September 19, 2014

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 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 (ADAMS Accession No. ML13088A192). By letter dated September 25, 2013 (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).

By letter dated December 2, 2014 (ADAMS Accession No. ML13316B387), the NRC staff completed its acceptance review of part two of SHINE's application for a construction permit and determined that this second and final portion of SHINE's two-part construction permit application, as supplemented, contained the remainder of the preliminary safety analysis report required by 10 CFR 50.34(a) and was submitted in accordance with the requirements of 10 CFR 2.101(a)(5). Therefore, the application was determined to be complete for docketing, and was assigned Docket No. 50-608.

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 SHINE's preliminary safety analysis and environmental reports in order for the NRC staff to prepare a safety evaluation report and environmental impact statement, respectively.

This request for additional information (RAI) supplements, in part, the NRC's initial request for additional information related to the SHINE environmental report by letter dated September 11, 2013 (ADAMS Accession No. ML13231A041). 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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If you have any questions, please contact Steven Lynch at 301-415-1524 or by email at Steven.Lynch@nrc.gov.

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Docket No.: 50-608

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Request for Additional Information

cc: See next page

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**ADAMS Accession No.: ML14195A159** **NRR-088**

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|---|---|---|---|---|
| NAME | SLynch | PBlechman | KHalvey** | MBailey** |
| DATE | 07/14/2014 | 07/31/2014 | 03/07/2014 | 04/02/2014 |
| OFFICE | NRO | NSIR/DPR/NRLB/ABC | NRR/DPR/PRLB/BC | |
| NAME | KKavanagh* | MBrezovec* | AAdams | |
| DATE | 08/07/2014 | 08/21/2014 | 9/ 19 /2014 | |

*concurrence via email **OFFICIAL RECORD COPY**
**by memo dated

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. ML13172A234), in support of the development of its safety evaluation report. Additionally, the NRC staff has determined that additional information is required to complete the review of the SHINE environmental report in support of the development of its environmental impact statement.

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, as well as the guidance contained in NUREG-1537 Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537 Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048), 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

ENCLOSURE

fuel," as it appears in the relevant guidance listed above, may be interpreted to mean SHINE's "target solution."

This request for additional information (RAI) supplements, in part, the NRC's initial request for additional information related to the SHINE environmental report by letter dated September 11, 2013 (ADAMS Accession No. ML13231A041).

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

**General Information Request**

RAI G-1 Title 10 of the *Code of Federal Regulations* (10 CFR 50.34(a)(8)), requires that a PSAR include:

> An identification of those structures, systems, or components of the facility, if any, which require research and development to confirm the adequacy of their design; and identification and description of the research and development program which will be conducted to resolve any safety questions associated with such structures, systems or components; and a schedule of the research and development program showing that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility.

Based on the review of SHINE PSAR, NRC staff understands that there are structures, systems, and components that require additional research and development, and that this information will become available in SHINE's final safety analysis report (FSAR). However, the information listed above has not been provided in sufficient detail in the SHINE PSAR for the NRC staff to determine the extent of additional research and development required for structures, systems, and components of the SHINE facility.

1) Identify structures, systems, or components of the facility, if any, which require research and development to confirm the adequacy of their design. Additionally, identify and describe the research and development program which will be conducted to resolve any safety questions associated with such structures, systems or components, including a schedule showing that such safety questions will be resolved at or before the latest date stated in the application for the completion of construction of the facility.

2) Provide a plan for developing the scope of the analytical methods verification and validation (V&V) because V&V is an important element in establishing the design basis. As one illustrative example, validation of the radiolytic gas formation calculations can impact design (e.g., determining recombiner capacity) and safety analysis (e.g., determining deflagration potential).

## CHAPTER 1 – THE FACILITY

The questions in this chapter are based on a review of Chapter 1 of the SHINE PSAR (ADAMS Accession No. ML13172A262) using guidance in NUREG-1537, Parts 1 and 2, as well as the ISG Augmenting NUREG-1537, Parts 1 and 2.

### Section 1.1 – Introduction

RAI 1.1-1 NUREG-1537, Parts 1 and 2, Sections 1.1, "Introduction," state that the PSAR Section 1.1, "Introduction," should provide "type and power level" of the reactor.

SHINE PSAR, Section 1.1, "Introduction," states there will be eight irradiation units (IUs) within the irradiation facility (IF), but does not provide the individual or combined power levels of the IUs within the irradiation facility.

Provide the individual and combined power levels of the IU within the IF.

RAI 1.1-2 NUREG-1537, Part 2, Section 1.1, "Introduction," *Acceptance Criteria*, states, in part, "[t]he design or location features included to address basic safety concerns should be outlined."

SHINE PSAR, Section 1.1, "Introduction," does not provide this information.

Provide a summary description of the design or location features, included to address basic safety concerns at the SHINE facility.

### Section 1.2 – Summary and Conclusions on Principal Safety Considerations

RAI 1.2-1 NUREG-1537, Part 1, Section 1.2, "Summary and Conclusions on Principal Safety Considerations," states "[t]he applicant should state safety criteria…."

NUREG-1537, Part 2, Section 1.2, "Summary and Conclusions on Principal Safety Considerations," states that the areas of review should include "safety criteria proposed by the applicant."

"Safety criteria" is not explicitly defined, provided, listed, or discussed in SHINE PSAR, Section 1.2, "Summary and Conclusions on Principal Safety Considerations."

Provide a summary description of the safety criteria involved in the design of the SHINE facility.

RAI 1.2-2 NUREG-1537, Part 1, Section 1.2, "Summary and Conclusions on Principal Safety Considerations," states, "[t]he applicant should … includ[e] brief discussions of the following:

…safety considerations that influenced the selection of the facility site…."

SHINE PSAR, Section 1.2.2, “Safety Considerations,” states that only two site-selection criteria are directly related to safety: the size and shape of the proposed parcel, and the seismic characteristics of the site.

Provide additional information addressing safety considerations, as applicable, of any additional site-selection criterion (e.g., proximity to an airport and proximity to an interstate highway).

RAI 1.2-3 NUREG-1537, Part 1, Section 1.2, “Summary and Conclusions on Principal Safety Considerations,” states, “[t]he applicant should … includ[e] brief discussions of the following:

… any inherent or passive safety features designed to contribute to facility safety.…”

SHINE PSAR, Section 1.2.3.2.2, “Criticality Safety,” states, “[t]he hierarchy of controls is as follows:

a. The facility and equipment is designed so that significant quantities of fissionable material cannot be placed in a favorable configuration for criticality.”

SHINE PSAR, Section 1.2.4.2.2, “Criticality Safety,” states, in part, “…, and measurement and independent verification of uranium concentration for transfers from safe geometry to unsafe geometry tanks.”

SHINE PSAR, Section 1.2.4.2.2, “Criticality Safety,” states, “[t]he criticality safety controls outside the TSV [target solution vessel] include criticality-safe equipment designs to preclude placing fissile material in a favorable configuration for criticality, and measurement and independent verification of uranium concentration for transfers from safe geometry to unsafe geometry tanks.” These statements seem to provide contradictory information.

Provide clarification regarding the facility design of vessels and piping with regard to criticality-safe geometry.

RAI 1.2-4 NUREG-1537, Part 2, Section 1.2, “Summary and Conclusions on Principal Consideration,” *Acceptance Criteria*, includes information on principal safety considerations, such as, “[a]ll modes of operation and events that could lead to significant radiological releases and exposure to the public should be discussed.”

SHINE PSAR, Section 1.2, “Summary and Conclusions on Principal Consideration,” does not provide definitions of facility operating modes or a summary discussion of modes of operation.

Provide a discussion regarding all modes of operation that could lead to significant radiological releases and exposure to the public.

RAI 1.2-5 NUREG-1537, Part 1, Section 1.2, "Summary and Conclusions on Principal Consideration," states, in part, "[t]he applicant should … includ[e] brief discussions of the following:

…any inherent or passive safety features designed to contribute to facility safety…."

SHINE PSAR, Section 1.2.4.2.2, "Criticality Safety," "Passive engineered controls," Item b., states, "[t]he target solution hold tank is located below the TSV, requiring motive force to move the solution into the TSV."

Provide additional discussion on this topic associated with the possibility of the target solution holding tank becoming pressurized. If the TSV experiences a vacuum condition, would inadvertent criticality become possible?

**Section 1.3 – General Description of the Facility**

RAI 1.3-1 SHINE PSAR, Figure 1.3-3, "Production Building Sections Preliminary Arrangement" (ADAMS Accession No. ML13172A283), shows two areas of the building labeled "containment area." However, in SHINE PSAR, Section 6a2.2.2 (ADAMS Accession No. ML13172A268), the SHINE application states, "[t]he SHINE facility does not employ a containment feature."

Provide additional information in SHINE PSAR, Section 1.3, to allow staff to understand if there are containment features involved in the building design. If there are no containment features involved in the building design, revise Figure 1.3-3, accordingly.

RAI 1.3-2 NUREG-1537, Part 1, Section 1.3, "General Description of the Facility," states, in part, "…Safety features of the facility that are likely to be of special interest should be briefly identified."

SHINE PSAR, Section 1.3.3.3, "Facility Systems," states, "[t]he neutron driver is not a safety-related system."

Provide additional information discussing why the neutron driver is not a safety-related system. It appears that upsets in the neutron driver system could result in unplanned higher rates of fission power.

**Section 1.5 – Comparison with Similar Facilities**

RAI 1.5-1 NUREG-1537, Part 2, Section 1.5, "Comparison with Similar Facilities," *Acceptance Criteria*, states, in part, that "reasonable assurance that radiological exposures of the public would not exceed the regulations and guidelines of the proposed facility ALARA program [as low as reasonably achievable]."

SHINE PSAR, Section 1.5, "Comparison with Other Facilities," does not contain a discussion of this topic.

Provide a brief discussion and reference to the applicable SHINE PSAR sections, with regard to expected radiological exposures of the public and with respect to the SHINE facility ALARA program.

## CHAPTER 2 – SITE CHARACTERISTICS

The following questions of this chapter are based on a review of Chapter 2 of the SHINE PSAR (ADAMS Accession No. ML13172A263) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

### Section 2.1 – Geography and Demography

RAI 2.1-1 NUREG-1537, Part 1, Section 2.3.2, "Site Meteorology," states that sufficient information be provided "to support the dispersion analyses of airborne releases from the facility."

NUREG-1537, Part 2, Section 2.1, "Geography and Demography," states that the reviewer should determine that land use in the area of the facility is sufficiently stable or well enough planned that likely potential radiological risks to the public can be analyzed and evaluated with reasonable confidence.

In addition to depicting the site boundary on SHINE PSAR, Figure 2.1-3, "Boundaries and Zones Associated with the Facility" (ADAMS Accession No. ML13172A285), provide a tabulation of the distance from the center of the site and/or the expected airborne release point to the site boundary in each of the 16 compass directions.

RAI 2.1-2 NUREG-1537, Part 2 Section 2.1, "Geography and Demography," states that the PSAR should contain sufficient demographic information to allow accurate assessments of the potential radiological impact on the public resulting from the siting and operation of the proposed facility.

In addition to the three nearest residences located in the northwest, north-northwest, and south-southwest directions provided in SHINE PSAR, Section 2.1.2.1, "Resident Population," provide the distances to the nearest residences in the remaining 13 directions. Since the dominant wind directions are from the west and the south (see Figure 2.3-19, "Annual Wind Rose Southern Wisconsin Regional Airport [2005-2010]"), provide specific information with respect to the nearest residents in the east and north directions.

### Section 2.2 – Nearby Industrial, Transportation, and Military Facilities

RAI 2.2-1 NUREG-1537, Part 2, Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," states that the information contained in this section should be "complete enough to support evaluations of potential risks posed by these facilities to the safe operation and shutdown of the reactor during its projected lifetime."

SHINE PSAR, Section 2.2.3.1.3, "Toxic Chemicals," states, "[t]he control room is not safety-related. The control room operators are not required to operate safety-related equipment to ensure the safety of the public. Therefore, a toxic gas release is not a hazard to the facility."

Provide additional information describing why an onsite or offsite toxic gas release during normal operations would not initiate an accident that could endanger the public and/or cause damage to the facility condition, should the control room operators become incapacitated.

RAI 2.2-2 NUREG-1537, Part 2, Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," states in part, "[t]he reviewer should focus on facilities, activities, and materials that may reasonably be expected to be present during the projected lifetime…."

a) From 2003 to 2012, the Southern Wisconsin AirFest was an activity held at the Southern Wisconsin Regional Airport. Provide additional information clarifying how the results and conclusions presented in SHINE PSAR, Section 2.2.2.5, "Evaluation of the Aircraft Hazard," would be affected if the AirFest or a similar event were held at the Southern Wisconsin Regional Airport during the operation of the SHINE facility.

b) Because NUREG-1537, Part 2, does not provide acceptance criteria to be used to evaluate the aircraft accident probability posed by nearby airports and airways, SHINE PSAR, Section 2.2.2.5.3, "Results of Evaluation of Airways and Airports," utilizes the IAEA-TECDOC-1347 (International Atomic Energy Agency (IAEA) 1987), "Consideration of external events in the design of nuclear facilities other than nuclear power plants, with emphasis on earthquakes," Section 4.3, "Design Basis for Aircraft Crash," acceptance criteria for aircraft accident probabilities of less than $10^{-5}$ per year. However, in SHINE PSAR Section 2.2.2.2, "Airways," the lack of NUREG-1537, Part 2 acceptance criteria resulted in utilizing NUREG-0800, "Standard Review Plan [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [Light-Water Reactor] Edition," Revision 4, Subsection 3.5.1.6, "Aircraft Hazards," to provide guidance in evaluating airways near the SHINE facility. For aircraft accidents, SRP 3.5.1.6 states that accidents "…with a probability of occurrence greater than an order of magnitude of $10^{-7}$ per year should be considered in the design of the plant." In SHINE PSAR, Section 2.2.3.1, "Determination of Design-Basis Events," SRP 3.5.1.6 acceptance criteria were used for evaluating potential accidents at the facility.

Provide additional information to justify utilizing IAEA-TECDOC-1347, as opposed to SRP 3.5.1.6 acceptance criteria for aircraft accidents.

**Section 2.4 – Hydrology**

(Applies to RAIs 2.4-1 through 4)

NUREG-1537, Part 1, Section 2.4, "Hydrology," states, in part, that the applicant should provide sufficient information about the water table, groundwater, and features at the facility site to support analyses and evaluations in the PSAR Chapters 11 "Radiation Protection Program and Waste Management, and 13, "Accident Analysis," of consequences of uncontrolled release of radioactive

material from pool leakage or failure, neutron activation of soils in the vicinity of the facility, or deposition and migration of airborne radioactive material released to the unrestricted area.

RAI 2.4-1 SHINE PSAR, Section 2.4.11.2, "Pathways," provides a particle flow analysis that only considers advective groundwater flow and predicts groundwater travel times and flow directions. Although the text does mention dispersivity (Section 2.4.11.3), the plume-spreading effects were not considered in the transport analysis. Without an understanding of the potential width of the contaminant plume, however, the analysis is inadequate in providing sufficient information to design a groundwater monitoring network (Chapter 11) or to evaluate the potential consequences of uncontrolled releases (Chapter 13). For instance, the potentiometric surfaces presented in SHINE PSAR Figure 2.4-4, "Simplified Groundwater Table Contours Based on Measured Groundwater Elevations in Monitoring Wells" (ADAMS Accession No. ML13172A288), suggest that any releases at the facility would flow undetected between Monitoring Wells SG-GW4A and SM-GW2A. Furthermore, the depth to bedrock may be as deep as 300 feet. Therefore, ample information must be presented regarding probable transport depths in order to allow the wells to be screened at the interval(s) most likely to detect potential releases.

Provide additional information and analysis on the spreading effects and transport depth of the contaminant plume to support the design of the groundwater monitoring network presented in Chapter 11 and ensure that the requirements of 10 CFR 20.1302(b) have been met.

RAI 2.4-2 SHINE PSAR, Table 2.4-13, "Summary of Parameters Used for Advective Travel Time Estimations" (Section 2.4.11.2), presents the results of the travel time analysis. The effective porosity for the expected case is 30 percent. The reference cited in the table for the porosity (Gaffield et al., 2002), however, indicates that a porosity of 20 percent is most representative of the site conditions. A porosity of 20 percent would result in a travel time of 6 years as opposed to 9 years presented in the table.

Provide additional information on the technical rationale for the 30-percent porosity or recalculate the expected travel times.

RAI 2.4-3 SHINE PSAR, Table 2.4-13 (Section 2.4.11.2), presents the results of the travel time analysis. An arithmetic average of the hydraulic conductivities was used in the expected case calculations. Typically, hydraulic conductivities are represented in a log-normal distribution, and geometric means are used to represent typical values.

Provide either additional information on the technical rationale for the averaging of the hydraulic conductivities or recalculate the expected travel times using a geometric mean for the hydraulic conductivity. Additionally, provide the Advanced Aquifer Test Analysis Software (AQTESOLVE) graphical output for the hydraulic conductivity calculations from the slug tests.

RAI 2.4-4 SHINE PSAR, Section 2.4.11.2, “Pathways,” indicates that travel times through the unsaturated zone had not been considered due to the limited information available. An estimation of potential lag times through the unsaturated zone, following a release, is important with respect to evaluating accident scenarios and designing monitoring frequencies and remedial options.

Provide additional information on the bounding estimates for travel time through the unsaturated zone.

RAI 2.4-5 NUREG-1537, Part 1, Chapter 2, “Site Characteristics,” states, in part, the applicant should discuss and describe the hydrological characteristics of the site and vicinity in conjunction with present and projected population distributions, industrial facilities and land use, and site activities and controls.

SHINE PSAR, Section 2.4.1.2, “General Setting – Groundwater,” mentions that there are irrigation wells operated on properties in the vicinity that have the potential to influence groundwater levels. These irrigation wells could also act as pathways for bringing any groundwater contamination released by the facility to the surface. The pumping of irrigation wells can also have a significant effect on groundwater flow directions.

Provide additional information (e.g., irrigation well location(s), pumping rates, screened intervals) for the potential consequences of an uncontrolled release. Potentiometric surfaces under pumping versus non-pumping conditions should also be presented.

**Section 2.5 – Geology, Seismology, and Geotechnical Engineering**

(Applies to RAIs 2.5-1 through 4)

NUREG-1537, Part 1, Section 2.5.2, “Site Geology,” states, in part, “[t]he applicant should discuss in detail the structural geology at the facility site, including the relationship of site structure to regional tectonics, and should pay particular attention to specific structural units of significance to the site such as, folds, faults, synclines, anticlines, domes, and basins.”

RAI 2.5-1 SHINE PSAR, Section 2.5.1.4, “Structural Geology,” provides a discussion of the major faults and folds and concludes that many of the faults are not capable based upon lack of evidence for Pleistocene or post-Pleistocene displacement. As noted in SHINE PSAR, Section 2.5.1, “Regional Geology,” Appendix A of 10 CFR Part 100 defines a capable fault as a fault with “[m]ovement at or near the ground surface at least once within the past 35,000 years or movement of a recurring nature within the past 500,000 years.”

Provide additional information explaining the basis for the determination that there are no capable faults, and provide additional information with respect to the recurring nature of the faults.

RAI 2.5-2 SHINE PSAR, Section 2.5.1.4.6, “Saint Charles Lineament (SCL),” states, in part, “[s]ince 1974, seven earthquakes of magnitude 2.5 or less have been recorded in regions surrounding the SCL.” Information pertaining to these earthquakes is not provided in the summary tables.

Provide information regarding these earthquakes in Table 2.5-1, “Historic Earthquake Epicenters Located Within Approximately 200 Miles (322 km) of the SHINE Site,” (page 2.5-26) or Table 2.5-3, “Recorded Earthquake Intensities (Modified Mercalli Intensity – MMI) (page 2.5-27), for Earthquakes Within Approximately 200 Miles (322 km) of the SHINE Site.”

RAI 2.5-3 SHINE PSAR, Section 2.5.2.2, “Structural Geology,” states, in part, “[d]espite the presence of the Arch, cross sections from Mudrey et al. (1982), suggest that the Cambrian and Ordovician sedimentary rock units beneath the SHINE site probably have very shallow to horizontal dips. These observations indicate little or no net deformation beneath the SHINE site over about the last 500 million years.” An NRC staff review of the Bedrock Geology of Wisconsin, map referenced in the PSAR (Mudrey et al., 1982), failed to locate the cross-sections being referenced in the text.

Provide additional information on the cross sections in the referenced document.

RAI 2.5-4 SHINE PSAR, Section 2.5.3.1, “Historic Earthquakes,” provides a list of databases and references that were used to identify historic earthquakes at the location of the SHINE facility. The most recent historic earthquake located within approximately 200 miles of the SHINE site was in 1985 (Table 2.5-1, page 2.5-26). Another database that includes six more recent earthquakes is compiled by the U.S. Geological Survey (USGS) at http://earthquake.usgs.gov/earthquakes.

Provide additional information justifying the exclusion of the earthquake information compiled by the USGS from analysis in the PSAR, or provide a re-analysis that takes this information into consideration in the PSAR.

RAI 2.5-5 NUREG-1537, Part 1, Section 2.5.1, “Regional Geology,” states, in part, “[t]he applicant should discuss all geologic and seismic hazards within the region that could affect the facility….”

SHINE PSAR, Section 2.5.2.4, “Non-Seismic Geological Hazards,” states in part, “Rock County contains carbonate bedrock susceptible to dissolution or karst formation (WGNHS, 2009). The Rock County Hazard Mitigation Plan (Vierbicher, 2010) indicates that no significant sinkholes have been reported in Rock County in recent years. The plan indicates a potential for karst features to form in the county, particularly in the eastern third of the county that lies to the east of the SHINE site.”

Provide additional information expanding the discussion of regional magnetic and gravity geophysical anomalies presented in SHINE PSAR, Section 2.5.1.5, "Regional Magnetic and Gravity Geophysical Anomalies," to include an evaluation of potential karst features at the SHINE site.

RAI 2.5-6 NUREG-1537, Part 1, Section 2.5.7, "Liquefaction Potential," states that the applicant should discuss soil structure. "If the foundation materials at the site adjacent to and under safety-related structures are saturated soils or soils that have a potential for becoming saturated, the applicant should prepare an appropriate state-of-the-art analysis of the potential for liquefaction at the site. The applicant should also determine the method of analysis on the basis of actual site conditions, the properties of the reactor facilities, and the earthquake, and seismic design requirements for the protection of the public."

NUREG-1537, Part 2, Section 2.5, "Geology, Seismology, and Geotechnical Engineering," instructs the reviewer to find that the information on the geologic features and geotechnical properties at the site has been provided in sufficient detail and in a form to be integrated acceptably into design bases for structures, systems, and operating characteristics of the reactor.

It is reported in SHINE PSAR, Section 2.5.7.1, "Site Soil Conditions," that geotechnical engineering field investigations were conducted that included standard penetrometer test (SPT) blow counts (N-values) measured in 14 boreholes. Details and an explanation were not given about how and whether these investigations were used to develop the soil parameters (engineering properties) listed in SHINE PSAR, Chapter 3 (Section 3.4.2.6.3.1).

Provide the report with details and results for the geotechnical investigations.

RAI 2.5-7 NUREG-1537, Part 1, Section 2.5.7, "Liquefaction Potential," pertains to the discussion of soil structure. "If the foundation materials at the site adjacent to and under safety-related structures are saturated soils, or soils that have a potential for becoming saturated, the applicant should prepare an appropriate state-of-the-art analysis of the potential for liquefaction at the site. The applicant should also determine the method of analysis on the basis of actual site conditions, the properties of the reactor facilities, and the earthquake and seismic design requirements for the protection of the public."

NUREG-1537, Part 2, Section 2.5, "Geology, Seismology, and Geotechnical Engineering," instructs the reviewer to find that the information on the geologic features and geotechnical properties at the site have been provided in sufficient detail and in a form to be integrated acceptably into design bases for structures, systems, and operating characteristics of the facility.

It is reported in SHINE PSAR, Section 2.5.7.3, "Liquefaction Assessment," that both the qualitative and quantitative liquefaction analyses demonstrate that there is no potential for liquefaction to occur within the underlying soils at the SHINE site. However, results given in SHINE PSAR, Tables 3.4-1, "Results of Analysis

for Representative Elements," and 3.4-2, "Out-of-Plane Shear Results of Analysis for Representative Elements" (ADAMS Accession No. ML13172A264, pages 3-38 – 3-40), indicate liquefaction analyses for the SHINE facility have been completed.

Provide additional information explaining whether the geotechnical investigation report referenced above includes the liquefaction analysis, or provide the liquefaction analysis report and results.

CHAPTER 3 – DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

The following questions in 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.

**Section 3.2 – Meteorological Damage**

RAI 3.2-1 NUREG-1537, Part 1, Section 2.3.1, "General and Local Climate," states, in part, "[t]he applicant should also estimate the weight of the 100-year return period snowpack and the weight of the 48-hour probable maximum precipitation for the site vicinity, if applicable, as specified by the USGS. Using these estimates for Chapter 3, the applicant should calculate the design loads on the roof of the reactor building, and compare them with local building codes for similar types of structures."

While SHINE PSAR, Section 2.3.1.2.9, "Snowpack and Probably Maximum Precipitation (PMP)," contains an estimate of the snowpack load and probable maximum precipitation, as described in NUREG-1537, and SHINE PSAR, Section 3.2.3, "Snow, Ice, and Rain Loading," the information developed in SHINE PSAR, Section 2.3.1.2.9, is not used to calculate the design loads.

Provide either additional information that explains why SHINE PSAR, Section 3.2.3, does not utilize the data developed under SHINE PSAR, Section 2.3.1.2.9, or calculate the design loads with the data from SHINE PSAR, Section 2.3.1.2.9, accordingly.

**Section 3.3 – Water Damage**

RAI 3.3-1 NUREG-1537, Part 1, Section 3.3, "Water Damage," states in part, that the applicant should specifically describe "… (2) the impact on systems resulting from instrumentation and control electrical or mechanical malfunction due to water, and (3) the impact on equipment, such as fans, motors, and valves, resulting from degradation of the electromechanical function due to water."

NUREG-1537, Part 2, Section 3.3, "Water Damage," *Acceptance Criteria*, states:

- The design criteria and designs should provide reasonable assurance that structures, systems, and components would continue to perform required safety functions under water damage conditions.

- For the design the applicant should use local building codes, as applicable, to help ensure that water damage to structures, systems, and components at the facility site would not cause unsafe reactor operation, would not prevent safe reactor shutdown, and would not cause or allow uncontrolled release of radioactive material.

While SHINE PSAR, Section 3.3, “Water Damage,” discusses water damage and PSAR Section 3.3.1.1.2, “Compartment Flooding from Fire Protection Discharge,” deals with flooding due to malfunction of the Fire Protection System, there is no discussion of the effects of discharge of the Fire Protection System on structures, systems, and components (SSCs).

Provide additional information discussing the effects of discharge of the Fire Protection System on SSCs.

**Section 3.4 – Seismic Damage**

RAI 3.4-1 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. To verify that seismic design functions are met, the applicant should give the bases for the technical specifications.

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.

SHINE PSAR, Section 3.4.2.2, “Soil-Structure Interaction Analysis,” reports Soil-Structure Interactions are performed separately for mean, upper bound, and lower bound soil properties to represent potential variations of the in situ and backfill soil conditions surrounding the building. The Soil-Structure Interaction model is developed using the computer program Structural Analysis Software System Interface (SASSI).

a) Provide the reference manual and revision used for SASSI.

b) Provide additional information explaining whether the geotechnical investigations requested above also determined the dynamic soil properties used for the Soil-Structure Interaction analyses. Note: the soil dynamic properties necessary for Soil-Structure Interaction analyses are nonlinear.

c) Provide the report with details and results for the Soil-Structure Interaction analyses.

RAI 3.4-2 NUREG-1537, Part 1, Section 3.4, “Seismic Damages,” states that the applicant should specify and describe the structures, systems, and components that are required to maintain the necessary safety function if a seismic event should occur. The facility seismic design should 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.

NUREG-1537, Part 2, Section 3.4, states that the "review should include the designs and design bases of structures, systems, and components that are required to maintain function in case of a seismic event at the facility site." The finding required is that the facility design should provide reasonable assurance that the reactor can be shut down and maintained in a safe condition.

Additional information is needed in SHINE PSAR, Section 3.4.2.6.1, "Description of the Structures," for the NRC staff to determine the adequacy of structures, systems, and components required to maintain necessary safety functions should a seismic event occur.

Provide a comprehensive description of the SHINE facility structures.

(Applies to RAIs 3.4-3 through 4)

NUREG-1537, Parts 1 and 2, Section 3.4, "Seismic Damage," note that acceptable seismic performance has been established in the American National Standard Institute/American Nuclear Society (ANSI/ANS)-15.7, "Research Reactor Site Evaluation." With regard to seismic design, Section 3.2(2) of ANSI/ANS 15.7 states, "[r]eactor safety related structures and systems shall be seismically designed such that any seismic event cannot cause an accident which will lead to dose commitments in excess of those specified in 3.1."

RAI 3.4-3 SHINE PSAR, Section 3.4.2.6.5, "Structural Analysis Model," reports that a three-dimensional finite element Structural Analysis Model of the SHINE Facility structure was created using the SAP2000 computer program.

Provide the reference manual and revision for the SAP2000 computer program that was used.

RAI 3.4-4 SHINE PSAR, Section 3.4.2.6.6, "Structural Analysis Results," reports Structural Analysis Results were obtained from the SAP2000 model.

Provide the report with details and results for the SAP2000 finite element structural analyses.

RAI 3.4-5 NUREG-1537, Part 1, Section 3.5, "Systems and Components," states that the applicant should provide the design bases for the systems and components required to function for safe reactor operation and shutdown. This should include, at a minimum, the protective and safety systems; the electromechanical systems and components associated with emergency cooling systems, reactor room ventilation, confinement systems; and other systems that may be required to prevent uncontrolled release of radioactive material. The design criteria should include the conditions that are important for the reliable operation of the systems and components (e.g., dynamic and static loads, number of cyclic loads, vibration, wear, friction, and strength of materials).

NUREG-1537, Part 2, Section 3.5, "Systems and Components," states that the

reviewer should conclude there is sufficient information to support the design bases of the electromechanical systems and components to give reasonable assurance that the facility systems and components will function as designed to ensure safe operation and safe shutdown of the facility.

SHINE PSAR, Section 3.4.3, "Seismic Qualification of Subsystems and Equipment," states that seismic qualification of subsystems and equipment were completed using five methods.

Provide the details and results for seismically qualifying the SHINE facility subsystems and components. Include an applicable explanation of whether and how the nodal accelerations (at the locations indicated in PSAR Figures 3.4-4 through 3.4-14, ADAMS Accession No. ML13172A291) are used for the dynamic analyses of equipment.

RAI 3.4-6 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 finds the surveillance activities proposed provide reasonable assurance 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.

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 inservice testing provisions include periodic channel checks, and the capability for inplace functional testing.

Because the data recording capabilities of and data retrieval from the seismic instrumentation are not described,

a) Provide a summary description of the data these instruments record in the event of felt earthquake motions (i.e., acceleration time histories).

b) Provide an explanation of the data retrieval and processing procedure(s). Clarify whether a separate computer is required to view the digitized acceleration time histories, and generate response spectra.

RAI 3.4-7 NUREG-1537, Part 2, Section 3.4, "Seismic Damage," states that "[t]he applicant should demonstrate that all potential consequences from a seismic event are within the acceptable limits considered or bounded in the accident analyses of Chapter 13 to ensure that conditions due to a seismic event will not pose a significant risk to the health and safety of the public."

The SHINE site location is near the Southern Wisconsin Regional Airport. SHINE PSAR, Section 3.4.5.1, "Aircraft Impact Analysis," outlines the methodology for conducting and evaluating small aircraft impact analyses in support of the seismic envelope design for external hazards. The potential locations for 25 aircraft impact analyses of the SHINE facility are listed. In PSAR Table 3.4-4, "Aircraft Impact Analysis Results," the aircraft impact analyses results show that the performance of all barriers are acceptable to prevent transport of radioactive materials to unrestricted areas. However, the engineering report that describes the analyses' details states that all of the results are not referenced.

Provide the engineering report that describes the aircraft impact analyses' details that reports the results. Additionally, provide a summary of the results.

**Section 3.5 – Systems and Components**

RAI 3.5-1 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.

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.

SHINE PSAR, Section 3.5.1.2, "Quality Assurance (Quality Group Classifications for SSCs)," discusses how SR SSCs will be classified as QL-1 and IROFS SSCs will be classified as QL-2. The section goes on to state that SR SSCs shall have "the full requirements of the QAPD [Quality Assurance Program Description] in accordance with an approved Quality Assurance Plan (QAP)," and that IROFS SSCs shall have requirements "in conformance with an approved QAP...." This infers that IROFS SSCs shall not have "the full requirements of the QAPD in accordance with an approved Quality Assurance Plan (QAP)."

In addition, SHINE PSAR, Section 3.5.2, "Seismic Classification," states that SR SSCs and IROFS SSCs are both Seismic Category I.

a) Provide the basis referencing the definition of SR SSCs in 10 CFR 50.2, "Definition," the basis for using a modified definition of SR SSCs, the basis for utilizing only a portion of the requirements of 10 CFR 70.61, "Performance requirements," and the basis for why the 10 CFR 70.61 requirements do not encompass the SHINE's modified definition of SR SSCs.

b) Define and provide the basis for the difference between QL-1 and QL-2. In addition, if there are two SSCs (i.e., pipe, valve, tank, heat exchanger, etc.) that must meet the same performance characteristics but one SSC is governed by QL-1 and the other by QL-2, describe how they will be physically different. Finally, with respect to Seismic Category I, clarify what the differences are in Seismic Category I acceptance criteria under QL-1 and QL-2.

(Applies to RAIs 3.5-2 through 3)

NUREG-1537, Part 2, Section 3.5, "Systems and Components," *Acceptance Criteria*, states, in part, that the design criteria should include "response to transient and potential accident conditions analyzed in the safety analysis report (SAR)."

RAI 3.5-2 SHINE PSAR, Section 3.5.2, "Seismic Classifcation," states, in part, that SSCs that have "[t]he capability to prevent or mitigate potential accidents at the facility that could exceed the performance requirements in 10 CFR 70.61," are designated Seismic Category I. The performance requirements include

mitigating the effects of an "acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material…."

SHINE PSAR, Figure 1.3-2, "Production Building Floor Plans Preliminary Arrangement," has the following notation: "Heavy Outline Denotes Seismic Boundary." In addition, SHINE PSAR, Table 3.5-1, "System and Classifications" (pages 3-52 – 3-55), states that the facility structure is safety-related, Seismic Category I, and QL-1. There is no mention of the seismic classification of the north and south portions of the building outside the seismic boundary, which include chemical storage facilities.

This infers that these portions of the building are nonseismic and in a postulated design basis earthquake, they would collapse. If all of the access points into the "seismic boundary" are located on the north and south sides of the building, it is possible that personnel would not be able get in or out of the building after a design basis earthquake and individuals could be exposed to licensed material and/or hazardous chemicals.

Provide clarification on the seismic design of the north and south portions of the building and address how the 10 CFR 70.61 performance requirements are met.

RAI 3.5-3 SHINE PSAR, Table 3.5-1, "System and Classifications," states that Radiologically Controlled Area Ventilation Zone 1 is safety-related, QL-1, and Seismic Category I; Radiologically Controlled Area Ventilation Zone 2 is IROF, QL-2, and Seismic Category I; and Radiologically Controlled Area Ventilation Zone 3 is nonsafety-related, QL-3, and Seismic Category III. SHINE PSAR, Section 9a.2.1.1, "Radiologically Controlled Area Ventilation System" (ADAMS Accession No. ML13172A271), does not state that one normally goes through Radiologically Controlled Area Ventilation Zone 3 to get to Radiologically Controlled Area Ventilation Zones 1 or 2, but such a pathway can be inferred from PSAR Section and Figure 1.3-2. Thus, Radiologically Controlled Area Ventilation Zone 3 would be used for access and egress after a postulated event with a loss of offsite power or a design basis earthquake with a loss of offsite power.

Provide the basis for designating the Radiologically Controlled Area Ventilation Zone 3 nonsafety-related, QL-3, and Seismic Category III or provide a discussion of the alternate method of access/egress of the Radiologically Controlled Area Ventilation Zones 1 and 2, without causing outside contamination.

(Applies to RAIs 3.5-4 through 5)

As required by 10 CFR 50.34(a)(4), "[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."

RAI 3.5-4 In SHINE PSAR, Table 3.5-1, the Facility Instrument Air System, the Facility Control Room, the Stack Release Monitoring System, the Health Physics Monitors, the Facility Breathing Air System, the Facility Data and Communications System, the Emergency Lighting System, the Facility Ventilation Zone 4 System, and the Lighting System are all nonsafety-related, QL-3, Seismic Category III and the Standby Diesel Generator System is nonsafety-related, QL-3, Seismic Category II. In addition, the PSAR states that radiologically controlled area ventilation systems require power to operate.

Provide a discussion that addresses how facility personnel will be able to determine that the facility is in a safe condition (or put the facility in a safe condition) and how the facility will be maintained in a safe condition, in the event of a postulated design basis earthquake with a loss of offsite power and unavailability of the systems above.

RAI 3.5-5 SHINE PSAR, Section 3.5.2,"Seismic Classification," discusses the use of Seismic Category II SSCs over Seismic Category I SSCs (Seismic II/I). SHINE PSAR, Table 3.5a-1, "Appendix A to 10 CFR 50 General Design Criteria Which Have Been Interpreted As They Apply to the SHINE Irradiation Facility" (pages 3-88 – 3-93), discusses how the facility complies with 10 CFR Part 50, Appendix A, General Design Criteria. Based on SHINE's proposed implementation of the of the General Design Criteria, the NRC staff needs clarification on the following considerations with respect to Seismic Categories II/I:

General Design Criterion 1 provides that structures, systems, and components important to safety are to be designed, fabricated, erected, and tested to quality standards. Thus, General Design Criterion 1 applies to Seismic II/I since the Seismic II structures, systems, and components should be properly designed, fabricated, and installed to reduce the likelihood of a Seismic Category II structure, system, or component coming loose and falling on and damaging a Seismic Category I structure, system, or component.

General Design Criterion 2 provides that structures, systems, and components important to safety are to be designed to resist the effects of natural phenomena like earthquakes. General Design Criterion 2 applies to Seismic II/I because it specifies the natural phenomenon (i.e., earthquake) that must be considered in the design of these structures, systems, and components. If not considered, an earthquake could loosen a Seismic Category II structure, system, or component to the extent that it could cause an unsafe condition (i.e., fall on and damage a Seismic Category I structure, system, or component).

General Design Criterion 4 provides that structures, systems, and components important to safety are to be protected against the effects of internally-generated missiles. General Design Criterion 4 applies to Seismic Category II structures, systems, and components because it specifies protection against the effects of internally-generated missiles (i.e., fall on and damage of a Seismic Category I

structure, system, or component).

Based on the considerations above, dropped loads could cause the potential release of radioactive materials, a criticality accident, or damage to essential safety equipment, which could cause unacceptable radiation exposures.

Provide details of the Seismic II/I Program that will be put into place, including the Seismic Category II structural integrity criteria and the Seismic Category II support criteria.

**Section 3.5b – Radioisotope Production Facility**

RAI 3.5b-1 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."

SHINE PSAR, Table 3.5b-1, "Baseline and General Design Criteria for Radioisotope Production Facility" (pages 3-102 – 3-106), under the first column, "Baseline Design Criteria 10 CFR 70.64," lists the following criterion: "(7) Utility services. The design must provide for continued operation of essential utility services." Under the second table column, "As Applied to SHINE," the stated applicability is: "As Applied and Means of Compliance - The SHINE facility provides a standby diesel generator for asset protection of selected systems. Refer to SHINE PSAR, Section 8b for detailed information."

While SHINE PSAR, Table 3.5b-1 refers to PSAR, Section 8b, PSAR, Section 8b essentially refers to PSAR, Section 8a.

However, the standby diesel generator (SDG) is classified nonsafety-related and does not have to function after a design basis earthquake. In addition, SHINE PSAR, Section 8a2.1.4, "SHINE Facility Loads Supported by SDG," references Table 8a2.1-2, "Standby Diesel Generator Load List" (ADAMS Accession No. ML13172A270, page 8a2-6), but unlike Section 8a2.2.3, "Shine Facility Systems Served by the Class 1E UPSS [Uninterruptible Power Supply System]," which provides a list of what systems are supported by the Class 1E UPSS, does not provide a list of systems supported by the SDG system.

Provide a list of systems supported by the standby diesel generator and provide clarification on how Criterion 7 is met for the case of a postulated design basis earthquake with a loss of offsite power.

## CHAPTER 4 – IRRADIATION UNIT AND RADIOISOTOPE PRODUCTION FACILITY DESCRIPTION

The following questions of this chapter are based on a review of Chapter 4 of the SHINE PSAR (ADAMS Accession No. ML13172A265) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

### Section 4a2.2 – Subcritical Assembly

RAI 4a2.2-1 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," *Acceptance Criteria*, states, in part, "[t]he design bases for the fuel should be clearly presented…."

A uranium concentration range and enrichment is given in SHINE PSAR Table 4a2.1-1, "Target Solution Chemical and Physical Properties" (page 4a2-16). However, the uranium concentration range varies 30 percent, based on the average uranium concentration.

Provide the nominal or expected uranium concentration in the system.

RAI 4a2.2-2 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," *Acceptance Criteria*, states, in part, that the PSAR should consider "various phenomena that result in changes to the initial fuel composition and properties…[including] information on radiolytic gas formation" in the target solution.

While SHINE PSAR, Section 4a2.2.1.5, "Off-Gas Formation," discusses the formation rate of hydrogen and oxygen, additional information is needed for NRC staff to determine the adequacy of the uncertainty of the radiolysis rate.

Discuss uncertainty in the radiolysis rate and effects that this uncertainty may have on the sizing of systems in the irradiation units.

RAI 4a2.2-3 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," *Acceptance Criteria*, states, in part, that the PSAR should include a description of the "various phenomena that result in changes to the initial fuel composition;" this should include any changes in uranium concentration during operation, including evaporation of water. ISG, Part 2, Section 4a2.2.1, also states that the submittal should include "information on radiolytic gas formation, the transport, changes in void fraction, and removal of gas, the return of condensate following recombination and condensation of gas or bubbles outside the core vessel…."

SHINE PSAR, Section 4a2.2.1.5, "Off-Gas Formation," does not discuss the evaporation rate of water in the TSV and the water vapor content in the gas that enters the TSV off-gas system (TOGS). The vapor pressure of water changes rapidly with temperature in the vicinity of 140 degrees Fahrenheit (F). For example, increasing the water temperature from 140 degrees F to 150 degrees F increases the vapor pressure approximately 33 percent.

Provide the assumptions used to calculate TSV evaporation rates and water vapor content of the gases entering the TOGS.

RAI 4a2.2-4 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.1, "Normal Operating Conditions," *Acceptance Criteria*, states, in part, that the "reactivity impacts of radiolytic gas and void formation, fission product gas removal, fuel solution and acid addition, and condensate return to the core should be provided."

SHINE PSAR, Section 4a2.2.1.6, "TSV Operating Conditions," describes the operating conditions in the TSV and notes that there is no mechanical mixing. This infers that mixing occurs due to buoyancy and other natural processes. The PSAR does not discuss potential nonuniformities of power, void, temperature or chemical species within the TSV or if any of those nonuniformities may limit any operating conditions.

Discuss the extent and effects of nonuniformities on operation if mechanical mixing is not included in the design of the TSV.

RAI 4a2.2-5 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," *Acceptance Criteria*, states, in part, that the PSAR should include a description of the "various phenomena that result in changes to the initial fuel composition…[including] potential fuel and fission product precipitation…"

SHINE PSAR, Section 4a2.2.1.6, "TSV Operating Conditions," states that there is no precipitation out of the target solution, however IAEA TECDOC-1601, "Homogeneous Aqueous Solution Nuclear Reactors for the Production of Mo-99 [Molybdenum-99] and Other Short Lived Radioisotopes," states that as the fuel solution ages, fission products can approach solubility limits.

Provide information on how close the SHINE target solution will be to the solubility limits. Additionally, provide additional information discussing whether SHINE plans to use catalytic agents to mitigate precipitation, as discussed in PSAR, Section 4a2.4.1.1.

RAI 4a2.2-6 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," *Acceptance Criteria*, states, that the PSAR should include information on fuel operating parameters, taking into consideration "characteristics that could limit fuel barrier integrity." This should include temperature ranges during startup and normal operation.

Provide the normal temperature range for startup and approach to criticality.

RAI 4a2.2-7 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," states that the PSAR should include information on fuel operating parameters, taking into consideration "characteristics that could limit fuel barrier integrity." This should include irradiation times and burnup.

Provide the duration of the "short irradiation cycle" mentioned in SHINE PSAR, Section 4a2.2.1.9, "Chemical and Physical Changes in Target Solution," and the maximum expected burnup.

RAI 4a2.2-8 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," *Acceptance Criteria*, states, in part, that "[m]aintaining fuel barrier integrity should be the most important design objective."

SHINE PSAR, Section 4a2.2.1.10, "TSV Physical Structure," mentions a "credible deflagration." A strong deflagration or detonation could compromise the integrity of the primary system boundary.

Provide the pressure expected during a "credible deflagration," and discuss how this value was determined, as well as how it compares to the maximum pressure that each component of the primary system boundary can withstand.

RAI 4a2.2-9 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," *Acceptance Criteria*, states, in part, that the application should provide a summary of the "fuel development, qualification, and production program." This should include discussions on fuel characterization, provide information on radiolytic gas production, changes in pH, gas removal, and addition of fuel and acid to the vessel along with implications on reactivity.

SHINE PSAR, Section 4a2.2.1.13, "Target Solution History," briefly describes some of the history of uranyl sulfate development, but does not describe SHINE's Target Solution Qualification Program.

Provide a description of SHINE's Target Solution Qualification Program, including specific historical target solution data and their origin (references) that have been used for validation and safety calculations presented in the current SHINE PSAR. Include tests, experiments, and analyses that will be (or have been) performed to validate the historical data.

**Section 4a2.3 – Neutron Driver**

RAI 4a2.3-1 While the ISG Augmenting NUREG-1537 does not have a section dedicated to the neutron driver assembly system (NDAS), which is unique to SHINE, the PSAR should provide the same level of detail for this system as is expected for other systems and components. This is in alignment with 10 CFR 50.34(a)(4), which requires 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."

For instance, the PSAR should include information regarding corrosion control, susceptibility to radiation damage, and the physical description, including materials and physical dimensions.

1) Provide the physical characteristics of the NDAS (e.g., construction materials, dimensions).

2) SHINE PSAR, Section 4a2.3, "Neutron Driver," states, that "most materials will not have radiation damage concerns," but does not specify which components will have radiation damage concerns. Describe what radiation damage concerns there are for affected materials and components.

3) Provide the expected activity of the NDAS due to activation of its components at the end of one irradiation cycle and at the end of its expected life.

**Section 4a2.4 – Target Solution Vessel and Light Water Pool**

(Applies to RAIs 4a2.4-1 through 3)

As required by 10 CFR 50.34(a)(4), "[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."

RAI 4a2.4-1 SHINE PSAR, Section 4a2.4.1.1, Design Considerations," specifies that the construction of, and materials for, the TSV follow the intent of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (ASME Code), Section III (ASME, 2011).

Provide a discussion of the applicable ASME Code, how the SHINE design meets the intent of the code, and the features of the SHINE design that prevent application of the code as written.

RAI 4a2.4-2 SHINE PSAR, Section 4a2.4.1.5, "Chemical Interactions and Neutron Damage," states that a materials surveillance and inspection program for the TSV and other primary system boundary (PSB) components will be described in the final safety analysis report (FSAR).

Provide a list of surveillance and inspection requirements, as well as information to show that the design will allow the required periodic surveillance and inspections to be performed.

RAI 4a2.4-3 SHINE PSAR, Section 4a2.4.2.1, “Design of Light Water Pool,” states that the steel liner of the light water pool is designed to withstand the chemical environment of the target solution in the event of a breach that leaks target solution into the pool. However, if any accumulation or plateout of fission products occurred on the liner surfaces (including corners, imperfections on weld points, etc.), this could lead to increased local dose rates that might challenge the limits in 10 CFR Part 20, “Standards for Protection Against Radiation.”

Provide information discussing whether the design characteristics of the pool liner preclude any accumulation or plateout of fission products that could challenge the limits in 10 CFR Part 20.

**Section 4a2.5 – Irradiation Facility Biological Shield**

RAI 4a2.5-1 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.4, “Biological Shield,” *Acceptance Criteria*, states that “[t]he principal objective of the shield design should be to ensure that the projected radiation dose rates and accumulated doses in occupied areas do not exceed the limits of 10 CFR Part 20, ‘Standards for Protection Against Radiation,’ and the guidelines of the facility’s ALARA (as low as reasonably achievable) program discussed in Chapter 11 of the SAR.”

SHINE PSAR, Section 4a2.5.2.2, “Geometry and Configuration,” states that the side wall of the IU cell biological shield consists of standard density concrete that is 6.0 feet (1.8 meters) thick and that the dose rates on the external surface of the shield wall is expected to be less than 1.0 millirem/hour. PSAR Section 4a2.5.3.1, “Shielding Calculations,” notes that the Monte-Carlo N-Particle (MCNP) Transport Code was used to determine the required shield thickness. PSAR Section 4a2.5.4, “Analysis,” states, in part, that analysis is performed to:

- Give detailed results of both neutron and gamma-ray dose rates at locations that could be occupied as well as to the unrestricted environment.

- Include shield penetrations and voids, such as beamports, thermal columns, and irradiation rooms or vaults, as well as the shielding of piping and other components that could contain radioactive materials or allow radiation streaming.

In order for the NRC staff to determine the adequacy of the shielding design of the IU cell, provide a list of the components inside the irradiation unit cell that are considered significant contributors (and the magnitude of these contributions) to the gamma and neutron flux and dose rates impinging on the interior shield wall. For each component describe the key assumptions included in the MCNP (or other computer code) radiation transport modeling used to determine shield wall thickness.

**Section 4a2.6 – Nuclear Design**

(Applies to RAIs 4a2.6-1 through 2)

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.1, "Normal Operating Conditions," *Acceptance Criteria*, states, in part, that there should be systems that are "sufficiently redundant and diverse to control all proposed excess reactivity safely and to safely shut down the [system] and maintain it in a shutdown condition."

RAI 4a2.6-1 SHINE PSAR, Section 4a2.6.1, "Normal Operating Conditions," states that the operators dump the solution to the TSV dump tank if the calculated 1/M curve violates the acceptable band. Additional information is needed for the NRC staff to verify that the system is adequate to mitigate a potential criticality.

Provide justification why operator action is needed for this action, as operator action can be very slow compared to an automated protection system, including an analysis that supports the adequacy of operator action response times. Additionally, discuss why there is not an automated protection system.

RAI 4a2.6-2 SHINE PSAR, Section 4a2.6.1, Normal Operating Conditions," states that the contents of the TSV "may be transferred" to the dump tank during startup if any allowed parameters are breached.

Provide a discussion indicating whether this wording is accurate. Should the text instead read, "will be transferred?" If the wording is correct as is, describe under what circumstances the contents would not be dumped, if the system goes outside of the allowable parameters.

(Applies to RAIs 4a2.6-3 through 4)

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.1, "Normal Operating Conditions," states that the PSAR should give reactivity worths for control rods, reflector units, and other in-core components for all anticipated configurations. While some information is presented on coefficients of reactivity in PSAR Section 4a2.6.4, additional information is needed to verify that the SHINE IUs will not become critical under any phase of operation.

RAI 4a2.6-3 Compare the reactivity worths of all components in the IU to the margin to criticality in the TSV for all phases of operation.

RAI 4a2.6-4 The SHINE system may have a positive void coefficient for the water in the cooling system since the fuel solution is over-moderated. However, a pipe break or other means of introducing voids, lowering the coolant density in the system, could result in a reactivity insertion. Additional information is needed to determine if voiding out the cooling system could turn the TSV from a subcritical system into a critical reactor.

Provide the reactivity worth for voiding out the cooling system over the full range from nominal coolant temperature and density to a fully voided cooling system.

(Applies to RAIs 4a2.6-5 through 6)

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.2, "Reactor Core Physics Parameters," states, in part, "the applicant should present information on core physics parameters that determine reactor operating characteristics…."

RAI 4a2.6-5 The SHINE PSAR does not discuss the effects of xenon-135 and samarium-149 on the TSV operation irradiation cycle.

Provide an estimate of the reactivity due to xenon-135 and samarium-149 over the cycle and its effect on neutron multiplication and fission power, since the time required to establish equilibrium xenon and samarium is significant compared to the length of an irradiation cycle.

RAI 4a2.6-6 Provide an uncertainty analysis for the reactivity worths, coefficients, and $k_{eff}$ values.

(Applies to RAI 4a2.6-7 through 8)

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.1, "Normal Operating Conditions," states that there should be systems that are "sufficiently redundant and diverse to control all proposed excess reactivity safely and to safely shut down the reactor and maintain it in a shutdown condition."

The SHINE irradiation unit system relies on dumping the solution to the TSV dump tank under abnormal conditions. SHINE PSAR, Section 4a2.6.3.6, "Redundancy and Diversity of Shutdown Methods," states that the dump system has redundant dump valves.

RAI 4a2.6-7 Additional information is needed for NRC staff to evaluate whether there are important attributes to redundancy and diversity beyond a second dump valve.

Provide additional detail on the design of the dump system relating to the redundancy of the dual valves and flow paths, addressing whether or not the system is single failure proof and addressing whether the system is sufficiently diverse so that it is not subject to common mode failures.

RAI 4a2.6-8 Provide additional information on the design of the dump valves related to:

a) The design drain rate of the TSV when the dump valves are open.

b) The delay time from when the conditions would trigger a dump signal until the dump valves start to open.

c) The duration of time it takes for the dump valves to open.

RAI 4a2.6-9 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.1, "Normal Operating Conditions," *Acceptance Criteria*, states, in part, "[t]he reactivity impacts of radiolytic gas and void formation, fission product gas removal, fuel solution and acid addition, and condensate return to the core should be provided." This analysis should also include the evaporation of water.

SHINE PSAR, Section 4a2.6.1.1, "Gas Management System Effects," states, in part, "[t]he radiolysis of water in the system causes an anticipated increase in reactivity during operation…"

The SHINE PSAR infers that water is constantly leaving the TSV through radiolysis and evaporation. A certain amount of water will be held up outside the TSV as it goes through the recombination and condensation process before it is returned to the TSV, increasing the reactivity in the system.

Provide quantitative estimates of the water inventory outside of the TSV, the reactivity increase caused by removing that water from the TSV, and the increase in fuel solution concentration.

**Section 4a2.7 – Thermal Hydraulic Design**

RAI 4a2.7-1 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.6, "Thermal-Hydraulic Design," states that the applicant should discuss possible system "instability following perturbation to the system (including from radiolytic gas generation)."

Provide linear stability analysis of the full system and an analysis and discussion of the expected bounds of any expected oscillations.

RAI 4a2.7-2 10 CFR Part 20.1001, "Purpose," establishes "standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission."

SHINE PSAR, Section 4a2.7.2, "Coolant Hydraulic Characteristics of the Target Solution Vessel," states, in part, "[p]lating out of chemicals on the TSV surfaces is not expected...." However, should plating out occur, increased local dose rates could occur, which might challenge the dose limits in 10 CFR Part 20.

Provide the basis for the conclusion that the plating out of chemicals on the TSV surfaces is not expected. Additionally, discuss whether that basis accounts for the possibility of defects/crevices in welds, pipes, and the vessel.

RAI 4a2.7-3 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.6, "Thermal-Hydraulic Design," *Evaluation Findings*, states, in part, that "[t]he information in the SAR includes the thermal-hydraulic analyses for the reactor. This includes radiolytic gas generation, changes in void fraction, and fuel solution mixing…."

SHINE PSAR, Section 4a2.7.5.1, "Target Solution Conditions," states, in part, that "[v]oid formation in the target solution is expected, and will be factored into

the nuclear calculations (void coefficients of reactivity) and thermal hydraulic calculations for final design."

Provide information on how the void fraction is currently calculated for SHINE PSAR design estimates of void reactivity. This information is needed for the NRC staff to verify that the system will not become critical.

**Section 4a2.8 – Gas Management System**

(Applies to RAIs 4a2.8-1 through 6)

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.7, "Gas Management System," *Review Procedures*, states that "[t]he reviewer should confirm that the design of the gas management system and the associated analysis are sufficient to provide reasonable assurance of safe operation of the reactor and compliance with all applicable chemical and radiological release criteria." SHINE PSAR, Section 4a2.8, discusses the gas management system.

RAI 4a2.8-1 The capacity of the TSV off-gas recombiner system may be sensitive to the conditions under which it will have to operate.

Provide the TSV operating condition envelope and design assumptions for the TSV off-gas recombiner system, including assumed design margins.

RAI 4a2.8-2 Provide the basis for an "alert to the operator" at a hydrogen concentration of 2.5 percent and automatic shutdown of the neutron driver at 3 percent. Discuss whether there is sufficient margin to the deflagration limits at these values. Provide information indicating where the measurement of the hydrogen concentration is taken.

RAI 4a2.8-3 Provide information discussing whether there are any other automatic trips that occur if the TOGS becomes inoperative or if there is a failure in the system that supplies the sweep gas.

RAI 4a2.8-4 SHINE PSAR, Table 4a2.8-1, "TSV Off-Gas System Major Components" (page 4a2-69), states that the condenser in the TSV off-gas condenser has a greater than 15 percent heat transfer margin. The vapor pressure of water changes rapidly with temperature in the vicinity of 140 degrees F. For example, increasing the water temperature from 140 degrees F to 150 degrees F increases the vapor pressure by approximately 33 percent. Noncondensable gas can significantly degrade the condensation efficiency in comparison to the condensation of pure steam.

Provide the TSV and off-gas system operating conditions and assumptions used to calculate the 15 percent margin.

RAI 4a2.8-5 SHINE PSAR Section 4a2.8.5 states that a pressure safety valve is connected to the TOGS piping to passively prevent an overpressurization within the PSB,

which may cause structural damage to the IU. The setpoint of the pressure safety valve will not exceed the design pressure of the PSB components. This setpoint value will be provided in the FSAR. The TOGS system contains radioactive fission products.

Provide information indicating whether the relief valve discharge passes through a system capable of filtering or scrubbing out radioactive fission products. Provide a description of such a system if it exists. If such a system does not exist, provide a discussion of why it is not necessary in relation to meeting radioactive release and dose requirements of 10 CFR Part 20.

RAI 4a2.8-6 SHINE PSAR, Section 4a2.8.5, “Abnormal Conditions,” states that no significant amount of nitrogen oxide (NOx) gas is present in the off-gas, and therefore, no scenario resulting in the release or accumulation of NOx gas is considered.

Provide the basis for asserting that NOx gas is not significant. Additionally, provide information indicating why there is no discussion of sulfur oxide (SOx) gas and scenarios related to SOx gas.

**Section 4b.1 – Facility Process and Description**

(Applies to RAIs 4b-1 through 2)

10 CFR 50.9, “Completeness and accuracy of information,” requires that information provided by the applicant must be complete and accurate.

RAI 4b-1 SHINE PSAR, page 4b-9, contains a typographical error: “ursanium oxide” should be “uranium oxide”.

Correct this typographical error.

RAI 4b-2 SHINE PSAR, page 4b-29, contains an apparent typographical error. The text in Section 4b.4.1.1.4.1(b.) reads: “The sulfuric acid washes of”.

Correct this this text to read: “The sulfuric acid washes off”

## CHAPTER 5 – COOLING SYSTEMS

The following questions in this chapter are based on a review of Chapter 5 of the SHINE PSAR (ADAMS Accession No. ML13172A267) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

### Section 5a2 – Irradiation Unit Cooling System

(Applies to RAIs 5a2.2-1 through 2)

The ISG Augmenting NUREG-1537, Part 1, Section 5a2, "Aqueous Homogeneous Reactor [AHR] Cooling System," states, in part, that "the applicant should give the design bases, descriptions, and functional analyses of the AHR cooling systems. The principal purpose of the cooling systems is to safely remove the fission heat and decay heat from the reactor and dissipate it to the environment. The discussions should include all significant heat sources in the reactor and should show how the heat is safely removed and transferred to the environment." Additionally, Section 5a2.2, "Primary Cooling System," specifies discussion of leak detection and allowable leakage limits, if any, and specifies the inclusion of schematic and flow diagrams of the system, showing such essential components as the heat source, heat sink, pumps, piping, valves, control and safety instrumentation, interlocks, and other related subsystems.

RAI 5a2.2-1 In SHINE PSAR, Section 5a2.2.9, "Secondary Cooling System Interaction," Section 5a2.3.5, "RPCS [Radioisotope Process Facility Cooling System] Cooling Functions and Operation," and Section 5a2.3.9, "Instrumentation and Control," pressure, flow, temperature, conductivity, and radiation detection instrumentation are discussed, with pressure being the apparent measurement used to identify system leaks. Additional information is needed for the NRC staff to determine the adequacy of pressure measurement to identify system leaks.

Discuss the ability of pressure measurements to identify the presence of small leaks and address how the location of leaks would be determined.

RAI 5a2.2-2 Additional information is needed for the NRC staff to determine the adequacy of instrumentation for the cooling system functions.

Provide additional detail on the instrumentation for the cooling system functions to ensure the intended functions are performed.

RAI 5a2.2-3 The ISG Augmenting NUREG-1537, Part 2, Section 5a2.2, "Primary Cooling System" *Acceptance Criteria*, states, in part, that "[t]he primary coolant should provide a chemical environment that limits corrosion of the primary coolant barrier, control and safety rod surfaces, reactor vessels or pools, and other essential components."

Chemicals are commonly added to nuclear plant water systems to adjust nuclear reactivity (e.g., boric acid), to control pH (e.g., lithium hydroxide, ammonia/amines), to remove oxygen (e.g., hydrazine), as a biocide (e.g., chlorine), etc. SHINE PSAR, Section 5a.2.2.2, "PCLS [Primary Closed Loop Cooling System] Process Functions," indicates that water quality will be maintained to reduce corrosion and scaling, but this section does not indicate how this will be done. Additional information is needed for NRC staff to understand the impact of potentially toxic additives used to maintain water quality on corrosion and scaling.

Provide a list of all potentially toxic chemicals expected to be on the SHINE site for water quality control or for other purposes, including locations and quantities.

## 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.

### Section 6a2.1 – Summary Description

RAI 6a2.1-1 NUREG-1537, Part 1, Section 6.1, "Summary Description," states:

> In this section of the SAR, the applicant should briefly describe all of the ESFs [engineered safety features] in the facility design and summarize the postulated accidents they are designed to mitigate. These summaries should include the design bases and performance criteria and contain enough information for an overall understanding of the functions of the ESFs and the reactor conditions under which the equipment or systems must function.
>
> Simple block diagrams and drawings may be used to show the location, basic function, and relationship of each ESF to the facility. Detailed drawings, - schematic diagrams, data, and analyses should be presented in subsequent sections of this chapter for specific ESFs.

NUREG-1537, Part 2, Section 6.1, "Summary Description," states:

> In this section of the SAR, the applicant should briefly describe all the ESFs in the facility design and summarize the postulated accidents whose consequences could be unacceptable without mitigation. A specific postulated accident scenario should indicate the need for each the ESF. The details of the accident analyses should be given in Chapter 13 of the SAR and the detailed discussions of the ESFs in Section 6.2 of the SAR. These summaries should include the design bases, the performance criteria, and the full range of reactor conditions, including accident conditions, under which the equipment or systems must maintain function.
>
> The applicant may submit simple block diagrams and drawings that show the location, basic function, and relationship of each ESF to the facility. The summary description should contain enough information for an overall understanding of the functions and relationships of the ESFs to the operation of the facility. Detailed drawings, schematic diagrams, data, and analyses should be presented in Section 6.2 of the SAR for each specific ESF.

The ISG Augmenting NUREG-1537, Part 1, Section 6a2, "Aqueous Homogeneous Reactor Engineered Safety Features," states, in part: "… the guidance in this section is general enough to apply to any type of reactor facility, as long as the unique features of each are addressed and appropriate ESFs are provided to ensure that operations are conducted within safe limits."

SHINE PSAR, Section 6a2.1, "Summary Description," contains a description of the ESFs for the IF, but does not contain enough information for an overall understanding of the functions of the ESFs and the conditions under which the equipment or systems must function.

a) Provide a description of the conditions under which each ESF must function.

b) Provide block diagrams and drawings to show the location, basic function, and relationship of each the ESF to the facility.

c) Specify whether the target solution preparation systems (TSPSs) are part of the irradiation facility or the radioisotope production facility.

d) Specify whether any valves or piping located in the target solution preparation system room are considered part of the confinement boundary for either or both the irradiation facility or the radioisotope production facility.

**Section 6a2.2 – Irradiation Facility Engineered Safety Features Detailed Description**

(Applies to RAIs 6a2.2-1 through 9)

NUREG-1537, Part 2, Section 6.2, "Detailed Descriptions," states, in part: "In this section of the SAR; the applicant should discuss in detail particular ESF systems that may be incorporated into the reactor design."

NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part: "The applicant should discuss in detail the confinement and the associated HVAC [heating, ventilation, and air conditioning] systems that function as ESFs."

NUREG-1537, Part 2, Section 6.2.1, "Confinement," states, in part: "If the HVAC and any air exhaust or liquid release systems associated with the confinement are designed to change configuration or operating mode in response to a potential accident analyzed in Chapter 13 and thereby mitigate its consequences, they should be considered part of the confinement ESF and should be discussed in this section of the SAR."

RAI 6a2.2-1 SHINE PSAR, Section 6a2.2.1, "Confinement," discusses a system called the "tritium purification system (TPS) confinement system," but the section did not provide sufficient information for the staff to understand the entire system.

Provide additional information that describes and defines the "TPS confinement system," including system boundaries and interfaces, with references to the appropriate diagram(s).

RAI 6a2.2-2 SHINE PSAR, Section 6a2.2.1.2, “Confinement System and Components,” states, in part: “This ESF effectively reduces the amount of ductwork in the confinement volume that needs to remain intact to achieve IU cell, TOGS shielded cell, or TPS glovebox confinement.”

Provide clarification regarding the meaning of this sentence.

RAI 6a2.2-3 SHINE PSAR, Section 6a2.2.1.2, “Confinement System and Components,” states, in part: “A failure of the TPS outside the glovebox is mitigated by the TPS confinement system. The TPS confinement system uses isolation valves to stop a tritium leak outside the glovebox when a leak is detected.”

Additional information is needed for the NRC staff to determine the adequacy of the design of the TPS confinent system.

Provide additional information on the design and function of the TPS confinement system, including the ability of the system to stop tritium leaks outside of the glovebox.

RAI 6a2.2-4 SHINE PSAR, Section 6a2.2.1.3, “Functional Requirements,” states, in part, “Active confinement components are designed to fail into a safe state if conditions such as loss of signal, loss of power, or adverse environments are experienced.” Additional information is needed for the NRC staff to determine the adequacy of the SHINE design to withstand and mitigate adverse environments.

Provide information on the assumed "adverse environments" and how components are designed to accommodate for them.

RAI 6a2.2-5 SHINE PSAR, Section 6a2.2.1.3, “Functional Requirements,” states, “Mechanical, instrumentation, and electrical systems and components are designed to ensure that a single failure, in conjunction with an initiating event, does not result in the loss of the system’s ability to perform its intended safety function. The single failure considered is a random failure and any consequential failures in addition to the initiating event for which the system is required and any failures that are a direct or consequential result of the initiating event.”

Additional information is needed for the NRC staff to understand the meaning of the second sentence of this section.

Provide clarification regarding the meaning of the second sentence. Additionally, provide the basis for how the system design meets the single-failure criterion stated, or provide the reference to the section of the PSAR, which describes that basis.

RAI 6a2.2-6 SHINE PSAR, Section 6a2.2.1.4, “Confinement Components,” discusses the “secondary confinement barrier of the IU cells,” but does not define or fully describe this term.

Explain precisely what comprises the “secondary confinement barrier of the IU cells.”

RAI 6a2.2-7 SHINE PSAR, Section 6a2.2.1.4, “Confinement Components,” indicates that the details of the TPS confinement system will be left to the FSAR. Additional information is needed for the NRC staff to determine the adequacy of waiting to provide details of the TPS confinement system in the FSAR.

Provide the rationale for leaving the details of TPS confinement to the FSAR.

RAI 6a2.2-8 SHINE PSAR, Section 6a2.2.1.4, “Confinement Components,” mentions systems that are “open to the IU cell, TOGS shielded cell atmosphere, or TPS glovebox,” but does not identify them.

Identify the systems that are open to the IU cell, TOGS shielded cell atmosphere, or TPS glovebox.

RAI 6a2.2-9 SHINE PSAR, Table 6a2.2-1, “Irradiation Facility Confinement Safety Functions” (page 6a2-9), references isolation valves on piping systems, but the applicant does not identify the valves, provide a list of the valves or reference a schematic which details the isolation valves.

Provide a list, schematic or reference to a list of the isolation valves.

RAI 6a2.2-10 NUREG-1537, Part 1, Section 6.2.1, “Confinement,” states, in part: “For the confinement to function as an ESF, the design bases for the consequence-mitigation functions should be derived from the accident analyses in SAR Chapter 13.”

NUREG-1537, Part 2, Section 6.2.1, “Confinement,” *Acceptance Criteria*, states, in part: “To be considered an ESF, design features must exist to mitigate the consequences of specific accident scenarios.”

SHINE PSAR, Section 6a2.2, “Irradiation Facility Engineered Safety Features Detailed Description,” contains a list of initiating events (IEs) that were included for the design-basis accident (DBA) review. A subsequent list gives IEs, which do not have radiological consequences that require mitigation by ESFs. However, Section 6a2.2 did not explain the basis for the determination of which IEs do not have radiological consequences.

Provide the basis for this determination and a reference to the basis or analysis, which supports this determination or to the section(s) of SHINE PSAR that contain(s) such an analysis.

RAI 6a2.2-11 NUREG-1537, Part 1, Section 6.2.1, “Confinement,” states, in part: “The discussion of mitigative effects should contain a comparison of potential radiological exposures to the facility staff and the public with and without the ESF”

NUREG-1537, Part 2, Section 6.2.1, “Confinement,” *Evaluation Findings*, states, in part: “This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the safety evaluation report:

- The scenarios for all potential accidents at the reactor facility have been analyzed by the applicant and reviewed by the staff. Mitigation of consequences by a confinement system has been proposed in the SAR analyses for any accident that could lead to potential unacceptable radiological exposures to the public, the facility staff, or the environment.

- The staff has reviewed the designs and functional descriptions of the confinement ESF; they reasonably ensure that the consequences will be limited to the levels found acceptable in the accident analyses of Chapter 13 of the SAR.

- The designs and functional descriptions of the confinement ESF reasonably ensure that control of radiological exposures or releases during normal operation will not be degraded by the ESF.”

SHINE PSAR, Section 6a2.2.1, “Confinement,” does not contain a comparison of potential radiological exposures to the facility staff and the public with and without the ESF.

Provide the comparative study or reference the section of SHINE PSAR, which provides this information.

RAI 6a2.2-12 NUREG-1537, Part 1, Section 6.2.1,”Confinement,” states, in part: “A schematic diagram of the system should be presented showing the blowers, dampers, filters, other components necessary for operation of the system and flow paths.”

SHINE PSAR, Section 6a2.2.1, “Confinement,” does not contain or reference the confinement ESF HVAC system schematic diagram.

Provide the schematic diagram(s) for this system.

RAI 6a2.2-13 NUREG-1537, Part 1, Section 6.2.1, “Confinement,” states, in part: “Automatic and manual trip circuits, bypasses, interlocks, and special I&C [instrumentation and control] systems for the ESF system should be described briefly in this section and in detail in Chapter 7.”

NUREG-1537, Part 2, Section 6.2.1, “Confinement,” *Areas of Review*, states, in part: “The reviewer should evaluate… [Thus, this section should contain a]…description of control and safety instrumentation, including the locations and functions of sensors, readout devices, monitors, and isolation components, as applicable.”

SHINE PSAR, Section 6a2.2.1, “Confinement,” discusses the confinement ESF system, but did not contain a description of the automatic and manual trip circuits, bypasses, interlocks, and special I&C systems.

Provide a brief description of automatic and manual trip circuits, bypasses, interlocks, and special I&C systems, including relevant schematics or functional block diagrams, or reference(s) to their location in SHINE PSAR, Chapter 7.

RAI 6a2.2-14 NUREG-1537, Part 1, Section 6.2.1, “Confinement,” states, in part: “Periodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints should be required and specified. See Chapter 14, “Technical Specifications,” of this format and content guide, for details on what technical specification requirements should be identified and justified in this section.”

NUREG-1537, Part 2, Section 6.2.1, “Confinement,” *Areas of Review*, states, in part: “The reviewer should evaluate… [Thus, this section should describe]… [s]urveillance methods and intervals included in the technical specifications that ensure operability and availability of the confinement ESFs, when required.”

a) SHINE PSAR, Section 6a2.2.1.5, “Engineered Safety Feature Test Requirements,” states, in part: "Engineered safety features are periodically tested to ensure that ESF components maintain operability…." However, plans for testing ESF functionality as well as operability were not fully described.

   Describe planned tests of ESFs for "functionality" as well as "operability" (an example would be leak tightness), including preoperational as well as post-commissioning testing.

b) SHINE PSAR, Section 6a2.2.1.6, “Design Bases,” states, in part: "Potential variables, conditions, or other items that will be probable subjects of a technical specification associated with the IF confinement systems and components are provided in Chapter 14." Additional information is needed on the probable subjects of technical specifications to determine the adequacy of the IF confinement systems and components.

   Provide the information on the probable subjects of technical specification requirements, including periodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints, in the appropriate location(s) in Section 6a2 that is specified in NUREG-1537, Part 1, Chapter 14.

**Section 6b.1 Summary Description of Engineered Safety Features**

RAI 6b.1-1 NUREG-1537 Part 1, Section 6.1, “Summary Description,” states:

> In this section of the SAR, the applicant should briefly describe all of the ESFs in the facility design and summarize the postulated accidents they are designed to mitigate. These summaries should include the design bases and performance criteria and contain enough information for an overall understanding of the functions of the ESFs and the reactor conditions under which the equipment or systems must function.
>
> Simple block diagrams and drawings may be used to show the location, basic function, and relationship of each ESF to the facility. Detailed drawings, - schematic diagrams, data, and analyses should be presented in subsequent sections of this chapter for specific ESFs.

NUREG-1537 Part 2, Section 6.1, “Summary Description,” states, in part:

> In this section of the SAR, the applicant should briefly describe all the ESFs in the facility design and summarize the postulated accidents whose consequences could be unacceptable without mitigation. A specific postulated accident scenario should indicate the need for each ESF. The details of the accident analyses should be given in Chapter 13 of the SAR and the detailed discussions of the ESFs in Section 6.2 of the SAR. These summaries should include the design bases, the performance criteria, and the full range of reactor conditions, including accident conditions, under which the equipment or systems must maintain function.
>
> The applicant may submit simple block diagrams and drawings that show the location, basic function, and relationship of each ESF to the facility. The summary description should contain enough information for an overall understanding of the functions and relationships of the ESFs to the operation of the facility. Detailed drawings, schematic diagrams, data, and analyses should be presented in Section 6.2 of the SAR for each specific ESF.

SHINE PSAR, Section 6b.1, “Summary Description Engineered Safety Features,” contains a description of the ESFs for the Radioisotope Production Facility but does not contain enough information for an overall understanding of the functions of the ESFs and the conditions under which the equipment or systems must function.

a) Provide a description of the conditions under which the system must function.

b) Provide block diagrams and drawings to show the location, basic function, and relationship of each ESF to the facility.

c) SHINE PSAR, Section 6b.1 states, in part: "The confinement systems provide for active isolation of piping and HVAC systems penetrating confinement boundaries in certain post-accident conditions." Explain what is meant by the word "**certain"** in this context.

**Section 6b.2 Radioisotope Production Facility Engineered Safety Features**

(Applies to RAIs 6b.2-1 through 4)

NUREG-1537, Part 2, Section 6.2, "Detailed Descriptions," states, in part: "In this section of the SAR; the applicant should discuss in detail particular ESF systems that may be incorporated into the reactor design."

NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part: "The applicant should discuss in detail the confinement and the associated HVAC systems that function as ESFs."

NUREG-1537, Part 2, Section 6.2.1, "Confinement," states, in part: "If the HVAC and any air exhaust or liquid release systems associated with the confinement are designed to change configuration or operating mode in response to a potential accident analyzed in Chapter 13, and thereby, mitigate its consequences, they should be considered part of the confinement ESF and should be discussed in this section of the SAR."

RAI 6b.2-1 SHINE PSAR, Section 6b.2.1.3, "Functional Requirements," states, in part: "Active confinement components are designed to fail into a safe state if conditions such as loss of signal, loss of power, or adverse environments are experienced."

However, the section does not discuss the postulated adverse environments in detail. Provide detailed information on the postulated adverse environments and how components are designed to accommodate for them.

RAI 6b.2-2 SHINE PSAR, Section 6b.2.1.3, "Functional Requirements," states, in part: "Mechanical, instrumentation, and electrical systems and components are designed to ensure that a single failure, in conjunction with an initiating event, does not result in the loss of the system's ability to perform its intended safety function. The single failure considered is a random failure and any consequential failures in addition to the initiating event for which the system is required and any failures that are a direct or consequential result of the initiating event."

Additional information is needed for the NRC staff to understand the meaning of the second sentence of this section.

Provide clarification regarding the meaning of the second sentence. Also,

provide the basis for how the system design meets the single-failure criterion stated, or provide the reference to the section of SHINE PSAR, which describes that basis.

RAI 6b.2-3 SHINE PSAR, Section 6b.2.1.4, “Confinement Components,” mentions systems that are open to the hot cell atmosphere, but does not specify those systems.

Identify the systems that are "open to the hot cell atmosphere."

RAI 6b.2-4 SHINE PSAR, Section 6b.2.1.4, “Confinement Components,” describes components used to achieve the confinement boundary but does not provide a schematic or a list of these components and their locations.

Provide a reference to a schematic or list of isolation valves included in the confinement boundary.

RAI 6b.2-5 NUREG-1537, Part 1, Section 6.2.1, “Confinement,” states, in part: “For the confinement to function as an ESF, the design bases for the consequence-mitigation functions should be derived from the accident analyses in SAR Chapter 13.”

NUREG-1537, Part 2, Section 6.2.1, “Confinement,” *Acceptance Criteria*, states, in part: “To be considered an ESF, design features must exist to mitigate the consequences of specific accident scenarios.”

In SHINE PSAR, Section 6b.2, “Radioisotope Production Facility Engineered Safety Features,” a list of IEs is provided, which were included for the DBA review. A subsequent list shows a list of IEs, which do not have radiological consequences that require mitigation by the ESFs. Additional information is needed for NRC staff to determine the adequacy of the basis for this determination and categorization.

Provide the basis for this determination or categorization of IEs or a reference to such a basis description, including the analysis, which supports the determination.

RAI 6b.2-6 NUREG-1537, Part 1, Section 6.2.1, “Confinement,” states, in part: “The discussion of mitigative effects should contain a comparison of potential radiological exposures to the facility staff and the public with and without the ESF.”

NUREG-1537, Part 2, Section 6.2.1, “Confinement,” *Evaluation Findings*, states, in part: “This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the safety evaluation report:

- The scenarios for all potential accidents at the reactor facility have been analyzed by the applicant and reviewed by the staff. Mitigation of

consequences by a confinement system has been proposed in the SAR analyses for any accident that could lead to potential unacceptable radiological exposures to the public, the facility staff, or the environment.

- The staff has reviewed the designs and functional descriptions of the confinement ESF; they reasonably ensure that the consequences will be limited to the levels found acceptable in the accident analyses of Chapter 13 of the SAR.

- The designs and functional descriptions of the confinement ESF reasonably ensure that control of radiological exposures or releases during normal operation will not be degraded by the ESF."

SHINE PSAR, Section 6b.2.1, "Confinement," does not contain the confinement ESF effectiveness comparison in the discussion of mitigative effects. Provide the comparative study, or reference the section of SHINE PSAR, which provides the information.

RAI 6b.2-7 NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part: "A schematic diagram of the system should be presented showing the blowers, dampers, filters, other components necessary for operation of the system and flow paths."

SHINE PSAR, Section 6b2.1, "Confinement," does not contain or reference the confinement ESF HVAC system schematic diagram. Provide the schematic diagram(s), specified above, for this system.

RAI 6b.2-8 NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part: "Automatic and manual trip circuits, bypasses, interlocks, and special I&C systems for the ESF system should be described briefly in this 'section' and in detail in Chapter 7."

NUREG-1537, Part 2, Section 6.2.1, "Confinement," *Areas of Review*, states, in part: "The reviewer should evaluate… [Thus, this section should contain a]…description of control and safety instrumentation, including the locations and functions of sensors, readout devices, monitors, and isolation components, as applicable."

SHINE PSAR, Section 6b.2.1, "Confinement," discusses the confinement ESF system for the Radiation Production Facility, but does not contain a description of the automatic and manual trip circuits, bypasses, interlocks, and special I&C systems.

Provide a brief description of the automatic and manual trip circuits, bypasses, interlocks, and special I&C systems, including the relevant schematics, functional block diagrams, or reference(s) to their location in SHINE PSAR, Chapter 7.

(Applies to RAIs 6b.2-9 through 12)

10 CFR 50.34(a)(5) states, in part, that the preliminary safety analysis report should contain, “an identification and justification for the selection of those variables, conditions, or other items which are determined as the result of preliminary safety analysis and evaluation to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design…”

NUREG-1537, Part 1, Section 6.2.1, “Confinement,” states, in part: “Periodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints should be required and specified. See Chapter 14, “Technical Specifications," of this format and content guide, for details on what technical specification requirements should be identified and justified in this section.”

NUREG-1537, Part 2, Section 6.2.1, “Confinement,” states, in part: “The reviewer should evaluate… [Thus, this section should describe]… [s]urveillance methods and intervals included in the technical specifications that ensure operability and availability of the confinement ESFs, when required.”

RAI 6b.2-9 SHINE PSAR, Section 6b.2.1.6, states, in part: “Potential variables, conditions, or other items that will be probable subjects of a technical specification associated with the RPF confinement systems and components are provided in Chapter 14.”

Additional information is needed on the probable subjects of a technical specification in order to determine the adequacy of the RPF confinement systems and components.

Provide information on the probable subjects of technical specification requirements associated with the RPF confinement systems and components, including periodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints.

RAI 6b.2-10 SHINE PSAR, Section 6b.2.1.2, “Confinement System and Components,” uses the term “in-place testing,” but does not state whether this refers to initial commissioning, post-commissioning periodic testing or surveillance, or both.

Explain whether the term “in-place testing” refers only to initial commissioning, or whether it also includes on-going testing or surveillance.

RAI 6b.2-11 SHINE PSAR, Section 6b.2.1.5, “Engineered Safety Feature Test Requirements,” states, in part: "Engineered safety features are tested to ensure that ESF components maintain operability…." However, plans for testing ESF functionality as well as operability are not described.

Describe planned tests of ESFs for "functionality" as well as “operability” (an

example would be leak tightness), including preoperational as well as post-commissioning testing.

RAI 6b.2-12 SHINE PSAR, Section 6b.2.1.2, "Confinement System and Components," states, in part: "The RV [radiologically controlled area ventilation system] serving the RCA [radiologically controlled area], outside of the IF, includes components whose functions are designated as nonsafety-related and IROFS."

Provide the reference to the explanation of the basis for safety classification of structures, systems, and components (i.e., important to safety, safety-related, nonsafety-related, and IROFS).

**Section 6b.3 – Nuclear Criticality Control**

(Applies to RAIs 6b.3-1 through 20)

As required by 10 CFR 50.34(a)(4), "[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.3-1 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 multiple places in SHINE PSAR (e.g., pgs. 1-4, 6b-17, and 14b-2), the applicant implies safety limits are determined utilizing MCNP and validated methods. Also, while Section 6b.3.1 provides NCS criteria, this information is insufficient.

a) State explicitly if safety limits are determined utilizing MCNP and validated methods.

b) Provide additional clarification as to exactly what methods and assumptions are proposed for use in determining if NCS criteria are met. Include summary description of a documented, reviewed, and approved validation report or reference manual (by NCS function and management) for each methodology that will be used to perform an NCS analysis (e.g., experimental data, reference books, hand calculations, deterministic computer codes, probabilistic computer codes). Additionally, provide the validation report and reference manual referred to in the PSAR.

RAI 6b.3-2 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," *Acceptance Criteria*, states, in part, that the reviewer should determine if the applicant commits to "establish[ing] and maintain[ing] NCS safety limits and operating limits for the possession and use of fissile material and to maintain[ing] management measures to ensure the availability and reliability of the controls."

SHINE PSAR, Section 6b.3, "Nuclear Criticality Control," has no discussion regarding applicable management measures as required in 10 CFR 70.62(d), and as defined in 10 CFR 70.4.

Provide either the relevant passages in the SHINE PSAR that address applicable management measures or provide information to discuss management measures. Specifically, describe change management, configuration control, quality assurance, and procurement programs and measures for assuring long term reliability and availability of engineered controls (such as geometry, absorbers, etc.).

RAI 6b.3-3 The term "credible" is utilized throughout SHINE PSAR, including Section 6b.3, with respect to both ISA applications and Nuclear Criticality Safety Evaluations (NCSE); however, this term is not defined.

Define the term “credible.”

RAI 6b.3-4 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, “Nuclear Criticality Safety for the Processing Facility,” states, in part, that the reviewer should determine “whether the margin of subcriticality for safety is sufficient to provide reasonable assurance of subcriticality.”

While the SHINE PSAR, including Section 6b.3, mentions a subcritical margin, additional information is needed for the NRC staff to determine the adequacy of the subcritical margin.

Identify and justify the use of a subcritical margin for use in NCSEs, accident analyses, and development of safety controls. This should include conservative assumptions that are incorporated into evaluations to assure that processes should be less reactive than evaluated. The NRC staff notes that this may be information that is included in the summary of the NCS reference manual.

RAI 6b.3-5 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, “Nuclear Criticality Safety for the Processing Facility,” *Acceptance Criteria*, states, in part, that the reviewer should determine whether the applicant commits to “establish[ing] and maintain[ing] NCS safety limits and operating limits….” This commitment should assume optimum credible conditions (i.e., the most reactive conditions physically possible or limited by written commitments to regulatory agencies) unless specified controls are implemented to control the limit to a certain range of values.

A commitment to establishing and maintaining NCS safety limits, including optimum credible conditions, is not clearly delineated in the SHINE PSAR.

Provide a discussion committing to establishing and maintaining NCS safety limits, including optimum credible conditions.

RAI 6b.3-6 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.”

Explain and justify this assumption, especially as one of the processes involves dissolution of special nuclear material (SNM) in metal form.

RAI 6b.3-7 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, states that the reviewer should determine whether the applicant’s use of geometry as a

controlled parameter is acceptable if, before beginning operations, all dimensions and nuclear properties that use geometry control are verified. The facility configuration management program should be used to maintain these dimensions and nuclear properties.

SHINE PSAR, Section 6b.3, "Nuclear Criticality Control," includes little discussion on the configuration management program (e.g., page 6b-16 and Table 6b.3-2).

Provide additional detail on the role of the configuration management program (i.e., the configuration control process, procedures addressing the process, and how the change management program will ensure that changes to the NCS basis are incorporated into procedures, evaluations, postings, drawings, other safety-basis documentation, and the ISA summary) to allow the staff to evaluate its implementation.

RAI 6b.3-8 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.

The SHINE PSAR does not address moderator as a controlled parameter.

Verify that this will not be a controlled parameter and how this will be addressed in the NCSEs.

(Applies to RAIs 6b.3-9 through 10)

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 concentration as a controlled parameter is acceptable (e.g., concentrations of SNM in a process are limited unless the process is analyzed to be safe at any credible concentration; when using a tank containing concentration-controlled solution, the tank is normally closed and locked to prevent unauthorized access; when concentration needs to be sampled, dual independent sampling methods are used; and, after identification of possible precipitating agents, precautions are taken to ensure that such agents will not be inadvertently introduced).

RAI 6b.3-9 The SHINE PSAR does not address concentration as a controlled parameter other than to state it is a control for selected equipment.

Discuss the use of concentration as a controlled parameter and how this will be addressed in the NCSEs.

RAI 6b.3-10 Page 6b-17 of the SHINE PSAR states, "Each of the tanks within the scope of this section features criticality safety controls that meet the double-contingency principle…the first criticality safety control is that each tank, with the exception of the tanks associated with liquid waste processing, is criticality safe by geometry

or by the combination of geometry and a layer of neutron absorbing material integral to the tank construction. The second, independent criticality-safety control is that the most reactive concentration of uranium in any tank results in k-eff less than or equal to 0.95."

Clarify how concentration is independently subcritical given the design concentrations for process equipment listed in the PSAR. Specifically, clarify how the most reactive concentration of uranium in the uranyl sulfate preparation tank, 1-TSPS-01T, independently results in k-eff less than or equal to 0.95.

(Applies to RAIs 6b.3-11 through 12)

The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," *Areas of Review*, states, in part, that:

- Criticality accident analyses should be identified, including the assumption that all criticality accidents are high-consequence events and that the applicant's bases and methods are based on using preventive controls.

- Criticality 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.

- Criticality management measures should ensure that the reliability and availability of the safety controls are adequate to maintain subcriticality.

RAI 6b.3-11 SHINE PSAR, Chapter 13, (page 13b-29), states that "an inadvertent criticality event inside a shielded concrete vault within the facility is not an event of significant concern." Also, on page 6b-3, the PSAR states that inadvertent nuclear criticality in the radioisotope production facility is a design basis accident that does not have consequences requiring mitigation by ESFs. In addition, on page 6b-11, SHINE commits to ANSI/ANS-8.10-1983 (R2005), "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement" (ANSI/ANS, 2005a).

Any inadvertent criticalities are reportable to the NRC and are indication of a loss of applicable process controls.

Provide additional information providing the bases for asserting that an inadvertent criticality event inside a shielded concrete vault is not an event of significant concern and that an inadvertent nuclear criticality in the radioisotope production facility is a DBA that does not have consequences requiring mitigation by ESFs. Include a discussion demonstrating that under all normal and

abnormal credible conditions, subcriticality will be maintained.

RAI 6b.3-12 The staff understands that SHINE plans to utilize accelerators, which incorporate deuterium and potentially have a unique upset condition, should this material be entrained in the process solutions.

Provide a discussion of the considerations taken into account relating to the use of deuterium with respect to criticality safety at the SHINE facility.

RAI 6b.3-13 The ISG to NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," *Acceptance Criteria*, states, in part, that the reviewer should determine whether "the applicant describes a program that ensures compliance with the double-contingency principle, where practicable." In a very few processes, double-contingency protection may not be practicable. In those rare instances, the applicant should provide adequate justification for why such cases are acceptable.

The applicant commits to the double contingency principle in multiple passages in the PSAR, including Section 6b.3, (e.g., pages 1-4, 6b-12, and 17); however, no mention is made as to whether there are any planned exceptions to the double-contingency principle.

Clarify that all processes will be compliant with the double-contingency principle or provide justifications for those which will not.

RAI 6b.3-14 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 understands/acknowledges that use of a single NCS control to maintain the values of two or more controlled parameters constitutes only one component necessary to meet the double-contingency protection.

Provide clarification, indicating whether a single NCS control is used to maintain the values of two or more controlled parameters, and acknowledge that any such a control constitutes only one component necessary to meet the double-contingency protection.

RAI 6b.3-15 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states that "the reviewer should review all aspects of the applicant's NCS program, including management, organization, and technical practices. The reviewer should identify and note any items or issues relating to the NCS program and commitments that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the commitments made in the license application are implemented through procedures and training."

While SHINE PSAR, Section 6b.3, "Nuclear Criticality Control," commits to ANSI/ANS-8.26, "Criticality Safety Engineer Training and Qualification Program," 2007 on page 6b-11 and also on page 6b-12, this is not explicitly discussed as a

requirement of the NCS program and it is somewhat confused with a more general training commitment for plant personnel.

Provide an explicit commitment to having NCS staff trained and qualified to this ANSI guidance. Also provide, as supplemental information, the training and qualifications of staff evaluating the processes for NCS in the initial facility design.

RAI 6b.3-16 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states that the reviewer should determine if the applicant's use of mass as a controlled parameter is acceptable under stated circumstances, that is, when mass limits are derived for a material that is assumed to have a given weight percent of SNM, determinations of mass are based on either (1) weighing the material and assuming that the entire mass is SNM or (2) conducting physical measurements to establish the actual weight percent of SNM in the material; when fixed geometric devices are used to limit the mass of SNM, a conservative process density is assumed in calculating the resulting mass; and, when the mass is measured, instrumentation subject to facility management measures is used.

This information is not apparent in the discussion of mass as a controlled parameter in SHINE PSAR, Section 6b.3, page 6b-18.

Provide clarification of the use of this controlled parameter, if applicable.

RAI 6b.3-17 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 density as a controlled parameter is acceptable.

SHINE PSAR, Section 6b.3, "Nuclear Criticality Control," does not address density as a controlled parameter. Verify whether density will be a controlled parameter and how this parameter will be addressed in the NCSEs.

RAI 6b.3-18 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.

SHINE PSAR, Section 6b.3, "Nuclear Criticality Control," does not address enrichment or other likely SNM components (e.g., plutonium) as a controlled parameter.

Verify whether enrichment will be a controlled parameter and how this parameter will be addressed in the NCSEs.

RAI 6b.3-19 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 reflection as a controlled parameter is acceptable.

SHINE PSAR, Section 6b.3, “Nuclear Criticality Control,” does not address reflection as a controlled parameter.

Verify whether reflection will be a controlled parameter and how this parameter will be addressed in the NCSEs.

RAI 6b.3-20 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 interaction as a controlled parameter is acceptable (i.e., the structural integrity of the spacers or racks should be sufficient for normal and credible abnormal conditions).

While other aspects of interaction are addressed, SHINE PSAR, Section 6b.3, does not explicitly state that use of interaction is a controlled parameter.

Specify whether interaction control will be used, and how it would be applied.

RAI 6b.3-21 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 volume as a controlled parameter is acceptable. SHINE PSAR, Section 6b.3, “Nuclear Criticality Control,” does not appear to address volume as a controlled parameter.

Specify whether volume will be a controlled parameter and explain how this parameter will be addressed in the NCSEs.

RAI 6b.3-22 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, “Nuclear Criticality Safety for the Processing Facility,” *Areas of Review*, 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.”

SHINE PSAR, Section 6b.3.1, “Criticality-Safety Controls,” provides information on nuclear criticality safety evaluations.

Provide a representative sample of several nuclear criticality safety evaluations to improve staff’s understanding of the methods of processes being utilized.

## CHAPTER 7 – INSTRUMENT AND CONTROL SYSTEMS

The following questions of this chapter are based on a review of Chapter 7 of the SHINE PSAR (ADAMS Accession No. ML13172A269) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

### Section 7a2.2 – Design of Instrumentation and Control Systems

RAI 7a2.2-1 NUREG-1537, Part 1, Chapter 7, "Instrumentation and Control Systems," Section 7.2.2, "Design-Basis Requirements," states, in part, that the "design bases for the I&C system, subsystems, and components should include the following, as applicable:

- The range of values that monitored variables may exhibit for normal operation, shutdown conditions, and for postulated accidents.

- The specification of precision and accuracy requirements for the instruments, control subsystems, or components."

SHINE PSAR, Table 7a2.2-2, "IF Verification Matrix Design Criteria, Bases, Description" (Sheet 9 of 10), states, in part, that "the amount and rate of reactivity increases during the fill and irradiation processes are limited through physical and control system design to ensure that the effects of postulated reactivity accidents can neither (1) result in damage to the primary system boundary greater than limited local yielding, nor, (2) sufficiently disturb the target solution vessel, its support structures or other target solution vessel internals to impair significantly the capability to drain the target solution vessel." However, there is insufficient information supporting these assertions for the staff to determine if the design provides reasonable assurance that the design criteria will be met.

Provide additional information to support the assertions in this section of the PSAR, particularly supporting details on the accuracy anticipated for the reactivity control and the criteria for determining that draining of the target solution vessel is not impaired.

### Section 7a2.3 – TSV Process Control Description

RAI 7a2.3-1 NUREG-1537, Part 2, Section 7.3, "Reactor Control System," *Acceptance Criteria*, states, in part: "The RCS [Reactor Control System] should give continuous indication of the neutron flux from subcritical source multiplication level through the licensed maximum power range."

SHINE PSAR, Section 7a2.3.2.1, "Mode 1 - Startup Mode," states that the startup process calculates the subcritical multiplication factor M from the neutron flux level and plots 1/M versus the fill volume (height). This is then compared to a predicted graph of acceptance values for the same parameter. However, it is not clear how bias and uncertainties associated with the benchmarking of

criticality calculations, together with the expected variability in process parameters and instrumentation readings are being considered.

Provide additional information regarding the uncertainties in these computations, including a quantitative estimate of the expected overall uncertainty in their subcritical reactivity values during startup.

**Section 7a2.4 – TSV Reactivity Protection System**

RAI 7a2.4-1 NUREG-1537, Part 2, Section 7.4, "Reactor Protection System," *Acceptance Criteria*, states, in part: "The reactor should have operable protection capability in all operating modes and conditions, as analyzed in the SAR."

SHINE PSAR, Section 7a2.4.1, "TRPS [Target Solution Vessel Process Control System] Description," states that the only nuclear trips are on high neutron flux, source range and high range. However, there is apparently no anticipatory trip(s) provided for high startup rates or short periods, which are usually needed to adequately limit the fission reaction during high-reactivity transients.

Provide analyses supporting the adequacy of this trip to avoid a possibly unacceptable high reactivity transient, considering uncertainties and possible reactivity insertion events. Additionally, explain why a period trip in the source range would not be necessary, noting that the source range period is already provided.

**Section 7b.3 – Production Facility Process Control Systems**

RAI 7b.3-1 The ISG Augmenting NUREG-1537, Part 2, Section, 7b.3, "Process Control Systems," *Acceptance Criteria*, states, in part: "The system should be designed with sufficient control of reactivity for all required production and SNM fuel reconditioning process operations…."

SHINE PSAR, Section 7b.3, "Production Facility Process Control Systems," states, in part, that the radiological integrated control system (RICS) "[m]onitors and controls inter-equipment process fluid transfers in the RPF. For transport requiring a pump, the RICS controls the ability of the pump to be energized, and for specific transfers, provides controlled fluid flow transfers based on closed-loop flow control. The operator initializes the transfer of fluids." To preclude the possibility of criticality accidents, it is necessary for the applicant to control quantities of fissionable materials and to assure the quality of both software and operating procedures. However, there is insufficient information regarding how the key parameters are monitored to ensure adequate criticality control.

Provide additional information regarding the adequacy of the facility's instrumentation to detect deviations from nominal concentrations and quantities, should they occur.

**Section 7b.4 – Engineered Safety Feature and Alarming**

RAI 7b.4-1. NUREG-1537 Part 2, Section 7.5, “Engineered Safety Features Actuation Systems,” *Acceptance Criteria*, states, in part: “The range and sensitivity of ESF actuation system sensors should be sufficient to ensure timely and accurate signals to the actuation devices.”

SHINE PSAR, Section 7b.4.1.2.3, “Uranyl Nitrate Conversion System Over-Temperature Alarm,” states, in part, that “the RICS monitors the temperature of each UNCS [uranyl nitrate conversion system] in the RPF with independent redundant sensors. These sensors measure the temperature at the outlet of the UNCS.”

Provide information to justify why the sensor location at the outlet is appropriately representative of the process.

## CHAPTER 8 – ELECTRICAL POWER SYSTEMS

The following questions of this chapter are based on a review of Chapter 8 of the SHINE PSAR (ADAMS Accession No. ML13172A270) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

### Section 8a2.2 – Emergency Electrical Power Systems

RAI 8a2.2-1 NUREG-1537, Part 1, Section 8.2, "Emergency Electric Power Systems," states, in part: "In this section, the applicant should present a detailed functional description and circuit diagrams. In the design bases, the applicant should discuss if non-interruptible electrical power is required in the transfer from normal to emergency electrical service and if the transfer is manual or automated. The design bases should also provide voltage and power requirements for the emergency electrical power systems, the time duration over which these could be needed, and assurance that fuel will be available for the time required. The designs of the emergency electrical systems should provide that any use for non-safety-related functions could not cause loss of necessary safety-related functions. The design discussion should show how the emergency power supply system is isolated or protected, if necessary, from transient effects, such as power drains, short circuits, and electromagnetic interference."

NUREG-1537, Part 2, Section 8.2, "Emergency Electrical Power Systems," *Acceptance Criteria*, states in part: "Any non-safety-related uses of an emergency electrical power system should not interfere with performance of its safety-related functions."

SHINE PSAR, Section 8a2.2.1, "Class 1E UPSS [Uninterruptible Power Supply System]," references SHINE PSAR Figure 8a2.2-1, "One-Line Diagram – Uninterruptible Electrical Power Supply System" (ADAMS Accession No. ML13172A298), for UPSS components configuration. SHINE PSAR, Section 8a2.1.11, "Raceway and Cable Routing," states, in part, "[n]on-Class 1E circuits are electrically isolated from Class 1E circuits by isolation devices in accordance with IEEE [Institute of Electrical and Electronics Engineers] 384 (IEEE, 2008)."

SHINE PSAR, Figure 8a2.2-1 shows the Class 1E/non-Class 1E boundaries for uninterruptible power supply system Divisions A and B as horizontal dashed lines with arrows pointing upward toward what the annotation indicates is the non-Class 1E side. For both divisions, the drawing shows the Class 1E/non-Class 1E boundaries to be situated between the first load circuit breakers from the respective facility 480-Vac standby diesel generator (SDG) bus supplying each division's Class 1E battery charger and Class 1E 480V-208Y/120V voltage-regulating transformer and the respective input/supply circuit breakers for those battery chargers and voltage-regulating transformers.

Class 1E isolation devices are located and designed to function to isolate non-Class 1E circuits with sustained overloads or faults from otherwise unaffected Class 1E circuits powered from a common source to preserve the continuity of power to the otherwise unaffected Class 1E circuits.

Because the SDG buses normally provide power to both Class 1E and non-Class 1E loads, then theoretically, all the non-Class 1E load circuit breakers from the SDG busses, or their respective local supply breakers could be considered Class 1E isolation devices that must trip open to clear faults or sustained overloads on the non-Class1E loads in order to preserve continuity of power to the Class 1E loads.

However, is not clear which circuit breakers are considered Class 1E isolation devices. It is necessary to know which circuit breakers serve as Class 1E isolation devices, because even though they may be enclosed in the switchgear for non-Class 1E busses, and considered physically part of the non-Class 1E portion of the electrical power distribution system, they must perform a Class 1E function. Therefore, they must be classified as Class 1E themselves.

Provide additional information to explain the design approach to Class 1E isolation and to designate which circuit breakers in the electrical power distribution systems for the SHINE facility are to serve as Class 1E isolation devices. Additionally, explain the bases for those designations, how the type of circuit breakers designated as Class 1E isolation devices will be reasonably assured of meeting the specifications for such devices in accordance with IEEE Standard 384-2008.

CHAPTER 9 – AUXILIARY SYSTEMS

The following questions of this chapter are based on a review of Chapter 9 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.

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

(Applies to RAIs 9a2.1-1 through 2)

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."

RAI 9a2.1-1 SHINE PSAR, Section 9a2.1.1, "Radiologically Controlled Area Ventilation System," discusses the following systems: Radiological Controlled Area (RCA) Zone 2 Supply Air (RVZ2SA), RCA Ventilation System Zone 1 (RVZ1) Exhaust, RCA Ventilation System Zone 2 (RVZ2) Exhaust, and RCA Ventilation System Zone 3 (RVZ3). In reviewing this section with Figure 9a2.1-1, "RVZ1 Ventilation Flow Diagram," and Figure 9a2.1-2, "RVZ2SA and RVZ2 Ventilation Flow Diagram" (ADAMS Accession No. ML13172A300), the following was noted;

a) The section states that RCA Zone 2 Supply Air supplies air to RCA Ventilation System Zone 2 and RCA Ventilation System Zone 3, but there is no mention of where RCA Ventilation System Zone 1 gets its supply air from. SHINE PSAR, Figure 9a2.1-2, has an arrow after the supply fans that states: "Supply Air Flows to Additional Rooms" but provides no clarification as to what rooms/areas receive the air. PSAR, Figure 9a2.1-1 has an arrow going into the irradiation unit cell and an arrow going into the hot cell. Both arrows have the following statement "Transfer Air from Zone 2." It is not clear if the supply to the irradiation unit and hot cells is via dedicated ductwork or from ambient air drawn from the room.

   Clarify the source of air supply for RCA Ventilation System Zone 1, the rooms/areas that receive air from the supply fans identified in Figure 9a2.1-2, and the air supply source to the irradiation unit and hot cells identified in Figure 9a2.1-1.

b) The section states that RCA Ventilation System Zone 3 is supplied by the RCA Ventilation System Zone 2 Supply Air subsystem, is exhausted to RCA Ventilation System Zone 2, and is maintained at a higher pressure than RCA Ventilation System Zone 2. However, this PSAR section provides no details on how this is accomplished and Figure 9a2.1-2 has the following annotations, which may or may not be associated with RCA Ventilation System Zone 3: an arrow after the supply fans is labeled - "Supply Air Flows To Additional Rooms," but does not identify what rooms/air receive the air; an arrow to the exhaust fans states - "Exhaust Flows From Additional Zone 2

Rooms," which infers preclusion of any air from RCA Ventilation System Zone 3; and at the two Zone 3 airlocks an "Offset Airflow" from Zone 3 to Zone 2, which may not be sufficient total exhaust airflow for RCA Ventilation System Zone 3.

Provide additional information on the exhaust and pressure maintenance for RCA Ventilation System Zones 2 and 3, as well as figures, including an RVZ3 flow diagram.

RAI 9a2.1-2 SHINE PSAR, Section 9a2.1.2, "Non-Radiological Area Ventilation System," discusses the Facility Ventilation Zone 4 (FVZ4) system. While the SHINE PSAR states that this is a nonradiologcial controlled area ventilation system, additional information on the potential for contamination in this area is needed for the NRC staff to determine the adequacy of the FVZ4 ventilation system.

Provide additional information on the FVZ4 ventilation system, including information on where the system exhausts, whether there are any radiation detectors on the exhaust, and a FVZ4 flow diagram.

**Section 9a2.3 – Fire Protection Systems and Programs**

RAI 9a2.3-1 NUREG-1537, Section 9.3, "Fire Protection Systems and Programs," states that the application should discuss passive design features required by the facility design characteristics to, in part, limit fire consequences. The facility should be designed and protective systems should exist to prevent the uncontrolled release of radioactive material if a fire should occur.

Identify which fire detection and suppression systems are necessary to prevent or mitigate high or intermediate consequence accidents in the RPF (i.e., IROFS), and describe and commit to applying management measures that will assure that these systems and components are constructed, procured, installed, and tested to ensure that they will be available and reliable to perform their intended functions when needed.

(Applies to RAIs 9a2.3-2 through 3)

NUREG-1537, Part 1, Section 9.3, "Fire Protection Systems and Programs," states, in part, that the applicant should describe systems and programs designed to protect the reactor facility from damage by fire and discuss how the facility meets all local building and fire codes."

RAI 9a2.3-2 SHINE PSAR, Section 9a2.3.4.4, "Safety Evaluation of Fire Hazards," discusses egress from the SHINE facility as in compliance with the International Building Code and Life Safety Code, satisfying the requirements of Title 29 of the *Code of Federal Regulations*.

Fire Area 6 (PSAR Section 9a2.3.4.4.6.7, Figure 9a2.3-1, "Fire Area and Fire Zone Boundaries") of SHINE PSAR, Section 9a2.3, "Fire Protection Systems and

Programs," is the corridor in the facility structure that wraps around the north, west, and south sides of the building.

A fire in this area could make all egress (except the airlock at the southeast corner of the building) inaccessible.

Provide information on how building personnel can evacuate the building under such conditions.

RAI 9a2.3-3 Fire Areas (FAs) 1 and 3 utilize gaseous fire suppression systems, as described in SHINE PSAR, Sections 9a2.3.4.4.6.4.3 and 9a2.3.4.4.6.2.3, respectively. Gaseous suppression systems could result in asphyxiation during a release.

Describe how potential asphyxiation during a release of the gaseous suppression systems has been addressed in the design of the fire protection system and in the fire protection program in accordance with local building and/or fire codes.

(Applies to RAIs 9a2.3-4 through 5)

NUREG-1537, Part 2, Section 9.3, "Fire Protection Systems and Programs," *Acceptance Criteria*, states, in part, that "[m]ethods to detect, control, and extinguish fires should be stated in the plan."

RAI 9a2.3-4 In radiation areas, the smoke detection capability of ionization detectors could be adversely affected. Photoelectric smoke detector capability can be affected in areas of dust/particulates.

Provide the basis of choosing detectors, and what maintenance program will be used to assure that the detectors function properly.

RAI 9a2.3-5 The neutron moderation capability of firefighting foam is not discussed. Additional information is needed on the moderation capabilities of firefighting foams because local fire departments may use foam as part of their firefighting repertoire.

Provide additional information on foam, if any, that can or will be used in the facility and what training is proposed for the fire brigade and for offsite fire departments that may provide assistance.

RAI 9a2.3-6 NUREG-1537, Part 2, Section 9.3, "Fire Protection Systems and Programs," *Acceptance Criteria*, states, in part: "The fire protection plan should discuss the prevention of fires, including limiting the types and quantities of combustible materials."

As shown in SHINE PSAR Figure 9a2.3-1, "Fire Area and Fire Zone Boundaries," the Boiler Room (FA-17), which has a natural gas pipeline supplying the boiler, is adjacent (i.e., shares a common wall) to the Fire Brigade/Hazmat Room (FA-16) that contains the Fire Zone Panels.

Provide additional information on the potential for a fire in the Boiler Room and address the effects of the pipeline gas combustible load (until the pipeline can be shut off outside the Boiler Room) on the FA-17 and on the rest of the building.

RAI 9a2.3-7 NUREG-1537, Part 2, Section 9.3, "Fire Protection Systems and Programs," *Acceptance Criteria*, states, in part: "The facility should be designed and protective systems should exist to ensure a safe reactor shutdown and prevent the uncontrolled release of radioactive material if a fire should occur."

SHINE PSAR, Figure 9a2.3-1 indicates that there are fire zones inside of FA-1 and FA-2. However, the fire zones are not numbered.

Provide information indicating whether the fire zones will be numbered, and whether the fire zone numbers will be unique. Additionally, provide information indicating whether the Fire Hazards Analysis will provide assessments of each fire zone.

**Section 9b.7 – Other Auxiliary Systems**

RAI 9b.7-1 NUREG-1537, Part 2, Section 9.7, "Other Auxiliary Systems," *Acceptance Criteria*, states, in part, that "[t]he design, functions, and potential malfunctions of the auxiliary system should not cause accidents to the reactor or uncontrolled release of radioactivity."

SHINE PSAR, Section 9b.7.2, "RCA Material Handling," identifies the equipment used to move or manipulate radioactive material within the RCA and states that "the overhead cranes meet the requirements of ASME B30.2 and CMAA [Crane Manufacturers Association of America] 70."

Due to the size and weight of the shields and equipment that need to be moved, and the inventory of tritium and uranium onsite, provide additional assessments demonstrating the implementation of the requirements of ASME B30.2 and CMAA 70 to ensure that dropped, toppled, rolled or otherwise off-normal load events do not result in the loss of safety function or the release of radioactivity to the public.

RAI 9b.7-2 NUREG-1537, Part 2, Section 9.7, "Other Auxiliary Systems," states that the "design, functions, and potential malfunctions of the auxiliary system should not

cause accidents to the reactor or uncontrolled release of radioactivity."

In SHINE PSAR, Section 9b.7.2, "RCA Material Handling," statements are made in Sections 9b.7.2.6, 9b.7.2.7, and 9b.7.2.8 that the equipment is designed to prevent inadvertent criticality during material handling. However, no design details are provided. In addition, Section 9b.7.2 does not mention whether there is a need for technical specifications with respect to criticality control during materials handling.

Due to the consequences that may result from inadvertent criticality during materials handling, provide additional details on how the equipment will be designed to prevent inadvertent criticality and provide an assessment of why technical specifications are not needed or describe preliminary plans for technical specification safety limits and surveillance requirements.

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.

**Section 11.1 – Radiation Protection**

RAI 11.1-1 10 CFR 50.34(a)(3)(i) requires that preliminary design information provided for the facility include principal design criteria.

SHINE PSAR, Section 11.1.1.1, "Airborne Radioactive Sources," presents information on the management of airborne radioactive sources. It states that predicted personnel dose rates (including maintenance activity) due to airborne radioactivity and associated methodology will be presented in the Final Safety Analysis Report for the SHINE facility.

Provide design information in sufficient detail (including key assumptions) to demonstrate the manner in which airborne radioactive material concentrations to which workers may be exposed (especially during maintenance activities) will be controlled in order to meet the derived air concentrations contained in 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage." Specifically, provide the following:

a) The expected airborne radioactive material concentrations (partitioned into noble gases, radioiodines, and particulates) associated with normal operations of the facility compared to their respective derived air concentrations in various areas that could be occupied by workers. Use definitions for airborne radioactivity areas similar to the following in terms of the derived air concentrations: Zone 1 (<0.01 – 1.0 derived air concentration); Zone 2 (1.0 – 10 derived air concentrations); and Zone 3 (>10 derived air concentrations).

b) The expected airborne radioactive material concentrations associated with facility accidents compared to their respective derived air concentrations in various areas that could be occupied by workers.

c) Key assumptions associated with (a) and (b) above, including:

   (i) The basis for the production rate data in PSAR, Table 11.1-9, "TSV [Target Solution Vessel], Noble Gas and Iodine Production Rates, Annual Releases, and ECL [Effluent Concentration Limits] Fraction at the Site Boundary after 960 Hours of NGRS [Noble Gas Removal System] Holdup;

(ii) A description of leakage pathways (including holdup and filtration/adsorption) from the point of production to the point of worker exposure; and

(iii) For the ventilation system: Key parameters and assumptions associated with the estimates of airborne radioactive material concentrations in work areas.

RAI 11.1-2 The ISG Augmenting NUREG-1537, Part 2, Section 11.1, "Radiation Protection," states that the application should identify trained radiation workers.

SHINE PSAR, Section 9b.7.2, "RCA Material Handling," provides information on the equipment used to move or manipulate radioactive material within the RCA, but there is no discussion or reference to the training/qualification of personnel who operate the equipment. In addition, as required by 10 CFR 71.5, "Transportation of licensed material," any facility that ships or receive shipments from across state lines must assure that its personnel, who are expected to handle radioactive materials, are adequately trained and qualified in accordance with U.S. Department of Transportation 49 CFR 172, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, And Security Plans," Subpart H, "Training."

Provide additional information clarifying whether the training and qualification program for radiation workers will include elements to assure that personnel who are expected to handle radioactive materials are adequately trained and qualified in accordance with 49 CFR 172, Subpart H.

(Applies to RAIs 11.1-3 through 4)

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)."

NUREG-1537, Part 2, Section 11.1.3, "ALARA Program" *Acceptance Criteria*, states, in part: "The highest levels of facility management should be committed to the ALARA program."

RAI 11.1-3 SHINE PSAR, Section 11.1.2, "Radiation Protection Program," and Section 11.1.3, "ALARA Program," discuss SHINE's commitment to the radiation protection program implementation and the proposed content of the ALARA program. Responsibilities of the plant manager and the environment, safety and health manager (and his subordinate, the radiation protection manager) are outlined with regard to the control of occupational radiation exposure. Both individuals report to the chief operating officer, providing the needed separation of the radiation protection component from the operating component. Missing from the PSAR, however, is the commitment to develop a management policy

statement(s) that demonstrates SHINE's commitment to maintaining occupational and public radiation exposures ALARA.

Provide such a commitment to develop an ALARA policy statement(s).

RAI 11.1-4 SHINE PSAR, Section 11.1.3, "ALARA Program," states, in part, that the "ALARA concept is also incorporated into the design of the facility. The plant is divided into radiation zones with radiation levels that are consistent with the access requirements for those areas. Areas where on-site personnel spend significant amounts of time are designed to maintain the lowest dose rates reasonably achievable." Additional information is needed on the radiation zones for the NRC staff to determine their consistency with ALARA principles.

Provide the radiation zone designations based on a consideration of neutron and gamma dose rates for locations that could be occupied, as well as the unrestricted environment as referenced in SHINE PSAR, Section 4a2.5.4. Use definitions for radiation zones similar to the following: Zone 1 (background – 2 millirem/hour); Zone 2 (2 - 100 millirem/hour); and Zone 3 (>100 millirem/hour). Using the preceding radiation zone definitions (or equivalent), provide a tabulation of radiation zone designations that could be occupied by radiation workers, even on a transient basis. Also include doses resulting from anticipated operational occurrences and accidents.

RAI 11.1-5 10 CFR 20.1902, "Posting requirements," defines the manner in which various radiological control areas should be demarcated. Included therein are requirements for Radiation Areas, High Radiation Areas, Very High Radiation Areas and Airborne Radioactivity Areas.

SHINE PSAR, Section 11.1.5.1.1, "Radiological Zones," Item b, "Restricted Area," defines the types of restricted areas to be used for the purpose of radiological control. All of the posting requirements noted above have been included except for a Very High Radiation Area.

Provide either (a) a commitment that all Very High Radiation Areas included in the plant design will meet the requirements of 10 CFR Part 20, Subpart G, "Control of Exposure From External Sources in Restricted Areas," or (b) Provide a basis for not including Very High Radiation Areas in the plant design (i.e., why such controls will not be necessary).

(Applies to RAIs 11.1-6 through 8)

NUREG-1537, Part 2, Section 11.1.7, "Environmental Monitoring," *Acceptance Criteria*, states, in part, that "[t]he methods and techniques to sample and analyze the radiological effect of facility operation should be complete, applicable, and of sufficient validity that the environmental impact can be unambiguously assessed."

SHINE's proposed radiological environmental monitoring program for plant operation is provided in SHINE PSAR, Section 11.1.7, "Environmental Monitoring." Additional information is needed for the NRC staff to determine the adequacy of several elements of the proposed operational radiological environmental monitoring program.

RAI 11.1-6 SHINE PSAR, Section 11.1.7.2.2.1, "Air Sampling Locations," discusses the proposed air monitoring program. When discussing the equipment that will be used for air sampling, the applicant uses the term CAM (continuous air monitor). The conventional use of the term "continuous air monitor" denotes equipment that both samples and quantifies the activity on the sample media (i.e., real-time monitoring). Normally, CAMs are not used for such purposes and the NRC guidance document, NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors," that the applicant cites, does not specify CAMs for environmental air sampling.

Clarify whether the term "air monitoring" is intended to refer to sample collection followed by laboratory analysis or real-time air monitoring.

RAI 11.1-7 SHINE PSAR, Section 11.1.7.2.3, "Ingestion Pathway (Biota Monitoring)," discusses the proposed monitoring program for the ingestion pathway. This section notes that because radioiodine and particulate activity is not expected to be present in measureable quantities in effluent releases, biota sampling will only be included if certain conditions are met. These conditions include: (a) The presence of radioiodine or particulates on an environmental air sample, or (b) Effluent releases of radioiodine or particulates that would result in a dose at the property line of 1 millirem/year or more. The PSAR also notes that dairy production takes places 0.5 miles from the facility and goat milk production occurs 0.7 miles from the facility. Given the presence of cow and goat milk production so close to the SHINE facility, it is apparent that routine milk sampling as part of the radiological environmental monitoring program is warranted becuase: (1) the proposed sampling of effluents and the environment may not result in timely recognition of an environmental impact issue if an off-normal release occurs in the beginning of a sample period (presumably a one-week interval), considering the remaining collection period and subsequent laboratory analysis; (2) milk, especially goat milk, is a more sensitive indicator of radioiodine impact on the environment; and (3) routine milk sampling could also demonstrate the adequacy of inplant controls. Beyond the regulatory requirements aspect, milk pathway sampling provides an opportunity to establish a relationship with neighboring dairies that can foster confidence in plant operations.

Provide additional information regarding exclusion of ingestion pathway monitoring and determine, in light of the above NRC staff comments, whether it is appropriate to add milk sampling to the radiological environmental monitoring program.

RAI 11.1-8 The large number (40) of direct exposure monitoring stations (e.g., thermoluminescent dosimeter) recommended in NRC guidance documents for

nuclear power plants is noted in SHINE PSAR, Section 11.1.7.2.1, "Direct Radiation Monitoring," as well as a statement regarding why that number of monitoring stations does not appear warranted for the SHINE facility. As a result, the applicant proposed nine direct radiation-monitoring locations, based on the smaller source term compared to nuclear power plants. Additional information is needed for the NRC staff to determine whether the number of direct monitoring locations should not be based on source term alone or whether consideration should also be given to the variability of wind direction and the expected "signal-to-noise ratio" (plant contribution versus background). The ability to demonstrate the SHINE facility's impact on the environment is enhanced by having additional direct monitoring stations that increase the statistical power of the analysis. The applicant proposed only four direct monitoring locations at the site boundary (north, east, south, and west). Such a relatively small number of monitoring locations decreases the probability of detecting the impact of effluent releases associated with normal and off-normal operations, and accidents.

Provide additional information further justifying use of only four direct monitoring locations, or propose additional monitoring locations at the site boundary and special interest areas, such as population centers and nearby residences and schools.

**Section 11.2 – Radioactive Waste Management**

(Applies to RAIs 11.2-1 through 2)

In accordance with 10 CFR Part 20, an as low as reasonably achievable (ALARA) program is required and 10 CFR 50.34(a)(3)(i) requires that preliminary design information provided for the facility include principal design criteria.

NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," *Acceptance Criteria*, states, in part, "the program should be designed to address all technical and administrative functions necessary to limit radiation hazards related to radioactive waste."

RAI 11.2-1 The Mo-99 extraction columns are a frequent (400 target solution volumes per year) and initially highly radioactive solid waste generated by the proposed SHINE facility. As a supplement to material presented in SHINE PSAR, Section 9b.7.2, "RCA Material Handling," and Section 11.2, "Radioactive Waste Management," additional information is needed on criteria for the handling of this waste stream and the handling of the extraction column in and from the supercells to the shielded vaults and further to packaging and shipping for disposal. This information is needed for the NRC staff to ascertain safety, as well as SHINE's ability to meet the regulatory requirement regarding hazardous material identification in shipping papers (10 CFR 20, Subpart K, "Waste Disposal"), and conformance with ALARA goals.

Provide the following information so that staff may assess compliance with the ALARA requirement of 10 CFR Part 20:

a) Describe the inlet and outlet connections of the Mo-99 columns that permit frequent remote replacement while providing leak-tightness and preventing the spread of contamination during replacement. Provide the estimated dose rate from an extraction column at time of removal and after 2 weeks storage in the supercell.

b) Provide information on the material handling methods of moving shielded containers of an extraction column from the supercell to the shielded vaults at the other end of the facility from the supercells. If this material handling includes movement by crane, include a load drop in the accident analyses or justify why such an event need not be considered.

c) Clarify how long extraction columns are maintained in shielded vault storage. SHINE PSAR, Table 11.2-3, "Waste Methodology for Columns," says approximately 400 days of decay are required to be Class A; PSAR, Section 9b.7.5.4.2, "Solid Radioactive Waste Handling Hot Cell," says they are transferred to the storage vault for an additional 6 months.

d) Provide information on the transfer of an extraction column into one of the six separate shielded storage vaults shown on figures presented in SHINE PSAR, Chapter 1, "The Facility."

e) Clarify, whether there are any differences between the handling of the Mo-99 columns.

RAI 11.2-2 SHINE PSAR, Section 4b.4.1.1.4.1, "Uranyl Nitrate Preparation Process Sequence," explains part of the process for reusing target solution and states that the solid salts discharged from the centrifuge are moved to solid radioactive waste packaging in a 55-gallon drum. PSAR, Section 11.2.2.2.6, "Target Solution Clean-up," identifies that this waste stream is Class B. There is no discussion of the radiation levels emanating from these drums, no discussion of sealing the drums during handling to prevent spills, and no discussion of design features implemented to assure doses to workers are ALARA during these evolutions. PSAR, Table 11.2-6, "Waste Methodology for [ ]" (the rest of the table name is withheld as proprietary information) identifies that the waste stream must be sampled for waste characterization prior to solidification, but there is no discussion of how this is accomplished in an ALARA manner.

Provide discussion of the design features and design review procedures used to assure that the ALARA considerations committed to in SHINE PSAR, Section 11.1.3, "ALARA Program," are effectively implemented for each of the identified waste streams and the handling operations required during their processing.

(Applies to RAIs 11.2-3 through 4)

NUREG-1537, Part 1, Appendix A, describes the applicability of 10 CFR 50.9, "Completeness and accuracy of information," to non-power reactors. As required by 10 CFR 50.9, the information provided by the applicant must be complete and accurate.

RAI 11.2-3 SHINE PSAR, Table 11.2-5, "Waste Methodology for Consolidated Liquids," contains errors, and at least one inconsistency, as identified below:

- The requirement to "sample the influent waste stream" should be changed to "obtain a representative waste tank sample." SHINE PSAR, Section 11.2.3.2.1, "Consolidated Liquids," identifies multiple influent streams. Sampling of individual inputs may provide detail, but a final representative sample after the tank has been isolated from new inputs is needed for accurate characterization. Regulatory Guide 1.21, "Measuring, Evaluating, and Reporting Radioactive Material in Liquid and Gaseous Effluents and Solid Waste," Revision 2, June 2009, contains guidance regarding sampling liquid radioactive waste.

- The basis for the requirement to provide a means to evaporate waste contains an arithmetic error. 55,000 gallons per year is more than 1000 gallons per week, not "…roughly 275 gallons per week."

- The basis for the requirement to process evaporator concentrate waste contains an arithmetic error. 36,000 gallons per year is almost 700 gallons per week, not "…roughly 180 gallons per week."

- PSAR, Table 11.2-1, "Waste Stream Summary," states liquid waste generation of 59,708 gallons per year, not 55,000.

Provide corrections to the identified errors or provide supplemental information justifying the inconsistent values.

RAI 11.2-4 SHINE PSAR, Table 11.2-1 presents estimates of waste generation rates and waste classification without sufficient discussion or quantitative values to assess the reasonableness of the estimates presented. For example:

- The total for all the liquid radioactive waste inputs is presented to five significant figures (59,708 gallons per year) but only one liquid waste stream has an estimated generation rate associated with it in the text (scrubber solution at 20,000 gallons per year).

- Coolant cleanup system spent ion exchange resins are not included in PSAR Table 11.2-1. A commitment to include this value in the FSAR exists in the text.

- There is insufficient chemical characterization data of the individual waste streams to allow assessment of the potential for unexpected chemical reactions or to estimate volumes of acids or bases that may be needed for pH adjustment.

- There is no identification of any anticipated upset or accident condition that could cause an input to the liquid waste processing system.

Provide a comprehensive liquid waste process flow diagram showing expected liquid waste generation rates (with chemical and radiological properties) for all liquid waste streams, washes, rinses, and chemical additions that flow to the consolidated radioactive liquid waste tanks. The process flow diagram should also quantify tank capacities and processing flow rates that demonstrate the capability to process wastes from normal operations and anticipated upset conditions with margin, or identify locations for interfacing with temporary mobile systems, as needed. The process flow diagram should include an estimate of the area needed for decay in storage of packaged waste and the criteria used to determine shielding requirements.

RAI 11.2-5 NUREG-1537, Part 2, Section 11.2.2, "Radioactive Waste Controls," *Evaluation Findings*, states, in part: "The descriptions of the plans and procedures provide reasonable assurance that radioactive wastes will be controlled at all times in a manner that protects the environment and the health and safety of the facility staff and public."

Disposal sites have established waste acceptance criteria, as identified in PSAR, Chapter 11.

The inputs to the consolidated radioactive liquid waste tanks are a mixture of strong acids and bases, chemicals in solution, and water, all containing fission products. This chemical mixture is then concentrated through evaporation to reduce the volume of waste to be solidified for packaging and disposal.

Provide references that support the validity of the assumption that the evaporator concentrates of the consolidated liquid waste stream can be solidified on Portland cement to meet the waste acceptance criteria of the potential disposal sites. Alternatively, commit to conducting a solidification testing program during construction of the facility to be able to define the requirements of the solidification Process Control Program in the PSAR.

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, and 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."

**Section 12.1 – Organization**

RAI 12.1-1 NUREG-1537, Part 2, Section 12.1, "Organization," *Areas of Review*, *s*tates, in part: "The organization of non-power reactor facilities is discussed in Chapter 14, 'Technical Specifications,' of the format and content guide. Additional details on the areas of review are given in this chapter of the format and content guide."

Appendix 14.1 of NUREG-1537, Part 1, Section 6.1.1, "Structure," states: "The information recommended by ANSI/ANS 15.1 should be clearly stated, including how and when the radiation safety staff communicates with the facility manager and level 1 management to resolve safety issues."

NUREG-1537, Part 1, Section 12.1.1, "Structure," states, in part: "The description of the organizational structure should include the radiation safety function and indicate how the staff implementing that function interacts with the staff responsible for reactor operations and the top administrative officials. The multilevel chart should show the relationship of the review and audit function to the organizational structure. The persons implementing the review and audit function should communicate with the management of the reactor facility but should report to an organizational level above this management to ensure independence of the review and audit function."

The SHINE PSAR provides the functional organization in Figure 12.1-1 (ADAMS Accession No. ML13172A304), and PSAR, Section 12.1, "Structure," states, in part: "The staff implementing the radiation safety function supports on-shift plant operations and interacts with Executive Management through the chain of command." However, the organization chart does not include the review and audit function or the radiation safety function.

a) Include the review and audit committee and the radiation safety function in the organization chart.

b) Describe the responsibilities of the review and audit committee and the radiation safety function, including the responsibility for the safe operation of the facility and for the protection of the health and for safety of SHINE staff and the public.

RAI 12.1-2 NUREG-1537, Part 2, Section 12.1, "Organization," *Acceptance Criteria*, states, in part, that "[t]he applicant should discuss the training of personnel, should reference the operator training program and the operator requalification program, and should include a review of compliance with the requirements of 10 CFR Part 55" ["Operators' Licenses"].

NUREG-1537, Part 1, Section 12.1.4, "Selection and Training of Personnel," states, in part: "The applicant should discuss the selection and training of personnel. If minimum requirements exist for the facility staff, they should be discussed in this section…The applicant and licensed operators shall comply with 10 CFR Part 55."

SHINE PSAR, Section 12.1.4, "Selection and Training Of Personnel," states, in part, "SHINE establishes and maintains formal and informal indoctrination and training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. The Training Manager (TM) is responsible to the PM [Plant Manager] for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety."

However, SHINE PSAR, Section 12.1.4, does not include:

- A reference to the operator requalification program.
- A review of planned compliance with the requirements of 10 CFR Part 55, as applicable.

Therefore, additional information is required for the staff to make a determination on the acceptability of the preliminary plans for training of personnel:

a) Include a reference to the preliminary plans for an operator training program and the operator requalification program in this section.

b) Provide a review of SHINE's planned compliance with the requirements of 10 CFR Part 55, as applicable, in this section.

c) Indicate if minimum qualifications requirements will exist for the facility staff.

**Section 12.2 – Review and Audit Activities**

RAI 12.2-1 NUREG-1537, Part 1, Section 12.2, "Review and Audit Activities," states, in part, "[t]he applicant should explicitly state who holds the approval authority

[committee or facility manager] and should specify the committee's authority and how it communicates and interacts with facility management and…corporate management."

SHINE PSAR, Section 12.2, "Review and Audit Activities," states: "The PM establishes review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. These activities are summarized and reported to Executive Management. Independent audits of the SHINE facility are conducted periodically." However, approval authority is not addressed. Therefore, additional information is needed from the applicant.

a) State who holds approval authority.

b) Provide additional detail on how the review and audit committees interact with management.

RAI 12.2.-2 NUREG-1537, Part 2, Section 12.2, "Review and Audit Activities," *Acceptance Criteria*, states, in part: "The applicant should give the details of the review function…The reviews should include 10 CFR 50.59 ["Changes, tests, and experiments"] safety reviews."

SHINE PSAR, Section 12.2.3, "Review Function," did not include this in the list of items required to be reviewed.

Add 10 CFR 50.59 safety reviews to the list of items to be reviewed or justify its exclusion.

RAI 12.2-3 NUREG-1537, Part 2, Section 12.2, "Review and Audit Activities," *Acceptance Criteria*, states, in part: "The applicant should give the details of the audit function. The minimum list of items to be audited should be that given in ANSI/ANS 15.1-1990 ['The Development of Technical Specifications for Research Reactors'], with the addition of plans such as the quality assurance plan, if the facility has one, and the physical security plan. The audit of facility operations should include items such as organization and responsibilities, training, reactor operations, procedures, logs and records, experiments, health physics, technical specification compliance, and surveillances."

NUREG-1537, Part 1, Section 12.2.4, "Audit Function," states, in part: "The applicant should list and discuss the items that must be audited by the committee. In addition to audits by the facility committee, the licensee may consider entering into an auditing agreement with other non-power reactor facilities to bring in staff members from other non-power reactors to perform an audit. This approach has been very productive at the facilities that have used it."

SHINE PSAR, Section 12.2.4, "Audit Function," includes a list of examples of activities to be audited.

Provide additional information expanding PSAR, Section 12.2.4, to include details addressing the items above, or justify their exclusion.

**Section 12.3 - Procedures**

RAI 12.3-1 NUREG-1537, Part 1, Section 12.3, "Procedures," states, in part: "The applicant should discuss the basic topics that the procedures do or will cover…The applicant should discuss the methodology used for developing procedures, including the approval process. The applicant should also discuss the process required to make changes to procedures including substantive and minor permanent changes, as defined in ANSI/ANS 15.1-1990, and temporary deviations to deal with special or unusual circumstances during operation. The applicant should note that 10 CFR 50.59 may apply to changes to procedures."

NUREG-1537, Part 2, Section 12.3, "Procedures," *Acceptance Criteria*, states, in part: "The applicant should discuss the method for the review and approval of procedures. The method should involve staff from reactor operations, radiation protection, and reactor administration and the review committee, as appropriate to the procedure under review and approval." Section 12.3 also states, "The applicant should propose a method for making changes to procedures. This method should cover minor changes with little or no safety significance, substantive changes that are safety significant, and temporary deviations caused by operational needs."

SHINE PSAR, Section 12.3, "Procedures," discusses operating procedures and the procedure program. It generally discusses the use of procedures and that the process for making changes and revisions is documented. However, additional detail is needed for the NRC staff to assess the adequacy of SHINE's preliminary operating procedures and procedure program, as addressed below:

a) Discuss the planned basic topics the procedures address or will cover.

b) Discuss the planned method for the review and approval of procedures.

c) Discuss the planned process required to make changes to procedures.

**Section 12.7 – Emergency Planning**

RAI 12.7-1 NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," Section 1.0, "Introduction," Evaluation Item 1.b., states that the reviewer should evaluate "[a] description of the location of the reactor facility including access routes."

Figure 1-1, SHINE Facility Site Layout, included in the Preliminary Emergency Plan, Revision 0, dated September 25, 2013, is not legible.
Provide a legible copy of the figure and/or an electronic copy that can be zoomed in and the site description, building names/numbers and labels, roads and parking lots, site boundaries showing fences and gates, major site features,

including access routes, and water bodies within approximately 1 mile of the site, which can be clearly read.

RAI 12.7-2 NUREG-0849, Section 3.0, “Organization and Responsibilities,” Evaluation Items 1.a. and 1.c., state that the emergency plan should describe “[t]he functions as applicable to emergency planning of Federal, State, and local government agencies and the assistance that they would provide in the event of an emergency” and “[t]he arrangements and agreements, confirmed in writing with local support organizations that would augment and extend the capability of the facility's emergency organization.”

The SHINE Preliminary Emergency Plan, Rev. 0, in Section 3.7, addresses arrangements and agreements made with local support organizations that would augment and extend the capability of the facility’s emergency organization.

Provide additional information describing whether letters of agreement with developed procedures for emergency response will be submitted with the Operating License application.

(Applies to RAIs 12.7-3 through 4)

NUREG-0849, Section 3.0, 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.”

RAI 12.7-3 The SHINE Preliminary Emergency Plan, Revision 0, Sections 3.3 and 3.4.4 describe the roles and responsibilities of on-shift Operators and ERO staff. Figure 3-1, shows both Operator and ERO Staff in the interrelationship diagram.

Specify whether the Operators and ERO staff are the same individuals under two different titles. In addition, describe the positions, duties, and responsibilities of the ERO staff, describe where that information can be found in the emergency plan, or justify why this information is not necessary.

RAI 12.7-4 The SHINE Preliminary Emergency Plan, Revision 0, Section 3.3, describes actions to be taken by the Operators when an emergency is declared.

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.

RAI 12.7-5 NUREG-0849, Section 3.0, Evaluation Item 1.f., states that the emergency plan should describe “[t]he identification by title of the individual in charge of directing emergency operations, including a line of succession, and responsibilities and authorities and those responsibilities which may not be delegated (such as notification and protective action decisions).”

The SHINE Preliminary Emergency Plan, Revision 0, Sections 3.2 and 3.3 describe the roles of the Shift Supervisor and the Emergency Director. However, the line of succession, authorities, and responsibilities is not clear between the shift supervisor and the emergency director.

Clarify the line of succession, and explain who is the SS if the SS is absent filling the roll of the ED, or explain why this information is not necessary.

(Applies to RAIs 12.7-6 through 7)

NUREG-0849, Section 3.0, Evaluation Item 1.g., states that the emergency plan should describe "the identification by title of the individual…including a line of succession, and authority and responsibilities for coordinating emergency preparedness planning, updating emergency plans and procedures, and coordinating plans with other applicable organizations."

RAI 12.7-6 The SHINE Preliminary Emergency Plan, Revision 0, Section 3.1, describes the Emergency Preparedness Manager's responsibilities; however the description does not include a line of succession for this individual and his/her authorities.

Provide this information or explain why it is not necessary.

RAI 12.7-7 The SHINE Preliminary Emergency Plan, Revision 0, Section 3.1, does not include the Emergency Preparedness Manager in any Organization Chart, or Line of Succession figure.

Show in the Emergency Plan figures where the Emergency Preparedness Manager fits into the SHINE Organization and Lines of Succession of the ED, or explain why this information is not necessary.

RAI 12.7-8 NUREG-0849, Section 4.0, "Emergency Classification System," states, in part, that "[e]ach class of emergency should be associated with particular emergency action levels and with particular immediate actions to provide appropriate graded response."

Provide a listing by title, with description, of implementing procedures for each class of emergency. Address whether this information is in an appendix to the emergency plan, or describe where in the SHINE application this can be found, or explain why this information is not necessary.

(Applies to RAIs 12.7-9 through 11)

NUREG-0849, Section 5.0, "Emergency Action Levels," states, in part, that each licensee's emergency plan should contain "emergency action levels, appropriate to the specific facility and consistent with Appendix I."

RAI 12.7-9 The first paragraph of Chapter 13 of the PSAR, Section 13b.2.5.5 "Quantitative Evaluation of Accident Evolution" states, "There is the possibility that an

inadvertent criticality event could occur within either a shielded area of the facility or an un-shielded area of the facility," however, Table 5-1 of the SHINE Preliminary Emergency Plan, Rev. 0, does not list an unshielded criticality accident as a postulated accident along with its associated emergency classification, maximum worker dose, and emergency action level

An unshielded criticality event has the potential for greater radiological impact than a shielded criticality event.

Supplement Table 5-1 and the emergency plan implementing procedures (EPIPs), as requested in RAI 12.7-9, to include this possible accident, or explain why this is not necessary.

RAI 12.7-10 The SHINE Preliminary Emergency Plan, Revision 0, Table 5.1, does not provide a full list of Emergency Action Levels for each accident condition.

Confirm that Table 5-1 will be provided with the full list of Emergency Action Levels for each accident condition with the FSAR.

RAI 12.7-11 The SHINE Preliminary Emergency Plan, Revision 0, Section 5.0, Emergency Action Levels," does not contain emergency action levels with initiating conditions, such as, effluent monitor set points appropriate to the facility and consistent with NUREG-0849 Appendix I.

Specify effluent monitors used to project dose rates and radiological effluent releases and include emergency action levels to initiate protective actions as per the guidance of NUREG-0849 or explain why this information is not necessary.

RAI 12.7-12 NUREG-0849, Section 6.0, "Emergency Planning Zones" (EPZs), Evaluation Items 1. and 2., states the emergency plan should identify the EPZ and, "if the EPZ is not consistent with Appendix II, the plan shall include an acceptable basis for the EPZ."

The SHINE Preliminary Emergency Plan, Revision 0, Section 6.0, "Emergency Planning Zones," addresses SHINE's implementation of ANSI/ANS-15.16-2008 and NUREG-0849 related to the identification of an EPZ at the SHINE facility. ANSI/ANS-15.16 and NUREG-0849 support an EPZ size of the "operations boundary," "100 meters," "400 meters," "800 meters," or a size "determined on a case-by-case basis." SHINE's proposed EPZ is not consistent with ANSI/ANS-15.16 or NUREG-0849.

Identify in the emergency plan, the EPZ size for the SHINE facility. If the EPZ is not consistent with ANSI/ANS-15.16-2008 or NUREG-0849, include an acceptable basis for the EPZ size selected or explain why an EPZ is not necessary.

RAI 12.7-13 NUREG-0849, Section 7.0, "Emergency Response," Evaluation Item 1.a., states that the emergency plan should cover "[t]he actions to notify and mobilize the

emergency organization and the applicable offsite support organizations for each emergency class."

The SHINE Preliminary Emergency Plan, Revision 0, Section 7.1.2, in Section 7.0, Emergency Response, does not clearly identify whose responsibility it is to classify an emergency event.

Clarify whose responsibility it is to classify an emergency event and incorporate this clarifying language into the next revision of the SHINE Emergency Plan, or explain why this information is not necessary.

RAI 12.7-14 NUREG-0849, Section 7.0, "Emergency Response," Evaluation Item 3., states that "[t]he emergency plan should provide a summary description of those actions that could be taken to mitigate or correct the problem for each emergency class."

The SHINE Preliminary Emergency Plan, Revision 0, Section 7.3, "Corrective Actions," addresses corrective actions for taking control of an emergency, however additional information is needed to assess the adequacy of actions that could be taken to mitigate or correct problems for each emergency class.

Provide a summary description of those actions that could be taken to mitigate or correct the problem for each emergency class, or describe where this detail can be found in the SHINE Preliminary Emergency Plan, or explain why this information is not necessary.

RAI 12.7-15 NUREG-0849, Section 7.0, "Emergency Response," Evaluation Item 2.a., states that the emergency plan should cover "[a] description of methods for gathering and processing information for assessment actions."

Describe the method(s) for assessing collateral damage to the facility, including IROFS, describe where this information can be found in the emergency plan, or explain why this information is not necessary.

RAI 12.7-16 NUREG-0849, Section 7.0, Emergency Response," Evaluation Item 4.a., states that the emergency plan should describe "[c]onditions for either partial or complete onsite evacuation, evacuation routes, and primary alternate assembly areas."

Confirm that alternate assembly areas and evacuation routes will be provided in the Final Safety Analysis Report (FSAR), as stated in Section 7.4.4 of Section 7.4, "On-site Protective Actions," of the SHINE Preliminary Emergency Plan, Revision 0.

(Applies to RAIs 12.7-17 through 18)

NUREG-0849, Section 7.0, Evaluation Item 4.b., states that the emergency plan should describe "[m]ethods to ensure personnel accountability and the

segregation of potentially contaminated personnel."

RAI 12.7-17 Describe the "contamination controls," as mentioned in Section 7.4.5 of Section 7.4, "On-site Protective Actions," of the SHINE Preliminary Emergency Plan, Revision 0 that will be in place throughout the facility and in close proximity to the contaminated area, describe where this is located in the emergency plan, or explain why this information is not necessary.

RAI 12.7-18 Define the threshold to categorize personnel being surveyed and evacuated through control points as "contaminated," and to be decontaminated before release, as stated in Section 7.4.5 of Section 7.4, "On-site Protective Actions," of the SHINE Preliminary Emergency Plan, Revision 0, or explain why this information is not necessary.

RAI 12.7-19 NUREG-0849, Section 7.0, Evaluation Item 4.c., states that the emergency plan should describe "[p]rotective measures and exposure guidelines for emergency personnel."

The SHINE Preliminary Emergency Plan, Revision 0, Section 7.4.7 of Section 7.4, On-site Protective Actions," does not include protective measures and exposure guidelines for emergency personnel.

Include protective measures and exposure guidelines for emergency personnel in the emergency plan or explain why this information is not necessary.

(Applies to RAIs 12.7-20 through 21)

NUREG-0849, Section 7.0, "Emergency Response," Evaluation Item 4.e., states that the emergency plan should describe "[t]he methods for monitoring radiation dose rates and contamination levels, both onsite and offsite, including provisions for transmitting collected information and data to the element of the emergency organization responsible for accident assessment."

RAI 12.7-20 Describe the methods for transmitting radiation dose rates and contamination levels onsite and offsite to the element of the emergency organization responsible for accident assessment.

RAI 12.7-21 The SHINE Preliminary Emergency Plan, Revision 0, Section 7.2.1, "Projections of Off-site Impacts," addresses source term information for emergencies; however the information provided is insufficient.

Provide the valid computer code(s) used to project doses or concentrations to the public or environment and associated assumptions, along with adequate justifications to show the validity of the assumptions, describe where this information can be found in the SAR, or justify why this information is not necessary.

RAI 12.7-22 NUREG-0849, Section 8.0, “Emergency Facilities and Equipment,” Evaluation Item 1, states that the emergency plan should describe an emergency support center (ESC).

Sections 7.2.2 and 8.2 of the SHINE Preliminary Emergency Plan, Rev. 0 do not clearly describe whether the ESC is a fixed area or capable of becoming mobile.

Provide a more complete description of the ESC such as its primary location, back-up location, capabilities, equipment, size, describe where this information is found in the Emergency Plan, or explain why this information is not necessary.

RAI 12.7-23 NUREG-0849, Section 8.0, “Emergency Facilities and Equipment,” states that “[t]he emergency plan should briefly describe the emergency facilities, types of equipment, and their location.”

Confirm that for each accident identified in Table 5-1 of the SHINE Preliminary Emergency Plan, Revision 0, the means of detecting accident conditions, the means of detecting any release of radioactive material or hazardous materials, and the means of alerting the operations staff of the accident conditions will be provided with the FSAR.

RAI 12.7-24 NUREG-0849, Section 8.0, “Emergency Facilities and Equipment,” Evaluation Item 3., states, in part, that “[t]he emergency plan should identify those measures that will be used to provide necessary assistance to persons injured or exposed to radiation.”

Describe where in the facility the first aid equipment is located, as stated in the SHINE Preliminary Emergency Plan, Revision 0, Section 8.4, “First Aid and Medical Facilities.” If First Aid equipment is staged throughout the SHINE facility, describe the locations of the First Aid equipment units.

(Applies to RAIs 12.7-25 through 6)

NUREG-0849, Section 8.0, “Emergency Facilities and Equipment,” Evaluation Item 3.c., states that the emergency plan should describe “[w]ritten agreements with hospitals to ensure that medical services are available and the staff is prepared to handle radiological emergencies.”

RAI 12.7-25 Identify the facilities and provide the written Letter of Agreement(s) with hospitals to ensure that medical services are available and the medical staff is prepared to handle radiological emergencies.

RAI 12.7-26 Describe whose responsibility it is for decontaminating the ambulance, medical personnel, and the medical facility and describe where the procedures for decontamination of emergency medical services/equipment/personnel can be found, or explain why this information is not needed.

RAI 12.7-27 NUREG-0849, Section 8.0, “Emergency Facilities and Equipment,” Evaluation Item 4., states that the emergency plan should “adequately identify the emergency communications systems that will be available to communicate instructions and information both onsite and offsite throughout the course of an emergency.”

As stated in the SHINE Preliminary Emergency Plan, Revision 0, Section 8.5.2, “Off-site Communications,” confirm that a description of the backup off-site communications system will be provided with the FSAR.

RAI 12.7-28 NUREG-0849, states that “[a]n emergency plan shall be prepared that addresses the necessary provisions for coping with radiological emergencies.”

The SHINE Preliminary Emergency Plan, Revision 0, Section 8.6, “Contingency Planning,” addresses arrangements made with alternate facilities and sources of alternate equipment.

Confirm that arrangements have been made with alternate facilities and ensure that sources of alternate equipment are available, and submit, in the FSAR, the written Letters of Agreement with those alternate facilities describing services, equipment, and provisions to be provided in an emergency.

(Applies to RAIs 12.7-29 through 30)

NUREG-0849, Section 9.0, “Recovery,” states, in part, that the “emergency plan should describe the criteria for restoring the reactor facility to a safe status.”

RAI 12.7-29 SHINE Preliminary Emergency Plan, Revision 0, Section 9.0, “Recovery,” characterizes recovery differently from the guidance of NUREG-0849, Section 9.0, which reads, “Recovery consists of those actions required to restore the facility and its impact on public health and safety to a safe status.”

Explain the bases for presenting a recovery condition that is different than provided by the guidance, and why the alternate is acceptable, or provide information to reflect conditions, as stated in the approved guidance.

RAI 12.7-30 The staff could not find in the SHINE Preliminary Emergency Plan, Revision 0, aspects of SHINE’s plans for adequately restoring the facility to a safe status after an accident and recovery after an emergency, the methods and responsibilities for assessing the damage to and status of the facility’s capabilities to safely control radioactive material, or hazardous chemicals associated with the process.

Identify the section within the SHINE Preliminary Emergency Plan, Revision 0, where this information can be found, describe the methods and responsibilities for assessing the damage to the facility and status of the facility’s capabilities to safely control radioactive material or hazardous chemicals associated with the process, or explain why this information is not necessary.

RAI 12.7-31 NUREG-0849, Section 9.0, “Recovery,” Evaluation Item 1.a., states that the emergency plan should specify “[t]hat the recovery procedure(s) will be written and approved as needed.”

Explain who will write and approve the recovery plans and procedures, what elements will be included, and where the plans will be kept.

RAI 12.7-32 NUREG-0849, Section 10.0, “Maintaining Emergency Preparedness,” Evaluation Item 1., states that “[t]he emergency plan should describe an initial training and periodic retraining program designed to maintain the ability of emergency response personnel to perform assigned functions…”

Confirm that the list of specific training topics to be provided in the FSAR, as stated in Section 10.1.2 of the SHINE Preliminary Emergency Plan, Revision 0, will include training targeted to personnel responsible for decision-making and transmitting emergency information and instructions, personnel responsible for accident assessment, radiological monitoring and analysis teams, first aid and rescue personnel, medical support personnel, police, security, ambulance and firefighting personnel.

(Applies to RAIs 12.7-33 through 34)

NUREG-0849, Section 10.0, “Maintaining Emergency Preparedness,” Evaluation Item 2.a., states that the emergency plan should provide for “[a]nnual onsite emergency drills, to be conducted as action drills.”

RAI 12.7-33 Describe how emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue, and other similar events; describe where this information is found in the emergency plan; or explain why this information is not necessary.

RAI 12.7-34 The staff did not find in the emergency plan the frequency, performance objectives, and plans for the emergency response training that SHINE will provide to workers. Include the items below in the emergency plan or explain why this information is not necessary:

a) The topics and general content of training programs for SHINE’s onsite and offsite emergency response personnel to satisfy the objectives described above;

b) The administration of the training program including responsibility for training, the positions to be trained, the schedule for training, the frequency of retraining, the use of team training, and the estimated number of hours of initial training and retraining;

c) The training to be provided on the use of protective equipment such as respirators, protective clothing, monitoring devices, and other equipment used in emergency response;

d) The training program for onsite personnel who are not members of the emergency staff; and

e) Any special instructions and orientation tours that SHINE would offer to fire, police, medical, and other emergency personnel (not employed by SHINE) who may be required to respond to an emergency to ensure that they know the emergency plan, assigned duties, and effective response to an actual emergency.

APPENDIX 12C – QUALITY ASSURANCE PROGRAM DESCRIPTION

The following questions of this chapter are based on a review of Appendix 12C in Chapter 12 of the SHINE PSAR (ADAMS Accession No. ML13172A275) using ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors."

**Appendix 12C Section 1 - Introduction**

RAI 12C.1-1 10 CFR 50.34(a)(7) requires each applicant for a construction permit to build a production or utilization facility to 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 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.

Confirm to what extent the SHINE QAPD implements the guidance provided in ANSI/ANS-15.8-1995 across the facility, identifying and justifying any deviations from the guidance.

RAI 12C.1-2 ANSI/ANS-15.8-1995, "Section 1.3, "Definitions," defines safety-related items: "Those physical structures, systems, and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents."

The SHINE Quality Assurance Program Description (QAPD), "Executive Summary" and Section 1, "Introduction," the last paragraph, state that SHINE utilizes a definition of safety-related systems, structures, and components (SSCs) for the Quality Level 1 SSCs, where appropriate, and utilizes a portion of the definition of Items Relied on for Safety (IROFS), from 10 CFR 70.4, "Definitions," for Quality Level 2 SSCs, where appropriate. Further, Section 1.3, Definitions, of the QAPD states that definitions for use at SHINE are located in a stand-alone document and are under document control.

Chapter 3, Section 3.5.1.1.1 of the SHINE PSAR, defines safety-related SSCs as those SSCs that are relied upon to remain functional during and following design

basis events to ensure: (a) the integrity of the primary system boundary; (b) the capability to shutdown the target solution vessel and maintain the target solution in a safe shutdown condition; or (c) the capability to prevent or mitigate the consequences of accidents that could result in potential off-site exposures comparable to the applicable guideline exposures in 10 CFR Part 20.

Chapter 3, Section 3.5.1.1.2 of the SHINE PSAR, defines IROFS as those SSCs, equipment, and activities of personnel that are relied upon to prevent or mitigate potential accidents at the facility that would exceed the performance requirements on 10 CFR 70.61 or to mitigate their potential consequences.

Clarify (a) how the QAPD definitions for safety-related SSCs for the Quality Level 1 SSCs and the definition of IROFS for Quality Level 2 SSCs are consistent with ANSI/ANS-15.8-1995 and (b) whether those definitions located in the stand-alone definitions document are consistent with those provided in Section 1.3 of ANSI/ANS-15.8-1995.

**Appendix 12C Section 1.2 - Application**

RAI 12C.1.2-1 ANSI/ANS-15.8-1995, Section 1.2, “Application,” states, in part, that “[a]ctivities included in the quality assurance program shall be, as a minimum, those related to the reactor safety and protection system, engineered safety features, and the applicable radiation monitoring systems as identified in the Limiting Conditions for Operations section of the Technical Specifications for a given reactor.”

The SHINE QAPD, Section 1.2, “Application,” states that “[a]ctivities included in this quality assurance program shall be, as a minimum, those related to accelerator safety, material processing safety, criticality safety, engineered safety features and applicable radiation monitoring systems, as identified in the Limiting Conditions for Operations section of the Technical Specifications.”

Provide clarification as to whether “accelerator safety,” as used in the QAPD, is comparable to “reactor safety and protection system,” as stated in ANSI/ANS-15.8-1995.

RAI 12C.1.2-2 ANSI/ANS-15.8-1995, Section 1.2, “Application,” states, in part, that the operating phase license or permit imposes additional requirements related to the conduct of operations. These additional program requirements are defined in Section 3 of the standard.

The SHINE QAPD, Section 3, “Facility Operations,” states that “[t]his section provides the elements of a quality assurance program for conduct of operation at the SHINE facility.” The last paragraph of the QAPD Section 1.2, “Application,” states that “[t]he operating phase will impose additional requirements related to the conduct of operations.”

Clarify what additional requirements related to the conduct of operations, beyond those already included in Section 3 of the QAPD, need to be imposed, and

whether this will be accomplished by revising the QAPD or other means.

**Appendix 12C Section 2.1 - Organization**

RAI 12C.2.1-1 ANSI/ANS-15.8-1995, Section 2.1, "Organization," states, in part, that "[p]ersons responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed, need sufficient authority, access to work areas, and freedom to: (a) identify problems; (b) initiate, recommend, or provide corrective action; and (c) ensure corrective action implementation."

The SHINE QAPD, Section 2.1, Subsection "Chief Operating Officer (COO)" states that "[a]uthority is also provided to access necessary work areas and encourages managers and employees to identify problems, initiate, recommend or provide corrective action and ensure corrective action implementation."

Clarify whom the authority is being provided to, and who "encourages managers and employees to identify problems, initiate, recommend or provide corrective action and ensure corrective action implementation."

(Applies to RAIs 12C.2.1-2 through 4)

ANSI/ANS-15.8-1995, Section 2.1, "Organization," states that "[t]he organizational structure and assignment of responsibilities shall be defined and documented such that: (a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and (b) quality achievement is verified by persons not directly performing the work."

RAI 12C.2.1-2 The SHINE QAPD Section 2.1, Subsection "Chief Operating Officer (COO)" states that "[t]he COO is responsible for all external operations of SHINE, including supplier organizations." It further states that the "COO is responsible for integrating all quality requirements as defined in the QAPD across the internal and external organization and reports to the CEO [Chief Executive Officer] on all matters concerning quality." The SHINE Functional Organizational Chart, as provided in Enclosure 1 of the QAPD, does not show a reporting line between the COO and external (supplier) organizations.

Provide clarification regarding the COO's responsibilities for external operations of SHINE and the consistency between the description provided in Section 2.1 and the Functional Organizational Chart shown in Enclosure 1 of the QAPD.

RAI 12C.2.1-3 The SHINE QAPD, Section 2.1, Subsection, “Chief Technology Officer (CTO)” states that the CTO is “responsible for leading the development of the technology necessary for the organization’s success and periodically reviews cost, schedule, program development activities, technical adequacy of design development, progress reports, quality assessment results, and other program-related information.”

Clarify how the CTO’s responsibilities align with the COO’s responsibilities, which include integrating all quality requirements, as defined in the QAPD across the internal and external organizations and reporting to the CEO on all matters concerning quality. Further, clarify how the CTO’s responsibilities to periodically review quality assessment results are depicted on the Functional Organizational Chart, as shown in Enclosure 1 of the QAPD.

RAI 12C.2.1-4 The SHINE QAPD, Section 2.1.2, “Quality Assurance Organizational Independence,” states that “[i]ndependence shall be maintained between the organizations performing the checking (quality assurance and quality control) functions and the organizations performing the functions.”

Clarify the definitions of “checking” and “quality control” as used in the QAPD.

**Appendix 12C Section 2.3 – Design Control**

RAI 12C.2.3-1 ANSI/ANS-15.8-1995, Section 2.3, “Design Control,” states: The responsible design organization shall prescribe, develop, document, and preserve the design of the structures, systems, and components of the research reactor facility.”

The SHINE QAPD, Section 2.3, “Design Control,” states, in part, that “[t]his section describes the requirements for establishing and implementing a process to control the design, design changes, and temporary modifications subject to the provisions of the QAPD.”

Clarify if the statement about control of temporary modifications is in reference to temporary modifications as discussed in ANSI/ANS-15.8-1995, Section 3.10, “Configuration Control,” or otherwise, clarify how it meets the requirements of the standard.

RAI 12C.2.3-2 ANSI/ANS-15.8-1995, Section 2.3.1, “Design Requirements,” states: “Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented.”

The SHINE QAPD, Section 2.3.1, “Design Requirements,” states: “Applicable design inputs, such as performance requirements, regulatory requirements, codes and standards, shall be identified and documented.”

Clarify how the QAPD provides for identification and documentation of design bases, as required by the standard.

RAI 12C.2.3-3 ANSI/ANS-15.8-1995, Section 2.3.3, “Design Verification,” states, in part, that “[i]n all cases, the design verification shall be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations.”

The SHINE QAPD, Section 2.3.3, “Design Verification,” states that “[i]n all cases, the design verification shall be completed prior to reliance upon safety-related SSCs.”

Clarify how the QAPD provides for completion of design verification prior to reliance upon the computer program to perform its function in operations. Also, clarify how the QAPD provides for completion of design verification prior to reliance upon the SSCs that are not classified as safety-related, but to which these quality requirements may apply, in accordance with the graded approach to quality.

RAI 12C.2.3-4 ANSI/ANS-15.8.1-1995, Section 2.3.5, “Commercial Grade Items,” states, in part, that “[w]hen a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier’s published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.”

The SHINE QAPD, Section 2.3.5, “Commercial Grade Items,” contains a similar statement but uses the term “item” instead of “component part.”

Clarify the definition of the term “item” and address the difference between “item” and “component part.”

**Appendix 12C Section 2.4 – Procurement Document Control**

RAI 12C.2.4-1 ANSI/ANS-15.8-1995, Section 2.4, “Procurement Document Control,” states, in part, that “[a]t each level of procurement, the procurement documents shall provide for access to the supplier’s plant facilities and records, for inspection or audit by the purchaser, the designated representative, or other parties authorized by the purchaser.”

The SHINE QAPD, Section 2.4, “Procurement Document Control,” states, in part, that “[a]t each level of procurement, the procurement documents shall provide for access to the supplier’s plant facilities and records, for inspection or assessment by SHINE, a designated representative or other parties authorized by SHINE.”

Clarify the definition of an “assessment” of supplier’s plant facilities and records by SHINE and how this definition meets the requirements for an audit.

RAI 12C.2.4-2 ANSI/ANS-15.8-1995, Section 2.4, “Procurement Document Control,” further states that “[t]he procurement documents shall include purchaser’s requirements for reporting and approving disposition of supplier nonconformances associated

with the items or services being procured."

The SHINE QAPD, Section 2.4, "Procurement Document Control," (second paragraph), states that "[p]rocedures for procurement documents shall include SHINE's requirements for reporting and approving disposition of supplier's non-conformances associated with the items or services being procured."

Clarify how the QAPD provides for the procurement documents, rather than procedures for procurement documents, to include the necessary requirements for reporting and approving disposition of supplier nonconformances, as required by ANSI/ANS-15.8-1995.

**Appendix 12C Section 2.5 – Procedures, Instructions, and Drawings**

RAI 12C.2.5 ANSI/ANS-15.8-1995, Section 2.5, "Procedures, Instructions, and Drawings," states: "Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings appropriate to the circumstances." It further states: "These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished."

The SHINE QAPD, Section 2.5, "Procedures, Instructions, and Drawings" (second paragraph), states: "Procedures shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished."

Clarify if the QAPD provides for instructions and drawings to include or reference appropriate quantitative or qualitative acceptance criteria, as required by ANSI/ANS-15.8-1995.

**Appendix 12C Section 2.7 – Control of Purchased Items and Drawings**

RAI 12C.2.7 ANSI/ANS-15.8-1995, Section 2.7.3, "Verification Activities," states, in part, that "[b]ased on the complexity of the product and importance to safety, the purchaser shall consider independently verifying the quality of the supplier's product through source surveillances, inspections, audits, or review of the supplier's nonconformances, dispositions, waivers, and corrective actions."

The SHINE QAPD, Section 2.7.3, "Verification Activities," states, in part, that "[b]ased on the complexity of the product and importance to safety, SHINE shall consider independently verifying the quality of a supplier's product through source surveillances, inspections, assessments or review of the supplier's non-conformances, dispositions, waivers and corrective actions."

Clarify the definition of an "assessment" of supplier's nonconformances, dispositions, waivers, and corrective actions and how this definition meets the requirement for an audit.

**Appendix 12C Section 2.10 – Inspections**

RAI 12C.2.10 ANSI/ANS-15.8-1995, Section 2.10, "Inspections," states, in part, that "[r]ecords of inspection personnel's qualification shall be established and maintained by the employer."

The SHINE QAPD, Section 2.10, "Inspections" (second paragraph), states, in part, that "records of inspection personnel's qualification shall be established and maintained by SHINE."

Clarify if the QAPD provides for the records of the inspection personnel's qualification to be maintained by their employer if that employer is not SHINE (e.g., a contractor of SHINE).

**Appendix 12C Section 3 – Facility Operations**

RAI 12C.3 ANSI/ANS-15.8-1995, Section 3, "Facility Operations," states, in part, that "[m]any of the program requirements [for conduct of operations] are satisfied by existing documentation, or by procedures and activities required by other standards and requirements of the chartering or licensing agency."

The SHINE QAPD, Section 3, "Facility Operations," states, in part, that "[m]any of the program requirements are satisfied by existing documentation, or by procedures and activities required by other standards and requirements of NRC and [the] State of Wisconsin."

Clarify what existing documentation, procedures, and activities satisfy the program requirements and identify which requirements are considered to be satisfied by such documents, procedures, or activities. In addition, clarify the meaning of the phrase "other standards and requirements of NRC and State of Wisconsin."

**Appendix 12C Section 3.3 – Performance Monitoring**

RAI 12C.3.3 ANSI/ANS-15.8-1995, Section 3.3, "Performance Monitoring," states, in part, that "[m]anagement shall document periodical observations and identify any deficiencies." It also states that "[m]anagement should assess deficiencies to ensure the execution of corrective actions that will prevent recurrence."

The SHINE QAPD, Section 3.3, "Performance Monitoring," states, in part, that "SHINE shall document periodic observations of operations and identify and assess any deficiencies to ensure the execution of corrective actions that will address or prevent recurrence."

Clarify the difference between the phrase "address or prevent recurrence" (as used in the QAPD) and "prevent recurrence" (as used in ANSI/ANS-15.8-1995).

**Appendix 12C Section 5 – Decommissioning**

RAI 12C.5 ANSI/ANS-15.8-1995, Section 5, "Decommissioning," states: "The quality assurance requirements for a facility during the decommissioning phase are addressed by the appropriate sections of this standard, and American National Standard for Decommissioning of Research Reactors, ANSI/ANS-15.10-1994 [4]."

The SHINE QAPD, Section 5, "Decommissioning," states: "The quality assurance requirements for the SHINE facility during the decommissioning phase are addressed by the appropriate sections of this QAPD and American National Standard for Decommissioning of Research Reactors, ANSI/ANS-15.1-1990;W2004."

Clarify what sections of the QAPD address the quality assurance requirements for a facility during the decommissioning phase. In addition, clarify why the QAPD includes references to a different ANSI/ANS standard (ANSI/ANS-15.1-1990: The Development of Technical Specifications for Research Reactors), compared to the one referenced in ANSI/ANS-15.8-1995, Section 5.

**Appendix 12C Enclosure 2 – Graded Approach to Quality**

(Applies to RAIs 12C.E2-1 through 4)

ANSI/ANS-15.8-1995, Section 1.3, "Definitions," defines safety-related items: "Those physical structures, systems, and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents."

RAI 12C.E2-1 The SHINE QAPD, "Graded Approach to Quality," Enclosure 2, defines three levels of implementation of the QAPD. It states that "QL-1 shall implement the full measure of this QAPD and shall be applied to Safety-Related Structures, Systems and Components."

(a) Clarify whether the definition of "safety-related" as used in Enclosure 2 is consistent with ANSI/ANS-15.8-1995, Section 1.3;

(b) Identify which section of the QAPD defines safety-related activities and systems, structures, and components.

RAI 12C.E2-2 The QAPD Enclosure 2, Graded Approach to Quality, states, in part: "QL-2 will include the quality activities performed by the licensee, generally on a continuing basis, that are applied to ensure the items are available and reliable to perform their safety functions when needed. These quality activities include configuration management, maintenance, training and qualifications, procedures,

assessments, incident investigations, records management and other quality assurance elements. These quality activities are embodied in this QAPD and will be further specified in the preliminary and/or final safety analysis report as appropriate."

Clarify the following:

(a) the meaning of the phrase "generally on a continuing basis," as used in the definition of QL-2 in Enclosure 2;

(b) why items that "are available and reliable to perform their safety functions when needed" are not considered safety-related SSCs;

(c) to what extent the requirements described in the QAPD will be applicable for the activities and SSCs defined under QL-2, to ensure their availability and reliability to perform their safety function; and

(d) to why the quality activities listed in the definition of QL-2 in Enclosure 2 are limited to configuration management, maintenance, training and qualifications, procedures, assessments, incident investigations, records management, and do not include other elements of the quality assurance program.

RAI 12C.E2-3 The QAPD Enclosure 2, Graded Approach to Quality, states, in part: "QL-3 will include the non-safety related 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."

Clarify to what extent the requirements described in the QAPD will be applicable to QL-3 quality activities and SSCs.

RAI 12C.E2-4 The QAPD Enclosure 2, Graded Approach to Quality, states, in part: "QL-2 will include the quality activities performed by the licensee, generally on a continuing basis, that are applied to ensure the items are available and reliable to perform their safety functions when needed. These quality activities include configuration management, maintenance, training and qualifications, procedures, assessments, incident investigations, records management and other quality assurance elements. These quality activities are embodied in this QAPD and will be further specified in the preliminary and/or final safety analysis report as appropriate."

SHINE PSAR, Chapter 3 "Design of Structures, Systems, and Components," Section 3.5.1.2.2, QL-2, states, in part: "This Quality Level shall be applied in conformance with an approved QAP and applies to the design of SSCs which are relied upon to limit the following in accordance with 10 CFR 70.61…"

Clarify why there is a difference between the definitions of Quality Level QL-2 as provided in the QAPD, Enclosure 2, and the one included in Section 3.5.1.2.2 of PSAR Chapter 3.

## 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.

**Generic Information Request**

RAI 13a2-G As required by 10 CFR 50.34(a)(4), 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."

Many of the accident analyses in Chapter 13 make assumptions about the source term and release fractions through barriers, based on the design characteristics of the various systems, structures and components in the system.

For example, SHINE PSAR, Section 13a2.2.1.4, "Quantitative Evaluation of Accident Evolution," states, in part: "The total release to the RCA through the IU cell penetrations during the accident is assumed to be no more than 10 percent of the airborne activity in the IU cell based on design characteristics of the penetrations."

a) Discuss whether these release fractions are design specifications that the facility is being designed to.

b) Provide information stating whether all of these assumptions are being tracked so that the design will account for all of the assumptions.

c) Discuss how these release fractions will be verified in the as constructed facility.

d) Describe whether there will be periodic testing over the facility's lifetime to ensure that the assumptions are still valid, as is done with periodic containment leakage testing in operating reactors.

Provide a discussion of how the design of the facility provides assurance that the assumed release fractions are bounding values, as compared to actual releases that would result in an accident scenario.

**Section 13a2.1 – Accident-Initiating Events and Scenarios**

RAI 13a2.1-1 The ISG Augmenting NUREG-1537, Part 2, Section 13a2.1, "Accident-Initiating Events and Scenarios," recommends that external events affecting more than one unit be considered as a possible maximum hypothetical accident.

SHINE PSAR, Section 13a2.1.1.1, "Initial Conditions and Assumptions," states, in part, "[b]ecause the SHINE facility is being designed to withstand external events … scenarios that involve multiple IUs are not analyzed further." However, a group of similar systems or components failing together as a result of a single external event is still considered a single failure.

Provide the basis for rejecting events that affect multiple units. For example, if a seismic or flooding event, or aircraft impact affected one unit, what measures would be in place to prevent that event from affecting the others?

(Applies to RAIs 13a2.1-2 through 8 and RAIs 13a2.2-1 through 3)

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 13a2.1-2 SHINE PSAR, Section 13a2.1.1.1, "Initial Conditions and Assumptions," states that the TSV is too robust to rupture.

Provide the basis for this statement. Include a thorough description of the TSV's robustness with respect to possible accident loadings and challenges to the integrity of the primary boundary including undetected corrosion and defects.

RAI 13a2.1-3 SHINE PSAR, Section 13a2.1.2.1, "Identification of Causes, Initial Conditions, and Assumptions," discusses the insertion of excess reactivity. Since the system is over-moderated, decreasing the density of the coolant or introducing voids in the primary closed loop cooling system (PCLS) would result in a positive reactivity insertion.

Provide additional information discussing whether the situation of decreasing the density of the coolant or introducing voids in the PCLS has been analyzed as a possible accident scenario. Provide the reactivity worth of changing the density of the coolant from nominal operating conditions to fully voided conditions. Compare that reactivity worth to the margin of criticality in the system.

RAI 13a2.1-4 SHINE PSAR, Section 13a2.1.2.2.3, “Moderator Addition Due to Cooling System Malfunction,” discusses the addition of moderator due to a cooling system malfunction.

Provide additional information discussing whether a TOGS condenser heat exchanger (HX) failure or recombiner HX failure and water ingress has been considered as a possible accident scenario.

RAI 13a2.1-5 SHINE PSAR, Section 13a2.1.2.2.1, “Increase in the Target Solution Density During Operations,” discusses increases in the target solution density during operations and concludes that “this event causes a positive reactivity addition, but not large enough to reach a critical condition…” However, additional information is needed to demonstrate that the system will not become critical.

Provide the expected reactivity insertion, following the maximum credible deflagration. The void fraction due to radiolytic decomposition will seldom, if ever, be zero, so it seems possible that the over-pressurization resulting from a deflagration could result in a $k_{eff}$ greater than that occurring during cold startup, since the concentration of the solution is greater than what it is during startup.

Describe the approach used to determine this maximum $k_{eff}$ value.

RAI 13a2.1-6 “Scenario C- Loss of or Reduced PCLS and LWPS [light water pool system] Flow” is the most limiting of the reduction of cooling events, as described in SHINE PSAR, Section 13a2.1.3.1, “Identification of Causes, Initial Conditions, and Assumptions.” It is described as a low probability event not expected to occur during the facility lifetime.

Provide the technical basis for this claim.

RAI 13a2.1-7 SHINE PSAR, Section 13a2.1.8.2, “General Scenario Description,” provides a general scenario description of potential power oscillations. However additional information is needed for the staff to verify that the system will not become critical.

Provide the expected magnitude of potential power oscillations, and a description of the mechanisms that are in place to ensure that they are “self-limiting.”

RAI 13a2.1-8 SHINE PSAR, Section 13a2.1.1.1, “Initial Conditions and Assumptions,” states that “the postulated [maximum hypothetical accident] MHA in the [irradiation facility] IF is a large rupture of the TSV dump tank resulting in a complete release of the target solution and fission product inventory into one IU cell.”

SHINE PSAR, Section 13a2.1.1.2, “General Scenario Description,” states that “the IF postulated MHA general scenario is a release of irradiated target solution to the IU cell as a result of a loss of TSV integrity.”

SHINE PSAR, Section 13a2.2.1.1, “Initiating Event,” states “the target solution

release in the IF is postulated to be a large rupture of the TSV and SASS resulting in a complete release of the target solution and fission product inventory into one IU cell."

Based on the statements above, additional information is needed for NRC staff to determine the adequacy of SHINE's evaluation of the maximum hypothetical accident in the irradiation facility.

Provide information indicating whether the maximum hypothetical accident in the irradiation facility is a result of a large rupture of the TSV or TSV dump tank.

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

RAI 13a2.2-1 SHINE PSAR, Section 13a2.2.1.5, "Radiation Source Term Analysis," lists the factors used to calculate the airborne and respirable source terms. The values used in this analysis for these factors are listed in Tables 13a2.2.1-2, 13a2.2.1-3, and 13a2.2.1-4.

Provide the technical basis for the quantities provided in Tables 13a2.2.1-2, 13a2.2.1-3, and 13a2.2.1-4 for each specific scenario considered.

RAI 13a2.2-2 SHINE PSAR, Section 13a2.2.2.1, "Initiating Events," states that a 5 degree C drop would not be expected to result in criticality. However, additional information is needed for the staff to verify that the system will not become critical.

Discuss what features limit the temperature drop to 5 degrees C. Provide information indicating how much the temperature would have to drop before criticality occurs.

RAI 13a2.2-3 SHINE PSAR, Figure 9a2.1-1, "RVZ1 Ventilation Flow Diagram," shows a HEPA filter located in the outlet duct of the irradiation unit ventilation system. While a description of this filter is also provided in SHINE PSAR, Section 9a2.1.1, there is no mention of this filter in PSAR Chapter 13, "Accident Analysis."

Additional information is needed on this filter for NRC staff to determine the adequacy of SHINE's accident analysis.

Provide information indicating whether decontamination credit has been given to the filter identified above in the accident analysis.

RAI 13a2.2-4 SHINE PSAR, Section 13a2.2.1.6, "Radiological Consequence Analysis," provides a high-level description of the SHINE radiological dose consequence analysis.

Additional information is needed for NRC staff to determine the adequacy of SHINE's radiological dose consequence analysis as part of its accident analysis.

Provide information on dose calculations, including a description of the methods and codes used, important input parameter values, and calculated values of dose components (e.g., inhalation dose, immersion dose, ground contamination dose, etc.) Also, provide information describing any important assumptions made while performing dose calculations.

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

(Applies to RAIs 13b.1-1 through 2 and 13b.2)

As required by 10 CFR 50.34(a)(4), "[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, "Radiosiotope Production Facility Accident Analyses," the NRC staff has determined that the "use of ISA methodologies, as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS, 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 13b.1-1 The ISG Augmenting NUREG-1537, Part 2, Section 13b.1, "Radioisotope Production Facility Accident Analysis Methodology," states that an "integrated safety analysis should be performed for each process or process segment" in the radioisotope production facility.

The cover letter to part two of the application for a construction permit, dated May 31, 2013, (ADAMS Accession No. ML13172A361), states that the ISA Summary will be provided in the Operating License Application. Based on the process descriptions and hazards identified in the PSAR, certain engineered safety features should be identified and described in the PSAR if they will be constructed or procured and installed under the construction permit.

Address the following:

a) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;

b) The consequence and the likelihood of occurrence of each potential accident sequence identified, and the methods used to determine the consequences and likelihoods; and

c) Each passive engineered or active engineered IROFS, the characteristics of the IROFS' preventive, mitigative, or other safety function; and the assumptions and conditions under which the IROFS is relied upon to support compliance with the performance requirements of 10 CFR 70.61.

RAI 13b.1-2 The ISG Augmenting NUREG-1537, Part 2, Section 13b.1.1, "Operations Conducted Outside of the Reactor," states that "[t]he information in this section (13b, part 2) should provide the reviewer the assurance that the objectives stated in Part 1 of this section in NUREG-1537, Part 1, have been achieved. All potential accidents at the facility have been considered and their consequences adequately evaluated."

Several sections of SHINE PSAR, specifically in Chapters 1, 3, 4, 6, 9, and 13, contain information regarding radiological hazards, chemical hazards, and facility hazards. Chapter 9 indicates that there are nearly 400 accident scenarios, but Sections 13b.1 and 13b.2 describes only 6 accident sequences in the Radioisotope Production Facility (RPF).

The accident analysis describes a few example accident scenarios that the SHINE PSAR states are bounding, but does not describe all accident scenarios that could result in high or intermediate consequences. In order for NRC staff to determine the adequacy of SHINE's accident analysis, additional information is needed on all accident scenarios that could result in high or intermediate consequences, including a designation of the IROFS that prevent or mitigate consequences. Similarly, information is also needed that describes all accident sequences that could result in high or intermediate chemical consequences, including an identification of the SSCs provided for their prevention and mitigation.

Additionally, SHINE PSAR, Section 13b.2, "Analyses of Accidents with Radiological Consequences," states that active engineered controls are fail-safe; however, the application does not describe the accident sequences or active engineered controls in sufficient detail for staff to confirm that actuation of the controls are not necessary for them to perform their safety function.

a) Provide the consequence and likelihood of each potential accident sequence, and the methods used to determine the consequences and likelihoods.

Additionally, provide each of the IROFS in each accident scenario, and describe each engineered IROFS' safety function and its availability and reliability to perform that safety function when needed, including any engineered IROFS that will be the sole item preventing or mitigating a high or intermediate consequence accident. Describe all passive engineered and active engineered IROFS that prevent or mitigate the accident scenarios with high or intermediate consequences. For accident sequences involving chemical consequences, identify the SSCs provided for the prevention and mitigation of the accident sequence.

b) Provide the basis for asserting that active engineered controls are fail-safe.

RAI 13b.2 The ISG Augmenting NUREG-1537, Part 2, Section 13b.2, Chemical Process Safety for the Radioisotope Production Facility, states that the application should include a chemical process description, chemical accident description, chemical accident consequences, chemical process safety controls, and chemical process surveillance requirements.

Additionally, the ISG Augmenting NUREG-1537, Part 2, Section 6b, states that the chemical performance requirements in 10 CFR 70.61(b)(4) and (c)(4) have been found to be acceptable criteria for chemical-related accident sequences.

As used in the ISG, the term, "performance requirements" is not intended to mean that the performance requirements of 10 CFR 70.61 are required by regulation, only that their use as accident consequence and likelihood criteria would be found acceptable by NRC staff. Chemical exposure criteria different from those described in this ISG will be acceptable if an adequate basis is provided for the NRC staff to make the determination needed to issue or continue a license.

The PSAR application states that exothermic reactions between chemicals stored on site are prevented by segregation and isolation.

Identify the incompatible chemicals and identify their storage and use locations in the facility, to demonstrate adequate segregation and isolation.

CHAPTER 19 – ENVIRONMENTAL REVIEW (ER)

The following questions of this chapter are based on a review of Chapter 19 of SHINE's Environmental Review (ADAMS Accession Nos. ML13172A307 and ML13172A309) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, and 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."

**Section 19.2 – Proposed Action**

RAI 19.2-1 The ISG Augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the applicant should describe the equipment material used during construction.

Table 19.2.0-2, "Proposed Construction/Demolition Equipment Used in the Construction, Preoperational, and Decommissioning Phases" (ADAMS Accession No. ML13172A307) of the SHINE Environmental Review (ER) provides proposed equipment to be used in the construction, preoperational, and decommissioning phases. By letter dated October 4, 2013, SHINE's response to RAI Transportation Request No. 3 states that a concrete batch plant would be located on site. However, a concrete plant was not identified in Table 19.2.0-2 of the ER.

Provide clarification as to whether a concrete batch plant would be located on the proposed SHINE site. Additionally, if a concrete batch plant would be located on site, provide the following information:

a) The type of concrete plant (e.g., ready mix, central mix).

b) The volume of concrete required for construction and volume of component raw materials required for the mix.

c) The likely source of procurement for the raw materials.

d) Estimated air emissions associated with the concrete batch plant.

e) If necessary, update the data, assumptions, calculations, or analyses in the ER based on the whether or not a concrete batch plant would be located on site.

RAI 19.2-2 The ISG Augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the applicant should provide a schedule describing the major phases of the proposed action, including construction, operational, and decommissioning activities.

Additional information is required on the schedule and activities for these phases:

a) Section 19.2 of the SHINE ER, "Proposed Action," identifies a 12-month construction period and the response to RAI Proposed Action Request No. 3 states that SHINE assumed a 12-month construction period. However, by letter dated October 4, 2013, SHINE's response to RAI Air Quality Request No. 1 states that the actual construction schedule would be 12 months, however SHINE used 24 months as a conservative measure to estimate emissions. Similarly, the response to RAI Air Quality Request No. 5 states that the duration of decommissioning activities would be 12 months, however the response to Proposed Action Request No. 3 states that SHINE assumed a 6-month decommissioning period, which was used to estimate diesel fuel usage.

   Provide clarification regarding the length of the construction, operational, and decommissioning phases and, if necessary, update the data, assumptions, calculations, or analyses in the ER based on the length of the construction, operations, and decommissioning phase.

b) Section 19.2 of the SHINE ER, "Proposed Action," states that a preoperational phase would occur prior to full commercial operations. The ER states that this preoperational phase requires an average of 390 workers (451 at peak times) and a monthly average of 190 truck deliveries and 9 offsite waste shipments.

   Clarify whether this preoperational phase was included within the construction phase or the operational phase described in Chapter 4 of the ER. Similarly, clarify whether the preoperational phase was included within the timeframes provided for the construction or operation phase. If necessary, update the data, assumptions, calculations, or analyses in the ER based on the preoperational phase.

RAI 19.2-3 The ISG Augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the applicant should describe treatment and packaging procedures for radioisotope products. By letter dated October 4, 2013, SHINE's response to RAI Proposed Action Request #11 states that "…iodine is expected to be packaged in solution vials (less than 1 liter in size) containing the iodine in a solution of NaOH, which will then be packaged in an approved shipping container. The xenon is expected to be packaged in gas cylinders with an internal volume of less than 1 liter. These product cylinders would then be placed in approved shipping containers and transported to the customers."

Provide a comparable description of the expected material form, volume, and packaging that would be associated with the distribution of SHINE's Mo-99 product.

RAI 19.2-4 The ISG Augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," and Section 19.4.1, "Land Use," state that the applicant should estimate the footprint

of major buildings and the number of acres that would be changed on a temporary and permanent basis during construction, operation, and decommissioning. In addition, the applicant should present the proposed facility layout, and identify current or proposed building areas.

Provide additional information on the following topics:

a) Footprint of the Production Facility Building: Section 19.4.1.2, "Visual Resources," of the SHINE ER states that the production facility building would have a bounding length of 416 feet and width of 167 feet (which equals a footprint of 69,472 square feet). However, SHINE PSAR, Section 2.2.2.5.1, "Evaluation of Airways," assumes bounding dimensions of 316 feet in length and 316 feet in width (which equals a footprint of 99,856 sq. ft.). Furthermore, by letter dated October 4, 2013, SHINE's response to RAI Proposed Action Request No. 5 provides a footprint for the production facility building of 54,000 square feet.

   Provide the approximate footprint and bounding dimensions of the production facility building at the proposed SHINE facility.

b) Total Footprint vs. Permanently Affected Acres: By letter dated October 4, 2013, SHINE's response to RAI Proposed Action Request No. 5 provides a total footprint of 350,000 square feet, which accounts for buildings, parking lots, roads, and the stormwater swale. However, Table 19.4.1-1 of the ER states that 25.85 acres (10.46 hectare) would be permanently disturbed. The SHINE ER, Section 19.4.1, further explains that land permanently converted to industrial facilities includes land used for the construction of facility buildings, employee parking lot, facility access road/driveway, stormwater detention area, and access road drainage ditches.

   Explain what additional areas, beyond those included in the approximate 350,000 square feet (8 acres) footprint, would be permanently converted.

c) Total Temporarily Impacted Acres: The SHINE ER, Section 19.2, states that construction activities would affect 51 acres (20.6 hectare), of which 25.1 acres (10.2 hectare) would be temporarily disturbed. However, Table 19.4.1-1 of the ER states that 14.54 acres (5.88 hectare) would be temporarily disturbed.

   Clarify the number of temporarily disturbed acres during construction, operations, and decommissioning.

d) Facility Layout: Figure 19.4.1-1 in the SHINE ER presents a conceptual illustration of the proposed SHINE facility. However, the relative orientation of the facility buildings presented in Figure 19.4.1-1 are not consistent with building locations presented in SHINE ER Figures 19.2.1-1 and 19.4.1-2.

   Provide an updated facility layout that identifies the name and location of

buildings and areas relevant to the proposed action.

RAI 19.2-5 The ISG Augmenting NUREG-1537, Part 1, Section 19.2, Proposed Action, states that the applicant should estimate the number of full-time onsite workers during each of the major phases of the proposed action. Furthermore, ISG augmenting NUREG-1537, Part 1, Section 19.4.2, "Air Quality and Noise," states that the applicant should estimate onsite and vehicle emissions during construction, operations, and decommissioning.

The SHINE ER, Section 19.2, "Proposed Action," identifies a maximum of 421 workers, and a monthly average of 303 truck deliveries and 9 off-site waste shipments during construction. SHINE's response to RAI Air Quality Request No. 1 states that there would be a peak of 420 vehicles during construction. However, Sections 19.4.2.2.1 and 19.4.7.2.1 of the ER states that the peak construction traffic volume is estimated to be 451 vehicles and 14 trucks per day. Section 19.4.2.2.2 of the ER, states that during operations, approximately 118 work-related vehicles per day are expected. However, Section 19.2 of the ER identifies 150 permanent workers, 36 truck deliveries per month, and 1 waste shipment per month during the operational phase, while SHINE's response to Air Quality Request No. 10 states that SHINE assumed 150 vehicles per day during operations.

a) Provide clarification of the approximate number of peak workers needed during construction, operation, and decommissioning. Specify whether the peak number of preoperational workers (451) has been included in the construction or operational estimates and analyses within Chapter 4 of the ER. As appropriate, revise the data, calculations, or other analyses for construction and operations based on the number of peak workers (e.g., Table 19.4.7-1).

b) Provide clarification of the approximate number of vehicles assumed during construction, operation, and decommissioning. Please identify and distinguish between worker vehicles, truck deliveries, and offsite waste shipments. Specify whether the peak number of worker vehicles and trucks during the preoperational phase (451 workers and an average of 190 truck deliveries and 9 off-site waste shipments) has been included in the construction or operational phase. As appropriate, revise the data, calculations, or other analyses based on the number of workers, truck deliveries, and off-site waste shipments.

**Section 19.3 – Description of the Affected Environment**

RAI 19.3 The ISG to NUREG-1537, Part 1, Section 19.3.4, "Water Resources," states that the applicant should estimate the amount of water that would be obtained from a public water supply system.

By letter dated October 4, 2013, SHINE submitted a non-proprietary water balance-flow diagram (1-HR-SK-001, Rev A) to the NRC. However, NRC's

review of the provided water balance identified a discrepancy between total municipal water supplied (6070 gal/day) and total water use (6073 gal/day or 6072 gal/day). In addition, a comparison between the proprietary version of the water-balance (Figure 19.2.3-1) and the nonproprietary version appears to reveal a discrepancy in the volume of water required for process makeup on the downstream side of the water demineralizer, as compared to the volume of makeup water (113 gal/day), despite the recycling of liquid waste streams. Explain and provide an updated water balance flow-diagram that properly balances water flow and realistically bounds the estimated volume of makeup water required.

**Section 19.4 – Impacts of Proposed Construction, Operations, and Decommissioning**

RAI 19.4-1 The ISG to NUREG-1537, Part 1, Section 19.4.2, "Air Quality and Noise," states the applicant should estimate fugitive dust emissions during construction, operation, and decommissioning.

By letter dated October 4, 2013, SHINE's responses to RAIs Air Quality Request No. 1 and Air Quality Request No. 5 indicate that SHINE used an estimate of 25.67 of permanently disturbed acres to calculate fugitive dust emissions. However, Table 19.4.1-1 states that 25.67 acres (10.5 hectare) of agricultural land would be permanently converted to industrial use and 0.18 acre (0.07 hectare) of open land would be permanently converted to industrial use, for a total of 25.85 acres (10.46 hectare) of permanently converted land.

Address why SHINE used an estimate of 25.67 acres (10.39 hectare) or 25.85 acres (10.46 hectare) of permanently converted land to estimate fugitive dust emissions.

## FINANCIAL ANALYSIS

RAI FA-1 10 CFR Part 50, Appendix C.I.A.1, “Estimate of Construction Costs,” states that the estimate of construction costs for production and utilization facilities other than nuclear power reactors should be itemized by categories of cost in sufficient detail to permit an evaluation of its reasonableness.

Additional information is needed on the bases for the total production plant costs, support facility costs, plant equipment, and a 1-year supply of uranium inventory, for the NRC staff to determine the adequacy of SHINE’s estimated construction costs.

Provide the bases from which the estimates were derived.