March 25, 2015

Richard Vann Bynum, Ph.D.
Chief Operating Officer
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. – REQUEST FOR ADDITIONAL INFORMATION REGARDING APPLICATION FOR CONSTRUCTION PERMIT (TAC NOS. MF2305, MF2307, AND MF2308)

Dear Dr. Bynum:

By letters dated October 15, 2014, and December 3, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML14296A190 and ML14356A528), SHINE Medical Technologies, Inc. (SHINE) responded to the U.S. Nuclear Regulatory Commission (NRC) staff's September 19, 2014, request for additional information (RAI) (ADAMS Accession No. ML14195A159) to complete the review of SHINE's preliminary safety analysis and environmental reports supporting a construction permit application.

In the course of reviewing SHINE's RAI responses submitted on October 15, 2014, the NRC staff determined that additional information was required to complete the review of SHINE's preliminary safety analysis and environmental reports in order to prepare a safety evaluation report and environmental impact statement, respectively. Therefore, the NRC staff issued a supplemental request for information on January 6, 2015 (ADAMS Accession No. ML15005A407), which SHINE responsed to, in part, by letter dated February 6, 2015 (ADAMS Accession No. ML15043A395).

In the course of reviewing SHINE's RAI responses submitted on December 3, 2014, and February 6, 2015, the NRC staff has determined that additional information is required to complete the review of SHINE's preliminary safety analysis and environmental reports in order to prepare a safety evaluation report.

This request for additional information supplements the NRC's previous requests for additional information related to SHINE's construction permit application dated September 11, 2013, September 19, 2014 (ADAMS Accession Nos. ML13231A041 and ML14195A159), and January 6, 2015. The specific information requested is addressed in the enclosure to this letter. It is requested that SHINE respond to this request within 30 days of the date of this letter. Timely responses to RAIs contribute toward an efficient and effective review of the submitted application.

In accordance with 10 CFR Section 50.30(b), SHINE must execute its response in a signed original document under oath or affirmation. SHINE's response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in this response that SHINE considers sensitive or proprietary must be marked in accordance with

10 CFR 2.390, “Public inspections, exemptions, requests for withholding.” Any information related to security should be submitted in accordance with 10 CFR 73.21, “Protection of Safeguards Information: Performance requirements.” Following receipt of the additional information, NRC staff will continue its evaluation of SHINE’s construction permit application.

If you have any questions, please contact Steven Lynch at 301-415-1524 or by email at Steven.Lynch@nrc.gov.

Sincerely,

/RA/

Alexander Adams, Jr., Chief
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No.: 50-608

Enclosure:
Request for Additional Information

cc: See next page

cc:

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ADAMS Accession No.: ML15055A116 **NRR-088**

OFFICE	NRR/DPR/PRLB	NRR/DPR/PRLB	NRR/DPR/PRLB
NAME	SLynch	AAdams	SLynch
DATE	03/19/2015	03/25/2015	03/25/2015

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REQUEST FOR ADDITIONAL INFORMATION
SHINE MEDICAL TECHNOLOGIES, INC.
REGARDING PRELIMINARY SAFETY ANALYSIS REPORT
AND ENVIRONMENTAL REPORT
CONSTRUCTION PERMIT APPLICATION
DOCKET NO. 50-608
TAC NOS. MF2305, MF2307, AND MF2308

By letter dated May 31, 2013 (SMT-2013-023, Agencywide Documents Access and Management System (ADAMS) Accession No. ML13172A361), SHINE Medical Technologies, Inc. (SHINE) submitted the second and final part of its two-part application for a construction permit. Part one of SHINE's construction permit application, primarily consisting of SHINE's environmental report, was submitted by letter dated March 26, 2013 (SMT-2013-012, ADAMS Accession No. ML13088A192). By letter dated September 25, 2013 (SMT-2013-033, ADAMS Accession No. ML13269A378), SHINE supplemented this submission with a discussion of preliminary plans for coping with emergencies, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34(a)(10), completing its application for a construction permit.

In the course of reviewing SHINE's construction permit application, the U.S. Nuclear Regulatory Commission (NRC) staff has determined that additional information is required to complete the review of the SHINE Preliminary Safety Analysis Report (PSAR) submitted on May 31, 2013 (ADAMS Package No. ML13172A324), in support of the development of its safety evaluation report.

By letter dated September 19, 2014 (ADAMS Accession No. ML14195A159), NRC staff issued a request for additional information. SHINE responded to the NRC staff's request by letters dated October 15, 2014, and December 3, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML14296A190 and ML14356A528).

In the course of reviewing SHINE's RAI responses submitted on October 15, 2014, the NRC staff determined that additional information was required to complete the review of SHINE's preliminary safety analysis and environmental reports in order to prepare a safety evaluation report and environmental impact statement, respectively. Therefore, the NRC staff issued a supplemental request for information on January 6, 2015 (ADAMS Accession No. ML15005A407), which SHINE responsed to, in part, by letter dated February 6, 2015 (ADAMS Accession No. ML15043A395).

In the course of reviewing SHINE's RAI responses submitted on December 3, 2014, and February 6, 2015, the NRC staff has determined that additional information is required to complete the review of SHINE's preliminary safety analysis and environmental reports in order to prepare a safety evaluation report.

The SHINE irradiation facility, including the irradiation units, and radioisotope production facility, as described in the SHINE PSAR, are primarily evaluated using the appropriate 10 CFR regulations, 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

ENCLOSURE

Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048), as well as 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 referenced in NUREG-1537, Parts 1 and 2, as well as the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE PSAR.

For the purposes of this review, the term "reactor," as it appears in the relevant guidance listed above, can be interpreted to mean "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to mean SHINE's "target solution."

In order to avoid repeating reference numbers for specific information requests, the reference numbers used in this this request for additional information are a continuation of the numbering used in the previous requests for additional information issued on September 19, 2014, and January 6, 2015.

This request for additional information supplements the NRC's previous requests for additional information related to SHINE's construction permit application dated September 11, 2013, September 19, 2014 (ADAMS Accession Nos. ML13231A041 and ML14195A159), and January 6, 2015.

Responses to the following RAIs are needed to continue the review of the SHINE construction permit application.

GENERAL INFORMATION REQUEST

The following question is based on a review of the SHINE construction permit application (ADAMS Accession No. ML130880226) using the requirements of 10 CFR 50.33, "Contents of appliations; general information."

RAI G-3 Title 10 of the *Code of Federal Regulations* (10 CFR) Paragraph 50.33(e), requires that an application shall state, in part, the class of license applied for.

On October 17, 2014, the NRC published a direct final rule in the *Federal Register* (FR), which went into effect on December 31, 2014 (79 FR 62329). This rulemaking modified the definition of *utilization facility* in 10 CFR 50.2, "Definitions," to include "an accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608."

In Section 2.4, "Class of License," of Enclosure 4 to SHINE letter dated March 26, 2013 (ADAMS Accession No. ML13088A192), SHINE stated, in part, that "this application is for the [construction permit] for a production facility under 10 CFR 50. Additional future applications will be for the production facility operating license under 10 CFR 50…"

In light of the recent rulemaking modifying the definition of *utilization facility* in 10 CFR 50.2 to include SHINE's irradiation units, additional information is needed for the NRC staff to determine the adequacy of the description of the class of license applied for in the SHINE construction permit application, as required by 10 CFR 50.33(e).

a. Provide additional information clarifying the types and numbers of facilities (i.e., production and/or utilization facilities) that the SHINE construction permit application supports.

b. Provide information describing any necessary modifications to the SHINE construction permit application to meet the regulatory requirements for any type of facility not previously considered, as applicable.

c. Relate the use of SHINE-specific facility designations (e.g., Production Facility, Medical Isotope Production Facility, Radioisope Production Facility, and Irradiation Facility) to the 10 CFR 50.2 definitions of *production facility* and *utilization facility*.

CHAPTER 3 – DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

The following questions of this chapter are based on a review of Chapter 3 of the SHINE PSAR (ADAMS Accession No. ML13172A264) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, as well as SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 3.4 – Seismic Damage

RAI 3.4-8 NUREG-1537, Part 1, Section 3.4, "Seismic Damage," states that the applicant should include information on the facility seismic design to provide reasonable assurance that the reactor could be shut down and maintained in a safe condition or that the consequences of accidents would be within the acceptable limits in the event of potential seismic events.

NUREG-1537, Part 2, Section 3.4, "Seismic Damage," states that the reviewer should find sufficient information to conclude that the design to protect against seismic damage provides reasonable assurance that the facility structures, systems, and components will perform the necessary safety functions described and analyzed.

While SHINE's response to RAI 3.4-1(b) provided additional information on free field site response analyses using the SHAKE2000 computer program, the response did not include a reference for the version of the SHAKE2000 computer program used in SHINE's seismic analysis.

Provide the reference for the version of the SHAKE2000 computer program used in SHINE's seismic analysis.

RAI 3.4-9 NUREG-1537, Part 1, Section 3.4, "Seismic Damage," states that in order to verify that seismic design functions are met, the applicant should give the technical specifications necessary to ensure operability, testing, and inspection of associated systems, including instrumentation and controls.

NUREG-1537, Part 2, Section 3.4, "Seismic Damage," states that the reviewer find that the surveillance activities proposed provide reasonable assurance that the safety-related functions of the structures, systems, and components (SSCs) that are required to respond to, or mitigate the consequences of, seismic damage to the facility will be maintained.

SHINE PSAR, Section 3.4.4, "Seismic Instrumentation," states that the seismic instrumentation operates during SHINE facility operation. The maintenance and repair procedures will keep the maximum number of instruments in service. The in-service testing provisions include periodic channel checks, and the capability for in-place functional testing.

However, in response to RAI 3.4-6, SHINE states that seismic instrumentation will not be installed at the SHINE facility, citing no regulatory requirement for such instrumentation under 10 CFR Part 50 or Part 100. SHINE instead states that "procedures will be used to systematically assess the operability and functionality of the plant SSCs. The magnitude of the event will be determined using information available from the U.S. Geological Survey (USGS) or other authoritative source."

While the USGS and other authoritative sources could provide information such as the epicenter location or focal mechanism for a felt earthquake at the SHINE facility, they cannot provide the acceleration time histories or response spectra experienced at the facility needed to conduct post-earthquake quantified evaluations and re-qualifications of the facility Seismic Category I and Seismic Category II SSCs. Additional information is needed for NRC staff to determine that the safety-related functions of the structures, systems, and components that are required to respond to, or mitigate the consequences of, seismic damage to the facility will be maintained.

Provide a discussion of the methodology that will be used to develop procedures for post-earthquake evaluations and re-qualifications of Seismic Category I and Seismic Category II SSCs without onsite seismic instrumentation recording information such as acceleration time histories and response spectra.

Section 3.5 – Systems and Components

RAI 3.5-6 SHINE PSAR, Section 3.5.1, "Classification of Systems and Components Important to Safety," discusses the classification of SSCs.

Title 10 of the *Code of Federal Regulations*, Part 50.2, "Definitions," provides definitions including that for safety-related SSCs. The definition states:

> *Safety-related structures*, systems and components means those structures, systems and components that are relied upon to remain functional during and following design basis events to assure:
>
> (1) The integrity of the reactor coolant pressure boundary
>
> (2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
>
> (3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 50.34(a)(1) or § 100.11 of this chapter, as applicable.

Title 10 of the *Code of Federal Regulations*, Part 70.4, "Definitions," provides the definition for *items relied on for safety* (IROFS). The definition states:

> *Items relied on for safety* mean structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.

Title 10 of the *Code of Federal Regulations*, Part 21.3, "Definitions," defines a "basic component." As it would apply to the SHINE facility, the definition states:

> …basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

SHINE PSAR, Section 3.5.1.1, "Nuclear Safety Classifications for SSCs," states:

> SHINE uses a modified definition from 10 CFR 50.2 'Definitions' to develop the definition of SR [safety-related] SSCs, where appropriate, and utilizes a portion of 10 CFR 70.4 'Definitions' for the definition of IROFS SSCs.

In the responses to RAIs 3.5-1 and 3.5-4, SHINE proposes a six-part definition of *safety-related structures, systems and components*, which modifies the 10 CFR 50.2 definition of *safety-related structures, systems, and components* to include performance requirements for SSCs important to safety in the SHINE radioisotope production facility, and eliminates the classification of certain SSCs as IROFS. While five of the six parts of this modified definition are performance-based, the fourth part of this definition (i.e., "[t]hat the potential for an inadvertent criticality accident is not credible") is not performance-based.

Additional information is needed for the NRC staff to evaluate the adequacy of SHINE's modified definition of *safety-related structures, systems, and components*. Furthermore, additional information is needed for NRC staff to determine the relationship between definition of basic component in 10 CFR 21.3 to SHINE's proposed definition of *safety-related structures, systems, and*

components.

Additionally, the NRC staff notes that despite SHINE's statement that this revised definition of *safety-related structures, systems, and components* eliminates the classification of certain structures, systems, and components as items relied on for safety, the term "IROFS" still appears in several places in the SHINE PSAR.

a. Provide a performance-based definition for the fourth part (i.e., with respect to the credibility of an inadvertent criticality accident) of the six-part definition of *safety-related structures, systems, and components* or provide a discussion of why it is not necessary.

b. Discuss how SHINE's definition of *safety-related structures, systems, and components* relates to the 10 CFR 21.3 definition of basic component. (i.e., Describe whether SHINE's defined safety-related structures systems, and components can also be considered basic components under 10 CFR 21.3).

c. Remove references to items relied of for safety from the SHINE PSAR if there are no longer SSCs that will bear this designation. Otherwise, clarify how IROFS will be utilized as part of SHINE's ongoing safety basis

RAI 3.5-7 As required by 10 CFR 50.34(a)(4), the information in the PSAR shall contain "[a] preliminary 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…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

In response to RAI 3.5-4 SHINE stated, in part, that the Control Room is part of a safety-related, Seismic Category I structure, but that the other SSCs are not defined as safety-related based on SHINE's definition of safety-related structures, systems, and components.

While SHINE's response to RAI 3.5-4 also states that safety-related systems are automatic and would put the facility in a safe condition without operator intervention, there is no discussion on how control room operators or other facility personnel will determine the facility is in a safe condition or how personnel will maintain the facility in a safe condition.

Under the conditions of a postulated design basis earthquake and a loss of offsite power, conditions could exist which would inhibit facility personnel from determining that the facility is in a safe condition and maintaining the facility in a safe condition using necessary safety-related equipment:

- SHINE PSAR Tables 2.3-2 and 2.3-3 show that the outdoor temperature can vary between −37°F and 104°F. While Control Room ventilation is supplied via Facility Ventilation Zone 4 (FVZ4), which is nonsafety-related, the Control

Room has no heating, ventilation, and air conditioning (HVAC) system, which could impact Control Room habitability and equipment operability.

- The SHINE facility does not include emergency lighting, which could impact the ability of facility personnel to assess the facility status and to staff the Control Room.

- Since the Stack Release Monitoring System is not defined as safety-related, its unavailability could impact the ability of facility personnel to determine that there are no releases going up the stack.

- Since the Health Physics Monitors are not defined as safety-related, their unavailability could impact the ability of facility personnel to assess levels of contamination during egress from the facility.

- Since the Facility Data and Communication System is not defined as safety-related, its unavailability could impact the ability of control room personnel to determine the facility status and communicate with other facility personnel and offsite agencies.

- In the event of an earthquake, there is the possibility for both onsite and offsite toxic releases and smoke from fire. Since the Facility Breathing Air System is not defined as safety-related, its unavailability could impact the ability of facility personnel to determine the facility status.

Additional information is needed on the design of the SHINE control room and other SSCs for NRC staff to determine the adequacy of the design for the prevention of accidents and the mitigation of the consequences of accidents.

Taking into account the conditions described above, provide additional information describing how the design of the SHINE control room and other SSCs will allow control room operators or other facility personnel to determine the facility is in a safe condition or how personnel will maintain the facility in a safe condition in the event of a postulated design basis earthquake with a loss of off-site power.

Section 3.5b – Radioisotope Production Facility

RAI 3.5b-2 As required by 10 CFR 50.34(a)(4), an applicant needs to submit "[a] preliminary 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…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

In response to RAI 3.5b-1, SHINE provided the information on the systems supported by the standby diesel generator, and stated that Criterion 7 of 10 CFR 70.64 is met by the Uninterruptible Power Supply Chain.

Additional information is needed for the NRC staff to evaluate the standby diesel generator's ability to meet Criterion 7 of 10 CFR 70.64 to determine the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.

Provide additional information stating how the standby diesel generator meets Criterion 7 of 10 CFR 70.64, given that it and the systems it powers are classified as non-safety-related and how the Uninterruptible Power Supply Chain meets Criterion 7 of 10 CFR 70.64 during a loss of normal AC power.

CHAPTER 6 – ENGINEERED SAFETY FEATURES

The following questions of this chapter are based on a review of Chapter 6 of the SHINE PSAR (ADAMS Accession No. ML13172A268) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, as well as SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 6b.3 – Nuclear Criticality Control

(Applies to RAIs 6b.3-23 through 30)

As required by 10 CFR 50.34(a)(4), an applicant needs to submit "[a] preliminary 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…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

As stated in the ISG Augmenting NUREG-1537, Chapter 13, the NRC staff has determined that the use of integrated safety analysis (ISA) methodologies as described in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 2010, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR Section 70.61, designation of IROFS, 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. As used in this ISG, the term "performance requirements," when referencing 10 CFR Part 70, Subpart H, is not intended to mean that the performance requirements of Subpart H are required for a radioisotope production facility license, only that their use as accident consequence and likelihood criteria may be found acceptable by NRC staff.

RAI 6b.3-23 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part that "[c]riticality process safety controls should be provided for criticality safety, and a description of their safety function should be described. The applicant should use enough safety controls to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical" and that "NCS [nuclear criticality safety] limits on controlled parameters will be established to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety."

For example, the applicant could commit to base the safety limits on validated

calculation methods. These methods should be industry-accepted and peer-reviewed. Also, the applicant should commit to ensuring that methods used to develop NCS limits will be validated to confirm that they are used within acceptable ranges and that the applicant used both appropriate assumptions and acceptable computer codes.

In response to RAI 6b.3-1b, SHINE submitted a general validation report and a project-specific validation report, which provided the methods and assumptions used to determine that nuclear criticality safety criteria are met at the SHINE facility. Staff reviewed these reports and has determined that additional information is needed to determine that the methods used to validate NCS safety criteria are acceptable and that SHINE used both appropriate assumptions and acceptable computer codes.

a. The general validation report appears to be an off-the-shelf report, dated 2007. As described in ANSI/ANS-8.24, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations," verification and validation should be performed using the same operating systems, software, and hardware that will be used for performing evaluations and placing systems under configuration control.

   Provide additional information describing how the general validation report uses appropriate methods to validate NCS safety criteria, including information on the operating systems, software, and hardware used to perform evaluations and place systems under configuration control.

b. As described in NUREG-6698, "Guide for Validation of Nuclear Criticality Safety Calculational Methodology," prior to the initiation of validation activities, the operating conditions and parameters for which the validation is to apply must first be identified.

   For both the general and project-specific validation reports, describe the area of applicability with respect to the actual operations and describe the applicability of the benchmark experiments to these operations.

c. As described in NUREG-6698, the statistical results from the bias trends are used to establish safety limits. Both the general and project-specific validation reports are missing an evaluation of trends in the bias data, which may impact potential bias estimates.

   For both the general and project-specific validation reports, provide an evaluation of the trends in the bias data, describing potential impacts on the bias impacts.

d. The validation of two different libraries for different materials, introduces the possibility of human error in selecting a library for the evaluation (i.e., picking the wrong library).

Provide the methods SHINE uses to guard against the selection of the incorrect library for validation.

e. The project-specific validation report utilizes only a limited number of experiments to evaluate the bias and estimate uncertainty. For example, only four experiments were listed for the most applicable enrichment. Additionally, modeled results were compared with calculated results, as opposed to only with experimental data.

Explain why only a limited number of experiments are sufficient to evaluate bias and estimate uncertainty. Additionally, explain why modeled results were compared with calculated results, as opposed to only with experimental data.

RAI 6b.3-24 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, states, in part, that "[e]ach process that has accident sequences leading to criticality should have sufficient controls in place to ensure double-contingency protection. This may be provided by either (1) control of two independent process parameters, or (2) control of a single process parameter, such that at least two independent failures would have to occur before criticality is possible. The first method is preferable because of the inherent difficulty in preventing common-mode failure when controlling only one parameter." Additional discussions of the double-contingency principle are available on pages 5-7 and 5-A-8 of NUREG-1527.

In response to RAI 6b.3-10, SHINE states that tank 1-TSPS-01T meets double contingency by geometry and the configuration management program. NRC staff does not view the configuration management program as an independent control. As described in 10 CFR 70.4, configuration management is not normally considered a management measure because it assures the availability of the geometry control.

Provide additional information describing how tank 1-TSPS-01T meets the double contingency principle.

RAI 6b.3-25 NUREG 1520, Section 3.4.3.2, "Integrated Safety Analysis Summary and Documentation," states that an event defined as "not credible" "must be convincing despite the absence of designated [controls]. Typically, this can be achieved only for external events known to be extremely unlikely."

In response to RAI 6b.3-3, SHINE provides the basis for considering a criticality sequence to be "not credible." In this explanation, SHINE essentially quotes the three independent acceptable sets of qualities that could define an event as "not credible" from Section 3.4.3.2 of NUREG-1520.

In the response to RAI 13b.1-1, SHINE established, in Table 13b.1-1-2, "Likelihood Index Limit Guidelines," an event frequency associated with highly unlikely and unlikely that is consistent with the values found in NUREG-1520.

While SHINE provides three independent sets of qualities that could define an event as "not credible," SHINE's criteria does not take into account an absence of designated controls. Without a reliance on controls, consistent with the guidance in NUREG-1520, criticality, in certain situations, would be "credible," but "highly unlikely," due to the establishment of controls consistent with the methods proposed. Therefore, additional information is required for NRC staff to determine the adequacy of SHINE's use of the term "not credible" in its PSAR with respect to criticality safety.

Revise the definition of "not credible" to not include reliance on controls consistent with the guidance in NUREG-1520 and event frequency limits provided in Table 13b.1-1-2 or provide information why this is not necessary.

RAI 6b.3-26 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, states, in part, that the reviewer should determine "whether the margin of subcriticality for safety is sufficient to provide reasonable assurance of subcriticality."

In response to RAI 6b.3-4, SHINE states it intends to utilize a subcritical margin of 0.05 with additional considerations for uncertainty in the validation and modeling. In addition, SHINE states in multiple places in the PSAR that processes will be maintained to a $k_{eff} \leq 0.95$ (assuming a subcritical margin of 0.05).

The NRC staff's review of SHINE's response to RAI 6b.3-1, which requested the applicant's validation report and NCS reference manual, found that there was insufficient benchmarking of the code against experiments utilizing the materials and enrichments expected in SHINE's processes. For this reason, the proposed subcritical margin of 0.05 is not sufficient to adequately address the uncertainty associated with the neutron interactions of these process materials. The subcritical margin of 0.05, which SHINE quoted from NUREG-1520, was intended for facilities with enrichment less than five percent utilizing well established processes and for which there is significant experience and data. In contrast, the SHINE facility will be a first-of-a-kind facility using materials not normally utilized and of an enrichment up to 20 percent.

Provide additional information describing how SHINE will sufficiently benchmark against experiments utilizing the materials and enrichments expected to be used in SHINE facility processes for its proposed margin of subcriticality, or propose a new margin of subcriticality that appropriately takes into account materials and enrichment.

RAI 6b.3-27 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states that the reviewer should determine if, when they are relevant, the applicant considers heterogeneous effects. Heterogeneous effects are particularly relevant for low-enriched uranium processes, where, all other parameters being equal, heterogeneous systems are more reactive than homogeneous systems.

SHINE PSAR, Section 6b.3, “Nuclear Criticality Control,” states that “[h]eterogeneous effects are not considered applicable because the uranium enrichment is less than 20 percent.”

In the response to RAI 6b.3-6, SHINE elaborated on its treatment of heterogeneous effects by quoting LA-12808, “Nuclear Criticality Safety Guide,” stating that heterogeneous effects can be ignored for uranium with an enrichment above six percent uranium-235.

As shown in figures 22 through 25 of LA-10860-MS, “Critical Dimensions of Systems Containing U-235, Pu-239, and U-233,” heterogeneity does affect some parameters at greater than six percent enrichment in U-235.

Provide additional information acknowledging that heterogeneity effects will be considered when establishing NCS controls and limits, where such are credible and relevant.

RAI 6b.3-28 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, “Nuclear Criticality Safety for the Processing Facility,” states that the reviewer should determine whether the applicant’s use of moderator as a controlled parameter is acceptable.

In the response to RAI 6b.3-8, SHINE states that “preliminary criticality scoping safety assessments include optimum moderation conditions. The preliminary design does not contain systems that require moderation as the sole controlled criticality safety parameter and there are no plans to have moderation controlled areas.” While moderation may not be a “sole controlled safety parameter,” it is unclear whether SHINE will be reliant on moderation controls in any capacity. NRC staff needs additional information to determine whether SHINE considers moderation to be a controlled parameter.

Verify whether the SHINE facility will be reliant on moderation controls in any capacity as opposed to a sole control. If moderation controls will be used, provide information describing these controls.

RAI 6b.3-29 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, “Nuclear Criticality Safety for the Processing Facility,” states that the reviewer should determine whether the applicant’s use of enrichment as a controlled parameter is acceptable.

In response to RAI 6b.3-18 SHINE states that criticality scoping safety assessments have been performed using a uranium enrichment value of 21 percent to conservatively address uranium enrichment. NRC staff needs additional information to determine whether SHINE considers enrichment to be a controlled parameter.

Verify whether enrichment will be a controlled parameter controlled by independent verification, upon receipt of materials, to assure no out-of-spec materials are utilized.

RAI 6b.3-30 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, states, in part, that "[c]riticality process safety controls should be provided for criticality safety, and a description of their safety function should be described. The applicant should use enough safety controls to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical."

While SHINE states in response to RAIs 6b.3-1 and 6b.3-22, that the NCS reference manual and formal NCSEs have yet to be generated, the NRC staff need additional information to determine that enough safety controls have been considered to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical.

Provide additional information discussing the methodologies and assumptions that will be used to develop SHINE's NCS reference manual and provide a representative sample of nuclear criticality safety evaluations to demonstrate the methods used to demonstrate that under normal and abnormal credible conditions, all nuclear processes remain subcritical.

CHAPTER 12 – CONDUCT OF OPERATIONS

The following questions of this chapter are based on a review of Chapter 12 of the SHINE PSAR (ADAMS Accession No. ML13172A275) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, the SHINE Preliminary Emergency Plan, Revision 0, dated September 25, 2013 using NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," and SHINE's responses to requests for additional information dated September 19, 2014 and January 6, 2015 (ADAMS Accession No. ML14296A192 and ML15005A407).

RAI 12.7-36 NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," Section 3.0, "Organization and Responsibilities," Evaluation Item 1.b., states that the emergency plan should describe "[t]he reactor's emergency organization, including augmentation of the reactor staff to provide assistance for coping with the emergency situation, recovery from the emergency, and maintaining emergency preparedness."

On September 19, 2014, NRC staff requested additional information on the actions to be taken by operators when an emergency is declared. Specifically, in RAI 12.7-4, SHINE was asked to "describe the actions the on-shift operators will take if they cannot ensure their activities can be placed in a safe condition before reporting to the on-site assembly area."

SHINE's responses to RAIs 12.7-4 and 12.7-35 did not adequately address the actions of the on-shift operators, such as the Shift Supervisor, Senior Facility Operator, and Facility Operator, when an emergency is declared.

In order for the NRC staff to determine the adequacy of SHINE's emergency organization, additional information is needed on the actions of the on-shift operators when an emergency is declared.

a. In the event of an emergency, describe the actions that will be taken by on-shift operators if they cannot ensure their activities can be placed in a safe condition.

b. Following a design-basis, beyond design-basis, security, unplanned (e.g., a radiological release or chemical spill), or other type of on-site or off-site event, describe the actions taken by on-shift operators to ensure their activities are placed or remain in a safe condition.

c. In the event of an emergency, describe the programmatic process(es) for individuals and their activities, as well as the safety systems necessary to maintain safe shutdown.

APPENDIX 12C – QUALITY ASSURANCE PROGRAM DESCRIPTION

The following questions of this chapter are based on a review of Appendix 12C in Chapter 12 of SHINE's PSAR provided with SHINE's response to the staff's second RAI (ADAMS Accession No. ML15043A404) using ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors" and SHINE's responses to requests for additional information dated September 19, 2014, and January 6, 2015 (ADAMS Accession No. ML14296A192 and ML15005A407).

Appendix 12C Section 1 – Introduction

RAI 12C.1-5 As required by 10 CFR 50.34(a)(7), each applicant for a construction permit to build a production or utilization facility must include, in its preliminary safety analysis report, a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Regulatory Guide 2.5, Revision 1, states that the general requirements for establishing and executing a quality assurance program for the design, construction, testing, modification, and maintenance of research and test reactors in the American National Standards Institute/American Nuclear Society Standard (ANSI/ANS) 15.8-1995 provide an acceptable method for complying with the program requirements of 10 CFR 50.34, "Contents of applications; technical information."

Section 12.9, "Quality Assurance," of the SHINE PSAR states that the "SHINE QA-1, Quality Assurance Program Description (QAPD), is based on ANSI/ANS 15.8-1995 (R2005) (ANSI/ANS, 1995), 'Quality Assurance Program Requirements for Research Reactors,' with guidance from Regulatory Guide 2.5, Revision 1." However, it is not clear to what extent ANSI/ANS 15.8-1995 has been applied to the development of the SHINE QAPD for the facility.

SHINE's response to RAI 12C.1-3 stated, in part, "SHINE has revised the Executive Summary of the SHINE Quality Assurance Program Description (QAPD) to state, "SHINE has determined that ANSI/ANS 15.8-1995 is appropriate for use in the design of the facility even though this standard was written for research reactors."

In reference to SHINE's response to RAI 12C.1-3, ANSI/ANS 15.8-1995 is not a design standard and cannot be directly applied to the design of the SHINE facility.

Clarify whether SHINE has determined that ANSI/ANS 15.8-1995 is sufficient for use in the development of the SHINE QAPD, which is to be applied in the design, fabrication, construction, and operation of the SHINE facility.

RAI 12C.1-6 ANSI/ANS-15.8-1995, Section 1.3, "Definitions," defines an experiment as "[a]ny operation, hardware, or target (excluding devices such as detectors, foils, etc.) that is designed to investigate non-routine reactor characteristics or that is intended for irradiation within the pool, on or in a beamport or irradiation facility,

and that is not rigidly secured to a core or shield structure so as to be a part of their design."

The SHINE QAPD, Section 2.10, "Inspections," states, in part, that "[t]he inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication."

The SHINE QAPD Section 2.19, "Experimental Equipment," states that "[t]he quality assurance program shall provide controls over the design, fabrication, installation and modification of experimental equipment to the extent that these impact safety-related items."

The SHINE QAPD, Section 1.3, "Definitions," does not provide a definition of an experiment. Further, SHINE's response to RAI 12C.1-4 stated, in part, that "The definition of experiment is not listed in the SHINE QAPD, as SHINE does not plan on conducting experiments as defined in ANSI/ANS-15.8-1994 (R2013)."

Addtionally, it is not clear how SHINE's definitions of "audit" and "assessment" are related in Sections 2.7, "Control of Purchased Items and Services," and Section 2.18, "Assessment."

a. Clarify the basis for not providing a definition of experiment, if SHINE is planning to conduct experiments and utilize experimental equipment, as discussed in Sections 2.10 and 2.19 of the SHINE QAPD, respectively.

b. Provide additional information regarding the definitions of "audit," as used in the SHINE QAPD Sections 2.7, "Control of Purchased Items and Services," and 2.7.3, "Verification Activities," and "assessment," as used in Section 2.18, "Assessment." Provide clarification as to the difference between the two definitions, if any.

Appendix 12C Enclosure 2 – Graded Approach to Quality

RAI 12C.E2-6 ANSI/ANS-15.8-1995, Section 2.2, "Quality Assurance Program," states, in part, that "[t]he program shall identify the items and activities to which it applies and the extent of program application for each item and activity."

The SHINE QAPD Enclosure 2 – Graded Approach to Quality, states, in part, that "[t]he graded approach to quality is a process by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance." It further states that "QL-1 shall implement the full measure of this QAPD and shall be applied to Safety-Related Structures, Systems and Components. QL-2 will include the non-safety related quality activities performed by the licensee, that are deemed necessary by SHINE to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements."

SHINE's response to RAI 12C.E2-5 stated, in part, that "[t]he QL-2 classification is applicable to all nonsafety-related SSCs and activities, and is applied by SHINE to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements." It further stated that "SHINE design control and procurement procedures will consider the function of the nonsafety-related SSC or activity, the relative importance of that function, whether there are any codes, standards, or other requirements that apply, and determine the appropriate quality measures."

Addtionally, the definition of the QL-2 classification provided in the SHINE QAPD focuses on ensuring "the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements." Furthermore, the definition of the QL-2 classification provided in the QAPD does not indicate that the QL-2 classification is applicable to all non-safety related SSCs and activities, whereas and SHINE's response to RAI 12C.E2-5 states that it does.

a. Clarify if the QL-1 classification applies to safety-related activities, as well as safety-related SSCs.

b. Clarify how the definition of the QL-2 classification provided in the SHINE QAPD is based on safety significance considerations. Further, clarify whether the definition of the QL-2 classification is based on the application of the full scope of the QAPD to the activities affecting quality, as opposed to only design and procurement requirements, as described in the response to RAI 12C.E2-5.

c. Clarify if the QL-2 classification is intended to be applied only to selected non-safety related SSCs and activities.

CHAPTER 13 – ACCIDENT ANALYSIS

The following questions of this chapter are based on a review of Chapter 13 of the SHINE PSAR (ADAMS Accession No. ML13172A276) using the Final ISG Augmenting NUREG-1537, Parts 1 and 2 and SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 13a2.2 – Accident Analysis and Determination of Consequences

(Applies to RAIs 13a2.2-5 through 7)

The ISG Augmenting NUREG-1537, Part 2, Section 13a2, "Aqueous Homogeneous Reactor Accident Analyses," states that the applicant should include a systematic analysis and discussion of credible accidents for determining the limiting event in each category and that the mathematical models and analytical methods employed, including assumptions, approximations, validation, and uncertainties, should be clearly stated.

RAI 13a2.2-5 While SHINE's response to RAI 13a2.2-1 states that the basis for the internal dose conversion factors (DCFs) is International Commission on Radiological Protection Publication 30, "Limits for Intakes of Radionuclides by Workers," (ICRP 30) additional information is needed on this basis, as applied to offsite DCFs for members of the public, for the NRC staff to determine the adequacy of SHINE's radiological dose consequence analysis as part of its accident analysis.

Provide information supporting the acceptability of ICRP 30, which provides DCFs for adult workers, as the basis for calculating offsite doses to members of the public, including children.

RAI 13a2.2-6 In response to RAI 13a2.2-1, SHINE conservatively uses a respirable fraction (RF) of 1.0 for most accidents listed in Table 13a2.2.1-4, including the Mishandling and Malfunction of Target Solution. However, a value of 0.4 is used for the particulate RF in the maximum hypothetical accident, which is similar to the Mishandling and Malfunction of Target Solution. Additional information is needed for the NRC staff to determine the adequacy of SHINE's radiological dose consequence analysis as part of its accident analysis.

Provide a basis for the use of a RF value of 0.4 used in the maximum hypothetical accident, including an explanation for why it is different than the RF for the Mishandling and Malfunction of Target Solution accident.

RAI 13a2.2-7 While SHINE's response to RAI 13a2.2-4 indicates that MCNP5 was used to calculate fluxes and cross-sections specific to various target solution vessel configurations, additional information is needed for NRC staff to determine the adequacy of SHINE's radiological dose consequence analysis as part of its accident analysis, recognizing that the typical use of MCNP involves using existing cross section libraries.

Provide additional information on how MCNP is used to calculate cross sections and what these cross sections are used for at for the SHINE facility.

Section 13b.1 – Radioisotope Production Facility Accident Analysis Methodology

RAI 13b.1-3 As required by 10 CFR 50.34(a)(4), the preliminary safety analysis report should include "[a] preliminary 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…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

The ISG Augmenting NUREG-1537, Part 2, Section 13b.1.2, *"Accident Initiating Events,"* states that *"[i]nformation in the [safety analysis report] should allow the reviewer to follow the sequence of events in the accident scenario from initiation to a stabilized condition. The reviewer should confirm the following:*

- *The credible accidents were categorized, and the most limiting accident in each group was chosen for detailed analyses.*
- *The process was assumed to be operating normally under applicable technical specifications before the initiating event. However, the process may be in the most limiting technical specification condition at the initiation of the event.*
- *Instruments, controls, and automatic protective systems were assumed to be operating normally or to be operable before the initiating event. Maximum acceptable non-conservative instrument error may be assumed to exist at accident initiation.*
- *The single malfunction that initiates the event was identified.*
- *Credit was taken during the scenario for normally operating process systems. Protective actions were initiated by either the operating staff, control systems, or ESFs.*
- *The sequence of events and the components and systems damaged during the accident scenario were clearly discussed.*
- *Validated mathematical models and analytical methods that were employed, including assumptions, approximations, and uncertainties, were clearly stated.*
- *The radiation source terms were presented or referenced.*
- *The potential radiation consequences to the facility staff and the public were presented and compared with acceptance criteria.*

While Tables 13b.1-2-1 and 13b.1-1-4 provided in response to RAIs 13b.1-1 and 13b.1-2 provided potential accident sequences at the SHINE facility, additional information is needed for the NRC staff to evaluate SHINE's methodology for determining the sequence of events in an accident scenario from initiation to a stabilized condition.

Provide detailed accident sequence descriptions for at least four of the sequences listed in Table 13b.1-1-4, from the initiating events through the sequence's mitigated consequences. The descriptions should include the most limiting examples from a chemical accident, radiological accident, fire accident, and criticality accident, and should discuss the following:

a) The hazards involved in the accident, including source terms and initiating events. The initiating events should consider potential operator errors as well as external events and equipment failures;

b) An explanation of the methodology for selecting the numerical value of the likelihood of the initiating event;

c) An analysis of the unmitigated consequences, including the classification of unmitigated consequences as radiological or chemical, as well as less-than-intermediate, intermediate, or high;

d) A description of the accident progression, and the function(s) of IROFS, as applicable, in the accident sequence mitigation;

e) An explanation of methodology for selecting the numerical value for the availability and reliability of the IROFS, as applicable, and the resulting mitigated likelihood; and

f) An explanation of how the mitigated consequences were estimated.