From:	Lynch, Steven
To:	Jeff Bartelme
Cc:	Smith - NRR, Brian; Casto, Greg; Balazik, Michael; Dickson, Elijah; Smith, April; Munson, Jeremy; Hammelman, James; Tiktinsky, David
Subject:	Issuance of Request for Additional Information Related to the SHINE Medical Technologies, LLC Operating License Application (EPID No. L-2019-NEW-0004)
Date:	Tuesday, November 10, 2020 1:15:16 PM
Attachments:	SHINE Request for Additional Information Related to FSAR Chapters 6 and 13.pdf

Jeff,

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), and August 28, 2020 (ADAMS Accession No. ML20255A027), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted as part of the operating license application, and prepare a safety evaluation report. Specific chapters and technical areas of the SHINE operating license application covered by this RAI include the following:

- Chapter 6, "Engineered Safety Features"
- Chapter 13, "Accident Analysis"

It is requested that SHINE provide responses to the enclosed RAI within 30 days from the date of this electronic mail. In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Following receipt of the additional information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE's operating license application, additional RAIs for other chapters and technical areas may be developed. The NRC staff will transmit any further questions to SHINE under separate correspondence. If you have any questions, or need additional time to respond to this request, please contact me at 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Steve Lynch, Senior Project Manager
Non-Power Production and Utilization Facility Licensing Branch
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OFFICE OF NUCLEAR REACTOR REGULATION

REQUEST FOR ADDITIONAL INFORMATION

REGARDING OPERATING LICENSE APPLICATION FOR

SHINE MEDICAL TECHNOLOGIES, LLC

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), and August 28, 2020 (ADAMS Accession No. ML20255A027) SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of the SHINE operating license application, questions have arisen for which additional information is needed. This request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted as part of the operating license application, and prepare a safety evaluation report. Specific chapters of the SHINE operating license application covered by this RAI include the following:

- Chapter 6, "Engineered Safety Features"
- Chapter 13, "Accident Analysis"

Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE operating license application, which describes the SHINE irradiation facility, including the irradiation units, and radioisotope production facility , using the applicable 10 CFR regulations, as well as the guidance contained in NUREG-1537 Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537 Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048). The NRC staff is also using the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069), and "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A075). As applicable, additional guidance

cited in SHINE's FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE operating license application.

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

Responses to the following request for additional information are needed to continue the review of the SHINE operating license application.

Chapter 6 – Engineered Safety Features

The following regulatory requirements apply to RAIs 6b.3-1 through 6b.3-11:

> 10 CFR Part 50.34(b) states that the FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility as a whole.
>
> 10 CFR 50.34(b)(2) states that a description and analyses of the structures, systems and components of the facility, with emphasis upon the performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished.

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

RAI 6b.3-1 FSAR, Section 6b.3.1.4, states that an additional penalty of 0.01 was assigned to SHINE's proposed margin of subcriticality (0.05) to account for the limited number of experimental benchmarks available for uranyl sulfate systems in the validation of SHINE's computational method (MCNP5), resulting in a margin of subcriticality of 0.06. However, SHINE FSAR Section 4a2.6.2.6.1, "Uncertainties in K_{eff} Values Relying on MCNP Calculation," assigns a margin of subcriticality of 0.05 to the target solution vessel (TSV) dump tanks despite being subject to the same vulnerabilities as those necessitating an additional penalty of 0.01 and relying on the same computational method, cross-section library, and validation report.

a. Justify the use of a unique margin of subcriticality (0.05) for the TSV dump tanks, noting that any additional data obtained through 1/M experiments does not contribute to the validation of SHINE's computational method (MCNP5) and its determination of bias and bias uncertainty.

b. Describe how the use of a unique margin of subcriticality (0.05) for the TSV dump tanks is consistent with American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.24-2017, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations," as committed to in FSAR, Section 6b.3.1.3, "Use of National Consensus Standards."

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 (NCS) technical practices, which will ensure that the fissile material will be possessed, stored, and used safely.

RAI 6b.3-2 FSAR, Section 6b.3.1.5, states that if the double contingency principle (DCP) cannot be employed, consideration is given to the use of ANSI/ANS-8.10-2015, "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement," to allow single-contingency operations or mitigation of consequences. FSAR, Section 6b.3.1.3, states that SHINE is committed to following ANSI/ANS-8.10-2015, as endorsed by RG-3.71.

To understand if there are circumstances where the DCP cannot be employed, the applicant should identify any such cases in the license application in which the DCP is not practicable and should provide justification as to why the affected processes are acceptably safe.

a. Describe how ANSI/ANS-8.10 would be implemented in the event that the DCP cannot be employed given that ANSI/ANS-8.10, Paragraph 4.1(a), states that the provisions of the standard may only be applied in facilities where all operations involving fissionable materials are conducted remotely by personnel located outside of the shielded area.

b. RG-3.71 includes a clarification to ANSI/ANS-8.10 that the dose limits for an intermediate consequence event in 10 CFR Section 70.61, "Performance Requirements," may be used in lieu of the dose limits specified in Section 4.2.1 of the standard. State which dose limits would be applied if ANSI/ANS-8.10 were implemented.

c. Discuss any instances in which the DCP is not practicable at the SHINE facility. Provide a justification for any such instance.

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 NCS technical practices, which will ensure that the fissile material will be possessed, stored, and used safely.

RAI 6b.3-3 FSAR, Section 6b.3.1.5, states that processes within the radioisotope production facility (RPF) generally comply with the DCP. FSAR Section 6b.3.1.3 states that SHINE commits to ANSI/ANS-8.1-2014, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," which includes adherence to the DCP. However, SHINE does not define the terms "unlikely" or "credible" as they apply to the DCP.

Define the terms "unlikely" and "credible" as they relate to the DCP.

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 NCS technical practices,

which will ensure that the fissile material will be possessed, stored, and used safely.

RAI 6b.3-4 FSAR, Section 6b.3.1.8, states that 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 DCP is primarily a design principle as opposed to a representation of a state of existence. Therefore, the determination of whether a report to the NRC is required should be based on the likelihood of inadvertent criticality, not whether double contingency protection was maintained.

a. Describe the method in which NCS events are evaluated for whether a report to the NRC is required. Discuss whether SHINE intends to commit to the reporting requirements of 10 CFR 70, Appendix A for NCS events.

b. State whether SHINE commits to meeting the requirements of 10 CFR 70.50 and 70.52 with respect to reporting the occurrence of inadvertent criticality to the NRC.

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 in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

RAI 6b.3-5 The SSA states that reliability management measures are considered to be programmatic administrative controls. FSAR, Section 12.5, provides actions regarding reporting safety limit violations and occurrences requiring special reports other than a safety limit violation to the NRC, including observed inadequacies 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 whether failures and/or degradations to reliability management measures that negatively impact a control's ability to perform its intended safety function would be reported to the NRC.

Discuss how failures and degradations of reliability management measures are assessed with respect to reporting to the NRC.

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 in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

RAI 6b.3-6 FSAR, Section 6b.3.1.4, states that criticality safety limits are derived based on assuming optimum or most-reactive *credible* parameter values unless specific

controls are implemented to limit parameters to a particular range. The term "credible" is defined in the SHINE SSA, as it relates to abnormal conditions, changes in process conditions, and accident sequences. However, the definition provided does not address the use of the term "credible" as it relates to criticality safety parameter values.

Describe how the credibility of a most-reactive credible parameter value would be identified and how its credibility would be assessed.

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 in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

RAI 6b.3-7 FSAR, Section 6b.3.1.3, states that SHINE commits to following ANSI/ANS-8.7-1998, "Nuclear Criticality Safety in the Storage of Fissile Materials," as endorsed by Regulatory Guide (RG)-3.71, "Nuclear Criticality Safety Standards for Nuclear Materials Outside Reactor Cores." The staff reviewed a select sample of nuclear criticality safety evaluations (NCSEs) to evaluate the adequacy of SHINE's criticality safety program commitments and identified apparent inconsistencies with certain aspects of ANSI/ANS-8.7. ANSI/ANS-8.7, Paragraph 1, states that the standard cannot effectively cover all conditions of interest with respect to the storage of fissile material, and for this reason supplementary information is encouraged. ANSI/ANS-8.7, Paragraph 4.2.1, states that limits for the storage of fissile material shall be based on experimental data or on the results of calculations made through the use of validated computational techniques.

State how the design of the uranium receipt and storage system (URSS) storage rack meets ANSI/ANS-8.7-1998, as endorsed by RG-3.71. Explicitly discuss the experimental data or calculations performed using a validated computational technique used in its design.

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 NCS technical practices, which will ensure that the fissile material will be possessed, stored, and used safely.

RAI 6b.3-8 FSAR, Section 6b.3.1.3, states that SHINE commits to following ANSI/ANS-8.21-1995, "Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors," and that SHINE does not use soluble neutron absorbers as a means of criticality control and therefore does not commit to ANSI/ANS-8.14-2004, "Use of Soluble Absorbers in Nuclear Facilities Outside Reactors." These statements suggest that SHINE may use fixed neutron absorbers but not soluble. However, FSAR, Section 6b.3.2, does not include the use of either type of neutron absorber (fixed or soluble) as a means of criticality control. Additionally, no commitments or

discussion is provided regarding the use of neutron absorbers as a means of criticality control.

State whether SHINE uses, or plans to use, neutron absorbers as a means of criticality control. If either type of absorber (fixed or soluble) is used, state SHINE's specific commitments regarding their use as a means of criticality control.

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 NCS technical practices, which will ensure that the fissile material will be possessed, stored, and used safely.

RAI 6b.3-9 FSAR, Section 6b.3.2, states that the correlation of process variables to an associated controlled parameter is established by experiment or plant-specific measurements. However, no details are provided as to how this commitment would be implemented.

Explain how this commitment would be implemented for correlations established by both experiment and plant-specific methods. Explain how it is assured that inappropriate reliance is not placed on as-found conditions or on process assumptions and characteristics that are not controlled.

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 in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

(Applies to RAIs 6b.3-10– 6b.3-12)

10 CFR Part 50.34(b) states that the FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility as a whole.

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

The ISG augmenting NUREG-1537, Part 2, Chapter 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states, in part, that the applicant has designed a facility that will provide adequate protection against criticality hazards related to the storage, handling, and processing of licensed materials. The facility design must adequately protect the health and safety of workers and

the public during normal operations and credible accident conditions from the accidental criticality risks in the facility. It should also protect against facility conditions that could affect the safety of licensed materials and thus present an increased risk of criticality or radiation release. In order to demonstrate the adequacy of the applicant's license commitments, a sample of NCSEs was provided in support of the review. The following questions of this chapter are based on a review of the NCSEs provided.

RAI 6b.3-10 SHINE document NCSE-2018-0011, Section 4.1.1, "Subcritical Mass Limits," states that the subcritical mass limits for operations in the Quality Control and Analytical Testing Laboratories (LABS) were derived based on the single parameter limits (SPLs) from ANSI/ANS-8.1. However, the SPLs used appear to be that of a material composition inconsistent with, and potentially nonconservative of, the materials associated with LABS operations.

a. Describe the methodology used to determine whether a composition-specific SPL may be used to establish NCS limits for another material composition.

Provide a justification for applying the SPLs of a material composition other than those associated with a specific process.
This information is necessary for the NRC staff to make the necessary evaluation findings described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3. Specifically, the requested information will support the NRC staff in concluding that SHINE will have the capability to perform adequate safety analyses of all production processes that will be conducted in the facility.

RAI 6b.3-11 FSAR, Section 6b.3.1.4, "Nuclear Criticality Safety Evaluations," states that NCSEs are conducted for each fissionable material operation (FMO) within the RPF to ensure that under normal and credible abnormal conditions, all nuclear processes are subcritical, including the use of an approved margin of subcriticality for safety. However, in SHINE document NCSE-2018-0011, Section 5.1, "Normal Process Conditions," it is not clear how SHINE applies the definition of fissionable material operation as described in the FSAR.

Stating that an operation does not qualify as an FMO, while acknowledging that there are credible accident sequences associated with the operation requiring the implementation of controls to limit its likelihood of occurrence, is inherently contradictory. Additionally, stating that an operation does not qualify as an FMO effectively bypasses SHINE's commitment to perform an NCSE per FSAR, Section 6b3.3.1.4.

Clarify the statements in the FSAR regarding what qualifies as an FMO and when an NCSE is required with information from SHINE document 1500-09-01, "Criticality Safety Program," as applicable.

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

RAI 6b.3-12 SHINE document NCSE-2018-0010, "Nuclear Criticality Safety Evaluation of the Radioactive Liquid Waste Immobilization System (RLWIS)," Section 4.1.1, "Subcritical Limits Uranyl Sulfate," provides a methodology to derive the limits for uranium concentration. However, the proposed methodology is imprecise and does not necessarily provide an adequate demonstration that RLWIS operations are below the appropriate upper subcritical limit.

Provide a justification for using the stated methodology to determine NCS limits, demonstrating assurance that the USL is not exceeded using information from CALC-2018-0009, "Single Parameter Limits for Fissile Material" (2018), and any other supporting analyses, as applicable. Update the FSAR with a justification for using the stated methodology.

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.

Validation and Verification of Computational Methods

RAI 6b.3-13 10 CFR Part 50.34(b) states that the FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility as a whole.

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

The ISG augmenting NUREG-1537, Part 2, Chapter 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states, in part, that for each methodology used to perform a nuclear criticality safety analysis, a validation report should be generated.

FSAR, Section 6b.3.1.3, states that SHINE commits to ANSI/ANS-8.24-2017, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations;" however, this is not sufficient to satisfy the ISG augmenting NUREG-1537 acceptance criteria related to validation. SHINE provided document CALC-2018-0012, "MCNP5 Validation for Reactivity in Solution Systems for the SHINE Facility," Revision 0, which contains information related to the ISG augmenting NUREG-1537 acceptance criteria; however, this is not equivalent to providing explicit commitments in the FSAR.

Provide information that addresses the ISG augmenting NUREG-1537 acceptance criteria related to validation. Specifically address the following criteria:

a. a summary of the validation methodology, including the method used to select benchmark experiments, determine bias and bias uncertainty, and determine the upper subcritical limit;

b. a summary of the physical systems and area(s) of applicability covered by the validation report;

c. a description of the methods used to justify applying the methodology outside the area(s) of applicability;

d. a summary of the plant-specific benchmark experiments used to validate the methodology;

e. a justification of the proposed margin of subcriticality; and

f. a description of the controlled software and hardware.

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.

Criticality Accident Alarm System and Emergency Response

RAI 6b.3-14 10 CFR 50.68(a) states that the applicant shall comply with the requirements of 10 CFR 70.24, "Criticality accident requirements," or meet certain alternative requirements, as described in 10 CFR 50.68(b), in lieu of maintaining a criticality accident alarm system as described in 10 CFR 70.24.

10 CFR 70.24(a) requires, in part, that each licensee authorized to possess special nuclear material (SNM) in a quantity exceeding 700 grams of contained uranium-235 (U-235), 520 grams of U-233, 450 grams of plutonium, 1.5 kilograms of contained U-235 if no uranium enriched to more than 4 wt.% U-235 is present, or 450 grams of any combination thereof, maintain in each area in which such licensed SNM is handled, used, or stored, a criticality accident alarm system.

The ISG augmenting NUREG-1537, Part 2, Chapter 6b3.2, "Nuclear Criticality Safety in the Radioisotope Production Facility," states, in part, that the applicant should state clearly how the design of the facility or process provides for criticality control and should identify how the requirements of 10 CFR 70.24 were considered.

FSAR, Section 6b.3.3, "Criticality Accident Alarm System," states that the SHINE facility provides a criticality accident alarm system (CAAS) to detect a criticality event in the areas *in which non-exempt quantities of fissile material* greater than the limits identified in 10 CFR 70.24(a) are used, handled, or stored outside the irradiation units, where "exempt fissile material" is defined as SNM that meets the requirements from classification as fissile material as specified in 10 CFR 71.15. However, the requirements of 10 CFR 70.24 regarding whether a CAAS is

required are based on specific, objective criteria of SNM mass quantities by isotope (or combinations thereof). It does not provide any distinctions as to whether such SNM quantities are, or should be considered, fissile or fissile-exempt, nor does it provide any exceptions for SNM quantities in excess of those limits. As such, SNM quantities greater than the limits established by 10 CFR 70.24 require CAAS coverage regardless of whether they meet the requirements from classification as fissile material as specified in 10 CFR 71.15.

Revise the FSAR to be consistent with the requirements of 10 CFR 70.24, or justify why those requirements do not need to be met for certain areas of the facility.

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 a criticality accident alarm system that meets the acceptance criteria in Section 6b.3 of the ISG; and will have in place an NCS program.

Organization and Administration of the Criticality Safety Program

RAI 6b.3-15 10 CFR 50.34(b)(6) states that the FSAR shall include information concerning facility operation, including the applicant's organizational structure, allocations or responsibilities, and personnel qualification requirements.

The ISG augmenting NUREG-1537, Part 2, Chapter 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states, in part, that the applicant's surveillance requirements should be considered acceptable if the applicant has met certain acceptance criteria or has identified and justified an alternative, including meeting the intent of ANSI/ANS-8.19, "Administrative Practices for Nuclear Criticality Safety," and ANSI/ANS-8.20, "Nuclear Criticality Safety Training," as they relate to training.

FSAR, Section 6b.3.1.2, discusses the minimum qualification entry requirements for criticality safety staff, including fissile material handlers. This suggests that fissile material handlers are considered part of the criticality safety staff. However, Section 6b.3.1.2 further states that there are three qualification levels for criticality safety staff and specific functional area qualifications for fissile material handlers. This suggests that fissile material handlers have separate qualification requirements from the criticality safety staff.

FSAR, Section 6b.3.1.2, states that SHINE's NCS training program consists of two tiers, with Tier 1 being directed toward personnel who manage, work in, or work near areas where a potential for criticality exists and Tier 2 being specific to NCS staff. However, it is not clear whether NCS staff are required to receive both tiers, or simply Tier 2, of training.

a. Clarify whether fissile material handlers are considered part of the criticality safety staff. State the difference in qualification requirements for fissile material handlers and criticality safety staff.

b. Clarify which training requirements apply to NCS staff.

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 in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

RAI 6b.3-16 10 CFR 50.34(b)(6)(i) states that the FSAR shall include information concerning facility operation, including the applicant's organizational structure, allocations or responsibilities, and personnel qualifications requirements.

The ISG augmenting NUREG-1537, Part 2, Chapter 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states, in part, that the applicant's NCS organization and administration should be acceptable if certain acceptance criteria are met, including a commitment to provide distinctive NCS postings in areas, operations, work stations, and storage locations relying on administrative controls for NCS; and a commitment to require personnel to perform activities in accordance with written and approved procedures. Unless a specific procedure deals with the given situation, personnel shall take no action until the NCS staff has evaluated the situation and provided recovery procedures.

FSAR, Section 6b.3.1, "Nuclear Criticality Safety Program," states that the criticality safety program (CSP) is executed by qualified NCS staff using written procedures, SHINE facility management has a responsibility to require that activities involving fissile material be conducted using written procedures, and personnel are required to take no action until the NCS staff has evaluated the situation and provided recovery instructions for situations in which existing procedures are inadequate or do not exist. However, these statements only provide commitments in terms of the responsibilities of facility management and NCS staff and are not equivalent to a commitment to require personnel to perform activities in accordance with written and approved procedures. Additionally, the FSAR does not address the use of NCS postings in areas, operations, workstations, and storage locations relying on administrative controls.

a. State whether SHINE commits to conduct activities that affect NCS in accordance with written and approved procedures. For situations in which a specific procedure is inadequate or does not exist, state whether personnel are required to take no action until the NCS staff has evaluated the situation and provided recovery procedures.

b. State whether SHINE commits to using NCS postings in areas, operations, workstations, and storage locations relying on administrative controls.

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 in place a staff of managers, supervisors, engineers,

process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

RAI 6b.3-17 10 CFR 50.34(b)(6)(iv) states that the FSAR shall include information concerning facility operation, including the applicant's plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components.
The ISG augmenting NUREG-1537, Part 2, Chapter 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states, in part, that the applicant's surveillance requirements should be considered acceptable if the applicant has met certain acceptance criteria or has identified and justified an alternative, including a commitment to conduct and document periodic NCS audits such that all NCS aspects of surveillance requirements will be audited at least every two years.

FSAR, Section 6b.3.1.7, suggests that an audit of the overall effectiveness of the CSP is performed at least every three years. Additionally, reviews of NCSEs and calculations are performed such that each evaluation and calculation is reviewed at least once every three years. These commitments appear to be inconsistent with the ISG augmenting NUREG-1537 acceptance criterion that requires such audit aspects be performed at least every two years.

Provide a justification for performing NCS audits such that all NCS aspects will be audited every three years, as opposed to at least every two years.

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 in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

RAI 6b.3-18 10 CFR 50.34(b)(6)(iv) states that the FSAR shall include information concerning facility operation, including the applicant's plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components.

The ISG augmenting NUREG-1537, Part 2, Chapter 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states, in part, that the applicant's surveillance requirements should be considered acceptable if the applicant has met certain acceptance criteria or has identified and justified an alternative, including a commitment to include NCS audit requirements in the Administrative Controls section of the facility technical specifications.

Audit requirements are included in the Administrative Controls section of the facility technical specifications (Appendix A to the FSAR, "Technical Specifications and Bases"). However, this is not equivalent to a commitment to include audit requirements in the Administrative Controls section of the facility technical specifications.

State whether SHINE commits to include NCS audit requirements in the Administrative Controls section of the facility technical specifications.

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 credible postulated criticality accident scenarios can be performed and adequate preventive and mitigative controls and measures will be included in the production facility technical specifications as required by 10 CFR 50.36.

RAI 6b.3-19 10 CFR 50.34(b)(6)(iv) states that the FSAR shall include information concerning facility operation, including the applicant's plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components.
The ISG augmenting NUREG-1537, Part 2, Chapter 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states, in part, that the applicant's surveillance requirements should be considered acceptable if the applicant has met certain acceptance criteria or has identified and justified an alternative, including a commitment to conduct and document walkthroughs of all operating SNM process areas such that all areas will be reviewed at some specified frequency. The reviewer should consider the complexity of the process, the degree of process monitoring, and the degree of reliance on administrative controls in assessing the acceptability of the specified frequency.

FSAR, Section 6b.3.1.7, states that operations are reviewed at least annually to verify that procedures are being followed and that process conditions have not been altered to affect the NCSE. NCS staff conduct and participate in routine audits of NCS practices, including compliance with procedures. However, it is not clear whether these oversight activities include a physical walkthrough of operating process areas, and a justification for the frequency in which these oversight activities are performed is not provided.

State whether SHINE commits to have NCS staff conduct and document walkthroughs of all operating SNM process areas such that all areas will be reviewed at some frequency. Provide a justification for the specified frequency.

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 in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

RAI 6b.3-20 10 CFR 50.59 states, in part, that licensees may make changes in the facility as described in the FSAR, make changes in the procedures as described in the FSAR, and conduct tests or experiments not described in the FSAR without obtaining a license amendment if certain criteria are met. 10 CFR 50.59(a)(1) defines "change" as a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the

function, or an evaluation that demonstrates that intended function will be accomplished.

FSAR, Section 6b.3.1.5, states that process or design changes that could affect NCS limits or controls are evaluated using the facility change process requirements of 10 CFR 50.59. Such changes include new design, operation, or modification to existing SSCs; computer programs; processes; operating procedures; or administrative controls. This appears to be inconsistent with the definition of "change" in 10 CFR 50.59, and thus does not provide a satisfactory commitment to evaluate all appropriate changes against 10 CFR 50.59 criteria. Specifically, changes to methodologies, such as a change to computational code validation methodology that could impact code bias, bias uncertainty, or the approved margin of subcriticality, would not be subject to SHINE's commitment to evaluate the change against 10 CFR 50.59 criteria, despite 10 CFR 50.59(c) requiring an evaluation of such a change.

Clarify how SHINE intends to meet the requirements of 10 CFR 50.59, including a discussion of which changes SHINE will evaluate and the method in which such changes will be evaluated.

Chapter 13 – Accident Analysis

RAI 13-1 When licensing non-power production or utilization facilities, there have been questions as to what standards and criteria should be used in evaluating design-basis accidents to evaluate the design basis of systems, structures and components that mitigate radiological releases to the environment (exposure to any individual in the unrestricted area). Presently, no radiological accident dose criterion is set forth in regulation and subsequent guidance to assess the risk to public health and safety resulting from the operation of non-power production or utilization facilities. Instead, the standards of 10 CFR Part 20, "Standards for Protection Against Radiation," have been applied for evaluating the effects of a postulated accident, for instance:

- Before January 1, 1994, the accident dose criteria used to license a research reactor were generally compared to the public dose limits of 10 CFR 20.1 through 20.602 and Appendices. Therefore, the accident criteria the staff generally found acceptable for accident analyses were less than the public dose limits of 0.5 rem whole body and 3 rem thyroid for members of the public.

- On January 1,1994, the NRC amended 10 CFR Part 20 to reduce the dose limit to a member of the public to 0.1 rem total effective dose equivalent (TEDE) with an implementation date of January 1, 1994. In lieu of an accident dose criterion, under 10 CFR 20.1301(d), a licensee or license application may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem. The 0.5 rem refers to the TEDE, defined in 10 CFR 20.1003, as the sum of the effective dose equivalent and the committed effective dose equivalent.

However, as discussed in NUREG-1537, there are several instances the staff has accepted very conservative accident analyses that exceed the 10 CFR Part 20 public dose limits discussed above.

In the FRN, the NRC proposed to amend its regulations that govern the license renewal process for non-power reactors, testing facilities, and other production or utilization facilities, licensed under the authority of Section 103, Section 104a, or Section 104c of the AEA, as amended, that are not nuclear power reactors.[1] In this rule, the NRC collectively refers to these facilities as non-power production or utilization facilities (NPUFs). The NRC has determined that the public dose limit of 0.1 rem (0.001 Sv) TEDE is unduly restrictive to be applied as accident dose criteria for NPUFs, other than those NPUFs subject to 10 CFR part 100.[2] However, the NRC considers the accident dose criteria in 10 CFR part 100 applicable to accident consequences for power reactors, which have greater potential consequences resulting from an accident, to be too high for NPUFs

[1] See 82 FR 15643, March 30, 2017.

[2] The NRC Atomic Safety and Licensing Appeal Board stated that the standards in 10 CFR part 20 are unduly restrictive as accident dose criteria for research reactors (Trustees of Columbia University in the City of New York, ALAB–50, 4 AEC 849, 854–855 (May 18, 1972)).

other than testing facilities. For these reasons, the NRC proposed to amend its regulations in 10 CFR 50.34 to add an accident dose criterion of 1 rem TEDE for NPUFs not subject to 10 CFR part 100.

This is consistent with the guidance found in NUREG-1537, Part 2, which provides discussion on a postulated accident scenario whose potential consequences are shown to exceed and bound all credible accidents. For non-power facilities, this accident is called the maximum hypothetical accident. Since the consequences of the postulated maximum hypothetical accident should exceed those of any credible accident at the facility, the accident is not likely to occur during the life of the facility. The maximum hypothetical accident is used to demonstrate that the maximum consequences of operating the facility at a specific site are within acceptable limits.

The accident dose criterion of 1 rem TEDE in the proposed NPUF rule is based on the Environmental Protection Agency's (EPA) Protection Action Guides (PAGs), which were published in the EPA document, 400-R-92-001, “Manual of Protective Action Guides and Protective Actions for Nuclear Incidents.” In January 2017, the EPA published an update to its PAGs in EPA-400/R-17/001, “PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents.” This update to the EPA PAGs did not change the basis for the 1 rem TEDE early phase PAG published in 1992. The purpose of the EPA PAGs is to support decisions on protective actions to provide reasonable assurance of adequate protection of the public from unnecessary exposure to radiation.

The EPA PAGs are dose guidelines to support decisions that trigger protective actions such as staying indoors or evacuating to protect the public during a radiological incident. The PAG is defined as the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. Three principles considered in the development of the EPA PAGs include: (1) prevent acute effects; (2) balance protection with other important factors and ensure that actions result in more benefit than harm; and, (3) reduce risk of chronic effects. In the early phase of the nuclear incident, which may last hours to days, the EPA PAG recommends the protective actions of sheltering-in-place or evacuation of the public to avoid inhalation of gases or particulates in an atmospheric plume and to minimize external radiation exposures between 1 rem to 5 rem. So, if the projected dose to an individual from an incident is less than 1 rem, no protective action for the public is recommended.

In its operating license application, SHINE selected accident dose criteria (in lieu of a criterion stated in the regulation) for members of the public as follows:

- Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 500 mrem TEDE for the duration of the accident; and,

Radiological consequences to workers do not exceed 5 rem TEDE during the accident. [SHINE justifies applying this criterion to a worker within the facility as opposed to the “control room” since immediate operator action inside the facility is not required to stabilize accident conditions. The SHINE irradiation units do

not share systems and components. Therefore, the design basis accidents assume no interconnective failures. As generally assumed in the sequence of events, SHINE states facility personnel evacuate the immediate area [the facility confinement] within 10 minutes upon actuation of the radiation area monitors.]

The SHINE FSAR Chapter 13, "Accident Analysis," provides the design basis accident analyses which are evaluated against the dose criterion.[3] The intent of these analyses is to evaluate the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.

The SHINE FSAR Chapter 14, "Technical Specifications," provides limiting conditions for operation of the production facility.[4] The safety margins contained within the design basis accidents are products of specific values and limits contained in the facilities technical specifications and other values, such as assumed accident or transient initial conditions or assumed safety system response times.

For a Part 50 license, the following is considered:

- Accident dose criteria, when compared against the maximum hypothetical accident, is a helpful aid in evaluating a proposed site with the objective of assessing the risk to public health and safety resulting from operation of the facility.

As discussed in the ISG Augmenting NUREG-1537, the maximum hypothetical accident is used to demonstrate that the maximum consequences of operating the nuclear facility at a specific site is within the acceptable accident dose limits. The maximum hypothetical accident is an accident with radiological consequences that bound all other credible accidents likely to occur over the life of the nuclear facility. Therefore, the assumed fission product release from the maximum hypothetical accident should be based upon a major accident, hypothesized for purposes of siting analysis or postulated from considerations of possible accidental events, that would result in potential hazards not exceeded by those from any accident considered credible.

- There is no 10 CFR Part 50 regulatory requirement for a worker accident dose criteria, other than the requirements in 10 CFR Part 20, "Standards for Protection Against Radiation.[5]" However, the SHINE Design Criterion 6 – Control Room, states:

[3] ADAMS Accession No. ML19211C323

[4] ADAMS Accession No. ML19211C339

[5] Note: 10 CFR Part 70 does contain a regulatory requirement for accident dose to workers because of lessons learned from fatal and near miss accidents at fuel cycle facilities involving chemicals commingled with special nuclear material.

> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

This criterion is similar to 10 CFR 50, Appendix A, General Design Criterion-19, *Control Room*, which is not applicable to NPUFs such as the SHINE facility. It is required for light water reactor nuclear power plant control room design where the operator's necessity to appropriately respond during an accident is properly viewed as having a potential impact on the public health and safety. The purpose is to provide a control room from which actions can be taken to operate the facility safely under normal conditions and to maintain the facility in a safe condition under accident conditions.[6]

At the SHINE facility, in the event of a design basis accident or transient, the other irradiation units will presumably be operating, and control room operators would need to take actions to continue to operate the facility safely and to maintain the facility in a safe condition. It therefore seems appropriate to assess the radiological consequences of the control room operator, given General Design Criteria 6, as their required operations are necessary to continue operation of the other irradiation units and maintain the facility in a safe condition under accident conditions.

It is noted that the NRC staff views the accident dose design criterion as a "figure of merit" and does not represent actual doses received due to a design-basis event or transient. The shielding design of the facility ensures the applicable limits in 10 Part CFR 20 are met and thus protecting the worker which is discussed in Chapter 11*,* "Radiation Protection Program and Waste Management," of the SHINE FSAR. Lastly, as low as reasonably achievable (ALARA) program practices such as work planning and source term minimization, coupled with existing radiation exposure procedural controls ensure worker doses are not adversely impact the licensee's ability to maintain doses resulting from plant operation within the applicable limits.

Therefore, the NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

a. Confirm the NRC staff's understanding of the SHINE-proposed accident dose criteria of 500 mrem TEDE to members of the public to serve the purpose as the site evaluation factor, as discussed in the *Federal Register* (FR), Volume 82, Number 60, dated March 30, 2017. Given the NRC-proposed draft rule, discuss a technical justification for the SHINE-proposed accident dose

[6] It is generally understood that an objective of the criteria is to ensure that the design of the control room and its habitability systems is such that a "shirt-sleeved" environment is provided for the control room operators. Such an environment is perceived to be supportive of facilitating operator response to normal and accident conditions and would minimize errors of omission or commission. Another objective is to ensure that the radiation dose levels in the control room would make it the "safest" location on site, thereby allowing the operators to remain in the control room and not evacuate. Any reduction in the ability of the operators to respond appropriately during an accident is properly viewed as having a potential impact on the public health and safety.

criterion, as necessary for the licensing of the SHINE Medical Isotope Production Facility; this should include a comparison to the basis for the NRC-proposed accident dose criterion of 1 rem TEDE in the draft NPUF rule (see: 82 FR 15643).

OR

Discuss whether SHINE would adopt, with justification, the accident dose criterion proposed in the NRC rule described in *Federal Register* Notice (FRN) 82 FR 15643, which provides reasonable assurance of adequate protection of the public in the unlikely event of radiological incident.

b. In light of the discussion provided above, provide a technical justification for why the worker dose criterion is assumed to be analyzed for facility personnel and not the operator(s) for the SHINE facility. Please provide accident analysis results for control room operators to be consistent with the SHINE Design Criteria, Criterion 6 – Control Room.

c. Clarify what 10 CFR Part 50 regulatory requirement SHINE is demonstrating to meet with the proposed worker accident dose criteria, and the basis for the dose value of 5 rem TEDE. Also clarify the purpose of the proposed worker accident dose criteria as there appears to be no necessary actions by the worker to maintain the facility in a safe condition under accident conditions. If there are necessary actions to control or mitigate the accident, provide these procedures and programmatic controls which can be implemented in the Technical Specifications (Administrative Controls or otherwise).

OR

If there are no necessary actions by the worker outside the control room to maintain the facility in a safe condition under accident conditions, then discuss whether it would be appropriate to remove from the SHINE FSAR, with justification, the proposed worker dose accident dose criteria.

RAI 13-2 The regulations that are most relevant to radiation protection are contained in 10 CFR Part 20 and 10 CFR Part 50. Additional requirements, specific to particular uses or classes of facilities, are found in other portions of the regulations.

Both 10 CFR Part 50 and 10 CFR Part 20 refer to various dose-based criteria and limits based on dosimetry methodologies defined by the International Commission on Radiological Protection (ICRP) in Publication 26, "Recommendations of the ICRP," and Publication 30, "Limits for Intakes of Radionuclides by Workers." The ICRP 30 dosimetry methodologies are applied in:

- 10 CFR Part 50 – through the TEDE criteria (defined in 10 CFR 50.2) for the design, construction, and operation of the facility under normal and accident conditions.

- 10 CFR Part 20 – through the TEDE limits (defined in 10 CFR 20.1003) to establish standards and practices for radiation protection purposes for

occupational and public health during normal operation. 10 CFR Part 20, Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” to provides direction in how to determine external and internal exposures. The appendix provides an appropriate method to derive the Annual Limits on Intake and Derived Air Concentrations based on ICRP 30 tissue weighting factors.

The tissue weighing factors are directly codified by 10 CFR 20.1003, *Definitions*, within the table labeled, *Organ Dose Weighting Factors*, as follows:

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red Bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bong surfaces	0.03
Remainder	0.30
Whole Body	1.00

For both 10 CFR Parts 50 and 20, the TEDE is defined as the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). Acceptable practices for computing design-basis accident radiological consequences in terms of TEDE are to apply the exposure-to-committed effective dose equivalent factors for inhalation of radioactive material found in Table 2.1 of Federal Guidance Report No. 11, “Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion.” The factors in the column headed “effective” yield doses corresponding to the committed effective dose equivalent. These tables are derived from the data provided in ICRP Publication 30 and have been found acceptable to the NRC staff as they meet the applicable regulatory requirements. Likewise, the exposure-to-effective dose equivalent factors for external exposure of radioactive material apply Federal Guidance Report No. 12, “External Exposure to Radionuclides.”

Therefore, by default, compliance with the dose-related regulations of Parts 50 and 20 are demonstrated when applying the exposure-to-dose conversion factors of Federal Guidance Reports 11 and 12.

The SHINE FSAR Chapter 13 design basis accident analyses are evaluated against the applicant-selected accident dose criteria. The design basis accidents range from anticipated events, such as a loss of electrical power, to a postulated maximum hypothetical accident that exceeds the radiological consequences of any accident considered to be credible. To compute radiological consequences, the SHINE FSAR states that the dose conversion factors were taken from ICRP Publication 119, “Compendium of Dose Coefficients based on ICRP Publication 60,” and Federal Guidance Report No. 12. It appears SHINE has applied a dosimetry methodology inconsistent with applicable dose-related regulations

under 10 CFR Part 50. Therefore, by applying dose conversion factors based on ICRP Publication 60 dosimetry methodologies for a Part 50 license application, the applicant does not comply with the applicable regulations. To be compliant with the dose-related regulations of Parts 50, the exposure-to-committed effective dose equivalent factors for inhalation of radioactive material should apply those found in Table 2.1 of Federal Guidance Report No. 11 and 12.

Therefore, the NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

Discuss how SHINE's selected dosimetry methodology satisfies applicable regulatory requirements and whether it will be necessary to re-compute the radiological consequences of all design-basis accidents in terms of TEDE to be in compliance with the NRC's regulations.

RAI 13-3 10 CFR Part 50.34requires that each applicant for a construction permit or operating license provide an analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility.

Regulatory Guide 1.145, Rev 1, "Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants," presents criteria for characterizing atmospheric dispersion conditions for evaluating the consequences of design basis accidents radiological releases at the site boundary as they relate to the applicable siting requirements where short-term atmospheric dispersion factors (χ/Q values) are computed at the 95th-percentile value (i.e., χ/Q value that is equal to or exceeded no more than 5 percent of the total time). Both NUREG-1537 and the ISG Augmenting NUREG-1537 refer to RG 1.145 with respect to accident analyses.

Regulatory Guide 2.2, "Development of Technical Specifications for Experiments in Research Reactors," as it pertains to the development of technical specifications based on the SHINE FSAR for the purposes of crediting natural consequence-limiting features such as solubility, absorption, and dilution and for installed features such as filters may be taken provided each such feature is specifically identified and conservatively justified by specific test or physical data or well-established physical mechanisms. In addition, with respect to installed features credit taken for their effectiveness should depend on the adequacy of the related quality assurance procedures undertaken, including the extent to which surveillance tests simulate the conditions to be met in practice. If assumptions regarding atmospheric dilution are involved, they should not be less conservative than those used in the analysis of design basis accidents.

It is noted here for further discussion that RG 1.111, "Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water-Cooled Reactors," provides regulatory positions on long-term atmospheric dispersion estimated for routine releases of effluent. For these assessments, it is typical regulatory practice to accept 50th-percentile χ/Q value.

The SHINE FSAR Chapter 13 design basis accident analyses are evaluated against the applicant-selected accident dose criterion. As presented by SHINE, the design basis accidents range from anticipated events, such as a loss of electrical power, to a postulated maximum hypothetical accident that exceeds the radiological consequences of any accident considered to be credible. SHINE identified these design basis accidents using the following sources of information:

- NUREG-1537 and the ISG Augmenting NUREG-1537;
- Process hazard analysis method within the integrated safety analysis process; and,
- Experience of the hazard analysis team.

SHINE selected accident dose criteria for members of the public as follows:

- Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 500 mrem total effective dose equivalent (TEDE) for the duration of the accident; and,
- Radiological consequences to workers do not exceed 5 rem TEDE during the accident.

The intent of these analyses is to evaluate the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility.

SHINE computed long-term 50th percentile (average) χ/Q values at the nearest point along the site boundary and at the nearest resident location. This is consistent with the staff guidance found in NUREG-1537, Chapter 11, *Radiation Protection*, for the purposes of demonstrating compliance with the limits of 10 CFR Part 20 to assess routine releases. These 50th percentile χ/Q values were also applied to the Chapter 13 design basis accident analyses which is non-conservative to demonstrate compliance with 10 CFR 50.34 when evaluating the radiological consequences of postulated design basis accidents (i.e., short-term events) for facility siting and operation.

It is acknowledged there can be a misinterpretation of certain statements found in NUREG-1537, Part 2, Chapter 13, since no explicit percentile χ/Q value is made for accident analysis purposes. However, Chapter 13, *Accident* Analysis, Subsection, *Radiological Consequences,* does refer to RG 1.145 as an acceptable method for demonstrating compliance with the applicable siting criteria. Regulatory Guide 1.145, Section 3, “Determinations of 5% [95th percentile] Overall Site χ/Q Values,” states in part, “The χ/Q values that are

exceeded no more than 5% of the total time around the exclusion area boundary… … should be determined…"

In other words, the purpose of evaluating the radiological consequences at the 95th-percentile value reasonably assures radiological consequences at the site boundary are not exceed more than 5 percent of the time. Therefore, by applying the long-term 50th-percentile χ/Q values imply the computed radiological consequences at the site boundary are met only 50 percent of the time. Staff experience with both long-term 50th- and short-term 95th percentile χ/Q values has shown non-linearity between the computed radiological consequence results which can range between three-orders-of-magnitude in difference depending on the site location.

Computing radiological consequences of design basis accidents at the 95th-percentile χ/Q value provides reasonable assurance that facilities' licensing bases will not be exceeded by more than 5.0 percent within any given year of operation.

SHINE calculation number 2012-03852 Rev 0, "Short-Term Diffusion Estimates for SHINE," provides the details of the analysis to calculate atmospheric dispersion factors to be used to assess the consequences of an accidental release of radioactive material. Both the overall bounding long-term and short-term 50th and 95th-percentile χ/Q values are reported to be 3.88E-4 s/m^3 and 5.66E-3 s/m^3 respectively. This difference in χ/Q values would impact the reported SHINE FSAR radiological consequences by about a factor of 15.

Therefore, the NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

a. Provide a postulated set of short-term atmospheric χ/Q values (95th-percentile) at the site boundary based on site-specific meteorological data to be presented in the SHINE FSAR.

b. Recompute the radiological consequences of each design basis accident with the short-term atmospheric χ/Q values.

RAI 13-4 10 CFR Part 50.34 requires that each applicant for a construction permit or operating license provide an analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility. It is the staff's understanding that the proposed radiological accident dose criterion serves the purpose of evaluating the suitability of the site from operation of the facility for the purposes of computing radiological consequences.

10 CFR, Section 50.36 requires an applicant for an operating license to include in the application proposed technical specifications as it relates to the evaluations and analysis of the offsite radiological consequences of postulated accidents with fission products.

10 CFR 50.36(c)(3), requires TSs to include items in the category of surveillance requirements, which are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions of operation will be met.

Regulatory Guide 1.145, Rev 1, “Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants,” presents criteria for characterizing atmospheric dispersion conditions for evaluating the consequences of design basis accidents radiological releases at the site boundary as they relate to the applicable siting requirements where short-term atmospheric dispersion factors (χ/Q values) are computed at the 95th-percentile value (i.e., χ/Q value that is equal to or exceeded no more than 5 percent of the total time). Both NUREG-1537 and the ISG Augmenting NUREG-1537 refer to RG 1.145 with respect to accident analyses.

Regulatory Guide 2.2, as it pertains to the development of technical specifications based on the SHINE FSAR for the purposes of crediting natural consequence-limiting features such as solubility, absorption, and dilution and for installed features such as filters may be taken provided each such feature is specifically identified and conservatively justified by specific test or physical data or well-established physical mechanisms. In addition, with respect to installed features credit taken for their effectiveness should depend on the adequacy of the related quality assurance procedures undertaken, including the extent to which surveillance tests simulate the conditions to be met in practice. If assumptions regarding atmospheric dilution are involved, they should not be less conservative than those used in the analysis of design basis accidents.

Design basis accidents are postulated accidents that a nuclear facility must be designed and built to withstand without loss to the systems, structures, and components necessary to ensure public health and safety. The design basis accidents 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. These accident analyses are intentionally conservative in order to compensate for known uncertainties in accident progression, fission product transport, and atmospheric dispersion. They can be thought of as loosely defined ‘classes’ of accidents that bound a number of facility processes, activities, and/or accident sequences identified through a risk-assessment. The quantification of the accidental release of fission products into the atmosphere, or accident radiological “source term,” is intended to be representative of a major accident involving significant damage which affects the design of plant systems and is one element used to determine site suitability. The safety margins contained within the design basis accidents are products of specific values and limits contained in the facilities technical specifications, as required by 10 CFR 50.36 and other values, such as assumed accident or transient initial conditions or assumed safety system response times.

Beyond design basis accident is a term used as a technical way to discuss accident sequences that are possible but were not fully considered in the design process because they were judged to be too unlikely. In that sense, they are

considered beyond the scope of design-basis accidents that a nuclear facility must be designed and built to withstand. However, as the regulatory process strives to be as thorough as possible, “beyond design-basis accident” sequences are analyzed to fully understand the capability of a design. Beyond design basis accidents are considered more unlikely than design basis accidents, non-safety-related systems, structures, and components can be credited for accident mitigation. For example, the 10 CFR 50.62, “Requirements for Reduction of Risk from Anticipated Transients without Scram (ATWS) events for light-water-cooled nuclear power plants,” allows the use of non-safety-related equipment for accident mitigation. These analyses often include multiple failures beyond those considered for design basis accident analyses, and thus more realistic assumptions are allowed in the analyses.

The staff reviews the radiological consequences of design basis accidents in six parts: (1) review of selected bounding design basis accidents; (2) review of accident source terms; (3) review of the major structures, systems, and components of the facility that are intended to mitigate the radiological consequences of a design basis accident; (4) review of the characteristics of fission product releases from the proposed site to the environment, (5) review of the meteorological characteristics of the proposed site; and, (6) review of the total calculated radiological consequence dose at the site boundary from the bounding design basis accidents.

The NRC staff generally does not accept design basis accident analyses that credit facility features that:

- are not safety-related;
- are not covered by technical specifications;
- do not meet single-failure criteria, or;
- rely on the availability of offsite power. Design basis delays in actuation of these features should be considered, especially for those features that rely on manual operator intervention.

Analysis inputs should be the most restrictive values of plant parameters selected from the range of design values possible during the specific event so that the postulated consequences of the event are maximized. It is generally inappropriate to use values characterized as “best estimates.” Other considerations should include:

- The range of values applicable during an accident may vary from accident to accident and will likely differ from the range that applies during normal operations.
- The use of different parameter values in different portions of the analyses or to perform a sensitivity analysis to determine the limiting value.

- Facility parameters associated with a technical specification limiting condition for operation. If the limiting condition for operation specifies a range, or a value with a tolerance band, the most restrictive value should be used.

- Consider situations where and how some parameters may change value during the accident. In these cases, the calculation should either assume the most restrictive value for the entire duration or the calculation should be performed in time steps, with the appropriate parameter values used for each time step.

- Parameters based on the results of less frequent surveillance testing, for example, efficiency testing of charcoal filters, the degradation that may occur between periodic tests should be considered in establishing the analysis value.

- Analysis parameters which affected by density changes that occur in the process stream. With regards to specified volumetric flow rates as limiting conditions of operations, the density used should be consistent with the density that is assumed in the surveillance procedure that demonstrates compliance with the limiting conditions of operations.

Lastly, a point of discussion regarding the application of the Single Failure Criterion is made when developing design basis accidents. The Single Failure Criterion, as a design and analysis tool, has the direct objective of promoting reliability through the enforced provision of redundancy in those systems which must perform a safety-related function.[7] As discussed in NUREG-1537, for the purposes of facility design and accident analysis, and the applicable SHINE Design Criteria, a single failure means an occurrence which results in the loss of capability of a component or protection system to perform its intended safety functions. Multiple failures resulting from a single occurrence are considered to be a single failure. Fluid and electric systems are considered to be designed against an assumed single failure if neither (1) a single failure of any active component (assuming passive components function properly) nor (2) a single failure of a passive component (assuming active components function properly), results in a loss of capability of the system to perform its safety functions.

In principle, the Single Failure Criterion as applied in design basis accident analyses is straightforward. Simply stated, it is a requirement that a system which is designed to carry out a defined safety function must be capable of carrying out its mission in spite of the failure of any single active component within the system or in an associated system which supports its operation. Application of the Single Failure Criterion involves a systematic search for potential single failure points and their effects on the system. Such a search is required by the Standard Review Plan and the Standard Format for the Content of Safety Analysis Reports for specified safety systems and components. The objective is to search for design weaknesses which could be overcome by increased redundancy, use of alternate systems or use of alternate procedures. In general, only those systems or components which are judged to have a credible chance of failure are assumed to fail when the Single Failure Criterion is

[7] ADAMS Accession No. ML060260236

applied. Such failures would include, for example, the failure of a valve to open or close on demand, the failure of an emergency diesel generator to start or the failure of an instrument channel to function.

The SHINE FSAR Chapter 13 design basis accident analyses are evaluated against the applicant-selected accident dose criterion. As presented by SHINE, the design basis accidents range from anticipated events, such as a loss of electrical power, to a postulated maximum hypothetical accident that exceeds the radiological consequences of any accident considered to be credible. SHINE identified these using the following sources of information:

- NUREG-1537 and the ISG Augmenting NUREG-1537;
- Process hazard analysis method within the integrated safety analysis process; and,
- Experience of the hazard analysis team.

The NRC staff has reviewed a sampling for both the irradiation facility and radioisotope production facility design basis accidents with a focus on the two maximum hypothetical accidents. It appears these maximum hypothetical accidents fit the description of beyond design basis accidents where multiple failures are assumed which is beyond typical consideration for licensing purposes.

Therefore, the NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

a. Re-assess the maximum hypothetical accidents considering the discussions above. It may be necessary to redefine the design basis accident source terms and sequence of events to meet the applicable public accident dose criteria.

b. As discussed above, the DBAs are not intended to represent actual event sequences, but surrogates to enable deterministic evaluations of the response of the facilities engineered safety features. Based on SHINE's use of a risk-assessment to define creditable accident sequences and the substantial operating experience of similar facilities, provide a discussion of the following:

    - How SHINE classified and binned the accident sequences from the SHINE safety analysis into each DBA;

    - Which technical specifications and limiting conditions of operations were developed from insights gained from the accident sequences identified from the SHINE safety analysis; and

    - How the accident sequences, which require workers to take preventive or mitigative actions in order to put the facility in a safe configuration, are reflected in the impacted DBA, including how these actions are controlled

through procedures and programmatic controls that may be implemented in the Technical Specifications (Administrative Controls or otherwise).

SHINE Safety Analyses (SSA) Report

RAI 13-5 10 CFR 50.34(b) states that the FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility.
10 CFR 50.34(b)(2) states that a description and analyses of the structures, systems and components of the facility, with emphasis upon the performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished.

10 CFR Part 50, paragraph 50.57(a)(3) states that an operating license may be issued upon finding that, "There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…"

The ISG to NUREG-1537 states in Section 13a2 that the information in this chapter should achieve the objectives stated in this chapter of NUREG-1537, Part 1 by demonstrating that the applicant has considered all potential accidents at the reactor facility and adequately evaluated their consequences.

The ISG to NUREG-1537 states NRC staff have determined that the use of Integrated Safety Analysis (ISA) methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features.

SHINE has prepared a document entitled "SHINE Safety Analyses (SSA) Report (TECRPT-2020-016) which discusses the safety analyses methodology; however, this methodology is not discussed in the FSAR.

Revise the FSAR to include a description of the accident analysis methodology and criteria. Discuss the types of hazards considered (e.g., radiological, chemical), the phases of operation analyzed in the accident analysis (startup, normal operation, shutdown, non-routine operations), the receptors considered, and the criteria used to determine the acceptability of accident consequences for each type of hazard (e.g. chemical, radiological) and each receptor (e.g., public, worker, control room operator). Also discuss consideration of non-routine activities such as (1) unplanned maintenance activities; (2) periods of extended shutdown, or (3) conditions outside of the established Limiting Conditions of Operations (LCOs). Maintenance activities can create situations where there could be reduced controls or barriers resulting in the release of hazardous

material and extended shutdown periods or conditions exceeding LCOs could introduce new accident scenarios.

RAI 13-6 10 CFR 50.34(b) states that the FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility.

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

10 CFR Part 50, paragraph 50.57(a)(3) states that an operating license may be issued upon finding that, "There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…"

The ISG to NUREG-1537 states in Section 13a2 that the information in this chapter should achieve the objectives stated in this chapter of NUREG 1537, Part 1 by demonstrating that the applicant has considered all potential accidents at the reactor facility and adequately evaluated their consequences.

The SSA, as discussed in RAI 13-5, provides the results of the accident analyses which are summarized in Chapter 13 of the FSAR. The SSA also outlines the various programs related to the development, implementation and maintenance of the accident analysis.

Technical Specification Section 5.5.4 of FSAR Chapter (14) states that configuration management is applied to all safety related SSCs. This statement seems inconsistent with Item 7 in Section 5.3, "Programmatic Administrative Controls," of the SSA, which states that the configuration management program provides the means to evaluate "each change". The configuration management program should be applied to each proposed change because a change that involves a non-safety-related SSC could introduce an unanalyzed condition or a new hazard with significant consequences.

Revise the FSAR to clarify that configuration management is applied to "each change" not only to "safety-related SSCs" or explain why such a revision is not necessary.

RAI 13-7 10 CFR 50.34(b) states that the FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility.

10 CFR 50.34(b)(2) states that a description and analyses of the structures, systems and components of the facility, with emphasis upon the performance requirements, the bases, with technical justification therefor, upon which such

requirements have been established, and the evaluations required to show that safety functions will be accomplished.

10 CFR Part 50, paragraph 50.57(a)(3) states that an operating license may be issued upon finding that, "There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…"

The ISG to NUREG-1537 states in Section 13a2 that the information in this chapter should achieve the objectives stated in this chapter of NUREG 1537, Part 1 by demonstrating that the applicant has considered all potential accidents at the reactor facility and adequately evaluated their consequences.

The ISG to NUREG-1537 states NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features.

SHINE has stated in the SSA that they are using guidance from NUREG-1520 to support their accident analyses in the FSAR. The following items identified from SHINE's SSA summary are not consistent with the regulatory guidance in Chapter 3 of NUREG-1520. The staff needs this information to assess the completeness of the applicant's accident analyses and the adequacy of the applicant's accident analyses methodology. Furthermore, the staff needs this information to verify the applicant's implementation of the SSA methodology for reasonable assurance that the applicant will conduct operations without endangering the health and safety of the public.

a. Section 2.5.2 of the SSA states that the dose calculations were made using both the site boundary and the location of the nearest resident as dose receptors. Revise the SSA dose calculations and FSAR, as necessary, to consider the distance to the end of the owner-controlled area, or the maximum exposed individual. Alternatively, justify use of the nearest resident.

b. In the SSA, SHINE assigns a failure frequency index of -5 to some safe-by-design controls without further justification. Similarly, SHINE assigns a failure probability index of -4 or -5 to passive engineered controls with high design margin without further justification. Using these assumptions, failure of a safe-by-design component is inherently considered highly unlikely and therefore the accident sequence need not be developed and further analyzed. According to guidance in Chapter 3 of NUREG-1520, the default failure frequency or failure probability index for such controls is -3. The approach taken in the SSA is not consistent with the guidance in NUREG-1520. Re-evaluate the applicable accident sequences using the assumptions

from NUREG-1520. Alternatively, provide the analysis that justifies assigning the associated failure frequencies or failure probability indices.

c. According to Tables 2.4.1 and 2.4.2 of the SSA, SHINE may assign a failure frequency index of -4 and a failure probability index of -3 to an enhanced specific administrative control. Given that this facility is first of a kind and the reliability of human actions in its operation has not been studied to the extent of those in a nuclear reactor or typical fuel cycle facility, it is unlikely these indices could be justified without a detailed analysis. According to the guidance in NUREG-1520, the default failure frequency or failure probability index for such controls is -2. Re-evaluate the applicable accident sequences using the assumptions from NUREG-1520 for administrative controls. Alternatively, provide the analysis that justifies assigning the associated failure frequencies or failure probability indices.

d. As cited in NUREG-1520, the methodology should contain information on management measures applied to ensure designated safety controls are reliable and available to perform their intended safety function, i.e., management measures are necessarily distinct from the IROFS to which they are applied. The applicant's SSA describes "Reliability Management Measures" as programmatic administrative controls that are applied to credited controls. These Reliability Management Measures include maintenance, inspections, and testing. Appendix A appears to credit those measures as safety related. For those accident sequences in Appendix A that credit Reliability Management Measures as preventing or mitigating an accident sequence, the staff needs clarification on the credited controls to which the Reliability Management Measures are applied. If the credited controls are also Reliability Management Measures, the applicant should reevaluate the applicable accident sequences to identify and evaluate the failure likelihood of the controls to which the Reliability Management Measures are applied.

RAI 13-8 10 CFR 50.34(b) states that the FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility.

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

10 CFR Part 50, paragraph 50.57(a)(3) states that an operating license may be issued upon finding that, "There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…"

The ISG to NUREG-1537 states in Section 13a2 that the information in this chapter should achieve the objectives stated in this chapter of NUREG 1537,

Part 1 by demonstrating that the applicant has considered all potential accidents at the reactor facility and adequately evaluated their consequences.

The ISG to NUREG-1537 states NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features.

The SSA included consequence categories comparable to the performance requirements in 10 CFR 70.61(b)(1) – (4), 70.61(c)(1) – (2) and 70.61(c)(4). However, the SSA does not discuss a comparable consequence category as provided in performance requirement 70.61(c)(3), i.e., a 24-hour release of radioactive material outside the restricted area in concentrations of 5000 times the values in Table 2 of Appendix B to Part 20. Furthermore, the SSA does not include credible accident sequences exceeding a comparable threshold. This threshold, as put forth in 70.61(c)(3), protects the public from releases that may result in intermediate consequences as described in Section 2.3.2 of the SSA.

Describe how the SSA considers a consequence category comparable to performance requirement 70.61(c)(3). Alternatively, justify its exclusion as a consequence category in the SSA.

Criticality Safety

RAI 13-9 10 CFR 50.34(b) states that the FSAR shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analyses of the structures, systems and components and of the facility.

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

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

The ISG to NUREG-1537 states NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features.

a. FSAR Section 6b.3 states that the CSP is *intended* to meet the applicable criticality safety requirements of 10 CFR 70. Explicitly state which 10 CFR 70 requirements the applicant considers applicable and intends to meet. Explicitly state whether the CSP meets, not intends to meet, these requirements.

b. The accident analyses methodology contained in the SSA (see RAI 13-5) states the risk of criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes *within the RPF* are subcritical, including use of an approved margin of subcriticality for safety. Additionally, FSAR Section 6b.3, "Nuclear Criticality Safety in the RPF," suggests that the CSP is only applicable to activities performed in the RPF. However, SSA Summary Table 2.8-1, "FSAR Accident Analyses for the Irradiation Facility," includes accident sequences in the Irradiation Facility (IF) that could result in inadvertent criticality. Describe how subcriticality is assured under normal and credible abnormal conditions for all nuclear processes performed within the IF, excluding the target solution vessels (TSVs). Specifically, describe how subcriticality is assured in the event of failure of a target solution vessel, TSV dump tank, and/or connected systems that can result in target solution migration into unintended or unanticipated locations.

Chemical Safety

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

i. the 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,
vi. proposed technical specifications 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 technical specifications should consider chemical hazards

Technical Specification, 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.

Technical Specification, 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 how the nuclear safety program or chemical control program identifies and manages chemical hazards.

Provide a description of the activities associated with the nuclear safety program and chemical control program that minimizes the probability and consequences of accidents resulting in a hazardous chemical release. 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.