April 15, 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 responded 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 its review of SHINE's preliminary safety analysis 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), January 6, 2015, and March 25, 2015 (ADAMS Accession No. ML15055A116). 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 me at 301-415-1524 or by email at Steven.Lynch@nrc.gov.

Sincerely,

/RA/

Steven T. Lynch, Project Manager
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.: ML15099A607 **NRR-088**

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DATE	04/13/2015	04/15/2015	04/15/2015

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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 (RAI). SHINE responded to the NRC staff's request by letters dated October 15, 2014, and December 3, 2014 (ADAMS Accession Nos. ML14296A190 and ML14356A528, respectively).

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 RAI on January 6, 2015 (ADAMS Accession No. ML15005A407), which SHINE responded 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 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 Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048), as well as the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537,

ENCLOSURE

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 in 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 RAI are a continuation of the numbering used in the previous RAIs issued on September 19, 2014, January 6, 2015, and March 25, 2015.

This RAI supplements the NRC's previous RAIs related to SHINE's construction permit application dated September 11, 2013, September 19, 2014 (ADAMS Accession Nos. ML13231A041 and ML14195A159), January 6, 2015, and March 25, 2015 (ADAMS Accession No. ML15055A116).

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

CHAPTER 9 – AUXILIARY SYSTEMS

The following questions of this chapter are based on a review of Chapter 6 of the SHINE PSAR (ADAMS Accession No. ML13172A271) 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 RAI dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 9a2.1 – Heating, Ventilation, and Air Conditioning Systems

RAI 9a2.1-3 NUREG-1537, Part 2, Section 9.1, "Heating, Ventilation, and Air Conditioning Systems," *Acceptance Criteria*, states, in part: "The design and operating features of the system should ensure that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur."

a. While SHINE provided information on the source of air supply for Radiological Controlled Area (RCA) Ventilation System Zone 1 (RVZ1), in response to RAI 9a2.1-1(a), PSAR Figures 9a2.1-1, "RVZ1 Ventilation Flow Diagram," and 9a2.1-2, "RVZ2SA and RVZ2 Ventilation Flow Diagram" were not revised. SHINE's response also did not clarify what areas/enclosures/rooms are considered RVZ1, RCA Ventilation System Zone 2 (RVZ2), and RCA Ventilation System Zone 3 (RVZ3). Additionally, a revised RVZ3 flow diagram was not provided as requested in RAI 9a2.1-1(b).

Additionally, while the text in SHINE PSAR Section 9a2.1.1, "Radiologically Controlled Area Ventilation System," describes RVZ1, RVZ2, and RVZ3, Figure 9a2.1-2 indicates the existence of a "Zone 4."

SHINE PSAR Section 9a2.1.1 also describes a negative pressure differential between RVZ2 and RVZ3. However, there is insufficient information describing air flow and pressure differentials between other zones.

In response to RAI 3.5-3 SHINE states, "…the RVZ3 fans are not operating…" while Figure 9a2.1-2 shows no fans associated with RVZ3. Figure 9a2.1-2 only depicts the Zone 3 airlocks. No other areas are shown to be part of RVZ3 and there is no discussion in the RAI response as to what RVZ3 encompasses.

Therefore, additional information is needed for NRC staff to assess the adequacy of the design of SHINE RCA System Zones to ensure that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur.

i. Provide additional information stating what areas/enclosures/rooms are considered RVZ1, RVZ2, and RVZ3, as well as revised flow diagrams and descriptions for RVZ1, RVZ2, and RVZ3. Ensure consistency between figures and descriptions in the text of SHINE PSAR Section 9a2.1, "Heating Ventilation, and Air Conditioning Systems." Include a description and flow diagram for "Zone 4," as applicable.

ii. Clarify whether a negative pressure differential is maintained to keep air flowing from low contamination areas towards high contamination areas, both in rooms and between zones. Include information describing whether a negative pressure differential is maintained between the RCA and outside the RCA.

b. SHINE's response to RAI 9a2.1-1 discusses "RPF Airlocks" and an "IF Airlock" supplied by RVZ2 Supply Air. The response also states that "RVZ3 areas include the RCA airlocks." Additionally, Figure 9a2.1-2 shows two "Zone 3 Airlocks" and Figure 9a2.1-2-1, "Facility Ventilation Zone 4 Flow Diagram," shows an arrow to the "RPF Airlocks" and an arrow to the "Irradiation Facility Airlock." However, SHINE PSAR Figure 1.3-2, "SHINE General Arrangement" depicts the following airlocks:

- Receiving Airlock/Man Door Airlock (RCA NE corner)
- Airlock Emergency Exit (RCA NW corner)
- Two Airlocks by Shipping (RCA SE Corner)
- Airlock by Health Physics (RCA SW Corner)

Additional information is needed relating the discussion of airlocks in response to RAI 9a2.1-1, the airlocks shown in Figures 9a2.1-2 and 9a2.1-2-1, and the airlocks shown in Figure 1.3-2 in order for NRC staff to assess the adequacy of the design of SHINE RCA System Zones to ensure that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur.

Provide additional information relating the discussion of airlocks in response to RAI 9a2.1-1, the airlocks shown in Figures 9a2.1-2 and 9a2.1-2-1, and the airlocks shown in Figure 1.3-2.

CHAPTER 11 – RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

The following questions of this chapter are based on a review of Chapter 11 of the SHINE PSAR (ADAMS Accession No. ML13172A274) 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 11.1 – Radiation Protection

RAI 11.1-10 NUREG-1537, Part 2, Section 11.1.1 states in part, "All sources of radiation should be discussed by the applicant. This discussion should include the … exposure rates, energy level, encapsulation (sealed or unsealed), use, storage conditions and locations…"

SHINE PSAR Section 11.1.1, (page 11-2) "Radiation Sources," indicates that radiation shielding is designed to ensure that the use and storage conditions for the radiation sources have the appropriate controls and shielding. In addition, the shielding will ensure that the exposure rates assure conformance with ALARA practices as required by 10 CFR 20.1101.

Additional information is needed for the NRC staff to evaluate the consistency of SHINE's shielding design based on the types and locations of radiation sources.

a. Specify the sections of 10 CFR Parts 20 (e.g., ALARA, occupational dose limits, public dose limits) and the exposure rates that will be implemented by shielding.

b. Provide additional information on the type(s) and location(s) of shielding used at the SHINE facility to ensure compliance with ALARA practices, the administrative dose limits, and the occupational dose limits.

(Applies to RAIs 11.1-11 through 13)

10 CFR 20.1101, "Radiation protection programs," Item (b) requires licensees to "…use, to the extent practical, procedures and engineering controls…to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)."

RAI 11.1-11 NUREG-1537, Part 2, Section 11.1.1 states, in part, that maximum annual dose and collective doses for major radiological activities shall be shown to be within the applicable limits of 10 CFR Part 20.

SHINE PSAR Section 11.1.1.1 (page 11-3), "Airborne Radioactive Sources," states that "[t]he tritium purification system and neutron driver are designed such that the estimated annual doses to the [maximally exposed individual] and the nearest resident are below the regulatory limits specified in 10 CFR 20.1101(d)."

Additional information is needed for the NRC staff to determine the adequacy of SHINE's implementation of the applicable limits of 10 CFR Part 20.

Clarify that all the activities in the SHINE Radioisotope Production Facility are designed to meet the requirements of 10 CFR 20.1101(d), as the current statement in the SHINE PSAR only applies to the tritium purification system and neutron driver.

RAI 11.1-12 NUREG-1537, Part 2, Section 11.1.3, "ALARA Program," states, in part that "[f]acility management should ensure that sufficient emphasis is placed on and sufficient resources are given to ALARA considerations during design, construction, and operation of facilities…"

SHINE PSAR Section 11.1.3.2.1, "General Design Considerations for ALARA Exposures," indicates that ALARA is applied to the general design considerations and methods without any explanation.

Additional information is needed for the NRC staff to determine that sufficient emphasis is placed on ALARA considerations for the design of the SHINE facility.

Describe how ALARA is applied to the general design considerations and methods.

RAI 11.1-13 SHINE PSAR Section 11.1.3.2, "ALARA Program Design Considerations," states in part, that "[t]he basic management philosophy guiding the SHINE facility design effort so that radiation exposures are ALARA can be expressed as: [d]esign structures, systems and components to reduce the radiation fields and control streaming, thereby reducing radiation exposure during operation, maintenance, and inspection activities."

Additional information is needed for the NRC staff to determine whether the design of structures, systems, and components to reduce radiation fields and control streaming are designed to meet ALARA requirements.

Describe how the ALARA concepts of time, distance and shielding are incorporated into the design of structures, system and components for employee work stations.

RAI 11.1-14 NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," states, in part, that "[a]ll sources of radiation should be discussed by the applicant, [including] the physical and chemical form…"

SHINE PSAR Section 11.1.1 (page 11-2), states that special nuclear material inventories are tabulated in Tables 4b.4-1 and 4b.4-13 for the SHINE Radioisotope Production Facility (RPF).

The amount of U-235 represented in Table 4b.4-1 (based on the inventory of special nuclear material and the level of enrichment) does not seem to agree with the amount of U-235 process inventory specified in Table 4b.4-13.

Specify the quantity of special nuclear material and U-235 processed at one time in the RPF, ensuring that the values in Tables 4b.4-1 and 4b4-13 are consistent.

RAI 11.1-15 NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," states in part that, "The applicant should present the best estimates of the maximum annual dose and the collective doses for major radiological activities during the full range of normal operations for facility staff and members of the public. The doses shall be shown to be within the applicable limits of 10 CFR Part 20."

a. SHINE PSAR Section 11.1.1, (page 11-2) contains a commitment to implement sufficient shielding to ensure direct exposure rates do not exceed 0.25 mrem/hr, except during tank transfers.

   Additional information is needed on the dose rates that will occur during the tank transfers to ensure consistency with ALARA and the dose limits.

   Explain why dose rates during tank transfers that exceed 0.25 mrem/hr are acceptable and consistent with ALARA principles. Explain why shielding will not be used for the tank transfers.

b. SHINE PSAR section 11.1.1.1, (page 11-3) provides annual dose estimates for the maximum exposed member of the public, but does not state whether the dose rate limit in 10 CFR 20.1301 will also be met.

   Demonstrate that in addition to meeting the annual dose limit, the dose rate limit in 10 CFR 20.1301 will also be met.

RAI 11.1-16 NUREG-1537, Part 2, Section 11.1.1 states, in part, that "[l]iquid effluent volumes and radionuclide concentrations should be shown to be within the requirements of 10 CFR Part 20."

SHINE PSAR Section 11.1.1.2, (page 11-3 and 11-4) "Liquid Radioactive Sources," describes liquid radioactive sources at the SHINE facility.

Additional information is needed for the NRC staff to determine the adequacy of the design of the SHINE facility to protect workers and the public from radiation exposures due to liquid radioactive sources.

Provide a description of the safety features in place to prevent exposures to liquid radioactive sources, (e.g., regular maintenance, shielding, berms).

RAI 11.1-17 NUREG-1537, Part 2, Section 11.1.2, "Radiation Protection Program," states, in part, that "[p]rocedures should be organized and presented for convenient use by

operators and technicians at the appropriate locations, and should be free of extraneous material."

SHINE PSAR Section 11.1.2.1.5, (pg 11-8) "Commitment to Written Radiation Protection Procedures," states that radiation work permits (RWPs) will be used for both routine and non-routine activities.

Additional information is needed for NRC staff to determine the adequacy of the organization of SHINE's radiation protection program procedures. The description of RWPs appears contradictory because it requires RWPs for routine activities which should already be covered by existing operating procedures.

Clarify the conditions under which RWPs will be used. Clarify under what conditions routine activities, typically covered by existing operating procedures, would also require RWPs.

RAI 11.1-18 NUREG-1537, Part 2, Section 11.1.4, "Radiation Monitoring and Surveying," states, in part, that the "procedures and equipment should be designed to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary."

a. SHINE PSAR Section 11.1.4.1, "Radiation Monitoring," indicates that radiation area monitors (RAMs) will be used at the SHINE facility. However, there is no information on the location or conditions that will be present for these monitors to be installed.

   Additional information is needed for NRC staff to determine the adequacy of the design of the SHINE facility ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

   Provide additional information on the location and conditions that will result in the instillation of RAMs. Provide sufficient information to determine if RAMs will be used in locations where exposures may exceed administrative limits under normal operations or credible accident conditions, as determined by the Integrated Safety Analysis or equivalent means.

b. SHINE PSAR Section 11.1.4, provides a general overview of the survey and monitoring program. However, there is no indication of the facility function/program responsible for overseeing and implementing this program or the plan to use written procedures.

   Additional information is needed for NRC staff to determine that the radiation protection program will oversee the adequacy of the design of the SHINE facility to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

   Describe the function or program (e.g., radiation protection program) that is responsible for implementing the radiation survey and monitoring program.

Also, establish that the program will have written procedures that specify the types, times, and methods for radiation sampling and monitoring.

c. SHINE PSAR Section 7a2.7.4.3, (page 7a2-45), "Audible and Visual Alarm Devices," states that radiation alarms have present activation levels.

Additional information is needed for NRC staff to determine that radiation alarms have the appropriate oversight to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

Specify the alarm levels or identify the function or program (e.g., radiation protection program) responsible for setting these limits and the methodology to be used to establish these values (e.g., administrative limits).

d. SHINE PSAR section 11.1.4.1(g), (page 11-18), "Control Point Monitoring," states the radiological monitoring equipment will be calibrated and maintained.

Additional information is needed for NRC staff to determine that radiation monitoring equipment will have the appropriate calibration and maintenance to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

Provide additional information to clarify which group (e.g., the radiation protection program) is responsible for maintaining and checking the radiological monitoring equipment.

RAI 11.1-19 NUREG-1537, Part 2, Section 11.1.4, "Radiation Monitoring and Surveying," states, in part, that "[i]n coordination with the information presented in Chapter 6, 'Engineered Safety Features,' the applicant should describe the interface between the radiation monitoring system and the engineered safety features."

SHINE PSAR Section 6b.2.1.2, (page 6b-5) "Confinement System and Components," and Table 6b.1-1, "Summary of RPF Design Basis Events and ESF Provided for Mitigation," indicate that the confinement systems for the hot cell and the radiological integrated control system (RICS) are considered safety-related systems, structures and components (SSCs).

Additional information is needed for the NRC staff to determine that the radiation monitoring systems are adequate to remain available and reliable to support the engineered safety features.

Since RICS depends in part on the automatic notification from the continuous air monitoring system (CAMS) and radiation area monitoring system (RAMS), clarify whether these items used to support the RICS for the hot cells and other potentially high radiation areas are safety-related systems, structures and components (SSCs). Demonstrate that radiation monitors (e.g., CAMS and

RAMS) used as SSCs or to support SSCs have appropriate controls (e.g., management measures) to ensure they remain available and reliable.

RAI 11.1-20 NUREG-1537, Part 2, Section 11.1.5, "Radiation Exposure Control and Dosimetry," states, in part, that the "[d]esign of the facility…should prevent uncontrolled radiation releases to the environment or to the work areas during normal operations."

SHINE PSAR 11.1.5.1.1, (page 11-19) "Radiological Zones," describes radiation zones that have varied definitions and span of control.

Additional information is needed for the NRC staff to understand how these radiological zones operate and are used to (1) control the spread of contamination, (2) control personnel access to avoid unnecessary exposure of personnel to radiation, and (3) control access to radioactive sources present in the facility.

Provide additional information describing how the radiological zones are defined, how they work, how each zone is physically separated from other zones, and how the zones are maintained.

RAI 11.1-21 NUREG-1537, Part 2, Section 11.1.5, states, in part, that the "design of entry control devices…should alert workers to, or prevent unauthorized entry into, high radiation areas and very high radiation areas, as appropriate."

SHINE PSAR 11.1.5.2, (page 11-21) "Access and Egress Control," refers to active and passive engineered safeguards to control access to high radiation areas.

Additional information is needed for NRC staff to determine the adequacy of the design of entry control devices to alert workers to, or prevent unauthorized entry to specified radiation areas, as appropriate.

a. Provide a description of the active and passive safety systems that are used to control access to high radiation areas.

b. Clarify whether the "engineered safeguards" discussed in PSAR Section 11.1.5.2, (page 11-21) are security-related, consistent with the guidance in NUREG-1537, Section 12.8, "Security Planning."

RAI 11.1-22 NUREG-1537, Part 2, Section 11.1.5, states, in part, that the "design bases of radiation shielding, ventilation, and remote handling and decontamination equipment should be planned so radiation doses are maintained ALARA and should be within the regulatory limits."

a. SHINE PSAR Section 9a2.1.1, (page 9a2-2) "Radiologically Controlled Area Ventilation System," indicates the automatic cell ventilation dampers are safety-related.

Additional information is needed for the NRC staff to determine the adequacy of the design basis for the SHINE automatic cell ventilation dampers to ensure ALARA considerations are maintained.

Since these items are safety-related, identify the management measures required to ensure the dampers remain available and reliable to ensure radiation doses are maintained ALARA and within regulatory limits.

b. SHINE PSAR section 9a2.1.1, (page 9a2-3) "Radiologically Controlled Area Ventilation System," indicates flow control valves will maintain constant pressure for the fume hoods.

Additional information is needed for the NRC staff to determine that appropriate minimum pressure gradient will be maintained across the fume hood threshold.

Demonstrate that a minimum pressure gradient will be maintained across the fume hood threshold consistent with guidance in Regulatory Guide 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication." Show that, if the gradient drops below this level, the pressure drop will be identified and corrected.

(Applies to RAIs 11.1-23 through 25)

The ISG Augmenting NUREG-1537, Part 2, Section 11.1, "Radiation Protection," states, in part:

"[I]ndividuals who are not workers, as defined in 10 CFR 70.4, may be permitted to perform ongoing activities…in the controlled areas if the licensee…[p]rovides training that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the ISA…"

Additional information is needed for the NRC staff to determine whether SHINE has ensured that individuals are aware of the risks associated with accidents involving licensed activities.

RAI 11.1-23 While SHINE PSAR Section 13b.2.1.2, "Identification of Initiating Events and Causes," discusses a rupture of five noble gas storage tanks, it does not identify the credible accident events that could initiate this accident sequence.

Identify the potential credible accident sequences that could result in the radiological maximum hypothetical accident (MHA). Provide sufficient information to describe the initiating events and demonstrate that the consequences are calculated for both the credible unmitigated conditions (without SSCs) and mitigated conditions (with SSCs).

(Applies to RAIs 11.1-24 through 25)

As required by 10 CFR 50.34(a)(4), the preliminary safety analysis report shall 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."

As set forth in ISG Augmenting NUREG-1537, Part 1, Section 13b, "Radioisotope Production Facility Accident Analyses," the NRC staff has determined that the "use of 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,"] application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS [items relied on for safety], and establishment of management measures are acceptable ways of demonstrating an adequate margin of 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 the 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 11.1-24 SHINE PSAR section 13b.2.1.4, page 13b-5 identifies mitigating structures, systems, and components that should not be included in the unmitigated accident analysis. The mitigating structures, systems, and components cannot be credited during the unmitigated portion of the accident analysis. The MHA, under unmitigated conditions, could be bound by a 100 percent release of the contents of the five noble gas storage tanks to the environment.

a. Recalculate the MHA for both the worker and the public excluding mitigation, assuming credible accident conditions consistent with the rupture of the five noble gas storage tanks.

In addition, safety systems used to prevent or mitigate a credible event must remain available and reliable under the credible accident conditions. For example, a credible accident (e.g., seismic event, fire, explosion, airplane crash) that can result in rupture of the five noble gas storage tanks may also result in failure of the fail-safe bubble-tight isolation dampers, etc.

b. Provide justification for the assumptions in PSAR Section 13b.2.1.7, (page 13b-7) "Radiological Consequence Analysis," used to mitigate the MHA. Provide justification that the safety related systems, structures, and

components relied on to mitigate the MHA will remain available and reliable under credible accident conditions.

RAI 11.1-25 SHINE PSAR Section 13b.2.1.1, (page 13b-5) "Initial Conditions and Assumptions," identifies systems that are mitigative without designating them as IROFS or safety-related structures, systems, and components.

Designate all mitigative or preventive systems relied on to meet the performance requirements of 10 CFR 70.61 (or equivalent) as safety-related structures, systems, and components or IROFS, as applicable, and designate appropriate management measures. Provide a commitment to evaluate all credible accidents under unmitigated conditions and implement safety-related structures, systems, and components or IROFS, as applicable, and management measures to ensure intermediate and high consequence events comply with the performance requirements of 10 CFR 70.61 (or equivalent).

Section 11.2 – Radioactive Waste Management

(Applies to RAIs 11.2-6 through 8)

NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," states, in part, that the "SAR should contain a commitment to comply with applicable regulations for managing radioactive wastes."

Additional information is needed for NRC staff to determine the adequacy of SHINE's commitment to comply with applicable regulations for managing radioactive wastes.

RAI 11.2-6 SHINE PSAR Section 11.2, "Radioactive Waste Management," states that SHINE is committed to comply with all applicable local and national regulations for managing radioactive wastes.

Provide a summary list of the regulations and any standards or guidance that SHINE intends to follow to demonstrate its commitment to complying with applicable regulations for managing radioactive wastes.

RAI 11.2-7 SHINE PSAR Section 11.1.1.2, (page 11-4) "Liquid Radioactive Sources" indicates that solid waste will be sent to disposal facilities.

Provide additional information indicating that these disposal facilities will have appropriate licenses for managing radioactive wastes (i.e., licensed disposal facilities).

RAI 11.2-8 SHINE PSAR Sections 11.2.3.1, 11.2.3.2, and 11.2.3.3, (pages 11-49 through 11-49) describe the control of solid, liquid and gaseous waste streams.

Provide a description of the survey or monitoring equipment [e.g., continuous air monitoring system (CAMS) and radiation area monitoring system (RAMS)] and

program that will be used to ensure wastes remain in these designated controls/processes and identify any loss of control or unplanned releases.

Section 11.3 – Respiratory Protection Program

(Applies to RAIs 11.3-1 through 3)

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, "Respiratory Protection Program," states, in part, that the applicant should "[i]nstall appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed occupational derived air concentration values in 10 CFR Part 20."

Additional information is needed for NRC staff to determine the adequacy of the ventilation system at the SHINE facility.

RAI 11.3-1 SHINE PSAR Section 9a2.1.1 indicates that air which passes from radiation controlled area ventilation Zone 2 (RVZ2) to radiation controlled ventilation Zone 1 (RVZ1) is first passed through HEPA filtration. This appears to imply that the zones are isolated from each other and that air is filtered between each zone.

Provide additional information to clarifying whether each zone can be isolated from the other zones automatically using the automatic isolation dampers and whether the air is filtered between each zone.

RAI 11.3-2 SHINE PSAR Section 9a2.1.1 (page 9a2-2) indicates that the ventilation air in the exhaust header is tested before being exhausted to the stack.

Provide additional information to demonstrate that the tests will verify some pre-defined differential pressure gradient across the filters and measure the level of contamination following the filters. Additionally, indicate the type of action that will be taken (e.g., a notification will be sent to the control room or other appropriate facility for action) if a specified differential pressure or contamination level is exceeded.

RAI 11.3-3 SHINE PSAR Section 9a2.1.1 (page 9a2-3) states that fume hood exhaust ducts are controlled automatically to compensate for changes in pressure drops for loading of filters.

Additional information is needed for NRC staff to determine the adequacy of the ventilation system at the SHINE facility.

Justify that an acceptable differential pressure will be maintained across facility air filters. Indicate whether this will be done through monitoring or some other process. Describe any notification that may be generated to change the filters if a set-point is exceeded.

RAI 11.3-4 The ISG Augmenting NUREG-1537, Part 2, Section 11.3, (pages 11-57 through 11-59) states, in part, that the applicant should "[d]escribe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used."

SHINE PSAR Sections 9a2.1.1 and 11.3, "Respiratory Protection Program," do not provide the minimum flow velocity at openings, maximum differential pressure across filters, or types of filters to be used.

Additional information is needed for NRC staff to determine the adequacy of SHINE design criteria for the ventilation and containment systems.

Describe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used. In addition, state which safety function is responsible for maintaining the respiratory program (e.g., the radiation protection program).