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

January 11, 2022

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO THE RADIATION MONITORING SYSTEM(S) (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 Package Accession No. ML20357A084), December 15, 2020 (ADAMS Package Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), 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."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report, submitted in connection with the operating license application, and prepare a safety evaluation report. The specific technical area of the SHINE operating license application covered by this RAI is Chapter 7, "Instrumentation and Control Systems."

It is requested that SHINE provide responses to the enclosed RAI within 60 days from the date of this letter. To facilitate a timely and complete response to the enclosed RAI, the NRC staff is available to meet with SHINE to clarify the scope of information and level of detail expected to be included in the RAI response. SHINE may coordinate the scheduling and agendas for any such meetings with the responsible project manager assigned to this project.

In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Following

receipt of the additional information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE's operating license application, additional RAIs for other chapters and technical areas may be developed. The NRC staff will transmit any further questions to SHINE under separate correspondence.

If SHINE has any questions, or needs additional time to respond to this request, please contact me at 301-415-2856, or by electronic mail at Michael.Balazik@nrc.gov.

Sincerely,

Signed by Balazik, Michael
on 01/11/22

Michael Balazik, 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 MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO THE RADIATION MONITORING SYSTEM(S) (EPID NO. L-2019-NEW-0004) DATED: JANUARY 11, 2022

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REQUEST FOR ADDITIONAL INFORMATION REGARDING

THE RADIATION MONITORING SYSTEM(S)

DESCRIBED IN OPERATING LICENSE APPLICATION CONSTRUCTION

PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

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 Package Accession No. ML20357A084), December 15, 2020 (ADAMS Package Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), 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."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted in connection with the operating license application, and prepare a safety evaluation report. The specific chapter of the SHINE operating license application covered by this RAI is Chapter 7, "Instrumentation and Control Systems."

Several instrumentation and control (I&C) systems are used to monitor and control the SHINE facility. This includes the radiation monitoring system (RMS). The RMS monitors radiation levels to generate alarms at high radiation levels or high levels of airborne effluent streams and generate signals to actuate safety components. The RMS performs its functions at a facility level independent from the irradiation units (IUs).

On May 26, 2020 (ADAMS Accession No. ML20148M279), the NRC staff issued a RAI requesting information on how the RMS meet the applicable SHINE design criteria. SHINE submitted responses to these RAIs and associated FSAR updates on August 28, 2020 (ADAMS Package Accession No. ML20255A026). These RAIs were necessary for the NRC staff to determine that there is reasonable assurance that the RMS are appropriately designed and will reliably provide adequate protection of public health and safety, and that applicable regulatory requirements are met. The following requests for information identify additional information needed for the NRC staff to perform its review of the RMS.

The NRC staff previously issued a set of RAIs related to the highly integrated protection system (HIPS)platform on July 1, 2021 (ADAMS Accession No. ML21172A195), and target solution vessel (TSV) reactivity protection system (TRPS) engineered safety features actuation system (ESFAS) on September 27, 2021 (ADAMS Accession No. ML21252A753). The NRC staff is preparing additional sets of RAIs related to SHINE's instrumentation and control systems (ICSs) focused on the Neutron Flux Detection System and the Process Integrated Control System.

Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE operating license application, which describes the SHINE irradiation facility including the IUs, and radioisotope production facility, using the applicable regulations, 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.

For the purposes of this review, the term "reactor," as it appears in NUREG-1537, the ISG Augmenting NUREG-1537, and other relevant guidance can be interpreted to refer to SHINE's "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate within the context of the application and corresponding with the technology described by SHINE in its application. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to refer to SHINE's "target solution."

Chapter 7 – Instrumentation and Control Systems

Radiation Monitoring System

The following regulatory requirement is applicable to RAIs 7-27 through 7-35:

Paragraph (b)(2) of 10 CFR 50.34, "Contents of applications; technical information," requires, in part, that an FSAR include "[a] description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations."

FSAR Section 7.7, “Radiation Monitoring Systems,” states:

> This section describes systems and components that perform radiation monitoring functions within the SHINE facility. Radiation monitoring systems and components include:
>
> - safety-related process radiation monitors included as part of the engineered safety features actuation system (ESFAS), target solution vessel (TSV) reactivity protection system (TRPS), and tritium purification system (TPS);
> - nonsafety-related process radiation monitors included as part of other facility processes;
> - area radiation monitoring consisting of the radiation area monitoring system (RAMS);
> - continuous air monitoring consisting of the continuous air monitoring system (CAMS); and
> - effluent monitoring consisting of the stack release monitoring system (SRMS).

FSAR Section 3.1, “Design Criteria,” contains Table 3.1-1, “Safety-Related Structures, Systems, and Components,” which includes entries for ESFAS, TRPS, and TPS, but not for RAMS, CAMS, and SRMS. FSAR Section 3.1 contains Table 3.1-2, “Nonsafety-Related Structures, Systems, and Components,” which includes entries for RAMS, CAMS and SRMS.

RAI 7-27 Design Criteria 1-8

Note 2 of SHINE FSAR Chapter 3, “Design of Structures, Systems, and Components,” Table 3.1-1, states that “[t]he generally-applicable design criteria 1-8 from Table 3.1-3 are not specifically listed even though they are generally applicable to most SSCs.” However, it is not clear to the NRC staff whether these design criteria are applicable to each radiation monitoring system (i.e., parts of ESFAS, TRPS; and TPS, RAMS, CAMS, and SRMS).

Confirm whether SHINE Design Criteria 1 - 8 are applicable to each radiation monitoring system. Update the SHINE FSAR to describe the relation of the radiation monitoring systems design bases to each 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 the facility, as required by 10 CFR 50.34.

RAI 7-28 System Configuration

NUREG-1537, Part 2, Section 7.7, “Radiation Monitoring Systems,” states, in part, that “[t]he applicant should address all equipment, devices, and systems used for monitoring or measuring radiation intensities or radioactivity … [t]his section should detail the operating principles, designs, and functional performance of the I&C aspects of the system [RMS].” Although there may be different types of radiation monitoring systems (as is the case in the SHINE application), the guidance in NUREG-1537, Part 2, Section 7.7, does not provide specific guidance for different types of radiation monitoring systems,

rather the guidance in Section 7.7 is understood to be applicable to all radiation monitoring systems.

The acceptance criteria of NUREG-1537, Part 2, Section 7.7 states the following:

- The instrument ranges should be sufficient to cover the expected range of variation of the monitored variable under the full range of normal operation and if assumed in the SAR analysis, accident conditions.

- The sensitivity of each system should be commensurate with the precision and accuracy to which knowledge of the variable is required by analysis or design basis.

In addition, NUREG-1537, Part 2, Section 7.6, “Control Console and Display Instruments,” provides guidance for evaluating the control console and display instruments to determine that they include signals from instrument systems monitoring activities, and other system process variables analytically or digitally processed outputs based on monitored variables. The acceptance criteria in NUREG-1537, Part 2, Section 7.3, “Reactor Control Systems,” states the following:

- The system should give reliable information about the status and magnitude of process variables necessary for the full range of normal reactor operation.

The radiation monitoring systems described in FSAR Section 7.7 should conform to the acceptance criteria and guidelines so that the controlled variables can be maintained within prescribed ranges for normal operations, anticipated transients, and accident conditions, including the effects of maloperation or failure of the system. Accordingly, the SHINE FSAR should describe the design bases, acceptance criteria, and guidelines used for design of the RMS, as well as analysis of the adequacy of the designs to perform the functions necessary to monitor and control the SHINE facility.

(a) Monitored and displayed variables

NUREG-1537, Part 2, Section 7.7, describes that the systems should be designed to interface with either analog or digital computerized reactor control system or reactor protection system if applicable.

SHINE FSAR Chapter 3, Table 3.1-3, “SHINE Design Criteria,” states, in part, the SHINE design criteria as follows:

> SHINE Design Criterion 13, “Instrumentation and controls,” instrumentation is provided to monitor variables and systems over the expected range of variation of the monitored variable during normal and transient operation. Also, this criterion requires that the information provided be sufficient to verify that individual safety limits are protected by independent channels. (Note:

per FSAR Chapter 3 Tables 3.1-1 and 3.1-2 SHINE Design Criteria 13 applies to TRPS, ESFAS, CAMS, RAMS, and SRMS).

SHINE Design Criterion 38, “Monitoring radioactivity releases,” means are provided for monitoring the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material. Potential effluent discharge paths and the plant environs are monitored for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents. (Note: per FSAR Chapter 3 Table 3.1-2 SHINE Design Criteria 38 applies to TRPS, ESFAS, TPS, CAMS, RAMS, and SRMS).

SHINE FSAR Table 7.7-1, “Safety-Related Process Radiation Monitors,” identifies the safety-related process radiation monitors, monitored locations, total available channels, minimum required channels, and operability requirements. In addition, Tables 7.4-1, “TRPS Monitored Variables,” and 7.5-1, “ESFAS Monitored Variables,” identify the radiation variables monitored by the TRPS and ESFAS, respectively. These tables identify range, accuracy, and response time. Further, Section 7.7.1.3.4, “Independence,” describes that safety-related process radiation monitors provide analog communication to the ESFAS and TRPS controls. This section also describes that these radiation monitoring data is provided to non-safety systems through one-way isolated outputs.

SHINE FSAR Section 7.7.1.2.1, “Instrument and Controls,” states, in part, the “Safety-related radiation monitoring channels produce a full-scale reading when subject to radiation fields higher than the full-scale reading; however, they are expected to remain on-scale during accident conditions." Therefore, the NRC staff seeks clarification on the response of the radiation monitoring channels when subject to radiation fields that are higher than the full-scale reading.

1. Identify the means (e.g., radiation monitor and associated control room indications) provided for monitoring each: (1) the primary confinement boundary, (2) hot cell, and (3) glovebox atmospheres (to detect potential leakage of gaseous or other airborne radioactive material).

   Identify the means (e.g., radiation monitor and associated control room indications) provided for monitoring the potential effluent discharge paths and the plant environs for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents.

2. Clarify the statement in Section 7.7.1.2.1 regarding response of the radiation monitoring channels is compatible with the digital equipment in the HIPS equipment (i.e., Is the associated HIPS value “full-scale” and valid or invalid?) when subjected to radiation fields higher than the full-scale reading.

The information requested is necessary to support the following finding in Section 7.7 of NUREG-1537, Part 2:

- The systems should be designed to interface with either analog or digital computerized RCS [reactor control system] or RPS [reactor protection system] if applicable.

(b) Tritium measurement and monitored variable

SHINE Design Criterion 38, "Monitoring radioactivity releases," states that:

> Means are provided for monitoring the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material. Potential effluent discharge paths and the plant environs are monitored for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents.

SHINE FSAR Section 7.7.1.4.1, "Functionality," describes that the TPS process monitors the tritium concentration within the TPS gloveboxes. SHINE FSAR Table 7.7-1, includes tritium as a monitored material. Based on this information, it is not clear to the NRC staff what instruments or monitors will be used for measuring tritium concentrations within the TPS gloveboxes. Also, it is not clear to the NRC staff whether tritium concentrations within the TPS gloveboxes will be presented to the operator in the control console.

SHINE FSAR Section 7.7.4.1, "System Description," describes that CAMS would be used to measure tritium activity to alert personnel when airborne contamination is above preset limits. Also, SHINE FSAR Section 7.7.5.1, "System Description," describes that the effluent monitoring system includes capabilities to collect and analyze tritium. Based on this information, it is not clear to the NRC staff whether tritium measurements by TPS process monitors, CAMS, and effluent monitors would be transmitted to the Process Integrated Control System. Therefore, it is not clear to the NRC staff what information will be presented to the operator in the control room to monitor the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material.

In RAI 7-20 (a)(2) (ADAMS Accession No. ML21253A234), the NRC staff also requested identification of variables transmitted to the ESFAS, which may overlap with the information being requested in this RAI.

Update the SHINE FSAR to describe the radiation instrument and controls in place to measure tritium concentrations, as well as the information provided to operators in the control room related to tritium concentration for performing manual protective actions in accordance with SHINE Design Criterion 38.

(c) Setpoint Methodology and Calculations

NUREG-1537, Part 2, Section 7.7, describes, in part, that the instrument ranges should be sufficient to cover the expected range of variation of the monitored variable under the full range of normal operation and if assumed in the safety analysis report analysis, accident conditions. This section also describes that the sensitivity of each system should be commensurate with the precision and accuracy to which knowledge of the variable is required by analysis or design basis.

Subparagraph (c)(1)(ii)(A) of 10 CFR 50.36, "Technical specifications," describes that limiting safety system settings (LSSS) are settings for automatic protective devices related to those variables having significant safety functions. This requires that a LSSS is specified for a variable on which a safety limit has been placed, the setting must be chosen so that automatic protective action will correct the abnormal situation before a safety limit is exceeded.

SHINE FSAR Section 7.7.1.2.1 states, in part, that "Setpoints are selected based on analytical limits and calculated to account for known uncertainties in accordance with the setpoint determination methodology." In addition, SHINE FSAR Section 7.7.1.4.3, "Setpoints, Calibration and Surveillance," states, in part, that "Setpoints for safety-related process radiation monitors are selected based on analytical limits and calculated to account for known uncertainties in accordance with the setpoint determination methodology."

SHINE technical specification (TS) Table 3.7.1-a, "Safety-Related Radiation Monitoring Instruments," identifies the setpoints for the safety-related radiation monitors. However, the SHINE FSAR does not describe the methodology used to determine these setpoints. The SHINE FSAR Section 7.2.1 states that a setpoint methodology is used for establishing and calibrating setpoints for safety-related I&C functions. This FSAR section generally describes SHINE's setpoint methodology but lacks specificity in calculating setpoints for various types of instruments used in varying applications. The setpoints for protective function should be based on a documented analysis methodology that identifies assumptions and accounts for instrument uncertainties, such as environmental allowances and measurement computational errors associated with each element of the instrument channel.

1. Identify all **automatic protective actions** that are initiated based on a (radiation monitor related) setpoint other than those of TRPS and ESFAS (which are addressed by the response to RAI 7-20). The following additional questions apply to the non-TRPS/ESFAS setpoints.

2. Revise the SHINE FSAR to describe the setpoint methodology used to establish the setpoints or LSSS from the analytical limits for the variables monitored. The description of the setpoint methodology should include parameters typically consider instrument precision, sensitivity, accuracy, loop uncertainties, and computational errors.

3. Provide a definition of the equipment accuracy identified in SHINE FSAR Table 7.7-1 and that used in the setpoint methodology.

The information requested is necessary to support the following finding in Section 7.4 of NUREG-1537, Part 2:

- The protection channels and protective responses are sufficient to ensure that no safety limit, limiting safety system setting, or related limiting condition of operation discussed and analyzed in the SHINE FSAR will be exceeded. (Also, see RAI 7-20(f) in which the NRC staff requested information on the setpoint methodology used to establish the setpoints or LSSS from the analytical limits for the variables monitored by the TRPS and ESFAS.).

RAI 7-29 Safety-Related Process Radiation Monitors Design

NUREG-1537, Part 2, Section 7.7 describes, in part, that information should be provided for the NRC staff to evaluate the signal processing equipment, computer hardware and software that controls sampling, detection, signal processing and logic, power supplies, and actuation systems that accomplish a function for the system.

SHINE FSAR Section 7.7.1.1, "System Description," states, in part:

> Safety-related process radiation monitors provide input to the safety-related ESFAS or TRPS control systems. These components monitor for either fission products (via beta detection) or tritium. Beta detection radiation monitors are part of the ESFAS or TRPS. The type of safety-related process radiation monitor (fission product or tritium) is selected based on the location and identity of the radioactive material present. The ESFAS and TRPS process radiation monitors (beta detection) are intended to detect abnormal situations within the facility ventilation systems and provide actuation signals to the ESFAS controls. Safety-related tritium monitors are part of the TPS. The TPS monitors are installed within various portions of the TPS to detect potential tritium releases, provide actuation signals to the ESFAS controls, and provide interlock inputs to the TRPS controls.

SHINE FSAR Sections 7.7.1.3, "Design Bases," and 7.7.1.4, "Operation and Performance," describe design bases and operation and performance of the safety-related process radiation monitors. Based on the information in the SHINE FSAR, the NRC staff does not have a clear description of the radiation monitoring equipment to be installed in the facility (i.e., technology included).

Revise the FSAR to describe whether the safety-related process radiation monitors use analog or digital technology. If the safety-related process radiation monitors use digital technology (per NUREG-1537, Part 2, Section 7.7) describe how the hardware and software for these radiation monitors meet the guidelines of Institute of Electrical and Electronics Engineers (IEEE) Std. 7-4.3.2-1993, "IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations," and Regulatory Guide (RG) 1.152, Revision 1, "Criteria for Digital Computers In Safety Systems of Nuclear Power Plants," and software meets the guidelines of American National Standards Institute/American Nuclear Society (ANSI/ANS)-10.4-1987, "Guidelines for the Verification and

Validation of Scientific and Engineering Computer Programs for the Nuclear Industry."

The information requested is necessary to support the following finding in Section 7.7 of NUREG-1537, Part 2:

- The designs and operating principles of the instrumentation and control of the radiation detectors and monitors have been described, and have been shown to be applicable to the anticipated sources of radiation.

RAI 7-30 Safety-Related Process Radiation Monitors Design Measure

NUREG-1537, Part 2, Section 7.7 states that, "The systems and equipment should be designed for reliable operation in the environment in which they will function." This section also describes that consideration should be given to the need for single failure protection, seismic and environmental qualification protection, and diversity.

SHINE FSAR Section 7.7.1.4.2, "Reliability, Adequacy, and Timeliness," describes reliability for the safety-related process radiation monitors. SHINE FSAR Section 7.7.1.3, describes the design bases for the safety-related process radiation monitors, including single failure, independence, and redundancy.

(a) Single failure

SHINE FSAR Section 7.7.1.3.3, "Single Failure," describes that safety-related redundant monitors are used for locations requiring radiation monitoring, and for locations where spurious actuation of the process radiation monitor could significantly impact overall facility operation, a third sensing channel was added. Adding redundant monitors increases the reliability of the system. Further, SHINE FSAR Section 7.7.1.3.5, "Redundancy," describes how the system meets the single failure criterion by using redundant safety-related monitors. However, the FSAR does not describe how these monitors are assigned to each division of the ESFAS and TRPS.

1. Update the SHINE FSAR to demonstrate that single failures in the safety-related process radiation monitors do not result in loss of the protection or mitigation function.

2. Update the SHINE FSAR to identify radiation monitors that are only assigned to Division A for TRPS and ESFAS, as appropriate, as well as radiation monitors that include a third sensing division (Division C).

(b) Independence

SHINE FSAR Section 7.7.1.3.4, describes independence of the safety-related process radiation monitors. This section provides information about communication, physical, and electrical independence. SHINE FSAR Section 7.7.1.3.7, "Fire Protection," notes that physical separation is used to achieve separation of redundant sensors. This section also notes that wiring for redundant channels uses physical separation and isolation to provide

independence for circuits. However, the information in FSAR Sections 7.7.1.3.4 and 7.7.1.3.7 does not provide sufficient information for the NRC staff to assess how independence is implemented to prevent the failure of the safety-related process radiation monitors and provide reliable operation. The FSAR should describe how the safety-related process radiation monitors include electrical and communications independence both within the safety-related radiation monitoring channels and between the safety-related process radiation monitors and non-safety-related systems. For communication independence, the FSAR should demonstrate that credible failures such as a logical or software malfunction of the non-safety system would not affect the functions of the safety-related process radiation monitors.

Section 7.7.1.3.4 of the FSAR states that the safety-related process radiation monitors from separate divisions are physically separated from each other and independently powered from the associated UPSS division. However, the information provided is insufficient to evaluate how the safety-related process radiation monitors would be powered and how the system would be powered in case of a loss of power. The FSAR should describe electrical independence are used to maintain the independence of safety-related process radiation monitor circuits and equipment among redundant safety divisions or with non-safety systems so that the safety functions required during and following any analyzed accident can be accomplished.

Update the SHINE FSAR to explain how the safety-related process radiation monitors design implements communication and electrical independence to provide reliable operation.

(c) Defense-in-depth

NUREG-1537, Part 1, Section 7.1.2, “Design Criteria,” describes in part that the SAR should discuss diversity and redundancy of ICSs, and other defense-in-depth features.

Although the SHINE FSAR does not identify any SHINE Design Criterion or criterion for defense-in-depth, SHINE FSAR Section 7.7.1.3.1, “Design Bases Functions,” notes that radiation monitoring systems are provided for defense-in-depth. It is not clear to the NRC staff if other (non-safety-related) monitors are installed in certain areas, and therefore provide defense-in-depth to the safety-related radiation monitoring channels. Also, SHINE FSAR Sections 7.7.3.1 and 7.7.4.1 note that the RAMS and continuous air monitoring system CAMS provide defense-in-depth to alert personnel on the need to evacuate. Based on this information, it is not clear to the NRC staff whether the RAMS and CAMS are providing defense-in-depth to the safety-related radiation monitoring channels.

Confirm if only CAMS and RAMS provide defense-in-depth to safety-related process radiation monitors and provide a list of relevant information that would be transmitted to the operators.

Specifically, the information requested in parts (a) through (c) of RAI 7-30, above, is necessary to support the following evaluation findings in Section 7.7 of NUREG-1537, Part 2:

- The systems and equipment should be designed for reliable operation in the environment in which they will function.

- The systems should be designed not to fail or operate in a mode that would prevent the RPS from performing its safety function, or prevent safe reactor shutdown.

RAI 7-31 Safety-Related Process Radiation Monitors Logic Processing

SHINE FSAR Section 7.7.1.3.4, describes that the safety-related process radiation monitors provide analog signals to the TRPS and ESFAS. Further, SHINE FSAR Section 7.7.1.4.1, describes the functionality of the safety-related process radiation monitors, which transmits signals to the TRPS to actuate safety functions and the ESFAS to provide an actuation signal when radiation levels exceed pre-determined limits. SHINE FSAR Figures 7.4-1, "TRPS Logic Diagrams," and 7.5-1, "ESFAS Logic Diagrams," in the SHINE FSAR show the logic diagrams for the TRPS and ESFAS, respectively. While these figures show the actuation signal, the logic to process the analog signals and generate the actuation signal is not described.

Update the SHINE FSAR to describe where the logic and processing of the radiation monitor signals are performed, as well as identify what signals are transmitted to the TRPS and ESFAS.

The information requested is necessary to support the following finding in Section 7.7 of NUREG-1537, Part 2:

- The systems should be designed to interface with either analog or digital computerized RCS or RPS if applicable.

RAI 7-32 Effluent Monitoring System

The SHINE facility includes a SRMS to monitor effluents in the facility. This system, as described in SHINE FSAR Section 7.7.5, "Effluent Monitoring," includes the carbon delay bed effluent monitor (CDBEM), which monitors for noble gases at the exhaust of the process vessel vent system (PVVS) carbon delay beds to provide information about the health of the PVVS carbon delay beds and to provide the ability to monitor the safety-related exhaust point effluent release pathway when it is in use. SHINE FSAR Section 7.7.5.2.1, "Applicable Design Criteria," states, in part, that "The SRMS units are designed to operate under normal facility conditions and to detect radiation that may be indicative of anticipated transients or design basis accidents." However, the SHINE FSAR does not clearly describe what information will be presented to the operator for normal operation of the facility and if any manual protective actions are required based on detected radiation levels by the SRMS units that may be indicative of anticipated transients or design basis accidents. Also, the SHINE FSAR refers to but does not fully describe or explain what is the "safety-related exhaust point

effluent release pathway" and when it is used. SHINE FSAR Section 7.7.5.1, "System Description," notes that the CDBEM does not perform any accident mitigation or personnel protection, and instead it is used to monitor compliance with regulatory limits.

Update the SHINE FSAR to describe information necessary for normal operation of the facility and if any manual protective actions are required based on detected radiation levels by the SRMS units that may be indicative of anticipated transients or design basis accidents.

The information requested is necessary to support the following finding in Section 7.6 of NUREG-1537, Part 2:

- The outputs and display devices showing reactor nuclear status should be readily observable by the operator while positioned at the reactor control and manual protection systems.

RAI 7-33 Safety-Related Process Radiation Monitors Failure Modes

NUREG-1537, Part 2, Section 7.7, describes, in part, that the systems should be designed not to fail or operate in a mode that would prevent the RPS from performing its safety function, or prevent safe reactor shutdown.

SHINE FSAR Section 7.7.1.3.3, describes how the safety-related process radiation monitors design addresses single failure. This section describes that no single failure of a detector, control division, or power division will prevent the safety-related system from performing its safety function. However, the SHINE FSAR does not describe assessments performed to identify the potential failures and the associated analyses that confirm these failures would not "prevent the RPS from performing its safety function, or prevent safe reactor shutdown" or initiate a condition not considered in the accident analyses.

1. Update the SHINE FSAR to include a summary description of the potential safety-related process radiation monitors failures identified and confirm that they would not affect the operation of the TRPS and ESFAS, as requested by RAI 7-12. (Note: An audit can be used to confirm the description).

2. Update the SHINE FSAR to include a summary description of the fail-safe state of the safety-related radiation process monitors when the system loses electrical power and when other known failures manifest. (Note: An audit can be used to confirm the description).

The information requested is necessary to support the following finding in Section 7.7 of NUREG-1537, Part 2:

- The systems should be designed not to fail or operate in a mode that would prevent the RPS from performing its safety function, or prevent safe reactor shutdown.

RAI 7-34 Equipment Qualification

NUREG-1537, Part 2, Section 7.7, “Radiation Monitoring Systems,” describes that the systems and equipment should be designed for reliable operation in the environment in which they will function.

SHINE Design Criterion 13, “Instrumentation and controls,” states, in part, that instrumentation is provided to monitor variables and systems over the expected range of variation of the monitored variable during normal and transient operation.

SHINE FSAR Section 7.7.1.3.2, “Operating Conditions,” describes the environmental conditions for the different areas within the SHINE facility. However, this FSAR section does not include information for the NRC staff to confirm that the equipment environmental test results envelop the environmental conditions identified in FSAR Tables 7.2-2 through 7.2-5.

In addition, SHINE FSAR Section 7.7.1.3.7, “Fire Protection,” describes that the connection from the radiation monitoring components to the ESFAS or TRPS have certifications that demonstrate the ability to inhibit the propagation of flame in the event of a fire. SHINE FSAR Section 7.7.1.3.8, “Natural Phenomena Hazards and Dynamic Effects,” describes that process radiation monitors are Seismic Category I, designed in accordance with Section 8 of IEEE Std. 344-2013, “IEEE Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations.” SHINE FSAR Section 7.7.5.3.3, “Quality,” describes that the American National Standards Institute (ANSI) N13.1-1999, “Sampling and Monitoring Release of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities,” was applied to the design of the facility effluent monitors. However, the FSAR does not include information of how the radiation monitoring system meets these requirements.

1. Confirm that the radiation monitors equipment has been tested and qualified for the environmental conditions at the installed locations over the lifetime of the facility and/or describe the testing and qualification process.

2. Update the SHINE FSAR to include a summary explanation of how the radiation monitors meet SHINE-specific requirements for seismic, electrical, and other conditions anticipated within the facility.

The information requested is necessary to support the following finding in Section 7.7 of NUREG-1537, Part 2:

- The systems and equipment should be designed for reliable operation in the environment in which they will function.

RAI 7-35 The basis for the **Technical Specifications** in the FSAR

NUREG-1537, Part 1, Chapter 7, “Instrumentation and Control Systems,” states:

- In this chapter, the applicant should discuss … the bases of technical specification limiting safety system settings (LSSSs), limiting conditions of operation (LCOs), and surveillance requirements for the I&C systems....

NUREG-1537, Part 2, Section 7.7, “Radiation Monitoring Systems,” describes that the systems and equipment should be readily tested and capable of being accurately calibrated. This section also describes that the bases of TSs, including surveillance tests and intervals, should be sufficient to ensure that the systems will be operable and will perform their designed functions. (Please identify the FSAR section that includes this information. See questions 1 and 4 below.)

Subparagraph (c)(3) of 10 CFR 50.36 states: “Surveillance requirements [(SRs)] are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions for operation will be met.” (Identify the FSAR section that describes how the SRs for the radiation monitoring systems ensure the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions for operation will be met. See questions 1 and 4 below.)

SHINE FSAR Section 7.7.5.4.1, “Technical Specifications,” states, in part, that “[c]ertain material in this section provides information that is used in the technical specifications,” but does not provide additional specificity of how SR frequencies, completion times, and actions in TS Table 3.7.1-a ensure radiation levels within the facility and radiation released to the environment will be within allowable limits when channels are inoperable. Section 7.7.5.4.1 states, in part, that “significant material is also applicable to, and may be referenced by, the bases that are described in the technical specifications.” Information in the TS bases should summarize information provided in the FSAR. Information in the TS bases may provide details to partially address the questions below. If so, this information should be incorporated into the FSAR, as appropriate.

SHINE FSAR Section 7.7.1.2.1, “Instrumentation and Controls,” describes that the safety-related process radiation monitor setpoints were selected based on analytical limits and the monitors are periodically functionally tested and maintained. Further, SHINE FSAR Section 7.7.1.4.3, “Setpoints, Calibration and Surveillance,” notes that these monitors are tested periodically in accordance with SHINE TS to verify operability, and that they are calibrated using commercial radionuclide standards. SHINE TS SR 3.7.1 (Revision 4) defines the frequency for testing the safety-related radiation monitors, and SHINE TS SR 3.7.2 defines the frequency for testing the effluent monitors.

In addition, the TS bases describes that the scope of SHINE TS LCO 3.7.1 begins at the radiation monitoring input devices, includes the associated safety function modules (SFMs), and extends to the inputs to the scheduling, bypass,

and voting modules (SBVMs) or scheduling and bypass modules (SBMs). However, SHINE TS LCOs 3.2.1 and 3.2.2 identify the SRs for the SFM, SBVM or SBM for the TRPS and ESFAS, respectively. Based on this information these surveillances may overlap certain components, even though their surveillance frequency is different. The SHINE FSAR does not include sufficient information for the NRC staff to understand how these systems will be tested and maintained to ensure operability.

It is also not clear how the monitored locations in SHINE TS Table 3.7.1-a correlates to all of the 24 safety related process monitors listed in Table 7.7-1. It is also not clear how certain actions for multiple inoperable channels, such as damper closure, to compensate for the systems inability to automatically initiate the associated protective action describe in FSAR Sections 7.7.1.3.1 and 7.7.1.4.1.

1. Per Section 14.1 of the FSAR, “Technical Specifications,” SHINE states the TS were developed following the format and content guidance of ANSI/ANS-15.1-2007. Explain the reason for not having checks and calibrations in the TS for CAMS, RAMS, and effluent monitors (described in Table 7.7-2 and 7.7-3 in the FSAR) as established in Section 4.7 of ANSI/ANS-15.1, 2007, “The Development of Technical Specifications for Research Reactors,” provides guidance for radiation monitoring systems and effluents.

2. Describe how the SHINE FSAR Table 7.7-1, “Safety-Related Process Radiation Monitors,” corresponds to SHINE TS Table 3.7.1-a, “Safety-Related Radiation Monitoring Instruments.” Update the SHINE FSAR and/or TS to ensure consistent labeling for each radiation monitor.

3. Update the SHINE FSAR to describe how the surveillance frequencies were selected, considering how the whole instrument channel would be surveilled to ensure the continued operability of the radiation monitors when required.

4. Update the SHINE FSAR to explain how the scope of SHINE TS LCOs 3.2.1 and 3.2.2 and the scope of SHINE TS LCO 3.7.1 demonstrate operability of the radiation monitors.

The information requested is necessary to support the following finding in Section 7.7 of NUREG-1537, Part 2:

- The bases of technical specifications, including surveillance tests and intervals, should be sufficient to ensure that the systems will be operable and will perform their designed functions.