRC staff has identified potential inconsistencies that need to be resolved. Example 1: FSAR Chapter 7.4.4.1.5, "High PCLS Temperature," states: "The high PCLS temperature signal protects against a loss of cooling that could cause target solution heat-up (…Subsection 13a2.1.3, Scenarios 1…"	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
	Provide the safety analysis calculation for this scenario that includes the limit used in this analysis calculation (i.e., the AL). Confirm this value is consistent with the value used in FSAR Table 7.4-1 (i.e., 25 DEG C). Example 2: FSAR Chapter 7.4.4.1.9, "High-High TSV Dump Tank Level," states, in part: "The high-high TSV dump tank level signal protects against an overfill of the TSV dump tank (greater than the volume of target solution expected to be transferred from the TSV), compromising the ability of the TOGS to remove hydrogen from the TSV dump tank headspace (Subsection 13a2.1.9.2, Scenario 1)." **Provide the safety analysis calculation for this scenario that shows the value used in this analysis calculation (i.e., the AL). Verify this value with the value used in FSAR Table 7.4-1 (i.e., high level).** This information is needed to confirm proposed trip setpoints, time delays, accuracy requirements, and actuated equipment response to verify that the TRPS is consistent with the FSAR analyses of safety limits, limiting safety system settings (LSSS), and limiting conditions of operation (LCOs), and that this information is adequately included in the TSs (see Section 7.4, NUREG-1537, Part 2). The description of the analysis in Subsection 13a2.1.9.2, Scenario 1 does not identify the operating mode of the facility or TRPS. The high-high TSV dump tank level signal is functional in all operating modes of the TRPS, however, the TS only require this function to be operable in modes 1-4.	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
	Clarify the operating mode used in the analysis and why this mode the appropriate? **Open Technical Item 7.2.4-15** The basis for TS for instrument calibration level and demonstrated accuracy of 1 percent for power range detection is not clear. For example, is this a validated manufacturer specification? **Clarify the basis (or provide reference) for the instrument calibrations for power range detection.** This information is needed to confirm proposed trip setpoints, time delays, **accuracy requirements**, and actuated equipment response to verify that the TRPS is consistent with the FSAR analyses of safety limits, LSSS, and LCOs, and that this information is adequately included in the TSs (see Section 7.4, NUREG-1537, Part 2).	
7.4.3.7 Human Factors	**Open Technical Item 7.4.3-16** FSAR Chapter 7.4.3.7, "Human Factors," states, in part: "Both TRPS Divisions A and B respond to the activation of a push button. A manual IU Cell TPS [Tritium Purification System] Actuation on all eight TRPS subsystems is initiated via the manual TPS Isolation push button located on the ESFAS main control board panel (see Subsection 7.5.3.6)." This appears to imply one TPS, which was based on an older design version. The new design consists of three TPSs.	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
	Clarify if there are three manual operator buttons, each which actuates one of the TPSs. This information is needed to confirm the adequacy of the design to perform the functions necessary to ensure irradiation facility safety and its conformance to the design bases.	
7.4.4.1.5 High PCLS Temperature	**Open Technical Item 7.4.4-17** 7.4.4.1.5, "High PCLS Temperature," refers to protecting against over temperature from an FSAR Chapter 13a2.1.3.2, "Scenario 1 – Loss of Normal Power." It is not apparent how high PCLS temperature is protected given the measurement point of the temperature on flow inlet, and presumption that flow would cease upon loss of power. **Explain how Scenario 1 (loss of normal power) is protected against high PCLS temperature. Are there transients for loss of power events defined in Scenario 1 in which a high PCLS temperature could trip IU Cell Safety Actuation before Low PCLS Flow?** This information is needed to confirm the adequacy of the design to perform the functions necessary to ensure irradiation facility safety and its conformance to the design bases.	
7.4.5 TRPS – HIPS Design	**Open Technical Item 7.4.5-18** FSAR Chapter 7.4.5.2.3, "Predictability and Repeatability," states that the HIPS equipment performance requirements is 500 milliseconds, while FSAR Table 7.4-1 states that two functions that have a 450 millisecond "instrument response time." Furthermore, it is not clear how response times are directly applied in the accident analysis.	

SECTION	Open Items	Closure Path & Information Needs (Request for Confirmatory Information Response, Supplement, Updated FSAR, etc.)
	Clarify whether "instrument response time" is just for the instrument or includes the TRPS response time associated with the instrument. This information is needed to confirm proposed trip setpoints, time delays, accuracy requirements, and actuated equipment response to verify that the TRPS is consistent with the FSAR analyses of safety limits, LSSS, and LCOs, and that this information is adequately included in the TSs (see Section 7.4, NUREG-1537, Part 2).	