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

June 2, 2021

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO ACCIDENT ANALYSIS, CRITICALITY SAFETY, AND ELECTRICAL POWER SYSTEMS (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Accession No. ML20357A084), December 15, 2020 (ADAMS 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." Additionally, by letter dated January 29, 2021 (ADAMS Accession No. ML21029A038), SHINE submitted a related request for exemption from the monitoring requirements of 10 CFR 70.24, "Criticality accident requirements," paragraph (a).

During the NRC staff's review of SHINE's operating license application and associated exemption request, 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 and associated exemption request, submitted in connection with the operating license application, and prepare a safety evaluation report and exemption document. The specific chapters of the SHINE operating license application covered by this RAI includes the following:

- Chapter 6, "Engineered Safety Features"
- Chapter 8, "Electrical Power Systems"
- Chapter 13, "Accident Analysis"

It is requested that SHINE provide responses to the enclosed RAI within 30 days from the date of this letter. 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 and request for exemption from the requirements of 10 CFR 70.24(a).

As the NRC staff continues its review of SHINE's operating license application and associated exemption request, 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 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Sincerely,

Signed by Lynch, Steven
on 06/02/21

Steven T. Lynch, Senior Project Manager
Non-Power Production and Utilization Facility
Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Docket No. 50-608
Construction Permit No. CPMIF-001

Enclosure:
As stated

cc: See next page

cc:

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, LLC
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

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

Christopher Landers
Director, Office of Conversion
National Nuclear Security Administration,
NA 23
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Mark Paulson
Supervisor
Radiation Protection Section
Wisconsin Department of Health Services
P.O. Box 2659
Madison, WI 53701-2659

Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
Dept. of Materials Science and Engineering
University of Maryland
4418 Stadium Drive
College Park, MD 20742-2115

Mark Freitag
City Manager
P.O. Box 5005
Janesville, WI 53547-5005

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO ACCIDENT ANALYSIS, CRITICALITY SAFETY, AND ELECTRICAL POWER SYSTEMS (EPID NO. L-2019-NEW-0004) DATED: June 2, 2021

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ADAMS Accession No.: ML21145A060 **NRR-088**

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REQUEST FOR ADDITIONAL INFORMATION

REGARDING OPERATING LICENSE APPLICATION FOR

SHINE MEDICAL TECHNOLOGIES, LLC

CONSTRUCTION PERMIT NO. CPMIF-001

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 Accession No. ML20357A084), December 15, 2020 (ADAMS 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." Additionally, by letter dated January 29, 2021 (ADAMS Accession No. ML21029A038), SHINE submitted a related request for exemption from the monitoring requirements of 10 CFR 70.24, "Criticality accident requirements," paragraph (a).

During the NRC staff's review of SHINE's operating license application and associated exemption request, 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 (FSAR) and associated exemption request, submitted in connection with the operating license application, and prepare a safety evaluation report and exemption document. The specific chapters of the SHINE operating license application covered by this RAI includes the following:

- Chapter 6, "Engineered Safety Features"
- Chapter 8, "Electrical Power Systems"
- Chapter 13, "Accident Analysis"

Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE operating license application, which describes the SHINE irradiation facility, including the irradiation units (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."

Responses to the following RAI are needed to continue the review of the SHINE operating license application and associated exemption request.

Chapter 6 – Engineered Safety Features

The following regulatory requirements and guidance are applicable to RAIs 6b.3-21 through 6b.3-27:

Paragraph (b) of 10 CFR 50.34, "Contents of applications; technical information," states, in part, that "[t]he final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility as a whole…."

Furthermore, 10 CFR 50.34(b)(2) states, in part, that FSAR shall include "[a] description and analyses of the structures, systems and components of the facility, with emphasis upon the performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished…."

The ISG augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part, that the NRC staff is to determine that "the applicant has designed a facility that will provide adequate protection against criticality hazards related to the storage, handling, and processing of licensed materials. The facility design must adequately protect the health and safety of workers and the public during normal operations and credible accident conditions from the accidental criticality risks in the facility. It should also protect against facility conditions that could affect the safety of licensed materials and thus present an increased risk of criticality or radiation release."

RAI 6b.3-21 By letter dated January 29, 2021 (ADAMS Accession No. ML21029A102), SHINE stated in its response to RAI 13-9(a) that the criticality safety program (CSP) is applied to nuclear processes in the irradiation facility, excluding the target solution vessels (TSV). SHINE further stated in its response to RAI 13-9(a) that Chapter 6, "Engineered Safety Features," of the FSAR and Section 5.5.7, "Nuclear Criticality Safety," of the technical specifications (TSs) have been revised to identify the 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," requirements the CSP meets. However, the title of Section 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," of the FSAR suggests that the CSP may only apply to the SHINE radioisotope production facility and not the SHINE irradiation facility.

Clarify the applicability of the SHINE CSP within the SHINE facility, addressing the apparent inconsistency suggested by the title of Section 6b.3 of the FSAR, updating the FSAR as necessary. Specifically, revise the FSAR to clarify which processes of the SHINE facility, including processes of the radioisotope production facility and irradiation facility, the CSP applies.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE's nuclear criticality safety program provides reasonable assurance of the protection of the public health and safety, including that of workers.

RAI 6b.3-22 Section 6b.3 of the FSAR states that the CSP meets the criticality safety requirements of 10 CFR 70.61, "Performance requirements," paragraphs (b) and

(d). Section 6b.3 further states that SHINE processes generally comply with the double contingency principle. By letter dated December 10, 2020, SHINE stated in its response to RAI 6b.3-3 that the term "unlikely" – in the context of the double contingency principle – is used in its plain meaning as interpreted by the key stakeholders involved in the evaluation process, and that the conditions of a system, its construction, and the event sequence are considered when determining whether a process upset can qualitatively be considered unlikely. However, inconsistent with the statement above, Table 13a2.1-2, "Risk Matrix," of the FSAR defines "unlikely" as events with a frequency of occurrence between 10^{-4} and 10^{-5} events per year. The NRC staff notes that Section 13a2, "Irradiation Facility Accident Analysis," of the FSAR states that the SHINE Safety Analysis (SSA) methodology is applied to both the irradiation facility and the radioisotope production facility for consistency of the safety analysis for the entire SHINE facility, which includes postulated criticality events.

Discuss any terms (e.g., unlikely, credible, etc.) that have multiple meanings, interpretations, or applications amongst the double contingency principle, 10 CFR 70.61(b), and 10 CFR 70.61(d) in the application. Clarify how such terms are used and applied in the SHINE application.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE will have the capability to perform adequate safety analyses of all production processes that will be conducted in the facility.

RAI 6b.3-23 By letter dated December 10, 2020, SHINE committed in its response to RAI 6b.3-4 to follow the reporting requirements of 10 CFR Part 70, Appendix A, "Reportable Safety Events," for nuclear criticality safety (NCS)-related events. However, the reporting requirements of 10 CFR Part 70, Appendix A, heavily reference items relied on for safety (IROFS) and the integrated safety analysis (ISA).

Given that SHINE does not have IROFS or an ISA, describe how the reporting requirements of 10 CFR Part 70, Appendix A, will be implemented.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE's nuclear criticality safety program provides reasonable assurance of the protection of the public health and safety, including that of workers.

RAI 6b.3-24 Section 6b.3.1.8, "Criticality Safety Nonconformances," of the FSAR states that SHINE commits to following the reporting requirements of 10 CFR Part 70, Appendix A, and 10 CFR 70.50, "Reporting Requirements," for NCS-related events. However, Section 5.8.3, "Additional Event Reporting Requirements," of the TSs states that events which meet the reporting requirements of 10 CFR 70.50 and paragraphs (a)(1) through (a)(3), (b)(3), or (c) of 10 CFR Part 70, Appendix A, will be reported to the NRC, which includes events other than criticality events.

Clarify whether SHINE commits to following the requirements of 10 CFR Part 70, Appendix A, and 10 CFR 70.50 for events other than criticality events.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE's nuclear criticality safety program provides reasonable assurance of the protection of the public health and safety, including that of workers.

RAI 6b.3-25 Section 6b.3.1.8 of the FSAR states that SHINE commits to following the reporting requirements of 10 CFR Part 70, Appendix A. However, in describing the events to be reported to the NRC under 10 CFR Part 70, Appendix A, Section 5.8.3 of the TSs includes only those events that meet the criteria of paragraphs of 10 CFR Part 70, Appendix A, paragraphs (a)(1) through (a)(3), (b)(3), or (c).

Clarify whether SHINE commits to following the reporting requirements of 10 CFR Part 70, Appendix A, paragraphs (a)(4), (b)(1), (b)(2), and (b)(4).

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE's nuclear criticality safety program provides reasonable assurance of the protection of the public health and safety, including that of workers.

RAI 6b.3-26 Section 5.8.3 of the TSs states that events which meet the reporting requirements of 10 CFR 70.50, 10 CFR 70.52, "Reports of accidental criticality," or paragraphs (a)(1) through (a)(3), (b)(3), or (c) of 10 CFR Part 70, Appendix A, will be reported to the NRC. By letter dated December 10, 2020, SHINE stated in its response to RAIs 6b.3-4 and 6b.3-5 that Section 5.8.2, "Special Reports," of the TSs applies to criticality safety. Section 5.8.2(h) of the TSs describes a criterion for submitting a report to the NRC for "[a]n observed inadequacy in the implementation of administrative or procedural controls such that the inadequacy causes or could have caused the existence or development of an unsafe condition with regard to operations." However, it is not clear how "observed inadequac[ies] in the implementation of administrative or procedural controls" will be applied to passive and active engineered controls. It is also not clear what conditions would be considered an "unsafe condition."

a. Discuss the method in which events are evaluated to determine whether a report to the NRC is required for events involving active or passive engineered controls with respect to Sections 5.8.2 and 5.8.3 of the TSs.

b. Discuss how the failure or degradation of the reliability management measures applied to an active or passive engineered control is evaluated against the method described in part (a) of this RAI.

c. Provide information as to what constitutes an "unsafe condition" with respect to evaluating an event for reportability (e.g., the failure of any control, the failure of all controls, failures beyond a certain risk threshold, unanalyzed/improperly analyzed conditions, etc.).

For parts (a) through (c) of this RAI, update the FSAR, TSs, or TS bases, as may be appropriate.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE's nuclear criticality safety program provides reasonable assurance of the protection of the public health and safety, including that of workers.

RAI 6b.3-27 By letter dated December 10, 2020, SHINE stated in its response to RAIs 6b.3-4 and 6b.3-5 that Section 5.8.2 of the TSs applies to criticality safety. Section 5.8.2(e) of the TSs describes a criterion for submitting a report to the NRC for "[a] Safety System component malfunction that renders or could render the Safety System incapable of performing its intended safety function. If the malfunction or condition is caused by maintenance, then no report is required." However, Section 5.8.3 of the TSs states that events that meet the reporting requirements of 10 CFR Part 70, Appendix A, and 10 CFR 70.50 will be reported to the NRC, which includes failures and degradations due to improper maintenance.

Clarify how controls that are failed or degraded due to improper maintenance would be evaluated to determine whether a report to the NRC is required.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE's nuclear criticality safety program provides reasonable assurance of the protection of the public health and safety, including that of workers.

Criticality Accident Alarm System Exemption Request

The following regulatory requirements and guidance are applicable to RAIs CE-1 through CE-5:

Paragraph (a) of 10 CFR 70.24, "Criticality accident requirements," requires, in part, that "[e]ach licensee authorized to possess special nuclear material [SNM] in a quantity exceeding 700 grams of contained uranium-235, 520 grams of uranium-233, 450 grams of plutonium, 1,500 grams of contained uranium-235 if no uranium enriched to more than 4 percent by weight of uranium-235 is present, or 450 grams of any combination thereof … shall maintain in each area in which such licensed [SNM] is handled, used, or stored …," a criticality accident alarm system (CAAS).

The ISG augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part, that the NRC staff is to determine that "the applicant has designed a facility that will provide adequate protection against criticality hazards related to the storage, handling, and processing of licensed materials. The facility design must adequately protect the health and safety of workers and the public during normal operations and credible accident conditions from the accidental criticality risks in the facility. It should also protect against facility conditions that could affect the safety of licensed materials and thus present an increased risk of criticality or radiation release."

RAI CE-1 Enclosure 1 to SHINE's exemption request states that each neutron flux detection system (NFDS) is able to detect the minimum accident of concern if a criticality were to occur in the TSV dump tank, which would be evident to operators through the process integrated control system due to an increased count rate on the detectors. Enclosure 1 also states that the high-high TSV dump tank level instrumentation can detect a criticality accident in the TSV off-gas system (TOGS) and would alert personnel to take appropriate actions. However, no information is provided as to how the NFDS and high-high TSV dump tank level instrumentation are used for emergency response activities.

Discuss whether and how (if applicable) the NFDS and high-high TSV dump tank level instrumentation are relied upon or used for emergency response activities with respect to inadvertent criticality. State how the evidence of criticality (e.g., increased count rate, etc.) from these systems is available to personnel.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE's nuclear criticality safety program provides reasonable assurance of the protection of the public health and safety, including that of workers.

RAI CE-2 Enclosure 1 to SHINE's exemption request states that a criticality accident in the IU cells would produce radiation similar to that of normal operation of the subcritical assembly and, therefore, does not pose any additional risk to workers or the public. However, the exemption request does not address the potential need for personnel to enter the IU cells for activities such as maintenance.

Discuss any potential need for personnel to enter the IU cells (e.g., preventive maintenance, corrective maintenance, etc.), and provide a justification as to why CAAS coverage is not necessary for such situations.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE will develop, implement, and maintain an acceptable criticality accident alarm system.

RAI CE-3 Enclosure 1 to SHINE's exemption request states that material in the material staging building (MATB) meets the requirements of 10 CFR 71.15, "Exemption from classification as fissile material," paragraph (a), and therefore, does not pose a credible criticality risk based on the incredibility argument provided in Section 4.1.1, "10 CFR 71.15(a): Individual Package Containing 2 g or Less Fissile Material," of NUREG/CR-7239, "Review of Exemptions and General Licenses for Fissile Material in 10 CFR 71." However, the incredibility argument provided in Section 4.1.1 of NUREG/CR-7239 assumes a limited volume of 84.853 cubic meters (i.e., a cubic array of approximately 4.4 meters per side) based on what is considered feasible for transport applications, and it is not clear whether the MATB is limited to that same volume.

a. Provide information to demonstrate that criticality is not credible in the MATB, including a discussion of the process upsets and human errors necessary for a criticality to occur.

b. State whether material considered to be exempt from classification as fissile material per 10 CFR 71.15(a) will be stored with material considered to be exempt from classification as fissile material per 10 CFR 71.15(c), or if they will be segregated. Discuss any measures used to segregate such packages, if applicable.

c. State whether material in the MATB will be stored in compliance with 10 CFR 71.15, or merely in a state similar to what is required for compliance with 10 CFR 71.15.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE's conduct of operations will be based on nuclear criticality safety technical practices, which will ensure that fissile material will be possessed, stored, and used safely.

RAI CE-4 Section 6b.3.3.2, "Criticality Accident Alarm System Design," of the FSAR states, in part that: "[f]or maintenance or other conditions which would disable multiple detectors or the logic unit, administrative controls are used to secure the movement of fissile material and limit personnel access to the affected areas until alarm system coverage is restored. These administrative controls are specific to the various processes within the RPF [radioisotope production facility] and include short time allowances to restore the system to full operation in lieu of immediate process shutdown in areas where process shutdown creates additional risk to personnel." The requirements of 10 CFR 70.24 necessitate that CAAS coverage be maintained where more than a threshold quantity of SNM is handled, used, or stored; and that all personnel be evacuated in the event of a CAAS alarm actuation. Compliance with 10 CFR 70.24, therefore, generally necessitates that CAAS coverage be maintained, even during maintenance activities, unless one or more of the following conditions are met:

1) less than the threshold quantities of SNM described in 10 CFR 70.24(a) are present;

2) all personnel have been evacuated to an area of safety in accordance with 10 CFR 70.24(a)(3); and/or

3) compensatory measures are in place that provide CAAS coverage consistent with the requirement of 10 CFR 70.24(a)(1) (e.g., use of non-CAAS detectors with audible alarms for personnel remaining in or entering the area without CAAS coverage).

However, it is not clear how SHINE's use of administrative controls to "secure the movement of fissile material and limit personnel access" is consistent with 10 CFR 70.24 during maintenance or other conditions which would disable

multiple detectors or the logic unit (i.e., lapses in CAAS coverage) for areas requiring CAAS coverage outside of the IU cells and MATB.

Discuss how compliance with 10 CFR 70.24 is ensured during maintenance or other conditions which would disable multiple detectors or the logic unit (i.e., lapses in CAAS coverage), or request an exemption from the requirements of 10 CFR 70.24 in accordance with 10 CFR 70.17, “Specific exemptions,” for such situations.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE will develop, implement, and maintain an acceptable criticality accident alarm system.

RAI CE-5 Paragraph (b)(1) of 10 CFR 70.24 requires that each licensee authorized to possess specified amounts of special nuclear material to “[p]rovide the means for identifying quickly which individuals have received doses of 10 rads or more.” Section 6b.3.1.8.1, “Planned Response to Criticality Accidents,” of the FSAR states that SHINE maintains an emergency plan, which includes the planned response to criticality accidents. Section 8.6.2, “Assembly,” of the SHINE Emergency Plan states that SHINE has the capability of quickly identifying individuals that may have received a dose of 10 rads or more via the electronic dosimeters worn by personnel in the radiological controlled area (RCA). However, no information is provided as to whether SHINE has the capability to quickly identify individuals that may have received a dose of 10 rads or more outside of the RCA consistent with 10 CFR 70.24(b)(1).

Discuss the method in which SHINE quickly identifies individuals that have received a dose of 10 rads or more outside of the RCA, or clarify that it is not credible for individuals outside of the RCA to receive a dose of 10 rads or more due to a criticality accident.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE’s nuclear criticality safety program provides reasonable assurance of the protection of the public health and safety, including that of workers.

Chapter 8 – Electrical Power Systems

On January 29, 2021 (ADAMS Accession No. ML21029A103), SHINE provided responses to RAIs related to its electrical power systems. In RAI 8-3 the NRC staff requested SHINE to describe the standards and/or methodologies used to perform maintenance, testing, installation, and qualification for the safety-related batteries in the direct current (DC) system used in the uninterruptible electrical power supply system (UPSS). In response to RAI 8-3 (provided in the response to RAI 8-1), SHINE provided detailed descriptions of the design, testing, and installation of the safety-related equipment within the UPSS. SHINE stated that it will follow applicable portions of Institute of Electrical and Electronics Engineers (IEEE) Standard 384-2008, "Standard Criteria for Independence of Class 1E Equipment and Circuits," to ensure independence of safety-related electrical equipment. For the design of UPSS batteries and battery chargers, SHINE stated that it will use applicable portions of IEEE Standard 946-2004, "IEEE Recommended Practice for the Design of DC Auxiliary Systems for Generating Systems." For installation of the batteries and battery chargers SHINE stated that it will use applicable portions of IEEE Standard 484-2002, "IEEE Recommended Practice for Installation Design and Installation of Vented Lead-Acid Batteries for Stationary Applications." SHINE further stated that applicable portions of IEEE Standard 450-2010, "IEEE Recommended Practice for Maintenance, Testing, and Replacement of Vented Lead-Acid Batteries for Stationary Applications," will be used for the testing of batteries.

The NRC staff reviewed the applicable portions of each of the standards mentioned above for verification that the referenced portions are sufficient for meeting Criterion 27, "Electrical power systems," and Criterion 28, "Inspection and testing of electrical power systems," of SHINE's design criteria. However, it is not clear to the NRC staff how SHINE will be qualifying safety-related electrical equipment consistent with Criterion 4, "Environmental and dynamic effects," of SHINE's design criteria, which states that "[s]afety-related SSCs [structures, systems, and components] are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility."

The following regulatory requirements are applicable to RAIs 8-1 through 8-7:

Paragraph 50.34(b) of 10 CFR states, in part, that the final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole. As part of presenting its design bases, SHINE has established the following principal design criteria relevant to its electrical power systems:

- <u>Criterion 4 – Environmental and dynamic effects</u>

  Safety-related SSCs are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility.

- Criterion 27 - Electric power systems

  An on-site electric power system and an off-site electric power system are provided to permit functioning of safety-related SSCs. The safety functions are to provide sufficient capacity and capability to assure that:

  1) target solution design limits and primary system boundary design limits are not exceeded as a result of anticipated transients, and

  2) confinement integrity and other vital functions are maintained in the event of postulated accidents.

  The on-site uninterruptible electric power supply and distribution system has sufficient independence, redundancy, and testability to perform its safety functions assuming a single failure.

  Provisions are included to minimize the probability of losing electric power from the uninterruptible power supply as a result of or coincident with, the loss of power from the off-site electric power system.

- Criterion 28 - Inspection and testing of electric power systems

  The safety-related electric power systems are designed to permit appropriate periodic inspection and testing of important areas and features, such as wiring, insulation, connections, and switchboards, to assess the continuity of the systems and the condition of their components. The systems are designed with a capability to test periodically:

  1) the operability and functional performance of the components of the systems, such as on-site power sources, relays, switches, and buses; and

  2) the operability of the systems as a whole and, under conditions as close to design as practical, the full operation sequence that brings the systems into operation, including operation of applicable portions of the protection system, and the transfer of power among the on-site and off-site power supplies.

Paragraph 50.34(b)(2) of 10 CFR requires a description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, 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.

Paragraph 50.34(b)(2)(ii) of 10 CFR states, in part, that for facilities other than nuclear reactors, such items as the…electrical systems…shall be discussed insofar as they are pertinent.

RAI 8-8 In response to RAI 8-4, SHINE stated, in part, that "[s]afety-related SSCs associated with the electrical power systems are located in a mild environment, are not subject to harsh environmental conditions during normal operation or transient conditions and have no significant aging mechanisms." SHINE uses portions of IEEE Standard 323-2003, "IEEE Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations," for the qualification of safety-

related electrical equipment. In addition, SHINE uses IEEE Standard 344-2013, “IEEE Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations,” for the seismic qualification of safety-related electrical equipment.

The NRC staff recognizes that IEEE Standard 323-2003 provides information on the methodology to perform environmental qualification of safety-related electrical equipment, but does not provide specific details for the environmental qualification of batteries or battery chargers. The NRC staff notes that standards are available for such qualification, such as IEEE Standard 535, “IEEE Standard for Qualification of Class 1E Lead Storage Batteries for Nuclear Power Generating Stations,” for batteries and IEEE Standard 650, “IEEE Standard for Qualification of Class 1E Static Battery Charges and Inverters for Nuclear Power Generating Stations,” for battery chargers.

Provide the standards or methodology that will be used for the qualification of the UPSS safety-related systems, such as the batteries and the battery charger.

Consistent with the evaluation findings in Chapter 8 of NUREG-1537, Part 2, this information is necessary for the NRC staff to determine that design bases and functional characteristics of the SHINE electrical power systems are capable of providing the necessary range of safety-related services.

RAI 8-9 In response to RAI 8-1, SHINE stated that it follows specific sections of IEEE standards to meet SHINE’s facility-specific Design Criteria 4, 27, and 28. The specific portions of the standards used by SHINE are for the design, qualification, testing, installation, and maintenance of safety related electrical equipment. For example, SHINE states that “[t]he UPSS batteries are maintained in accordance with Section 5 of IEEE Standard 450-2010, ‘IEEE Recommended Practice for Maintenance, Testing, and Replacement of Vented Lead-Acid batteries for Stationary Applications.’” SHINE only commits to Section 5 of IEEE Standard 450-2010. The NRC staff notes that compliance with other sections of the standard may be important for maintenance of the SHINE batteries. For example, Section 6 of IEEE Standard 450-2010 covers test schedules; Section 7 provides procedures for battery testing, etc. SHINE also limits the application of IEEE standards to certain sections without providing justification regarding other potentially applicable and relevant sections of the same standards. The following table provides the list of IEEE standards and specific sections to which SHINE commits to implement related to its electrical power systems. This table also includes relevant IEEE standard sections that could be applicable to meet SHINE’s facility-specific design criteria.

IEEE Standards Used in the Design of SHINE's Emergency Electrical Power Systems		
IEEE Standard	**Standard Sections Committed to by SHINE**	**Potentially Applicable Standard Sections not Committed to by SHINE (Relevant SHINE Design Criteria)**
IEEE Standard 946-2004, "IEEE Recommended Practice for the Design of DC Auxiliary Systems for Generating Systems"	• 5.2 • 6.2 • 6.5 • 7.1 • 7.3 • Table 2 of Section 7.4 • 7.6 • 7.9	The following standard sections are from IEEE Standard 946-2020, "IEEE Recommended Practice for the Design of DC Power Systems for Stationary Applications": • 8, "Distribution System" (Criterion 27) • 9, "DC Power System Instrumentation, Controls, and Alarms" (Criterion 27) • 10, "Protection Against Electrical Noise, Lightning, and Switching Surges" (Criterion 27)
IEEE Standard 344-2013, "IEEE Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations"	• 8 • 9.3	• 4, "General Discussion of Earthquake Environment and Equipment Response" (Criterion 4) • 11, "Documentation" (Criterion 4)
IEEE Standard 485-2010, "IEEE Recommended Practice for Sizing Lead-Acid Batteries for Stationary Applications"	• 6.1.1 • 6.2.1 • 6.2.2 • 6.2.3 • 6.2.4 • 6.3.2 • 6.3.3	• 4, "Defining Loads" (Criterion 27) • 5, "Cell Selection" (Criterion 27)
IEEE Standard 450-2010, "IEEE Recommended Practice for Maintenance, Testing, and Replacement of Vented Lead-Acid Batteries for Stationary Applications"	• 5	• 6, "Test Schedule" (Criterion 28) • 7, "Procedure for Battery Tests" (Criteria 4, 27, and 28) • 8, "Battery Replacement Criteria" (Criteria 4, 27, and 28) • 9, "Records" (Criterion 4 and 28)
IEEE Standard 484-2002, "IEEE Recommended Practice for Installation Design and Installation of Vented Lead-Acid Batteries for Stationary Applications"	• 5 • 6	• 7, "Records" (Criterion 4 and 28)

Provide justification for excluding the potentially applicable sections of the IEEE standards listed in the table above to which SHINE has not committed to implement for its electrical power systems. Alternatively, describe how SHINE addresses the requirements of these sections of the IEEE standards to meet its facility-specific design criteria.

Consistent with the evaluation findings in Chapter 8 of NUREG-1537, Part 2, this information is necessary for the NRC staff to determine that design bases and functional characteristics of the SHINE electrical power systems are capable of providing the necessary range of safety-related services.

RAI 8-10 In response to RAI 8-1, SHINE stated, "SHINE applies NFPA 70-2017 to satisfy the SHINE Design Criterion 27 requirement to include provisions to minimize the probability of losing electrical power from the UPSS as a result of or coincident with the loss of power from the off-site electrical power system." However, it is not clear to the NRC staff what portions of NFPA 70-2017 are being applied to demonstrate conformance with Design Criterion 27.

In order to verify how the licensee minimizes the probability of losing electrical power, provide clarification on which portions of NFPA 70-2017 are used to meet SHINE's Design Criterion 27 requirement.

Consistent with the evaluation findings in Chapter 8 of NUREG-1537, Part 2, this information is necessary for the NRC staff to determine that design bases and functional characteristics of the SHINE electrical power systems are capable of providing the necessary range of safety-related services.

Chapter 13 – Accident Analyses

The following regulatory requirements and guidance are applicable to RAIs 13-11 through 13-24:

Paragraph (b) of 10 CFR 50.34 requires that each applicant for an operating license provide "[a] final analysis and evaluation of the design and performance of structures, systems, and components…," of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility. Further, 10 CFR 50.34(b) states that the FSAR shall include information that "describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility." Additionally, 10 CFR 50.34(b)(2) states, in part, that that FSAR shall include "[a] description and analyses of the structures, systems and components of the facility, with emphasis upon the performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished…."

Section 50.36, "Technical specifications," of 10 CFR requires an applicant for an operating license to include in the application proposed TSs as it relates to the evaluations and analysis of the offsite radiological consequences of postulated accidents with fission products. Specifically, 10 CFR 50.36(c)(2)(ii) requires that a TS limiting conditions of operation be established. Additionally, 10 CFR 50.36(c)(3) requires TSs to include items in the category of surveillance requirements, which 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 of operation will be met.

Paragraph (a)(3) of 10 CFR 50.57, "Issuance of operating license," states, in part, that an operating license may be issued upon finding that "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…."

The ISG Augmenting NUREG-1537 discusses in Section 13a2, "Aqueous Homogeneous Reactor Accident Analyses," that Chapter 13 of the FSAR should demonstrate that the applicant has considered all potential accidents at the facility and adequately evaluated their consequences. The NRC staff is requesting the following information to evaluate SHINE's accident analysis methodology and results to determine whether SHINE has demonstrated full consideration of all potential accidents and adequately evaluated their consequences. This information is needed for the NRC staff to make the reasonable assurance findings that SHINE (1) has adequately described the facility, including those analyses and evaluations demonstrating that safety functions will be accomplished and (2) can conduct the activities described in its application without endangering the health and safety of the public.

RAI 13-11 A design basis accident (DBA) is a postulated accident that a nuclear facility must be designed and built to withstand without loss to the structures, systems, and components necessary to ensure public health and safety. The DBAs are not intended to be actual event sequences, but rather, intended to be surrogates to enable deterministic evaluation of the response of a facility's engineered safety features. The safety margins contained within the DBAs are products of specific values and limits contained in the facility's TSs, as required by 10 CFR 50.36, and other values, such as assumed accident or transient initial conditions or assumed safety system response times.

The numeric values that are chosen as inputs to the DBA analyses should be selected with the objective of determining a conservative postulated dose. In some instances, a particular parameter may be conservative in one portion of an analysis but be nonconservative in another portion of the same analysis. For parameters addressed by TSs, the value used in the analysis should be that specified in the TSs. If a range of values or a tolerance band is specified, the value that would result in a conservative postulated dose should be used.

Following a comparison between SHINE's Chapter 13 credited design values to those listed within the TSs and other supporting calculational documents, the NRC staff found certain values either do not match or are outside and analyzed range within the design calculations. For these values, it is unclear to the NRC staff if the computed radiological consequences would result in the most limiting radiological consequences. Examples include:

- Insertion of Excess Reactivity (Subsection 13a2.1.2);

The SHINE FSAR DBA, Insertion of Excess Reactivity (Subsection 13a2.1.2), discusses the events sequence of events. Following the accelerator output being restored just prior to the TSV reactivity protection system (TRPS) Driver Dropout initiating, the power increases to a level that is greater than the steady state power before the upset occurred. This power level would result in a TRPS Irradiation Unit Cell Safety Actuation on high wide range neutron flux.

TS basis 2.21 provides a discussion of these limits. Specifically, this limit provides margin to an analytical limit of 240 percent fission power (300 kilowatts). The staff is assuming this analytic limit of 240 percent (300 kilowatts) fission power is the same being referenced in Chapter 13 to be the peak power calculated.

There appears to be a discrepancy between the DBA sequence description of the peak power analytical calculation and that specified in the TS bases.

- Reduction in Cooling (Subsection 13a2.1.3);

The SHINE FSAR DBA, Reduction in Cooling (Subsection 13a2.1.3), discusses the sequence of events. The sequence of events for the Reduction in Cooling DBA is initiated by a primary cooling closed loop system cooling flow being reduced, resulting in increased TSV temperature. A low primary closed loop cooling system flow or high temperature signal initiates a TSV reactivity protection system Driver Dropout, which causes the neutron driver assemble system high voltage power supply breakers to open, terminating the irradiation process by the accelerator.

TS Limiting Safety System Settings, Section 2.2 provides these limits, including LSSS 2.2.7, variable (a) for Low primary closed loop cooling system (PCLS) flow and LSSS 2.2.7, variable (c) for high PCLS temperature (PCLS).

There appears to be a discrepancy between the DBA accident sequence description for both the low primary closed loop cooling system flow and low PCLS temperature to those specified in the TSs.

Update Chapter 13 of the FSAR credited design values to reflect the most limiting TS value in terms of radiological consequences. Confirm that these are the most limiting value. For ease of reference, the NRC staff also requests that SHINE update the document entitled, “SHINE Response to Topic Request 5-B,” which provides in matrix form, credited DBA parameter values with their applicable FSAR reference and TS.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

RAI 13-12 SHINE assessed the sequence of events for a variety of DBAs which rely on the safety-related uninterruptible power supply system to automatically maintain power supply to the 125 volts DC uninterruptible power supply system buses A and B. Each neutron driver-assembly system high-voltage power supply de-energizes and the associated irradiation processes stop. The TSV dump valves open, draining the uranyl sulfate solution in the operating TSVs to their respective TSV dump tanks. The primary closed loop cooling system loses power to its pumps and forced convection cooling ceases while heat is removed by natural convection to the light water pool. Hydrogen generation continues to occur due to radiolysis from the decay of fission products. The SHINE accident analysis states that the TOGS blowers and recombiner heaters operate on interruptible power supply system power for at least five minutes. This is confirmed in SHINE FSAR Chapter 8*,* which discusses that the uninterruptible power-supply system provides power at a sufficient capacity and capability to allow safety-relates SSCs to perform their safety function and for equipment required to prevent hydrogen deflagration is powered for 5 minutes. However, the duration of the accident is computed for 30 days.

It is unclear to the NRC staff if 5 minutes is sufficient to prevent hydrogen deflagration once the target solution has drained to the TSV dump tanks as the radiological consequence analysis is performed over a period of 30 days.

Provide additional details and justification for the uninterruptible power supply system design to provide 5 minutes of emergency power to the TOGS blowers and recombiner heaters to perform their safety function.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that SHINE has evaluated the consequences of potential deflagration or detonation of combustible gases within the primary boundary.

RAI 13-13 For those accidents which release fission products to the primary confinement boundary, detection of airborne radiation in radiological ventilation zone 1 exhaust subsystem (RVZ1e) (five times background) actuates the primary confinement boundary isolation valves and an IU trip within 20-seconds of detection. SHINE indicates a sufficient time delay is provided by the holdup volume in RVZ1e to prevent radioactive gases from exiting through RVZ1e prior

to isolation. Based on the descriptions provided by SHINE, it appears that the fission products may be able to travel through the RVZ1e system, past the radiation detector and then subsequently past the first isolation damper unmitigated for the first 20-seconds of the event.

Further explain, with reference to applicable calculations, how the holdup volume provides the 20-second time delay before isolation. Justify the 20-second delay by describing the relative location of the radiation detector within the RVZ1e system and time of flight to transport the fission products to the first isolation dampers.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

RAI 13-14 Many of the SHINE DBAs discuss programmatic administrative controls that describe actions that are required to either prevent an accident from occurring or credit recovery actions to stop further release and dispersion of radioactive material. However, there are no references to these documents or discussions as to how they are controlled through SHINE's TS Administrative Controls. Additionally, none of the accidents list programmatic controls. Examples include:

1. For accidents resulting in a tritium release, SHINE credits recovery actions after 10-days to stop releases to the environment, indicating facility personnel would be trained to perform such actions.

2. For all accidents resulting in a release of radioactive material, SHINE credits a 10-minute evacuation time, indicating facility personnel would be trained to evacuate the immediate area upon actuation of the radiation alarms.

3. Consistent with the SHINE Design Criterion for the Control Room, SHINE credits the control room operators being present for the duration of the accident but provides no referenced procedure indicating control room operators are properly trained to respond to the accident as well as to not evacuate.

4. SHINE credits facility workers to resupply the nitrogen purge system tanks after 72 hours over a period of 30 days, indicating facility personnel would be trained to refill these tanks.

5. SHINE credits prevention of heavy load drops in part due to crane operation procedures which include safety load paths to avoid the radioactive liquid waste immobilization (RLWI) enclosure and supercell and required suspension of supercell and RLWI activities during a heavy lift. However, there is no reference to these procedures.

6. SHINE credits prevention of operator errors during the TSV system fill process, which limit the size of the solution addition steps. However, this is no reference to these procedures.

For each design-basis accident that discusses a procedure intended to prevent or mitigate the event, provide a reference and a discussion of how it is controlled through SHINE's TS Administrative Controls. Also, describe within the accident analysis how the procedure for recovery actions would be executed.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

RAI 13-15 For those accidents that release fission products to the light water pool system, the iodine dissolved in the pool water is credited for partitioning according to the pool pH, temperature, pool volume, and gas volume. The SHINE TSs specificity controls for a minimum water level and maintained temperatures. However, limiting conditions of operation for the light water pool pH are not provided.

a. Provide the TS limiting conditions of operation of the light water pool pH which is credited for iodine partitioning within the DBA.

b. Confirm from the calculations supporting the iodine partitioning factor assumption utilize the most limiting parameters for pool pH, temperature, pool volume, and gas volume.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

RAI 13-16 The primary confinement boundary contains the primary system boundary, which contains the fission products. The primary confinement boundary is primarily passive, and the boundary for each IU is independent from the others. During normal operations, the primary confinement boundary is operated within a normally-closed atmosphere without connections to the facility ventilation system; except through the primary closed loop cooling system expansion tank. The IU and TOGS shielded cells are equipped with removable shield plugs which allow entry into the confined area. Gaskets and other non-structural features are used, as necessary, to provide sealing where separate structural components meet.

All of SHINE's design-basis accidents that result in fission product or tritium releases to the primary confinement boundary credit leak path factors found in SHINE calculation CALC-2018-0048, Rev. 6, which subsequently references calculations from the document FAI/19-0035 Rev. 1. It is unclear from the analyses whether the shield plugs will perform their intended sealing function, as described.

a. Provide information on the reliability and performance of the shield plugs to prevent and mitigate the release of radioactive material. Additionally, clarify whether flow versus pressure drop in shield plug will be verified by

pressurizing primary confinement boundary. Indicate whether this is specified in TSs. If not, provide a justification for not specifying.

A review of SHINEs TSs, Section 3.4, “Confinement,” does not specify a maximum allowable leakage rate.

b. Provide the primary confinement boundary maximum allowable leakage rate and its limiting condition of operation.

SHINE refers to documents pertaining to the facility configuration management and maintenance systems which would ensure the reliability and integrity of the primary confinement boundary components to mitigate radiological consequences under postulated accident conditions. These documents are not listed or referenced. For example, it is unclear if there is a program to test and inspect the shield plug gaskets.

c. Provide a reference to the primary confinement boundary shield plug gaskets maintenance procedure(s) and a discussion of how this activity is controlled through SHINE’s TS Administrative Controls program.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

RAI 13-17 SHINE derived the material at risk (MAR) for the TSV target solution inventory at the end of a specified period of continuous 30-day irradiation cycles (normal operation is 5.5 days) with a downtime between cycles equating to a specified number of irradiation cycles. A conservative constant power level 137.5 kilowatt is used for the analysis, which is 110 percent of licensed-limit design operating power. The 110 percent increase in power has a near linear increase in MAR radionuclide inventory and subsequent similar increase in computed radiological consequence. The TSV inventory calculation includes effects from fission, transmutation, activation, and decay. There is no partitioning due to extraction between irradiation cycles. The calculation contains time steps from the start of irradiation through the end of the irradiation cycle and additional time steps that account for decay post-shutdown, as needed. The time period for the irradiation cycle was selected based on the anticipated replacement period for target solution. SHINE references the bounding MAR, unless otherwise stated, from the internal calculations contained in “CALC-2018-0010 Rev. 2, 'Bounding Fission Product Inventories and Source Terms.” The NRC staff finds the assumptions to derive the SHINE MAR to be acceptable. However, it is unclear to the NRC staff if the TSV MAR source term is bounding for certain dosimetrically important radionuclides (e.g., halogens and noble gases) where concentrations peak at different burn-up levels.

a. Describe the known uncertainties (e.g., thermal-hydraulic, nuclear parameters, software/code limitations, and other engineering factors) and the adequacy of the assumed 110 percent increase to develop the TSV MAR.

b. Based on SHINE's irradiation cycle calculations, identify and describe where halogen and noble gas radionuclide concentrations peak as a function of target solution inventory burnup (e.g., at the mid- and end-points of the operating cycle).

c. To identify margin between the MAR and normal operations, provide a comparison of the generation rate of iodine-131 between the most limiting irradiation cycle calculation at the end of a continuous irradiation cycle with a reduced downtime versus a normal operation cycle with a normal operations downtime.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

RAI 13-18 Since initial submission of the operating license application, SHINE has provided the NRC staff updated versions of the technical basis calculation documents supporting its accident analyses.

In order to ensure that all documentation has been consistently updated and licensing basis documents reflect the current design of the facility, confirm that the leak path factors reported in technical basis document Report Number FAI/19-0035, "Leak Path Factor Analysis for the SHINE Facility," Rev. 1 (published in February 2019), are still applicable to the SHINE analyses reported in CALC-2018-0048, "Radiological Dose Consequences," Revision 7, (Published in December 2020).

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

RAI 13-19 As part of its January 29, 2021, RAI response, SHINE indicated a distinction between safety-related controls and programmatic administrative controls, the SSA and Chapter 13 of the FSAR appear to cite procedures, maintenance, inspection and testing as safety-related controls to prevent or mitigate accident sequences. According to SHINE's definition of programmatic administrative controls and reliability management measures, SHINE establishes quality assurance elements like procedures, maintenance, inspection and testing to ensure safety-related controls are available and reliable and function, as intended. Therefore, programmatic administrative controls should not be credited as safety controls to prevent or mitigate accident sequences. Below are examples of SHINE crediting programmatic administrative controls as safety controls.

- Accident sequence 13a2.1.12-A in the SSA. Maintenance, inspection and testing appear to be credited as preventive safety-related controls. According to SHINE's definition of programmatic administrative controls, maintenance,

inspection and testing should be programmatic administrative controls, not preventive safety-related controls.

- Accident sequence 13b.2.7-A in the SSA. Maintenance and inspection appear to be credited as a preventive safety-related control. According to SHINE's definition of programmatic administrative controls, maintenance, inspection and testing should be programmatic administrative controls, not preventive safety-related controls.

- Tritium Purification System Accident Scenario 2. Maintenance, inspection, and testing appear to be credited as defense-in-depth safety-related controls. According to SHINE's definition of programmatic administrative controls, these procedures should be programmatic administrative controls, not preventive safety-related controls.

Revise Chapter 13 of the FSAR and the SSA to consistently refer to programmatic administrative controls and reliability management measures as quality assurance measures instead of as safety-related controls. Revisions to Chapter 13 of the FSAR and the SSA to remove programmatic administrative controls and reliability management measures as safety-related controls may require designating new safety-related controls that prevent or mitigate the associated accident sequences.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

RAI 13-20 As part of its January 29, 2021, RAI responses, SHINE submitted tables outlining the justification for certain passive engineered safety-related controls (PECs), including pipes, floor drains, and vault seals, to have failure probability indices (FPINs) of -4. Although guidance in NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," indicates that -4 is an option, it is caveated by a statement that -4 can rarely be justified. Furthermore, it has been shown that seismically designed pipes leak and floor drains and vault seals fail at probabilities greater than 10^{-4}.

Provide the engineering calculations (or other technical justification) or documented operating experience for single PECs or safe by design controls that resulted in crediting those controls with FPINs of -4. If engineering calculations or documented operating experience does not support applying FPINs of -4 or less, indicate the accident sequences and associated safety-related controls that will change. Alternatively, confirm that there are no single PECs or safe by design controls with FPINs of -4 or less.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13a.2. Specifically, the requested information will support the NRC staff in concluding that doses to the public are within acceptable limits, and the health and safety of the licensee staff and public are adequately protected.

Chemical Safety

RAI 13-21 As part of its January 29, 2021, RAI responses, SHINE submitted a markup of Chapter 13 of the FSAR, which includes its SSA methodology and a definition of "facility worker." For the purposes of exposure to chemical consequences, SHINE defines a facility worker as a control room operator or RCA worker.

Confirm that exposure to chemical consequences for facility personnel can occur only in the control room or radiologically controlled areas. If facility personnel neither in the control room nor radiologically controlled areas can be exposed to chemical consequences, describe the safety-related controls to mitigate those consequences.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13b.2. Specifically, the requested information will support the NRC staff in concluding that SHINE adequately described and assessed accident consequences that could result from the handling, storage, or processing of licensed materials and that could have potentially significant chemical consequences and effects.

RAI 13-22 Paragraph (b)(6) of 10 CFR 50.34 requires the FSAR to include:

i. [t]he applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements;
ii. managerial and administrative controls to be used to assure safe operation…;
iii. plans for preoperational testing and initial operations;
iv. plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems and components;
v. plans for coping with emergencies, which shall include items specified in appendix E; and
vi. proposed TSs prepared in accordance with the requirements of § 50.36.

This type of information forms the basis for safety programs that identify and manage the spectrum of hazards at the applicant's facility including chemical hazards. Chemical safety is specifically discussed in the ISG augmenting NUREG-1537, Part 1, as follows:

- Section 4b.4.2, "Processing of Unirradiated Special Nuclear Material," states that the application should provide "chemical accident prevention measures as appropriate."

- Section 12.1.6, "Production Facility Safety Program," states that the radioisotope production facility must have an established safety program that includes chemical hazards.

- Section 13b.3, "Analyses of Accidents with Hazardous Chemicals," states that the analyses of accidents for the production facility should include chemical hazards.

- Section 14b, “Radioisotope Production Facility Technical Specifications,” states that the TSs should consider chemical hazards.

TS, Section 5.5.1, “Nuclear Safety Program,” states, in part, the following: “The SHINE nuclear safety program documents and describes the methods used to minimize the probability and consequences of accidents resulting in radiological or chemical release.”

TS, Section 5.5.8, “Chemical Control,” states the following:

> The SHINE chemical control program ensures that on-site chemicals are stored and used appropriately to prevent undue risk to workers and the facility. The chemical control program implements the following activities, as required by the accident analysis:
>
> 1. Control of chemical quantities permitted in designated areas and processes;
>
> 2. Chemical labeling, storage and handling; and
>
> 3. Laboratory safe practices.

However, there is no description in the FSAR about how the nuclear safety program or chemical control program identifies and manages chemical hazards.

a. Provide a description of the activities associated with the nuclear safety program and chemical control program that minimize the probability and consequences of accidents resulting in a hazardous chemical release for chemical hazards that are under NRC’s regulatory jurisdiction. Additionally, provide an explanation regarding the relationship between the nuclear safety program and the chemical control program as it relates to the identification and management of chemical hazards under NRC’s regulatory jurisdiction.

b. The FSAR does not clearly indicate the identification and management of chemical hazards that are under NRC’s regulatory jurisdiction. Specific examples of activities that are identified in the FSAR and might be elements of the nuclear safety program that contributes to the identification and management of chemical hazards under NRC’s regulatory jurisdiction include:

   i. <u>Hazard identification and analysis</u>. The response to RAI 13-5, along with the revision of Section 13a2 of the FSAR, states that the SSA methodology includes the identification and evaluation of chemical hazards under NRC’s regulatory authority and the identification of controls where necessary to meet the safety criteria limits defined in Section 3.1 of the FSAR. Clarify whether the SSA is one of the elements of the nuclear safety program that contributes to the identification and management of chemical hazards under NRC’s regulatory jurisdiction.

ii. <u>Review and audit function</u>. The SHINE FSAR discusses the review and audit function discussed in Section 5.2, "Review and Audit," of the TSs. The discussion mentions radiological hazards but does not mention chemical hazards. Clarify whether the audit function applies to chemical hazards. If it does apply, specify whether the audit verifies that assumptions used as input to the safety analysis (e.g., chemical inventory limits) are implemented and that controls developed from the safety analysis are implemented. Specify whether there is a minimum frequency for the audit of the chemical safety aspects of the nuclear safety program.

iii. <u>Procedures</u>. The SHINE FSAR discusses its commitment to procedures in Section 5.4, "Procedures," of the TSs. Clarify whether the SHINE commitment to procedures include its use for implementing the chemical safety aspects of its nuclear safety program and implementing controls identified as being important for the management of chemical hazards under NRC's regulatory jurisdiction.

iv. <u>Training and qualification</u>. The SHINE FSAR discusses its commitment to training and qualifications in Section 5.5.2, "Training and Qualification," of the TSs. Clarify whether the SHINE commitment to training and qualification applies to personnel involved in the management of chemical hazards that are under NRC's regulatory jurisdiction.

v. <u>Configuration management</u>. The SHINE FSAR discusses its commitment to configuration management in Section 5.5.4, "Configuration Management," of the TSs. Clarify whether the SHINE commitment applies to changes that influence the management of chemical hazards that are under NRC's regulatory authority.

vi. <u>Special Reports</u>. The SHINE FSAR discusses its commitment to the preparation of Special Reports in Section 5.8.2, "Special Reports," of the TSs. Clarify whether the SHINE commitment includes the preparation of reports following incidents involving chemical hazards that are under NRC's regulatory jurisdiction.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13b.2. Specifically, the requested information will support the NRC staff in concluding that SHINE adequately described and assessed accident consequences that could result from the handling, storage, or processing of licensed materials and that could have potentially significant chemical consequences and effects.

RAI 13-23 Chapter 13 of the FSAR discusses how safety-related controls are incorporated into the FSAR and TSs. However, it does not discuss where in the TSs the limits that are important for the management of chemical hazards under NRC's regulatory authority are presented.

For example, Page 13b.3-3 of the FSAR identifies seismically qualified uranium receipt and storage system uranium storage racks and confinement barriers as important chemical process safety controls. However, these do not appear to be

identified as chemical safety controls in the TSs, but they are identified as criticality controls in Table 5.5.4.

Revise the FSAR to clarify the incorporation of chemical safety controls, as identified in Chapter 13 of the FSAR, into the TSs.

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13b.2. Specifically, the requested information will support the NRC staff in concluding that SHINE adequately described and assessed accident consequences that could result from the handling, storage, or processing of licensed materials and that could have potentially significant chemical consequences and effects.

RAI 13-24 *RCA workers*

Page 13b.3-2 of Chapter 13 of the FSAR discusses the methodology for estimating chemical concentrations RCA workers would experience in the event of a chemical release. The total source term, as stated in the FSAR, is assumed to be instantly well mixed within the building free volume. The results of this analysis are presented in Table 13b.3-2, "Hazardous Chemical Source Terms and Concentration Level." The table shows that concentrations predicted for RCA worker are well below Protective Action Criteria (PAC)-2 levels for most analyzed accidents. The FSAR concludes that the SHINE performance requirements for chemical exposure of RCA workers are met.

The simplified analysis SHINE used may underpredict the concentration that an RCA worker near the point of release. While the predicted concentrations are less than PAC-2 levels, the predicted concentrations of uranium are near the PAC-2 levels. For uranium oxide, the predicted concentration is 99.9 percent of the PAC-2 value.

a. Clarify the amount of conservatism in the factors that are included in the analysis that might offset the non-conservative effect of the instantaneous mixing model, particularly for chemicals whose concentration is predicted to be near PAC-2 levels. The level of conservatism in factors such as 1) the reasonableness of the assumption of the entire inventory being instantly released when the material is a powder or solution, 2) conservatism (if any) in the PAC-2 estimate developed for and used in the analysis, and 3) the effects of a short exposure time as a result of evacuation should be discussed.

Control Room Workers

Page 13b.3-2 of Chapter 13 of the FSAR discusses the methodology used for estimating the chemical concentration that control room workers would experience in the event of a chemical release. It states that the concentration used for the RCA worker exposure estimate is assumed to be released from the facility roll-up door and transported to the facility ventilation intake that services the control room. It also states that the computer code ALOHA was used to calculate the indoor concentration.

The calculation package that appears to be the basis for the predicted control room concentrations (CALC-2018-0049, Rev 4, Section 5.3) includes a reference to CALC-2020-0018 (an ARCON analysis that predicts X/Q values that are presented in the FSAR) but the analysis does not appear to use the X/Q value.

As presented in Table 13b.3-2 of the FSAR, most of the control room operator concentrations are greater than the RCA worker concentrations. These results are inconsistent with what would be expected if one assumes the RCA worker concentrations were released from the rollup door and transported to the ventilation intakes.

b. Clarify or revise the description of how the calculations were performed and/or the actual calculations to address the inconsistencies identified above. In addition, discuss the uncertainty or bias in the various parts of the analysis (e.g., conservatism in the release concentrations or rate and any conservatisms in the PACs).

This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 13b.2. Specifically, the requested information will support the NRC staff in concluding that SHINE adequately described and assessed accident consequences that could result from the handling, storage, or processing of licensed materials and that could have potentially significant chemical consequences and effects.