ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, LLC

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

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PUBLIC VERSION

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RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION PUBLIC VERSION

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

Chapter 6 – Engineered Safety Features

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.

SHINE Response

The SHINE nuclear criticality safety program (CSP) is applicable throughout the SHINE facility wherever fissile material is used, handled, or stored, with the exception of the target solution vessel (TSV).

SHINE has revised the title of Section 6b.3 of the Final Safety Analysis Report (FSAR) to remove the apparent inconsistency. SHINE has also revised the title of Section 6a2.3 of the FSAR to remove the similar apparent inconsistency. A mark-up of the FSAR incorporating these changes is provided as Attachment 1.

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.

SHINE Response

SHINE uses the term "unlikely" differently when applied to 10 CFR 70.61(b) events (i.e., accident sequences in categories other than inadvertent criticality) versus 10 CFR 70.61(d) events (i.e., inadvertent criticality accident sequences), due to how it is used in the definition of double contingency principle within American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.1-2014, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors" (Reference 3). For accident sequences that fall under 10 CFR 70.61(b), the term "unlikely" is applied as defined in Table 13a2.1-3 of the FSAR. As used within the double contingency principle, the term "unlikely" is a qualitative assessment of what is not likely to occur either due to system design features, engineered controls, or administrative controls. Clarification on how likelihood is determined for these two types of events has been incorporated into the SHINE Safety Analysis (SSA). Additionally, Section 13a2.1 of the FSAR has been revised to clarify the likelihood evaluation performed for inadvertent criticality accident sequences and accident sequences in categories other than inadvertent criticality. A mark-up of the FSAR incorporating these changes is provided as Attachment 1.

Events are considered credible unless they are: 1) an external event for which the frequency of occurrence can conservatively be estimated as less than once in a million years, 2) not physically possible, or 3) are caused by a sequence of events involving many unlikely human actions or errors for which there is no reason or motive. This definition is applied consistently throughout the SSA and the FSAR.

SHINE has not identified any additional terms which have multiple meanings, interpretations, or applications in the operating license application.

<u>RAI 6b.3-23</u>

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.

<u>SHINE Response</u>

As SHINE does not have an integrated safety analysis (ISA), nor does SHINE identify items relied on for safety (IROFS), SHINE has identified SHINE-specific reporting requirements which meet the intent of the reporting requirements of 10 CFR Part 70, Appendix A. SHINE has revised Section 5.8.3 of the technical specifications to include the following SHINE-specific reporting requirements which meet the intent of 10 CFR Part 70, Appendix A.

1. *One hour reports*. SHINE shall report to the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:
   (1) An inadvertent nuclear criticality.
   (2) An acute intake by an individual of 30 mg or greater of uranium in a soluble form.
   (3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could endanger the life of a worker or could lead to irreversible or other serious, long-lasting health effects to any individual located outside the owner controlled area.
   (4) An event or condition such that no credited controls, as documented in the SHINE Safety Analysis, remain available and reliable, in an accident sequence evaluated in the SHINE Safety Analysis.

2. *Twenty-four hour reports*. SHINE shall report to the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:
    (1) Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that described in the SHINE Safety Analysis, and which results in inadequate controls in place to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.
    (2) Loss or degradation of credited controls, as documented in the SHINE Safety Analysis, other than those items controlled by a limiting condition of operation established in section 3 of the technical specifications, that results in failure to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.
    (3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that could lead to irreversible or other serious, long-lasting health effects to a worker, or could cause mild transient health effects to any individual located outside the owner controlled area.
    (4) Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more safety-related structures, systems or components.

3. *Concurrent Reports*. SHINE shall concurrently report to the NRC Operations Center any event or situation, related to the health and safety of the public or on-site personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made.

The reporting requirement discussed in paragraph 2.(2) above excludes credited controls that are otherwise controlled by the limiting conditions for operation (LCO) established in Section 3 of the technical specifications, since operation in violation of an LCO, unless prompt remedial action is taken as permitted in Section 3, is reportable under Section 5.8.2 of the technical specifications.

In addition to the described revision to Section 5.8.3, SHINE has also revised Section 6b.3 of the FSAR to clarify the 10 CFR Part 70 reporting requirements for nuclear criticality safety (NCS)-related events. A mark-up of the FSAR incorporating these changes is provided as Attachment 1. A mark-up of the technical specifications incorporating the described revision to Section 5.8.3 is provided as Attachment 2.

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.

SHINE Response

SHINE applies the reporting requirements of Section 5.8.3 of the technical specifications to NCS-related events and events other than criticality events. Section 5.8.3 of the technical specifications includes the reporting requirements of 10 CFR 70.50, as well as SHINE-specific reporting requirements which meet the intent of the reporting requirements of 10 CFR Part 70, Appendix A, as described in the SHINE Response to RAI 6b.3-23.

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.

SHINE Response

As described in the SHINE Response to RAI 6b.3-23, SHINE has revised Section 5.8.3 of the technical specifications to include SHINE-specific reporting requirements which meet the intent of 10 CFR Part 70, Appendix A, including the intent of paragraphs (a)(4), (b)(1), (b)(2), and (b)(4).

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.

SHINE Response

a. Section 5.8.2 of the technical specifications includes reporting requirements for operation in violation of limiting conditions for operation established in Section 3, unless prompt remedial action is taken as permitted in Section 3. Many of the credited active and passive engineered controls described in the SHINE Safety Analysis are also described in Section 3 of the technical specifications. The loss or failure of these controls, when required to be operable, would be reportable to the NRC in accordance with the requirements of Section 5.8.2.d of the technical specifications. Events involving active or passive engineered controls may also be reportable under other provisions of Section 5.8.2 of the technical specifications.

   Additionally, SHINE has revised Section 5.8.3 of the technical specifications, as described in the SHINE Response to RAI 6b.3-23, to include reporting requirements that meet the intent of Appendix A to 10 CFR Part 70. This revised section includes reporting requirements for the loss or degradation of credited controls (e.g., active or passive engineered controls) documented in the SHINE Safety Analysis that are not otherwise controlled by a limiting condition of operation described in Section 3 of the technical specifications.

   Events are evaluated to determine whether a report to the NRC is required for events involving active or passive engineered controls in accordance with approved procedures and training. On-shift Operations personnel at the facility will be trained to recognize when events or identified conditions may be subject to reporting requirements (e.g., due to the involvement of safety-related structures, systems, or components [SSCs]). Procedural guidance, including additional information or examples of potentially reportable events, will be available to the operators to assist them in the determination of reporting requirements, particularly for short duration (e.g., one hour or four hour) reports.

Staff at the SHINE facility are trained to notify the control room and to use the corrective action program to identify and document issues. Issues identified in the corrective action program are evaluated by on-shift Operations personnel for reporting requirements. Issues identified in the corrective action program are also evaluated by Operations and Licensing personnel as part of the issue screening process, to ensure any regulatory reporting requirements are met.

SHINE has not identified the need to update the FSAR or the technical specifications with the above supplemental information.

b. The failure or degradation of the reliability management measures (i.e., programmatic controls) applied to an active or passive engineered control are evaluated similarly to the loss or failure of the active or passive engineered control itself. The failure or degradation of a programmatic control(s) may be identified via performance of audits and assessments required by the governing documents for the program, during failure investigations (e.g., if a failure to perform adequate required preventative maintenance were discovered during a component failure investigation), or during the normal course of business. Facility staff are trained to notify the control room and document identified issues using the corrective action program. On-shift Operations personnel will be trained to recognize that deficiencies in administrative activities (e.g., maintenance, procedure usage, configuration management, etc.) associated with safety-related SSCs may also be reportable to the NRC, and procedural guidance will be provided to assist the operator in making reporting decisions.

   SHINE has not identified the need to update the FSAR or the technical specifications with the above supplemental information.

c. With respect to evaluating an event for reportability under Section 5.8.2(h) of the technical specifications, SHINE considers an "unsafe condition" to exist when the event or condition results in inadequate controls in place to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

   SHINE has not identified the need to update the FSAR or the technical specifications with the above supplemental information.

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.

SHINE Response

Credited controls that are failed or degraded due to improper maintenance will be evaluated for reportability in accordance with the requirements of 10 CFR 70.50 and the SHINE specific reporting requirements described in the SHINE Response to RAI 6b.3-23. Reports will not be required when systems are declared inoperable as part of a planned evolution for maintenance or surveillance testing when done in accordance with an approved procedure and the SHINE technical specifications.

Criticality Accident Alarm System Exemption Request

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 offgas 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.

SHINE Response

The SHINE Response to RAI CE-1 will be provided by August 31, 2021.

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.

SHINE Response

The SHINE Response to RAI CE-2 will be provided by August 31, 2021.

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.

SHINE Response

The SHINE Response to RAI CE-3 will be provided by August 31, 2021.

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.

SHINE Response

The SHINE Response to RAI CE-4 will be provided by August 31, 2021.

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.

SHINE Response

The SHINE Response to RAI CE-5 will be provided by August 31, 2021.

Chapter 8 – Electrical Power Systems

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.

SHINE Response

SHINE applies the guidance of Sections 4.1, 5.1, 6.1, and 7 of the Institute of Electrical and Electronics Engineers (IEEE) Standard 323-2003, "IEEE Standards for Qualifying Class 1E Equipment for Nuclear Power Generating Stations" (Reference 4) and Sections 8 and 9.3 of IEEE 344-2013, "IEEE Recommended Practice for Seismic Qualification of Class 1E Equipment for Nuclear Generating Stations," (Reference 5) for the qualification of the uninterruptible electrical power supply system (UPSS) safety-related systems, such as the UPSS batteries and UPSS battery chargers.

For environmental qualification of the UPSS batteries, SHINE vendor specifications require documentation in the form of a certificate of conformance and/or associated qualification reports that demonstrate that the UPSS battery bank components will be acceptable within the specified environmental conditions for the service life. The SHINE vendor specifications contain requirements that the UPSS batteries remain capable of operating during normal and accident conditions. The vendor is required to perform initial qualification meeting the guidelines of Section 5.1 of IEEE Standard 323-2003, which allow for type testing, operating experience, analysis, and combined methods. Analysis alone cannot be used to demonstrate qualification. During the qualification of the UPSS batteries, the vendor is required to provide a battery life expectancy for normal expected temperature as well as for higher (event) ambient temperatures.

For seismic qualification of the UPSS batteries, SHINE vendor specifications require the UPSS batteries and battery racks to be seismically qualified using bounding values following the SHINE facility design basis event and with testing performed per the guidance of Sections 8 and 9.3 of IEEE Standard 344-2013. Sections 8 and 9.3 of IEEE Standard 344-2013 provide guidance for testing and extrapolation to similar equipment. SHINE vendor specifications require documentation of test results that demonstrate that the UPSS batteries function before, during, and after a seismic event during the entire life expectancy provided by the vendor.

IEEE Standard 535-2013, “IEEE Standard for Qualification of Class 1E Vented Lead Acid Storage Batteries for Nuclear Power Generating Stations” (Reference 6) was considered during the design of the UPSS batteries and issuance of vendor specifications. It was not invoked in the SHINE vendor specifications because Sections 4.1, 5.1, 6.1 and 7 of IEEE Standard 323-2003 and Sections 8 and 9.3 of IEEE Standard 344-2013 were considered sufficient to provide the necessary requirements for environmental and seismic qualification of the UPSS batteries.

For environmental qualification of the UPSS batteries, IEEE Standard 535-2013 allows for type testing, operating experience, analysis, and a combination of qualification methods. The guidance in IEEE Standard 535-2013 for these methods as it applies to environmental qualification of batteries is consistent with, and not appreciable more detailed than, the guidance for type testing, operating experience, analysis, and combined methods contained in Section 5.1 of IEEE Standard 323-2003. Therefore, SHINE considers Section 5.1 of IEEE 323-2003 to be sufficient for environmental qualification of the UPSS batteries.

For seismic qualification of the UPSS batteries, Section 8.4 of IEEE Standard 535-2013 provides a seismic qualification procedure. SHINE believes that this section of IEEE 535-2013 is consistent with and not appreciably more detailed than Sections 8 and 9.3 of IEEE Standard 344-2013. In fact, Section 8.4 of IEEE Standard 535-2013 defers to the IEEE Standard 344-2013 on five different occasions in lieu of providing independent guidance. Therefore, SHINE considers Sections 8 and 9.3 of IEEE Standard 344-2013 sufficient to demonstrate seismic qualification of the UPSS batteries.

For environmental qualification of the UPSS battery chargers and other UPSS safety-related equipment, SHINE vendor specifications require documentation in the form of a certificate of conformance and/or associated qualification reports that demonstrate that the components will be acceptable within the specified environmental conditions for the service life. The SHINE vendor specifications contain requirements that the UPSS battery chargers and other UPSS safety-related equipment remain capable of operating during normal and accident conditions. The vendor is required to perform initial qualification meeting the guidelines of Section 5.1 of IEEE Standard 323-2003, which allow for type testing, operating experience, analysis, and combined methods. Analysis alone cannot be used to demonstrate qualification.

For seismic qualification of the UPSS battery chargers and other UPSS safety-related equipment, SHINE vendor specifications require the UPSS battery chargers and other UPSS safety-related equipment to be seismically qualified using bounding values following the SHINE facility design basis event and with testing performed per the guidance of Sections 8 and 9.3 of IEEE Standard 344-2013. Sections 8 and 9.3 of IEEE Standard 344-2013 provide guidance for testing and extrapolation to similar equipment. SHINE vendor specifications require documentation of test results that demonstrate that the UPSS battery chargers and other UPSS safety-related equipment function before, during, and after a seismic event.

IEEE Standard 650-2017, "IEEE Standard for Qualification of Class 1E Static Battery Chargers, Inverters, and Uninterruptible Power Supply Systems for Nuclear Power Generating Stations" (Reference 7) was considered during the design and issuance of vendor specifications for the UPSS battery chargers and other UPSS safety-related equipment. It was not invoked in the vendor specifications because Sections 4.1, 5.1, 6.1, and 7 of IEEE Standard 323-2003 and Sections 8 and 9.3 of IEEE Standard 344-2013 were considered sufficient to provide the necessary requirements for environmental and seismic qualification of the UPSS battery chargers and other UPSS safety-related equipment.

For environmental qualification of UPSS battery chargers and other UPSS safety-related equipment, Section 5.3 of IEEE Standard 650-2017 provides specific type testing to be performed (i.e., sections 5.3.1.1 through 5.3.1.9). Although this is one reasonable approach to environmental qualification of equipment, SHINE believes that IEEE Standard 323-2003, which provides guidance for type testing that demonstrates that the equipment can perform the intended safety functions(s) for the required operating time before, during, and/or following the design basis event, as appropriate, is sufficient and provides additional flexibility. SHINE vendor specifications require documentation that demonstrates adequate environmental qualification and allows for type testing, operating experience, analysis, and combined methods, as described above. SHINE believes that this approach is sufficient and provides adequate environmental qualification without invoking the specific type testing discussed in IEEE Standard 650-2017.

For seismic qualification of battery chargers and other UPSS safety-related equipment, Section 5.3.1.8 of IEEE Standard 650-2017 provides guidance for seismic testing. This section states that the equipment shall be seismically qualified according to IEEE Standard 344 and does not provide additional guidance for testing methodologies. SHINE believes that the guidance provided in Sections 8 and 9.3 of IEEE 344-2013 provides more detailed guidance for seismic qualification than that provided in IEEE Standard 650-2017. SHINE believes that this guidance, combined with the vendor specifications that require the use of bounding values from the SHINE facility design basis event, are sufficient to demonstrate seismic qualification of the UPSS battery chargers and other UPSS safety-related equipment.

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 Stations"	• 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, "Recommended Practice for Sizing Lead-Acid Batteries for Generating Stations"	• 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.

SHINE Response

The following discussion provides the SHINE justification for excluding potentially applicable sections of the IEEE standards identified by the NRC to which SHINE has not committed to implement for its electrical power systems.

IEEE Standard 946-2020, "IEEE Recommended Practice for the Design of DC Auxiliary Systems for Stationary Applications" (Reference 8)

As described in the SHINE Response to RAI 8-1 (Reference 9) and Sections 8a2.2 and 8a2.3 of the FSAR, SHINE commits to a portion of IEEE Standard 946-2004, "IEEE Recommended Practice for the Design of DC Auxiliary Systems for Generating Stations," (Reference 10), not the 2020 version of this standard. SHINE considers the 2004 code year of IEEE Standard 946 to provide sufficient guidance and is not required to update the design of the facility to reflect the 2020 version of this standard.

SHINE understands that a justification for excluding Sections 7.4 and 7.5 of IEEE Standard 946-2004 from implementation in the design of the SHINE electrical power systems is of interest to the NRC staff. As discussed in the SHINE Response to RAI 8-1 and Subsection 8a2.2.3 of the FSAR, SHINE commits to Sections 5.2, 6.2, 6.5, 7.1, 7.3, Table 2 of 7.4, 7.6, and 7.9 of IEEE Standard 946-2004. Table 2 of Section 7.4 of IEEE Standard 946-2004 provides the detail for which instruments, alarms, and controls are needed, their location, and an allowance for grouping. The remainder of Section 7.4 of IEEE Standard 946-2004 provides information of a more general nature, such as why ground monitoring and undervoltage are monitored and alarmed. This information does not provide specific details needed to help satisfy SHINE Design Criterion 27, which is why SHINE did not commit to Section 7.4 of the standard beyond Table 2.

Section 7.5 of IEEE Standard 946-2004 notes, "The following equipment characteristics and system design features should be given consideration when sizing and selecting equipment." Section 7.5 is comprised of four sections that contain general discussions on the topics of load transfers, constant power DC loads, switching surges, and electrical noise. These sections do not provide detailed design requirements. SHINE vendor specifications provide the system requirements for loading and account for the capability of the battery charger to charge a fully discharged battery, feed an inverter, and carry necessary DC loads. In this way, the vendor specifications provide more specific requirements than the guidance of the load transfer section of Section 7.5 of IEEE Standard 946-2004. SHINE performed internal calculations to determine the direct current (DC) loading on the uninterruptible electrical power supply system (UPSS). DC loads are modeled as constant power loads and a margin of conservatism is included in the calculation. These internal calculations are more specific than the guidance of the constant power DC loads discussion in Section 7.5 of IEEE Standard 946-2004. SHINE vendor specifications require documentation for UPSS components that demonstrate surge withstand capabilities. There are no large inductive loads on the UPSS system, and motors are fed by variable frequency drives (VFDs) which do not feed back to the source when de-energized. These vendor specifications and design attributes are more specific than the guidance of the switching surges discussion in Section 7.5 of IEEE Standard 946-2004. SHINE vendor specifications provide direction for noise minimization relating to UPSS components. More details of noise minimization were provided in the SHINE Response to RAI 8-1 as part of the discussion of how SHINE addresses electromagnetic interference (EMI) and radiofrequency interference (RFI) requirements. The requirements of the SHINE vendor specifications are more detailed than the guidance of the electrical noise discussion in Section 7.5 of IEEE Standard 946-2004. By providing more specificity than the general guidance provided in Section 7.5 of IEEE Standard 946-2004 using vendor specifications, design attributes, and internal calculations, SHINE helps to satisfy SHINE Design Criterion 27 without committing to Section 7.5 for the design of the electrical power systems.

<u>IEEE Standard 344-2013, "Recommended Practice for Seismic Qualification of Class 1E Equipment for Nuclear Generating Stations" (Reference 5)</u>

Section 4.1 of IEEE Standard 344-2013 states, "This clause provides background information on earthquake behavior and on the performance of equipment during simulated seismic events. Numerical values provided are typical and illustrative and should not be considered as standards." Based upon this, SHINE considers Section 4 of IEEE Standard 344-2013 to be a source of general information and does not contain specific information that can be used to demonstrate seismic qualification of components in support of SHINE Design Criterion 4.

Section 11 of IEEE Standard 344-2013 provides guidance for documentation of seismic qualification. SHINE vendor specifications require documentation that demonstrates that the UPSS equipment is seismically qualified using bounding values following the SHINE facility design basis event. SHINE vendor specifications also require documentation of seismic qualification testing that was performed. SHINE vendor specifications require this documentation to demonstrate that UPSS equipment functions before, during, and after a seismic event. By requiring documentation that demonstrates that UPSS equipment will function before, during, and after a SHINE facility design basis seismic event, SHINE helps to satisfy SHINE Design Criterion 4 without committing to Section 11 of IEEE Standard 344-2013 for documentation of seismic qualification.

<u>IEEE Standard 485-2010, "Recommended Practice for Sizing Lead-Acid Batteries for Stationary Applications" (Reference 11)</u>

Section 4 of IEEE Standard 485-2010 provides general information for defining loads. By complying with Section 6.3.2 of IEEE Standard 485-2010, SHINE has calculated, from an analysis of each section of the duty cycle, the maximum capacity required by the combined load demands of various sections. This duty cycle that was analyzed takes into account the various loads needed to be carried by the UPSS batteries and the duration and timing of when these loads were expected to occur. By committing to the sizing methodology of Section 6.3.2 of IEEE Standard 485-2010, SHINE employs a section of the standard that provides more specific guidance in helping satisfy SHINE Design Criterion 27 without committing to Section 4 of IEEE Standard 485-2010, which is more general in nature.

Section 5 of IEEE Standard 485-2010 summarizes factors that should be considered in selecting a cell design for a particular application. SHINE vendor specifications provide requirements that address functions and characteristics; UPSS battery capacity; environmental conditions; electrical requirements to include characteristics at end of discharge and charging characteristics; maintenance requirements; orientation of battery racks; and seismic qualification requirements. By including requirements in vendor specifications that ensure the UPSS battery and associated cells that will be selected are consistent with the requirements of the facility design, SHINE helps satisfy SHINE Design Criterion 27 without committing to Section 5 of IEEE Standard 485-2010.

<u>IEEE Standard 450-2010, "Recommended Practice for Maintenance, Testing, and Replacement of Vented Lead-Acid Batteries for Stationary Applications" (Reference 12)</u>

Section 6 of IEEE Standard 450-2010 provides guidance for test schedules, Section 7 of IEEE Standard 450-2010 provides procedures for battery tests, and Section 8 of IEEE Standard 450-2010 provides criteria for battery replacement. SHINE vendor specifications require functional testing, factory acceptance testing, and site acceptance testing. SHINE vendor specifications require that the vendor provide maintenance, calibration, and surveillance activities necessary to ensure the 30-year design life of the UPSS batteries. In this way, SHINE will have performed the required testing and been provided the technical documentation necessary to determine the test schedules and procedures to ensure a 30-year design life for the UPSS batteries, which will help satisfy SHINE Design Criteria 4, 27, and 28 without committing to Sections 6 and 7 of IEEE Standard 450-2010. Additionally, this technical documentation of test schedules and procedures to ensure a 30-year design life will allow SHINE to keep informed of degrading conditions that could necessitate battery replacement, which will help satisfy SHINE Design Criteria 4, 27, and 28 without committing to Section 8 of IEEE Standard 450-2010.

Section 9 of IEEE Standard 450-2010 provides general guidance on maintaining records of battery inspections and tests. SHINE vendor specifications require that documentation of inspections and testing performed by the vendor be provided. SHINE vendor specifications require that the vendor provide maintenance, calibration, and surveillance activities necessary to ensure the 30-year design life of the UPSS batteries. Having the documentation of inspections and tests performed by the vendor in addition to the required activities to ensure a 30-year design life will allow SHINE to gather the required data and maintain records to verify the ability of the UPSS batteries to perform their safety-related function and help satisfy SHINE Design Criteria 4 and 28 without committing to Section 9 of IEEE Standard 450-2010, which is general in nature.

<u>IEEE Standard 484-2002, "Recommended Practice for Installation Design and Installation of Vented Lead-Acid Batteries for Stationary Applications" (Reference 13)</u>

Section 7 of IEEE Standard 484-2002 provides guidance on records and states, "Data obtained from receiving, storage, assembly, and freshening charge are pertinent to the maintenance and operational life of the battery." SHINE vendor specifications require that each UPSS battery cell be provided with a unique serial number, that the vendor provide documentation of inspections and testing performed by the vendor, and that the vendor provide maintenance, calibration, and surveillance activities necessary to ensure the 30-year design life of the UPSS batteries. These requirements in the SHINE vendor specifications will allow SHINE to gather required data specific to each UPSS battery cell that is necessary to perform the proper maintenance in support of the 30-year design life of the UPSS batteries, which helps satisfy SHINE Design Criteria 4 and 28 without committing to Section 7 of IEEE Standard 484-2002.

<u>**RAI 8-10**</u>

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.

SHINE Response

The following portions of National Fire Protection Association (NFPA) 70-2017, "National Electrical Code" (Reference 14), as adopted by the State of Wisconsin (Chapter SPS 316 of the Wisconsin Administrative Code), are used to meet the SHINE Design Criterion 27 requirement 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:

Parts I through VII of Article 240 provide the general requirements for overcurrent protection and overcurrent protective devices not more than 1000 volts nominal. As stated in 240.1 of this Article, overcurrent protection for conductors and equipment is provided to open the circuit if the current reaches a value that will cause an excessive or dangerous temperature in conductors or conductor insulation. This overcurrent protection isolates faults to specific loads and sections of circuitry and thus minimizes the probability of having the fault progress to portions of the circuit that could impact the ability of equipment to isolate the UPSS upon a loss of power from the off-site electrical power system. Specific sections of Article 240 that contribute to this minimization of fault progression are as follows:

- 240.12 provides requirements for electrical system coordination based upon short-circuit protection and overload indication based on monitoring systems or devices. This coordination ensures that protective devices are properly located in circuits to minimize the impact of faults and raise the overall reliability of the system.
- 240.30(A) provides requirements for the protection of overcurrent devices from physical damage, which minimizes the probability of an overcurrent device from failing to perform its function when required. This enhances the reliability of the protection provided by overcurrent devices and minimizes the probability of having the fault progress to other portions of the circuit.
- 240.85 provides requirements for the applications of circuit breakers that ensure circuit breakers are located in a circuit in which the nominal voltage between any two conductors does not exceed the circuit breaker's voltage rating. This minimizes the probability of unnecessary circuit breaker trips and raises the overall reliability of the system.

By complying with the sections of Article 240 of NFPA 70-2017 discussed above, SHINE ensures that overcurrent protection is in place to isolate faulted portions of the system before the fault impacts equipment necessary to isolate the UPSS upon a loss of power to the offsite electrical power system. In this way, compliance with the sections of Article 240 of NFPA 70-2017 discussed above helps satisfy the portion of SHINE Design Criterion 27 that requires 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.

Article 250 provides requirements for grounding and bonding of electrical installations that help ensure that damage due to ground faults is minimized and that faults do not spread to other parts of the circuit. This minimizes the probability that a ground fault will impact equipment necessary to isolate the UPSS upon a loss of power to the off-site electrical power system. Specific sections of Article 250 that contribute to this limitation of damage and fault progression are as follows:

- 250.4(A) provides requirements for the grounding of systems and electrical equipment and the bonding of electrical equipment and electrically conductive materials. These requirements limit the voltage to ground and establish an effective ground-fault current path for the system and components, which limits equipment damage and ground fault spread.
- 250.4(B) provides requirements for grounding and bonding electrical equipment in ungrounded systems. For grounding electrical equipment, these requirements provide for limiting the voltage imposed by lightning or unintentional contact with higher-voltage lines and limits the voltage to ground. For bonding electrical equipment, a low-impedance path is created for ground-fault current that is capable of carrying the maximum fault current likely to be imposed on it. These requirements protect equipment from damage due to ground fault and enhance the reliability of ungrounded portions of the electrical system.
- 250.21 provides requirements for ungrounded systems for ground detection sensing equipment. These requirements provide indication so that action can be taken in the event of a ground on ungrounded portions of the system, which prevents equipment damage or fault spread.
- 250.62 provides requirements for grounding electrode conductor material, which ensures the conductors are protected from corrosion. This helps to ensure the physical integrity and ability of the conductors to perform their function over time.
- 250.64(E) provides requirements for the installation of grounding conductors for raceways and enclosures. This ensures the conductors are installed in a manner that permits them perform their function to minimize component damage and the spread of grounding faults to other parts of the system.
- 250.68(B) provides requirements for an effective grounding path for grounding electrode conductors and bonding jumper connections to grounding electrodes. This ensures proper function of the grounding electrodes in minimizing the impact of a ground fault.

By complying with the sections of Article 250 of NFPA 70-2017 discussed above, SHINE ensures that grounding protection is in place to limit damage to electrical components due to ground faults and that these faults do not spread to other parts of the electrical distribution system that could impact the ability to isolate the UPSS upon a loss of power to the offsite electrical power system. In this way, compliance with the sections of Article 250 of NFPA 70-2017 discussed above helps satisfy the portion of SHINE Design Criterion 27 that requires 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.

As discussed in Subsection 8a2.2.4 of the FSAR, SHINE has a standby generator system (SGS) that provides a temporary source of nonsafety-related alternate power to the UPSS and selected additional loads for operational convenience and defense-in-depth. The SGS will carry loads in the event of a loss of the off-site electrical power system, which reduces the loads needed to be carried solely by the UPSS, and thus minimizing the probability of losing electrical power from the UPSS. SHINE applied the following sections of Article 700 of NFPA 70-2017 to ensure reliability of the SGS in performing this defense-in-depth function:

- 700.37 and 701.27 provide requirements for selective coordination which ensures that the electrical distribution system, to include interfaces with the SGS, is designed in a manner that faults are isolated in a manner that they minimize impact to the UPSS.
- 702.4 provides requirements that ensure the SGS is suitable for the maximum available short-circuit current and has sufficient capacity to carry required loads when performing its defense in depth function.
- 702.5 provides requirements for transfer equipment that ensures suitability for the intended use and ensures that design and installation are performed so as to prevent the inadvertent interconnection of normal and alternate sources of supply in any operation of the transfer equipment. By complying with this section, the electrical distribution system will not be negatively impacted by inadvertent operation of transfer equipment associated with the SGS.

By complying with the sections of Article 700 of NFPA 70-2017 discussed above, SHINE maximizes the reliability of the SGS system to perform its function of carrying loads in a timely and reliable manner in the event of a loss of off-site electrical power system, which reduces the loads needed to be carried solely by the UPSS. This reduction in load on the UPSS minimizes 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 as required by SHINE Design Criterion 27.

Chapter 13 – Accident Analyses

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.

<u>SHINE Response</u>

SHINE has performed an additional review of the document entitled, “SHINE Response to Topic Request 5-B,” along with the associated sections of the FSAR and technical specifications. One administrative error was identified in *Insertion of Excess Reactivity: Scenario 1 – Increase in the Target Solution Density During Operations*, in which an incorrect reference and TOGS pressure range were provided. The correct reference for the analysis included in the FSAR, TECRPT-2019-0013, evaluates a complete collapse of all void in the solution, making it independent of the TOGS pressure and bounding of all pressure transients. An updated version of “SHINE Response to Topic Request 5-B” has been provided in the NRC Reading Room.

No inconsistencies were identified between the credited design values in Chapter 13 of the FSAR and the most limiting technical specification values.

For *Insertion of Excess Reactivity: Scenario 4 - High Power Due to High Neutron Production and High Reactivity at Cold Conditions*, the scenario analyzed reaches a peak power of [ ]PROP/ECI. This is not inconsistent with the high wide range neutron flux analytical limit of 300 kW, because there are two types of high power events that have been analyzed as part of the safety analysis and the high wide range neutron flux limit is set based on the limiting event.

Because of the transient nature of the driver dropout event, described in Subsection 13a2.1.2 of the FSAR (and in more detail within Subsections 4a2.6.3.3 and 13a2.2.2.3 of the FSAR), the concern is exceeding the transient average power density of the target solution as defined in LCO 3.1.7 of the SHINE technical specifications. For the limiting core configuration this is [ ]PROP/ECI. In the scenario analyzed, the neutron driver drops out, all void leaves the solution, and the target solution cools for [ ]PROP/ECI prior to the driver restarting. When the driver restarts, there is a sharp increase in power, the void quickly builds back in, and the reactivity and power quickly decrease. Figure 4a2.6-6 of the FSAR shows a similar transient event in which the neutron driver drops out for 60 seconds. This evaluation uses nominal system parameters in the TRIAD multiphysics code to produce a best estimate result. The peak power of less than [ ]PROP/ECI for this nominal analysis demonstrates the highly conservative nature of the safety basis analysis, which calculates a peak power of [ ]PROP/ECI based on bounding coefficients of reactivity with uncertainties applied.

The scenario that sets the high wide range neutron flux analytical limit of 300 kW and the averaging time of 45 seconds for the power range neutron flux is a sustained high power event that causes a significant increase in the target solution temperature. These values are interdependent, with a higher wide range neutron flux limit requiring a lower averaging time and a lower wide range neutron flux limit allowing for a higher averaging time. The limits of 300 kW and 45 seconds were chosen to optimize this trade-off and ensure that the combination of the two neutron flux limits maintains the average temperature of the target solution below 176°F, as required by LCO 3.1.4 of the SHINE technical specifications.

No inconsistency was identified in the Reduction in Cooling event. The analysis for this event, as described in Subsection 13a2.2.3 of the FSAR, uses a primary closed loop cooling system (PCLS) flow of [ ]PROP/ECI and a PCLS supply temperature of 77°F. These values match the analytical limits documented in the bases for the low PCLS flow (limiting safety system setting [LSSS] 2.2.7 of the technical specifications) and high PCLS temperature (LSSS 2.2.8 of the technical specifications). The LSSSs provided in Table 2.2 of the technical specifications protect against these analytical limits.

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 deenergizes 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.

SHINE Response

Upon a loss of off-site power (LOOP), the uninterruptable electrical power supply system (UPSS) provides power to the TSV off-gas system (TOGS) blowers and recombiner heaters for five minutes. Approximately three minutes after a LOOP, the engineered safety features actuation system (ESFAS) provides a loss of external power signal to the TSV reactivity protection system (TRPS), which initiates an IU Cell Nitrogen Purge and sends a signal to the ESFAS to initiate an ESFAS IU Cell Nitrogen Purge. The IU Cell Nitrogen Purge causes the appropriate nitrogen purge system (N2PS) valves to enter their fail-safe position and inject nitrogen into the TSV dump tank to provide hydrogen control in the primary system boundary (PSB). N2PS injection overlaps with operation of the TOGS by approximately two minutes to ensure that combustible gas management is continuous.

During a normal LOOP event, N2PS injection ensures that hydrogen concentrations in the PSB are maintained below three percent by volume. During accident scenarios which include equipment failures along with the initiating event, hydrogen may reach deflagration concentrations. The maximum credible deflagration in these accident scenarios results in a pressure of less than 65 pounds per square inch absolute (psia)as described in Subsection 4a2.2.1.10 of the FSAR, and this pressure does not violate the PSB safety limits or lead to the release of radioactive materials.

As described in Subsection 9b.6.2 of the FSAR, the N2PS is sized to be able to service tanks and vessels containing irradiated target solution in both the irradiation facility (IF) and radioisotope production facility (RPF) for three days . The tubes of the N2PS are manifolded, so they will act in unison and have a common remote fill connection to allow for efficient refilling. An additional nitrogen gas tube is provided in N2PS to cover the loss of a tube for maintenance or replacement.

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.

SHINE Response

SHINE calculation CALC-2019-0040 details the sizing of the radiological ventilation zone 1 exhaust subsystem (RVZ1e) lag tank. The tank is comprised of two parts: the portion containing the RVZ1e radiation monitors and the portion relied on for providing holdup. The portion of the tank relied on for providing holdup is downstream of the portion containing the RVZ1e radiation monitors, and the redundant RVZ1e irradiation unit (IU cell) isolation valves are downstream of the portion relied on for providing holdup.

SHINE calculation CALC-2019-0040 utilized conservative values when calculating the required length of the part of the tank relied on for holdup. This includes, but is not limited to, a safety factor of 2 (making the calculated holdup time 40 seconds) and using the IU cell's maximum air temperature. Furthermore, the volume of the downstream conical reducer and the length of pipe between the downstream conical reducer and the isolation valves are not credited as part of the volume required for holdup. This allows for additional margin beyond that provided by the applied safety factor.

As mentioned above, the RVZ1e radiation monitors are located upstream of the holdup volume. These monitors initiate an IU Cell Safety Actuation on high radiation, as described in Subsection 7.4.4.1.15 of the FSAR. Part of this actuation is closing the RVZ1e IU cell isolation valves within 20 seconds of elevated radiation levels reaching the detectors. This includes a 15 second response time for the detectors (Table 7.4-1 of the FSAR) and the remaining five seconds is shared between the TRPS response and the RVZ1e isolation valves. Because the RVZ1e isolation valves close within 20 seconds of radiation reaching the detectors, the conservatively sized RVZ1e lag tank provides sufficient delay for the IU Cell Safety Actuation to be enacted by the TRPS and for the RVZ1e isolation valves to close prior to elevated radiation levels passing by the first RVZ1e isolation valve.

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.

SHINE Response

The SHINE Response to RAI 13-14 will be provided by August 31, 2021.

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.

SHINE Response

The SHINE Response to RAI 13-15 will be provided by August 31, 2021.

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.

SHINE Response

The SHINE Response to RAI 13-16 will be provided by August 31, 2021.

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.

SHINE Response

a. To develop the bounding target solution material-at-risk (MAR), a few notable conservatisms were used: a continuous 30-day irradiation cycle, a shortened downtime between irradiation cycles, no extraction between irradiation cycles, and an increase in operating power.

   The known uncertainty associated with software used to calculate the target solution MAR is discussed in the “Uncertainties” section of Section 13a2.2 of the FSAR. A nuclide-dependent multiplication factor ranging from 0 to 35 percent increase was applied to each nuclide in the target solution MAR in addition to the conservatisms discussed above. The multiplication factor only increases the nuclide inventory in the MAR.

Other uncertainties in generating the target solution MAR could include target solution void profiles, target solution temperature profiles, core configuration (solution height and uranium concentration), and geometrical tolerances of the TSV. These sources of uncertainty are negligible and modeling the power as 110 percent of the license-limit is adequate because the transmutation calculation in ORIGEN-S is held at a constant power level meaning the neutron flux will be as high as necessary to reach the given power level. During physical operation of the SHINE system, the high time-averaged neutron flux signal, as described in Subsection 7.4.4.1.3 of the FSAR, protects against exceeding analyzed TSV power level.

b. Most of the peak halogen and noble gas radionuclide concentrations occur at the end of the last irradiation cycle. The percent difference for all halogen and noble gas activities at their maximum compared to shutdown is less than 1 percent, except for radon-222, which is being built into the system from the uranium-238 decay chain.

c. The activities of iodine-131 at the end of the last irradiation cycle for the bounding and nominal cases are [ ]$^{PROP/ECI}$ and [ ]$^{PROP/ECI}$, respectively. The maximum net generation rates of iodine-131 during the last irradiation cycle for the bounding and nominal cases are [ ]$^{PROP/ECI}$ and [ ]$^{PROP/ECI}$, respectively. The net generation rate of iodine-131 is higher in the nominal case for the last cycle because the nominal case accounts for removal of iodine (and other elements) between irradiation cycles, where the bounding case assumes there is no removal of any elements between cycles and with the large inventory in the bounding case, decay losses are comparable to generation (i.e., the system is approaching saturation).

<u>RAI 13-18</u>

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.

<u>SHINE Response</u>

Leak path factors reported in Revision 1 of FAI/19-0035 are not utilized in Revision 7 of CALC-2018-0048. Radionuclide transport is calculated using equations presented in Section 5.1 of CALC-2018-0048, which is summarized in Section 13a2.2 of the FSAR. Documentation has been consistently updated and the SHINE licensing basis reflects the current design of the facility.

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.

SHINE Response

The SHINE Response to RAI 13-19 will be provided by August 31, 2021.

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.

SHINE Response

The SHINE Response to RAI 13-20 will be provided by August 31, 2021.

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.

SHINE Response

Chemical exposures to the radiologically controlled area (RCA) worker are determined using a simple concentration with the following formula:

$$concentration = ST/V$$

Where:

- ST is the source term, in milligrams (mg); and

- V is the free volume of the RPF, IF, or uranium receipt and storage system (URSS) and target solution preparation system (TSPS) rooms (depending on the release scenario), in cubic meters (m^3)

Chemical exposures to the control room worker are calculated by postulating the hazardous chemical is released from main production facility rollup door without confinement or dilution. ALOHA (Areal Locations of Hazardous Atmospheres) is then used to calculate the indoor concentration at a point 16.8 meters (m) directly downwind of the release (16.8 m being the distance from the rollup door to the facility ventilation zone 4 (FVZ4), or non-radiological, intake louver). The chemical is drawn into the building's non-radiological ventilation system through this louver and into the facility. The rate at which the chemical is drawn is determined by the air exchange rate for the building, which is 1.2 air exchanges per hour, consistent with Regulatory Guide 1.78, "Evaluating the Habitability of a Nuclear Power Plant Control Room During a Postulated Hazardous Chemical Release" (Reference 15) guidance for control rooms without automatic isolation capabilities.

It is possible that chemical exposure consequences can occur to facility personnel neither in the control room nor RCA. However, chemical consequences for these personnel will be no higher than the consequences for workers in those areas. The reasons for this are follows:

1. The concentration of chemical exposure for non-RCA workers will be lower than for RCA workers. This is because the release originates in the RCA and has increased dilution volume as it expands beyond the RCA.
2. The ventilation system which serves the control room also serves the rest of the non-radiologically controlled rooms in the SHINE facility, using the same air intake. Therefore, non-RCA facility workers outside the control room will experience the same consequences as the non-RCA workers in the control room.

Because none of the facility worker receptors in the RCA are exposed to chemical consequences in excess of Protective Action Criteria (PAC)-2 limits, no safety-related controls are needed to mitigate the consequences. The consequences to facility personnel neither in the control room nor RCA are bound by the consequences to RCA and control room personnel, so safety-related controls are likewise not needed for facility personnel outside these areas.

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. Hazard identification and analysis. 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. Review and audit function. 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. Procedures. 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. Training and qualification. 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. Configuration management. 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. Special Reports. 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.

SHINE Response

The SHINE Response to RAI 13-22 will be provided by August 31, 2021.

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.

SHINE Response

The SHINE Response to RAI 13-23 will be provided by August 31, 2021.

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.

SHINE Response

a. The analysis for the concentration of chemical exposure to the RCA worker (SHINE calculation CALC-2018-0049) incorporates several conservative factors, including:

   - No surface deposition of airborne materials is used.
   - For volatile chemicals modeled as evaporating from a pool, a very shallow (1 centimeter [cm] depth) pool is used in ALOHA. This maximizes airborne release quantity, and therefore maximum concentration of hazardous chemicals.
   - The leak path factor for releases in confinement structures (i.e., the supercell, the waste tank vaults, and the TSPS or URSS gloveboxes) is assumed to be 0.1. This is significantly higher than the normal leak rate from these systems based on the short duration of these type of events.
   - The damage ratio is assumed to be 1.0, meaning all material at risk is released from the container or vessel. This gives conservative, bounding results.
   - Conservative airborne release fractions (ARFs) and respirable fractions (RFs) from NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook" (Reference 16) are used. For example, the uranium oxide scenario uses the bounding ARF and RF listed for free-fall spills of powder up to 3 meters (i.e., 2E-3 and 0.3, respectively). However, in the technical basis for these values within NUREG/CR-6410, it notes that these are based on a 3 meter fall distance and that the values for a 1 meter fall of uranium oxide, more appropriate and still bounding for a drop in the SHINE glovebox, resulted in a maximum ARF and RF of 8E-5 and 0.5, respectively.

- Instantaneous release of the entire inventory is a conservative assumption applied in most scenarios. For the uranium oxide scenario, this is highly conservative given that the material at risk considered in the analysis is equivalent to the mass in approximately 10 storage canisters. For liquids, this is conservative because large vessel ruptures are unlikely with the low pressure in the systems.
- PAC values for most chemicals are taken from the Department of Energy (DOE) Protective Action Criteria (PAC) database. No conservatisms were used apart from any conservatisms embedded in the DOE's PAC value determinations. There are some chemicals used in the SHINE process which were not found in the PAC database, and therefore substitute PAC values, or temporary emergency exposure limits (TEELs) are determined. TEELs are developed as described in Section 13b.3 of the FSAR. These determinations did not use conservatisms apart from any conservatism embedded in the DOE method for determination.
- Evacuation of workers, except for events in the uranium receipt and storage or target solution preparation rooms, is not credited in the analysis. This is conservative, because 60-minute PAC values are used when workers will likely be exposed for less than 60 minutes. For events in the uranium receipt and storage or target solution preparation rooms, a two-minute evacuation time is postulated for analysis. This is conservative, because the room is physically small and, in the event of a hazardous chemical spill, will be evacuated immediately.

b. The control room operator chemical concentrations were calculated by placing the chemical release (i.e., source term) at the lower corner of the rollup door closest to the FVZ4 intake louver. The distance from the rollup door corner to the intake louver is calculated in SHINE calculation CALC-2020-0018. The CALC-2018-0049 analysis does not use the atmospheric dispersion (X/Q) value calculated in CALC-2020-0018, as ALOHA performs its own dispersion calculations. The reference to CALC-2020-0018 in CALC-2018-0049 is related to establishing the calculated distance between the rollup door and the FVZ4 intake louver. The use of the ALOHA dispersion over the CALC-2020-0018-calculated X/Q value results in a higher concentration by more than an order of magnitude. In addition, no confinement or dilution (except for atmospheric dispersion between the release point and the intake louver) is credited.

   In contrast to the assumed release location for the control room operator chemical concentration analysis described above, the RCA worker chemical concentrations were calculated assuming a release of the total source term into the facility as described in Section 13b.3 of the FSAR. SHINE has revised Section 13b.3 of the FSAR to clarify that, in modeling the chemical exposure to the control room operator, the same source term assumed to be released in the RCA worker analysis is assumed to be released from the facility rollup door and transported for the FVZ4 intake louver that services the control room. A mark-up of the FSAR incorporating this change is provided as Attachment 1.

   Additional conservatism in the control room chemical concentration analysis is as follows:

   - The chemical is postulated to be blown by wind directly across the face of the louver, using a slow (1 meter per second [m/s]), very stable (Pasquill class F) wind pattern. This minimizes the dispersion of hazardous chemical vapors and thereby maximizes the concentration at the intake louver.

- For volatile chemicals modeled as evaporating from a pool, a very shallow (1 cm depth) pool is used in ALOHA. This maximizes airborne release rate, and therefore maximum concentration of hazardous chemicals.
- For non-volatile chemicals, a direct, instantaneous release is used in ALOHA. This maximizes airborne release rate, and therefore maximum concentration of hazardous chemicals.

References

1. NRC letter to SHINE Medical Technologies, LLC, “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 (ML21145A060)

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

3. American National Standards Institute/American Nuclear Society, “Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors,” ANSI/ANS-8.1-2014, La Grange Park, IL

4. Institute of Electrical and Electronics Engineers, “Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations,” IEEE Standard 323-2003, New York, NY

5. Institute of Electrical and Electronics Engineers, “Recommended Practice for Seismic Qualification of Class 1E Equipment for Nuclear Generating Stations,” IEEE Standard 344-2013, New York, NY

6. Institute of Electrical and Electronics Engineers, “Qualification of Class 1E Vented Lead Acid Storage Batteries for Nuclear Power Generating Stations,” IEEE Standard 535-2013, New York, NY

7. Institute of Electrical and Electronics Engineers, “Qualification of Class 1E Static Battery Chargers, Inverters, and Uninterruptible Power Supply Systems for Nuclear Power Generating Stations,” IEEE Standard 650-2017, New York, NY

8. Institute for Electrical and Electronics Engineers, “Recommended Practice for the Design of DC Auxiliary Systems for Stationary Applications,” IEEE Standard 946-2020, New York, NY

9. SHINE Medical Technologies, LLC letter to NRC, “SHINE Medical Technologies, LLC Operating License Application Response to Request for Additional Information,” dated January 29, 2021 (ML21029A101)

10. Institute for Electrical and Electronics Engineers, “Recommended Practice for the Design of DC Auxiliary Systems for Generating Stations,” IEEE Standard 946-2004, New York, NY

11. Institute of Electrical and Electronics Engineers, “Recommended Practice for Sizing Lead-Acid Batteries for Stationary Applications,” IEEE Standard 485-2010, New York, NY

12. Institute of Electrical and Electronics Engineers, “Recommended Practice for Maintenance, Testing, and Replacement of Vented Lead-Acid Batteries for Stationary Applications,” IEEE Standard 450-2010, New York, NY

13. Institute of Electrical and Electronics Engineers, “Recommended Practice for Installation Design and Installation of Vented Lead-Acid Batteries for Stationary Applications,” IEEE Standard 484-2002, New York, NY

14. National Fire Protection Association, “National Electrical Code,” NFPA 70-2017, Quincy, MA

15. U.S. Nuclear Regulatory Commission, “Evaluating the Habitability of a Nuclear Power Plant Control Room During a Postulated Hazardous Chemical Release,” Regulatory Guide 1.78, Revision 1, December 2001

16. U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” NUREG/CR-6410, March 1998

ENCLOSURE 2
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, LLC

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

FINAL SAFETY ANALYSIS REPORT CHANGES
PUBLIC VERSION
(MARK-UP)

5 pages follow

6a2.3 NUCLEAR CRITICALITY SAFETY ~~IN THE IRRADIATION FACILITY~~

SHINE maintains a nuclear criticality safety program (CSP) that complies with applicable American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, as endorsed by Regulatory Guide (RG) 3.71, Revision 3, Nuclear Criticality Safety Standards for Fuels and Material Facilities (USNRC, 2018). A description of the CSP is provided in Section 6b.3.

Use, handling, and storage of fissile material in the irradiation facility (IF) is evaluated in accordance with the CSP, with the exception of the target solution vessel (TSV).

6a2.3.1 CRITICALITY SAFETY CONTROLS

Criteria used to select controls and the use of controlled parameters are described in Section 6b.3.2.

6a2.3.1.1 Subcritical Assembly System

A detailed description of the subcritical assembly system (SCAS) is provided in Section 4a2.2. The system is designed to maintain fissile material in a subcritical state during irradiation and to safely store the target solution following irradiation in the TSV dump tank.

Criticality Safety Basis

The nuclear criticality safety evaluation (NCSE) for the SCAS shows that the evaluated sections of the process will remain subcritical under normal and credible abnormal conditions. The TSV is designed to operate at a higher k_{eff} for the production of medical isotopes and is not considered as part of the NCSE. The effects of reactivity changes in the SCAS are provided in Subsections 4a2.6.3.3 and 4a2.6.3.4.

The remaining portions of the SCAS are safe-by-design. The TSV dump tank is shown to remain under the upper subcritical limit under the most reactive credible conditions of concentration, reflection, and corrosion. Piping which contains fissile solutions between the TSV and the TSV dump tank is shown to be within the evaluated single parameters limits.

6a2.3.1.2 Target Solution Vessel Off-Gas System

A detailed description of the TSV off-gas system (TOGS) is provided in Section 4a2.8. The major components of the system are condenser demisters, a zeolite bed, blowers, hydrogen recombiners, recombiner condensers, a recombiner demister, and a vacuum tank. Components of TOGS are located in the irradiation unit (IU) cell and the adjacent TOGS cell. Components in the IU cell are the vacuum tank, condenser demisters, recombiner demister, and associated piping. The remaining components are arranged on a skid in the TOGS cell.

The system is designed to maintain the hydrogen concentration in the primary system boundary below the lower flammability limit by circulating gas from the TSV during irradiation and from the TSV dump tank during cool-down through its demisters, zeolite bed, and recombiner. The TOGS operates at slightly negative pressure. Under normal conditions, the system does not contain significant quantities of fissile material.

6b.3 NUCLEAR CRITICALITY SAFETY IN THE RADIOISOTOPE PRODUCTION FACILITY

SHINE maintains a nuclear criticality safety program (CSP) that complies with applicable American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, as endorsed by Regulatory Guide (RG) 3.71, Revision 3, *Nuclear Criticality Safety Standards for Fuels and Material Facilities* (USNRC, 2018). The CSP meets the following criticality safety requirements of 10 CFR 70:

- The criticality accident requirements of 10 CFR 70.24;
- The criticality reporting requirements of 10 CFR 70.50, 10 CFR 70.52, and the SHINE-specific reporting requirements which meet the intent of 10 CFR 70, Appendix A, as described in the technical specifications;
- Application of 10 CFR 70.61(b) to criticality accidents, considering such accidents as high-consequence events; and
- Application of 10 CFR 70.61(d), ensuring that nuclear processes are subcritical under normal and credible abnormal conditions, including use of an approved margin of subcriticality and the use of preventative controls as the primary means of protection.

6b.3.1 NUCLEAR CRITICALITY SAFETY PROGRAM

The CSP is administered through a written nuclear criticality safety (NCS) policy and program description, with an additional program description for NCS training and qualification. The CSP is executed by qualified NCS staff using written procedures. The program description and written procedures are formally controlled through the SHINE document control procedure.

The goal of the CSP is to ensure that workers, the public, and the environment are protected from the consequences of a nuclear criticality event. In order to accomplish this goal, all practicable measures are implemented to prevent an inadvertent criticality from occurring. The CSP also contains provisions necessary to mitigate the consequences (i.e., criticality accident alarm system [CAAS] and emergency response activities) should an inadvertent criticality occur.

6b.3.1.1 Nuclear Criticality Safety Program Organization

The SHINE Chief Executive Officer holds overall responsibility for the CSP. The Safety Analysis Manager is the Responsible Manager for the CSP and may delegate administrative authority to an NCS Lead.

SHINE facility management holds the following responsibilities with respect to the CSP:

- Formulate and maintain the NCS policy and ensure that personnel involved in fissionable material operations (FMOs) are informed of the policy.
- Assign responsibility and delegate commensurate authority to implement the criticality safety policy and program.
- Ensure that everyone, regardless of position, is made aware of their responsibilities for implementing the requirements of the CSP.
- Ensure that appropriately trained and qualified NCS staff are available to provide technical guidance appropriate for the FMOs performed at the SHINE facility.
- Establish and maintain a training and qualification program for NCS staff.
- Establish a method to monitor the CSP.

with guidance obtained from the NCS staff. Action is taken to prevent recurrence for significant conditions adverse to quality. Records of NCS deficiencies and associated corrective actions are maintained in the corrective action program.

Upon the loss of double contingency protection, operations are suspended and processes rendered safe until double contingency protection can be restored. Adequacy of the affected controls is subsequently assessed as part of the corrective actions.

NCS events are reported to the NRC in accordance with the reporting requirements of 10 CFR 70.50, 10 CFR 70.52, and the SHINE-specific reporting requirements which meet the intent of 10 CFR Part 70, Appendix A, as described in the technical specifications.

6b.3.1.8.1 Planned Response to Criticality Accidents

The CAAS is described in Subsection 6b.3.3.

SHINE maintains an emergency plan which includes the planned response to criticality accidents. The emergency plan contains information on the provision of personnel accident dosimeters in areas that require the CAAS and arrangements for on-site decontamination of personnel and the transport and medical treatment of exposed individuals. The SHINE emergency plan is further described in Section 12.7.

6b.3.1.8.2 Criticality Safety Event Reporting

Facility procedures include provisions for rapid evaluation of the significance of NCS events, including immediate notifications of facility NCS staff and the assessment of events with respect to the loss or degradation of double contingency protection.

The significance and reportability of NCS events is based on the loss or degradation of NCS controls and not on the event sequence with respect to whether or not limits were exceeded.

If an NCS event cannot be affirmatively determined to not require a one-hour report within one hour, it is reported as an event requiring a one-hour report.

6b.3.2 CRITICALITY SAFETY CONTROLS

General

The failure of a single NCS control which maintains two or more controlled parameters is considered a single process upset when determining whether the DCP is met.

Passive engineered geometry controls are the most preferred type of NCS controls. Otherwise, the preferred hierarchy of NCS controls is (1) passive engineered, (2) active engineered, (3) enhanced administrative, and (4) administrative. Use of explicit NCS controls is preferred to reliance on the natural and credible course of events. Generally, control on two independent criticality parameters is preferred over multiple controls on a single parameter. If redundant controls on a single parameter are used, a preference is given to diverse means of control on that parameter.

Likelihood Evaluation

~~T~~For accident sequences in categories other than inadvertent criticality, the likelihood category definitions applied in the SSA are provided in Table 13a2.1-3. The determination of the likelihood of occurrence consists of the initiating event frequency (e.g., seismic event, process component failure, human error) and may be combined with an additional component failure or human error, including any recovery times (i.e., failure duration). In most cases, the initiating events are represented by single events or single failures.

The frequency of occurrence of an initiating event for an accident sequence is represented by a failure frequency index number (FFIN). The FFINs applied in the SSA are provided in Table 13a2.1-4. The bases for determining the FFIN for an accident sequence may include evidence or the type of control.

To determine the FFIN selected for an accident sequence initiator based on the type of control, several factors are considered including:

- administrative (i.e., human error);
- type of component failure (i.e., active versus passive);
- degree of redundancy (i.e., single component, redundant component);
- design margin (e.g., design pressure versus nominal pressure); and
- other factors including degree of enhancement for administrative controls (e.g., independent verification and step sign-off).

If the accident sequence is postulated to occur only if another condition or failure is present, an additional probability of component failure or condition is included in the evaluation. The failure probability index number (FPIN) represents this as a failure on demand, or as a probability that the condition exists. This can be evaluated as a simple probability of failure on demand or approximated as the product of a failure rate and a recovery time, defined in this analysis as a duration index number (DIN). The quantitative characterization of the FPIN and DIN applied in the SSA is provided in Table 13a2.1-5 and Table 13a2.1-6, respectively.

For inadvertent criticality accident sequences, the likelihood category definitions provided in Table 13a2.1-3 are not used. Each potential criticality accident sequence is assumed to have a high consequence and controls are determined through process analysis of the fissionable material operation and application of the double contingency principle to ensure that the entire process will be subcritical under both normal and credible abnormal conditions.

Sufficient controls are identified such that at least two unlikely, independent, and concurrent changes in process conditions are required before a criticality accident is possible, as required by the double contingency principle. Qualitative analysis, based on the interpretation and expert judgment of the nuclear criticality safety staff and key stakeholders during the evaluation process, is used to determine whether changes in process conditions are unlikely and independent.

Consequence Category Definitions

The consequence category definitions applied in the SSA are provided in Table 13a2.1-7. Numerical limits for the radiological and chemical exposure effects are included in the definitions for high and intermediate consequence for the public and facility staff. The low consequence

Estimation of the source term falls into two categories:

1) Non-volatile chemicals (e.g., solids, liquids with low vapor pressures), and
2) Volatile chemicals (i.e., liquids with vapor pressures in excess of 10 Torr at 100°F).

For non-volatile chemicals, the MAR is taken to be the largest quantity of the chemical present in a single vessel or process location. Values for the ARF and RF are taken from the guidance in NUREG/CR-6410, Nuclear Fuel Cycle Facility Accident Analysis Handbook (USNRC, 1998).

For volatile liquids, the MAR x ARF x RF product is replaced by the total mass released as calculated by the ALOHA (Areal Locations of Hazardous Atmospheres) computer code, Version 5.4.7.

To account for uncertainty in the MAR quantities, a multiplier of 1.2 is applied to the calculated source term.

The MAR and source terms for each chemical release scenario are presented in Table 13b.3-2.

Chemical Accident Consequences

A hazardous chemical consequence assessment was performed to demonstrate that potential consequences are within acceptable limits. This assessment determines if the release of hazardous chemicals from the SHINE facility could lead to exceeding the Protective Action Criteria (PAC) values.

A consequence analysis for the public and nearest residence was performed using the PAVAN (An Atmospheric Dispersion Program for Evaluating Design-Basis Accidental Releases of Radioactive Materials from Nuclear Power Stations) computer code (USNRC, 1982). The chemical exposure to the public and nearest residence is then calculated using the 95th percentile atmospheric dispersion factors (χ/Q) calculated using the PAVAN computer code.

To model the chemical exposure to the worker, the source term is used to determine the amount of each chemical released into the facility atmosphere. For the RCA worker, the total source term released into the facility is assumed to be well mixed within the building free volume (i.e., irradiation facility [IF] or radioisotope production facility [RPF]) to determine a chemical concentration. For the control room operator, the same ~~concentration~~total source term is assumed to be released from the facility roll-up door and is transported to the facility ventilation intake that services the control room. ALOHA is then used to calculate the indoor concentration at the location of the ventilation intake louver that services the control room.

Quantitative exposure standards are selected to meet acceptable limits for public and worker health and safety. The quantitative acceptance limits are taken from the PAC values (USDOE, 2018), which correspond to the Acute Exposure Guideline Levels (AEGLs), Emergency Response Planning Guidelines (ERPGs), or Temporary Emergency Exposure Limits (TEELs) values for such chemicals. Exceptions are applied to rhodium chloride, uranyl sulfate, and uranyl peroxide, which do not have published PAC values. For these chemicals, acceptance limits were developed using guidance from DOE-HDBK-1046-2016, Temporary Emergency Exposure Limits for Chemicals: Method and Practice (USDOE, 2016).

ENCLOSURE 2
ATTACHMENT 2

SHINE MEDICAL TECHNOLOGIES, LLC

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

TECHNICAL SPECIFICATIONS CHANGES
PUBLIC VERSION
(MARK-UP)

2 pages follow

5.8.3 Additional Event Reporting Requirements

1. Events which meet the reporting requirements of 10 CFR 70.50~~;~~ or 10 CFR 70.52~~; or paragraphs (a)(1) through (a)(3), (b)(3), or (c) of 10 CFR Part 70, Appendix A~~ shall be reported to the NRC as prescribed in the applicable regulation.

2. SHINE shall report to the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:

   a. An inadvertent nuclear criticality.

   b. An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

   c. An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could endanger the life of a worker or could lead to irreversible or other serious, long-lasting health effects to any individual located outside the owner controlled area.

   d. An event or condition such that no credited controls, as documented in the SHINE Safety Analysis, remain available and reliable, in an accident sequence evaluated in the SHINE Safety Analysis.

3. SHINE shall report to the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:

   a. Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that described in the SHINE Safety Analysis, and which results in inadequate controls in place to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

   b. Loss or degradation of credited controls, as documented in the SHINE Safety Analysis, other than those items controlled by a limiting condition of operation established in section 3 of the technical specifications, that results in failure to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

   c. An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that could lead to irreversible or other serious, long-lasting health effects to a worker, or could cause mild transient health effects to any individual located outside the owner controlled area.

   d. Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more safety-related structures, systems or components.

4. SHINE shall concurrently report to the NRC Operations Center any event or situation, related to the health and safety of the public or on-site personnel, or

protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made.

5.8.4 Startup Report

SHINE shall conduct startup testing in accordance with the Startup Testing Program, as described in FSAR Section 12.11. Following completion of startup testing, SHINE will submit a Startup Report to the NRC Document Control Desk that identifies the startup tests performed.

The Startup Report shall be submitted within 6 months of the completion of all startup testing activities.

5.9 Records

5.9.1 Lifetime Records

The following records are to be retained for the lifetime of the SHINE Facility:

1. Gaseous and liquid radioactive effluents released to the environs;
2. Offsite environment-monitoring surveys required by the technical specifications;
3. Radiation exposure for all monitored personnel; and
4. Updated drawings of the SHINE Facility.

Applicable annual reports, if they contain all of the required information, may be used as records in this section.

5.9.2 Five Year Records

The following records are to be maintained for a period of at least five years or for the life of the component involved if less than five years:

1. Normal SHINE Facility operation (but not including supporting documents such as checklists, log sheets, etc., which shall be maintained for a period of at least one year);
2. Principal maintenance operations;
3. Reportable occurrences;
4. Surveillance activities required by the technical specifications;
5. Facility radiation and contamination surveys where required by applicable regulations;
6. Radioactive material inventories, receipts, and shipments;
7. Approved changes in operating procedures; and
8. Records of meeting and audit reports of the review and audit group.

5.9.3 Records to be retained for at least one certification cycle

Records of retraining and requalification of operations personnel who are Licensed pursuant to 10 CFR Part 55 shall be maintained at all times while the individual is employed or until License is renewed.