April 22, 2022

2022-SMT-0049
10 CFR 50.30

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)
(2) NRC letter to SHINE Technologies, LLC, "SHINE Medical Technologies, LLC – Request for Additional Information Related to the Process Integrated Control System (EPID No. L-2019-NEW-0004)," dated April 18, 2022 (ML22088A166)

SHINE Technologies, LLC Application for an Operating License
Response to Request for Additional Information

Pursuant to 10 CFR Part 50.30, SHINE Technologies, LLC (SHINE) submitted an application for an operating license for a medical isotope production facility to be located in Janesville, Wisconsin (Reference 1). The NRC staff determined that additional information was required to enable the staff's continued review of the SHINE operating license application (Reference 2).

Enclosure 1 provides the SHINE response to the NRC staff's request for additional information.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on April 22, 2022.

Very truly yours,

DocuSigned by:
Jim Costedio
F52DB96989224FF...

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Technologies, LLC
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Technologies, LLC (SHINE) operating license application (Reference 2). The following information is provided by SHINE in response to the NRC staff's request.

Chapter 7 – Instrumentation and Control Systems

RAI 7-49

Note 1 of SHINE FSAR Chapter 3, "Design of Structures, Systems, and Components," Table 3.1-2, "Nonsafety-Related Structures, Systems, and Components," states that "[t]he generally-applicable design criteria 1-8 from Table 3.1-3 are not specifically listed. See corresponding FSAR section(s) for detailed discussions of SSC design." SHINE FSAR Section 7.3.2.1, "SHINE Facility Design Criteria," and Table 3.1-2 specifies that SHINE Design Criteria 13 is applicable to PICS. However, it is not clear to the NRC staff whether SHINE Design Criteria 1-8 are applicable to the PICS.

Confirm whether SHINE Design Criteria 1-8 are applicable to the PICS. Update the SHINE FSAR to describe the relation of the PICS design bases to the applicable SHINE Design Criteria 1-8.

This information is necessary for the NRC staff to understand the relation of the design bases to the principal design criteria of facility, as required by 10 CFR 50.34.

SHINE Response

SHINE Design Criteria 3 and 6 are applicable to the process integrated control system (PICS). SHINE does not rely on the PICS to satisfy SHINE Design Criteria 1, 2, 4, 5, 7, and 8.

SHINE has revised Subsections 7.3.2.1 and 7.6.2 of the FSAR to describe the relationship between the PICS design basis to SHINE Design Criteria 3 and 6. A markup of the FSAR incorporating these changes is provided as Attachment 1.

RAI 7-50

FSAR Chapter 7.6, "Control Console and Display Instruments," Section 7.6.1, "Description," includes descriptions of the control room, main control board, workstations, and other control room interface equipment. There is no listing of the "Control Console and Display Instruments,"

system in FSAR Tables 3.1-1 or 3.1-2. SHINE FSAR Section 7.6.2.1, “SHINE Facility Design Criteria,” states: “There are no SHINE facility design criteria that are uniquely applicable to the control console and display instruments.” SHINE FSAR Section 7.1.5, “Control Console and Displays,” states, in part:

> The operator workstations and main control board are provided as the HIS subset of components for the FCR. These components are included as part of the PICS and are classified as nonsafety-related.

In addition to the PICS, it appears that SHINE Design Criterion 13 should also be applicable to its control console and display instruments (e.g., operator workstations and main control board) since these instruments are key in monitoring variables and systems important to safety. SHINE Design Criterion 13, “Instrumentation and controls,” states:

> Instrumentation is provided to monitor variables and systems over their anticipated ranges for normal operation, for anticipated transients, and for postulated accidents as appropriate to ensure adequate safety, including those variables and systems that can affect the fission process, the integrity of the primary system boundary, the primary confinement and its associated systems, and the process confinement boundary and its associated systems. Appropriate controls are provided to maintain these variables and systems within prescribed operating ranges.

To ensure the underlying principles are met for SHINE Design Criterion 13 are satisfied for the control console and display instruments and to verify that appropriate controls are provided to maintain variables and systems within prescribed operating ranges, provide the following:

1. Identify any facility variables to be monitored and displayed for the control room operators that are important to the safe operation of the facility in addition to those already identified in Table 7.4-1 and Table 7.5-1 in the FSAR.

2. Identify if any of the variables to be monitored and displayed will be used by the control room operators to perform manual protective actions that are credited in the safety analyses.

This information is necessary for the NRC staff to understand the relation of the design bases to the principal design criteria of facility, as required by 10 CFR 50.34.

SHINE Response

SHINE Design Criterion 13 is applicable to the control console and display instruments. As described in Subsection 7.6.2.1 of the FSAR, the control console and display instruments were considered in the evaluation of the SHINE facility design criteria that was performed for the PICS.

As described in the SHINE Response to Part (a)(1) of RAI 7-20 (Reference 3), manual actuation of safety-related components is not required to mitigate the consequences of a design basis event. While manual protective actions are not credited in the SHINE Safety Analysis (SSA), Subsection 7.6.4.1 of the FSAR identifies variables to be monitored and displayed for the control room operators to support the safe operation of the SHINE facility.

RAI 7-51

NUREG-1537, Part 2, Section 7.3 states, in part, that "[t]he RCS should be designed for reliable operation in the normal range of environmental conditions anticipated within the facility."

SHINE FSAR Section 7.3.3.3, "Operating Conditions," describes that the PICS is designed to operate under normal environmental and radiological conditions, which are defined in SHINE FSAR Table 7.2-1, "Design Radiation Environments," through Table 7.2-6, "Primary Cooling Room Interior Design Environmental Parameters."

Describe how SHINE will ensure PICS and its components meet the SHINE defined environmental and radiological conditions for the areas where they would be installed.

The information requested is necessary to support the following evaluation finding in NUREG-1537, Part 2, Section 7.3:

> The RCS should be designed for reliable operation in the normal range of environmental conditions anticipated within the facility.

SHINE Response

The SHINE design and purchase specifications contain requirements for ensuring that the PICS equipment meets the design environmental and radiological conditions for the areas where the equipment will be installed. The vendor is required to provide documentation to demonstrate that the supplied PICS equipment meet these specified requirements. SHINE reviews vendor documentation to ensure the specified requirements are met and that the design life of the equipment meets the operational needs of the SHINE facility.

SHINE has revised Subsection 7.3.3.3 of the FSAR to enhance the description of how the PICS equipment meets the defined environmental and radiological conditions for the areas where they would be installed. A markup of the FSAR incorporating these changes is provided as Attachment 1.

RAI 7-52

SHINE FSAR Chapter 3.1 contains Shine Design Criterion 37 which states:

> Criterion 37 - Criticality control Criticality in the facility is prevented by physical systems or processes and the use of administrative controls. Use of geometrically safe configurations is preferred. Control of criticality adheres to the double contingency principle.
>
> A criticality accident alarm system to detect and alert facility personnel of an inadvertent criticality is provided.

SHINE FSAR Tables 3.1-1 and 3.1-2 state that SHINE Design Criterion 37 applies to the following systems:

- Engineered safety features actuation system (ESFAS)
- Hot cell fire detection and suppression system (HCFD)
- Iodine and xenon purification and packaging (IXP)

- Molybdenum extraction and purification system (MEPS)
- Radioactive drain system (RDS)
- Radioactive liquid waste storage (RLWS)
- Target solution preparation system (TSPS)
- Target solution staging system (TSSS)
- Uranium receipt and storage system (URSS)
- Vacuum transfer system (VTS)
- Criticality accident alarm system (CAAS)
- Facility fire detection and suppression system (FFPS)
- Quality control and analytical testing laboratories (LABS)
- Solid radioactive waste packaging (SRWP)

The double contingency principle can be defined as:

> Process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Provide the following and update the PICS section of the FSAR, as appropriate:

1. Clarify and identify the portions of the systems that conform to the double contingency principle and that are monitored or controlled by PICS.

2. If the PICS is used to meet the double contingency principle or its failure could adversely affect the ability to meet the double contingency principle, describe (or reference other FSAR section that contain that description) how the associated I&C (including appropriate portions of the PICS system) implements (or supports compliance with) the double contingency principle.

3. If the PICS is used to achieve the double contingency principle, describe the technical specification limiting conditions for operations to ensure sufficient operable I&C equipment to ensure the double contingency principle is met in each instance.

4. If the PICS is used to achieve the double contingency principle, or if an PICS failure could challenge the double contingency principle, then describe the associated algorithms and implementing equipment.

SHINE Response

1. SHINE has performed a review of the credited criticality safety controls for the SHINE facility and has determined that the PICS does not have control of any systems or processes that are required to meet the double contingency principle.

   Monitoring of fissionable material operations may be performed by the PICS, but this is not a credited function in the criticality safety evaluation. Additionally, the PICS may aid operators in the performance of administrative controls (e.g., using installed components controlled via PICS to recover process samples that are required to be analyzed), but execution of the control and confirmation that the control was executed properly is an administrative function to be carried out by SHINE personnel.

2. The PICS is not used to meet the double contingency principle, nor could its failure adversely affect the ability to meet the double contingency principle.

3. The PICS is not used to achieve the double contingency principle.

4. The PICS is not used to achieve the double contingency principle, nor could a PICS failure challenge the double contingency principle.

RAI 7-53

FSAR Chapter 7 does not describe the effect of the facility operating permissive on the PICS or associated controlled systems.

Clarify the functional effect of the facility operating permissive on the PICS and associated controlled systems.

This description is necessary for the NRC staff to understand the interlocks to limit personnel hazards or prevent damage to systems during the full range of normal operations, as required by 10 CFR 50.34.

SHINE Response

The facility master operating permissive switch does not interact with the PICS. The SHINE Response to RAI 7-24 (Reference 3) describes the operation of the facility master operating permissive switch, including the select engineered safety features actuation system (ESFAS) and target solution vessel (TSV) reactivity protection system (TRPS) actuations that occur when the facility master operating permissive switch is disengaged. Safety actuations that occur when the facility master operating permissive switch is disengaged take precedent over operations controlled by the PICS.

References

1. NRC letter to SHINE Technologies, LLC, “SHINE Medical Technologies, LLC – Request for Additional Information Related to the Process Integrated Control System (EPID No. L-2019-NEW-0004),” dated April 18, 2022 (ML22088A166)

2. SHINE Medical Technologies, LLC letter to the NRC, “SHINE Medical Technologies, LLC Application for an Operating License,” dated July 17, 2019 (ML19211C143)

3. SHINE Technologies, LLC letter to NRC, “Application for an Operating License Supplement No. 13 and Response to Request for Additional Information,” dated November 22, 2021 (ML21326A206)

ENCLOSURE 1
ATTACHMENT 1

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

FINAL SAFETY ANALYSIS REPORT CHANGES (MARK-UP)

7.3.2 DESIGN CRITERIA

The SHINE facility design criteria applicable to the PICS are stated in Table 3.1-2. The facility design criteria applicable to the PICS, and the PICS system design criteria, are addressed in this section. Discussion of other vendor-provided nonsafety-related control systems is also provided, where applicable.

7.3.2.1 SHINE Facility Design Criteria

The generally-applicable SHINE facility design criteria 3 and 6 apply to the PICS. The PICS is comprised, wherever practical, of noncombustible and heat resistant materials and is able to be manually operated from the facility control room.

SHINE facility design criterion 13 also applies to the PICS.

> SHINE Design Criterion 13 – Instrumentation is provided to monitor variables and systems over their anticipated ranges for normal operation, for anticipated transients, and for postulated accidents as appropriate to ensure adequate safety, including those variables and systems that can affect the fission process, the integrity of the primary system boundary, the primary confinement and its associated systems, and the process confinement boundary and its associated systems. Appropriate controls are provided to maintain these variables and systems within prescribed operating ranges.

The PICS interfaces with the safety-related TRPS, ESFAS, NFDS, and safety-related radiation monitors to provide nonsafety-related system status and measured process variable values for viewing, recording, and trending. The TRPS, ESFAS, NFDS, and safety-related radiation monitors and applicable operating ranges are described in Sections 7.4, 7.5, 7.7, and 7.8. The PICS is designed to operate in a normal environment and during normal radiological conditions (Subsection 7.3.3.3).

7.3.2.2 PICS System Design Criteria

7.3.2.2.1 Access Control

> PICS Criterion 1 – The PICS design shall incorporate design or administrative controls to prevent/limit unauthorized physical and electronic access to critical digital assets (CDAs) during the operational phase, including the transition from development to operations. CDAs are defined as digital systems and devices that are used to perform or support, among other things, physical security and access control, safety-related functions, and reactivity control.

The PICS and other vendor-provided nonsafety-related control systems do not allow remote access and include the capability to disable unneeded networks, communication ports, and removable media drives or provide engineered barriers (Subsection 7.3.3.5). Physical access to the SHINE facility is controlled in accordance with the physical security plan. Physical access to the control room and access to the equipment within is controlled as described in Subsection 7.6.3.4.

7.3.2.2.5 Operational Bypass

PICS Criterion 7 – Bypasses of PICS interlocks, including provisions for testing, shall be under the direct control of a control room operator and shall be indicated on control room displays.

Bypassing of interlocks is performed from the PICS workstations under the direct control of the control room operator. Bypassing an interlock generates a notification that is visible on the PICS workstation displays (Subsection 7.3.4.2). Interlocks applicable to each system served by the PICS are described in Subsection 7.3.1.

7.3.2.2.6 Surveillance

PICS Criterion 8 – Subsystems of and equipment in the PICS shall be designed to allow testing, calibration, and inspection to ensure functionality.

Testing, calibration and inspection of PICS equipment are allowable to ensure functionality as described in Subsection 7.3.4.2.

PICS Criterion 9 – Testing, calibration, and inspections of the PICS shall be sufficient to confirm that surveillance test and self-test features address failure detection, self-test capabilities, and actions taken upon failure detection.

Testing, calibration, and inspection of PICS equipment are described in Subsection 7.3.4.2.

7.3.3 DESIGN BASIS

7.3.3.1 Design Basis Functions

The PICS is designed to allow the operator to perform irradiation cycles, transfer target solution to and from the IU as well as through the main production facility, and interface with the TPS, supercell, waste handling, and auxiliary systems, as described in Subsection 7.3.1.

The PICS contains no safety-related controls and has no safety-related functions; however, the safety-related TRPS, ESFAS, NFDS, and safety-related radiation monitors provide nonsafety-related system status and measured process variable values to the PICS for viewing, recording, and trending. The PICS is also used to transmit discrete hardwired signals to the TRPS and ESFAS for deliberate operator action to return the TRPS or ESFAS to a normal operating state.

7.3.3.2 Modes of Operation

The modes of operation for the functions of the PICS that interface with individual IUs correspond to the mode of that IU (see Subsection 7.3.1). Portions of the PICS that monitor or control common or facility-wide systems are not mode-dependent.

7.3.3.3 Operating Conditions

~~The~~ PICS ~~control cabinets are~~equipment is located in ~~the non-RCAs of the main production facility and PICS components are in~~ various plant areas with varying environmental conditions. ~~The PICS is designed for the normal environmental and radiological conditions provided in~~

~~Tables 7.2-1 through 7.2-6.~~Design environmental and radiological conditions are determined for PICS equipment for the area where the equipment is installed. Design and purchase specifications contain requirements for ensuring that these conditions are met.

7.3.3.4 Software Development

The PICS is developed under a structured process commensurate with the risk associated with its failure or malfunction and the potential for challenging safety systems. The process for development of the PICS includes the definition of functional requirements, a documented development and implementation process, and a plan for verification of software outputs.

The PICS software development lifecycle process requirements, including V&V and configuration control requirements to ensure that hardware and software are installed in the appropriate system configuration and ensure that the correct version of the software/firmware is installed in the correct hardware components, are described in the PICS validation master plan. The PICS validation master plan additionally includes provisions for operational qualification testing to verify the operation and functionality of various aspects of the PICS, including operator graphics accuracy and functionality, security, interface communications, interlock functionality, and control logic operation and failure monitoring and handling.

Vendor-provided nonsafety-related control systems are developed under structured processes commensurate with the risk associated with their failure or malfunction and the potential for challenging safety systems.

The process for development of the NDAS control system includes the definition of functional requirements, a documented development and implementation process, and a plan of verification of software outputs. The NDAS control system software development lifecycle process requirements, including V&V and configuration control requirements to ensure that hardware and software are installed in the appropriate system configuration and ensure that the correct version of the software/firmware is installed in the correct hardware components, are described in the NDAS vendor software quality assurance plan.

Both the PICS and NDAS control systems are subject to acceptance by SHINE as part of factory acceptance testing, site acceptance testing, and system turnover processes.

Other vendor-provided nonsafety-related control systems, which include the building automation system, the supercell control system, and the RLWI control system, are independently developed by the vendor, and accepted by SHINE as part of factory acceptance testing, site acceptance testing, and system turnover.

7.3.3.5 Access Control and Cyber Security

The PICS and other vendor-provided nonsafety-related control systems do not use the secure development and operating environment implemented for the safety-related control systems described in Subsection 7.4.5, but rather incorporate features commensurate with the risk and magnitude of the harm that would result from unauthorized and inappropriate access, use, disclosure, disruption, or destruction of this nonsafety-related control system.

The PICS and other vendor-provided nonsafety-related control systems do not allow remote access. Remote access is defined as the ability to access the components of the operator

Although not a control station, the PICS is provided with an engineering workstation located in the PICS server room, which is used to perform system administrator functions.

The SHINE facility additionally contains local control stations for vendor provided nonsafety-related control systems. The vendor provided nonsafety-related control systems are further described in Subsection 7.3.2.

The building automation system contains two control stations, one located in the resource building and the other located in the main production facility mezzanine. The control stations are used for periodic adjustments and maintenance on systems served by the building automation system and is not used for normal operation.

The supercell contains an operator interface for the supercell control system used for controlling hot cell functions.

The radioactive liquid waste immobilization (RLWI) system contains an operator interface for the RLWI control system for controlling RLWI equipment functions.

A portable NDAS local control station is provided for controlling one NDAS unit at a time during maintenance and commissioning. The station performs the same functions as the control room NDAS control station, but is not normally connected to an NDAS unit, and is not used for normal operation. The NDAS local control station is also used for controlling an NDAS unit located in the NDAS service cell.

7.6.2 DESIGN CRITERIA

There~~re are no~~ SHINE facility design criteria ~~that are uniquely~~ applicable to the control console and display instruments ~~(other than criteria 1-8 identified in Section 3.1, Tables 3.1-1 and 3.1-2, which are generically applicable to the facility as a whole)~~are described in Subsection 7.6.2.1. The system design criteria uniquely applicable to the control console and display instruments are addressed in ~~this section~~Subsection 7.6.2.2.

7.6.2.1 SHINE Facility Design Criteria

There are no SHINE facility design criteria that are uniquely applicable to the control console and display instruments. The control console and display instruments were considered in the evaluation of SHINE facility design criteria that were performed as part of the PICS and described in Subsection 7.3.2.1.

7.6.2.2 System Design Criteria

7.6.2.2.1 Access Control

PICS Criterion 10 – The operator workstation and main control board design shall incorporate design or administrative controls to prevent or limit unauthorized physical and electronic access to critical digital assets (CDAs) during the operational phase, including the transition from development to operations. CDAs are defined as digital systems and devices that are used to perform or support, among other things, physical security and access control, safety-related functions, and reactivity control.