SHINE Medical Technologies, Inc.
Preliminary Safety Analysis Report (PSAR)
Requests for Additional Information

General Information Request

RAI G-1 10 CFR 50.34(a)(8) states that "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," is required to be submitted as part of the PSAR. This information has not been provided in sufficient detail in the SHINE application.

1) Identify any ongoing research that is being conducted by SHINE and identify the structures, systems, and components affected by this research. Provide a schedule for completing this research and resolving any outstanding issues related to the facility design. With respect to responses to requests for additional information in which the requested information is subject to the results of an uncompleted research and development program, provide a description of the program and projected dates for when the requested information will become available.

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

PSAR Section 1.1 – Introduction

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

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

It is acknowledged that the SHINE irradiation units do not meet the definition of a nuclear reactor contained in Section 50.2 of Title 10 of the *Code of Federal Regulations,* however the power level of the irradiation units is an important aspect of the facility design and should be provided here.

Provide the individual and combined power levels of the irradiation unit within the irradiation facility.

RAI 1.1-2 NUREG-1537, Part 2, Section 1.1, states that "[t]he design or location features included to address basic safety concerns should be outlined." PSAR Section 1.1 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.

PSAR 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 "The 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 PSAR Section 1.2.

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 states, "The applicant should include brief discussions of the following:

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

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 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 states, "The applicant should include brief discussions of the following: … any inherent or passive safety features designed to contribute to facility safety…."

PSAR Section 1.2.3.2.2, "Criticality Safety," states "The 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."

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

PSAR Section 1.2.4.2.2, "Criticality Safety," states, "The criticality safety controls outside the [target solution vessel] TSV 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, "Acceptance Criteria," includes information on principal safety considerations, such as, "All modes of operation and events that could lead to significant radiological releases and exposure to the public should be discussed."

PSAR Section 1.2 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 states, "The applicant should include brief discussions of the following: '… any inherent or passive safety features designed to contribute to facility safety…..'"

PSAR Section 1.2.4.2.2, "Criticality Safety," "Passive engineered controls," Item b., states, "The 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 target solution vessel experiences a vacuum condition, would inadvertent criticality become possible?

PSAR Section 1.3 – General Description of the Facility

RAI 1.3-1 PSAR Figure 1.3-3, "Production Building Sections Preliminary Arrangement," shows two areas of the building labeled "containment area." However, in Section 6a2.2.2, the application states that "The SHINE facility does not employ a containment feature."

Provide additional information in PSAR Section 1.3 to allow staff to understand if there are indeed 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, "The applicant should briefly describe the reactor facility as follows: …Safety features of the facility that are likely to be of special interest should be briefly identified."

PSAR Section 1.3.3.3, "Facility Systems," states, "The neutron driver is not a safety-related system."

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

PSAR Section 1.5 – Comparison with Similar Facilities

RAI 1.5-1 NUREG-1537, Part 2, Section 1.5, "Comparison with Similar Facilities," states that one of the acceptance criteria for this section is "reasonable assurance that radiological exposures of the public would not exceed the regulations and guidelines of the proposed facility [as low as reasonably achievable] ALARA program."

PSAR Section 1.5, "Comparison with Other Facilities," does not comply with the acceptance criteria in that no discussion of this topic is provided.

Provide a brief discussion and reference to applicable PSAR sections with regard to expected radiological exposures of the public with respect to the SHINE facility as low as reasonably achievable program (ALARA).

Chapter 2 – Site Characteristics

PSAR Section 2.1 – Geography and Demography

RAI 2.1-1 NUREG-1537, Part 2, Section 2.3, states that sufficient information be provided "to support the dispersion analyses of airborne releases from the facility."

NUREG-1537, Part 2, Section 2.1 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 Figure 2.1-3, "Boundaries and Zones Associated with the Facility," 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 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-southeast directions provided in 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]"), of particular concern are the nearest residents in the east and north directions.

PSAR 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."

PSAR, Section 2.2.3.1.3, "Toxic Chemicals," states that "The 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." This description is insufficient.

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 that "[t]he reviewer should focus on facilities, activities, and materials reasonably 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 PSAR Section 2.2.2.5, "Evaluation of the Aircraft Hazard," would be affected if the AirFest or a similar event were to return at some time 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, PSAR Section 2.2.2.5.3, "Results of Evaluation of Airways and Airports," utilizes the IAEA-TECDOC-1347 (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 probability of less than 10^{-5} per year. However, in PSAR Section 2.2.2.2, "Airways," the lack of a NUREG-1537, Part 2 acceptance criteria resulted in utilizing NUREG-0800, Standard Review Plan (SRP), 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 PSAR Section 2.2.3.1, "Determination of Design-Basis Events," SRP 3.5.1.6 was used as the acceptance criteria for evaluating potential accidents at facilities.

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

PSAR 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, features at the facility site to support analyses and evaluations in 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 reactor, or deposition and migration of airborne radioactive material released to the unrestricted area.

RAI 2.4-1 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 PSAR Figure 2.4-4, "Simplified Groundwater Table Contours Based on Measured Groundwater Elevations in Monitoring Wells," 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 that will assist in properly spacing and screening the monitoring wells.

RAI 2.4-2 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 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 AQTESOLVE graphical output for the hydraulic conductivity calculations from the slug tests.

RAI 2.4-4 PSAR Section 2.4.11.2 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, Section 2.0, "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. 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 these potential consequences of an uncontrolled release to be considered. Potentiometric surfaces under pumping versus non-pumping conditions should also be presented.

PSAR 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, that the 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 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 PSAR Section 2.5.1, “Regional Geology,” Appendix A of 10 CFR Part 100 defines a capable fault as a fault with “Movement 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 PSAR Section 2.5.1.4.6, “Saint Charles Lineament (SCL),” states, “Since 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,” or Table 2.5-3, “Recorded Earthquake Intensities (Modified Mercalli Intensity – MMI) for Earthquakes Within Approximately 200 Miles (322 km) of the SHINE Site.”

RAI 2.5-3 PSAR Section 2.5.2.2, “Structural Geology,” states “Despite 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.” A

review performed 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 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 at http://earthquake.usgs.gov/earthquakes.

Provide additional information justifying the exclusion of the earthquake information compiled by the U.S. Geological Survey 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 states, in part, that the applicant should discuss "all geologic hazards within the region that could affect the facility…"

PSAR Section 2.5.2.4, "Non-Seismic Geological Hazards," states, "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 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," requires the applicant to 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," requires 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 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 PSAR Chapter 3 (Section 3.4.3.6.3.1).

Provide the report with details and results for the Geotechnical Investigations.

RAI 2.5-7 NUREG-1537, Part 1, Section 2.5.7, pertains to 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, requires 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 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, the information in the report is insufficient. Results given in 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,” indicate liquefaction analyses for the SHINE facility have been completed, but the details are incomplete.

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

PSAR Section 3.2 – Meteorological Damage

RAI 3.2-1 NUREG-1537, Part 1, Section 2.3.1, "General and Local Climate," states that "The 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 PSAR Section 2.3.1.2.9, "Snowpack and Probably Maximum Precipitation (PMP)," has estimated the snowpack load and probable maximum precipitation as described in NUREG-1537, PSAR Section 3.2.3, "Snow, Ice, and Rain Loading," does not utilize the information developed in PSAR Section 2.3.1.2.9 to calculate the design loads.

Provide additional information explaining why PSAR Section 3.2.3 does not utilize the data developed under PSAR Section 2.3.1.2.9 or update PSAR Section 3.2.3 with the data in PSAR Section 2.3.1.2.9, accordingly.

PSAR Section 3.3 – Water Damage

RAI 3.3-1 NUREG-1537, Part 1, Section 3.3, "Water Damage," states 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, "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 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.

Provide additional information discussing the effects of discharge of the Fire Protection System on structures, systems, and components.

PSAR 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.

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 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.

PSAR Section 3.4.2.6.1, “Description of the Structures,” is overly brief and unclear.

Provide a comprehensive description of the SHINE facility structures.

(Applies to RAIs 3.4-3 through 4)

NUREG-1537, Part 1, Section 3.4, and NUREG-1537, Part 2, Section 3.4, note that acceptable seismic performance has been established in 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 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 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 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.

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

Provide the report with 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) are used for the dynamic analyses of equipment.

RAI 3.4-6 NUREG-1537, Part 1, Section 3.4 states that the applicant should, in order to verify that seismic design functions are met, 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 states that the reviewer find 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.

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

The data recording capabilities of and data retrieval from the seismic instrumentation is 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 the 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. 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. PSAR Table 3.4-4, "Aircraft Impact Analysis Results," reports the aircraft impact analyses results showing 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 reports 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.

PSAR Section 3.5 – Systems and Components

RAI 3.5-1 PSAR Section 3.5.1, "System and Classifications," discusses the classification of structures, systems, and components.

Title 10 of the *Code of Federal Regulations*, Part 50.2, "Definitions," provides definitions including that for safety-related structures, systems and components. 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." 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.

PSAR Section 3.5.1.1, "Nuclear Safety Classifications for [structures, systems, and components] SSCs," states:
"SHINE uses a modified definition from 10 CFR 50.2 'Definitions' to develop the definition of [safety-related] SR SSCs, where appropriate, and utilizes a portion of 10 CFR 70.4 'Definitions' for the definition of [items relied on for safety] IROFS SSCs."

PSAR Section 3.5.1.2, "Quality Assurance (Quality Group Classifications for SSCs)," discusses how safety-related structures, systems, and components will be classified as QL-1 and items relied on for safety structures, systems, and components will be classified as QL-2. The

section goes on to state that safety-related structures, systems, and components shall have "the full requirements of the [Quality Assurance Program Description] QAPD in accordance with an approved Quality Assurance Plan (QAP)," and that items relied on for safety structures, systems, and components shall have requirements "in conformance with an approved QAP...." Thus, by inference, items relied on for safety structures, systems, and components shall **not** have "the full requirements of the QAPD in accordance with an approved Quality Assurance Plan (QAP)."

In addition, PSAR Section 3.5.2, "Seismic Classification," states that safety-related structures, systems and components and items relied on for safety structures, systems, and components are both Seismic Category I.

Based on the above, provide the following information:

a) Provide the basis referencing the 10 CFR 50.2 definition, the basis for the modification of the 10 CFR 50.2 definition, the basis for utilizing only a portion of the 10 CFR 70.61 performance requirements, and the basis for why the 10 CFR 70.61 performance requirements do not encompass the applicant's modified 10 CFR 50.2 definition.

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," states that the design criteria should include "response to transient and potential accident conditions analyzed in the SAR."

RAI 3.5-2 In PSAR Section 3.5.2 the applicant states that SSCs that have "The 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. . . ."

PSAR Figure 1.3-2, "Production Building Floor Plans Preliminary Arrangement," has the following notation: "Heavy Outline Denotes Seismic Boundary." In addition, PSAR Table 3.5-1, "System and Classifications," 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.

Thus, one must conclude that these portions of the building are nonseismic and in a postulated design basis earthquake, they would collapse. Since 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 PSAR Table 3.5-1 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 non-safety-related, QL-3, and Seismic Category III. PSAR Section 9a.2.1.1, "Radiologically Controlled Area Ventilation System," does not provide a statement that one normally goes through Radiologically Controlled Area Ventilation Zone 3 to get to Radiologically Controlled Area Ventilation Zones 1 or 2, but the PSAR section and Figure 1.3-2 infer such a pathway. 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 non-safety-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)

10 CFR 50.34(a)(4), "Contents of applications; technical information," 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."

RAI 3.5-4 In 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 non-safety-related, QL-3, Seismic Category III and the Standby Diesel Generator System is non-safety-related, QL-3, Seismic Category II. In addition, the 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 it in a safe condition) and maintain it in a safe condition, in the event of a postulated design basis

earthquake with a loss of offsite power, with the above systems not available for use.

RAI 3.5-5 PSAR Section 3.5.2 discusses the use of Seismic Category II structures, systems, and components over Seismic Category I structures, systems and components (Seismic II/I). 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," discusses how the facility complies with 10 CFR 50, Appendix A General Design Criteria. With respect to Seismic II/I, the following are the applicable General Design Criteria:

General Design Criterion 1 requires that structures, systems, and components important to safety 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 requires that structures, systems, and components important to safety 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 requires protection for structures, systems, and components important to safety 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).

Thus, for General Design Criteria 1, 2, and 4, 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.

PSAR Section 3.5b – Radioisotope Production Facility

RAI 3.5b-1 10 CFR 50.34(a)(4), "Contents of applications; technical information," 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."

SHINE PSAR Table 3.5b-1, "Baseline and General Design Criteria for Radioisotope Production Facility," under the first table 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 Section 8b for detailed information."

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

However, this standby diesel generator is classified non-safety-related and does not have to function after a design basis earthquake. In addition, PSAR Section 8a2.1.4, "SHINE Facility Loads Supported by [standby diesel generator] SDG," references Table 8a2.1-2, "Standby Diesel Generator Load List," but unlike Section 8a2.2.3, "SHINE FACILITY SYSTEMS SERVED BY THE CLASS 1E [uninterruptible power supply system] UPSS," which provides a list of what systems are supported by the Class 1E uninterruptible power supply system, does not provide a list of systems supported by the standby diesel generator 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

PSAR Section 4a2.2 – Reactor Core

RAI 4a2.2-1 The ISG to NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," states that "the design bases for the fuel should be clearly presented."

A uranium concentration range and enrichment is given in Table 4a2.1-1. However, the uranium concentration range varies 30%, based on the average uranium concentration.

Provide the nominal or expected uranium concentration in the system.

RAI 4a2.2-2 The ISG to NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," states 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.

PSAR Section 4a2.2.1.5 discusses the formation rate of hydrogen and oxygen. This radiolysis rate may have a large uncertainty since available data obtained from aqueous homogeneous reactors is, generally, dated and poorly documented.

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 to NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," states 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. 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…"

PSAR Section 4a2.2.1.5 does not discuss the evaporation rate of water in the target solution vessel (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 140F. For example, increasing the water temperature from 140F to 150F increases the vapor pressure approximately 33%.

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 to NUREG-1537, Part 2, Section 4a2.5.1, "Normal Operating Conditions," states 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."

PSAR Section 4a2.2.1.6 describes the operating conditions in the TSV and notes that there is no mechanical mixing. Thus, mixing must occur due to buoyancy and other natural processes. The PSAR does not discuss potential non-uniformities of power, void, temperature or chemical species within the TSV or if any of those non-uniformities may limit any operating conditions.

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

RAI 4a2.2-5 The ISG to NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," states 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…"

PSAR Section 4a2.2.1.6 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 and Other Short Lived Radioisotopes" states that as the fuel solution ages, fission products can approach solubility limits.

Provide information on how close to the solubility limits the SHINE target solution will reach. 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 to 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 temperature ranges during startup and normal operation.

While the normal operating conditions of the TSV are listed in the PSAR, provide the normal temperature range for startup and approach to criticality.

RAI 4a2.2-7 The ISG to 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.

While the "short irradiation cycle" is mentioned in PSAR Section 4a2.2.1.9, provide the duration of this cycle and the maximum expected fuel burnup.

RAI 4a2.2-8 The ISG to NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," states that "maintaining fuel barrier integrity should be the most important design objective."

PSAR Section 4a2.2.1.10 mentions a "credible deflagration." A strong enough deflagration or detonation could compromise the integrity of the primary system boundary.

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

RAI 4a2.2-9 The ISG to NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," states 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.

PSAR Section 4a2.2.1.13 briefly describes some of the history of uranyl sulfate development, but there is no description of SHINE's fuel qualification program.

Provide a description of SHINE's fuel 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 PSAR. Include tests, experiments, analyses that will be (or have been) performed to validate the historical data.

PSAR Section 4a2.3 – Neutron Driver

RAI 4a2.3-1 While the ISG to 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), "Contents of applications; technical information," 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) PSAR Section 4a2.3 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.

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

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

10 CFR 50.34(a)(4), "Contents of applications; technical information," 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."

RAI 4a2.4-1 PSAR Section 4a2.4.1.1 specifies that the construction of and materials for the TSV follow the intent of the ASME Boiler and Pressure Vessel Code (BPVC), 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 PSAR Section 4a2.4.1.5 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 and evidence that the design will allow the required periodic surveillance and inspections to be performed.

RAI 4a2.4-3 PSAR Section 4a2.4.2.1 states that the steel liner of the light water pool is designed to withstand the chemical environment of the target solution. 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.

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 Par 20.

PSAR Section 4a2.5 – Irradiation Facility Biological Shield

RAI 4a2.5-1 ISG to NUREG-1537, Part 2, Section 4a2.4, "Biological Shield," states that "the 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."

PSAR Section 4a2.5.2.2, "Geometry and Configuration," states that the side wall of the irradiation unit 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 thicknesses. PSAR Section 4a2.5.4, “Analysis,” states that analysis is performed to (1) Give detailed results of both neutron and gamma-ray dose rates at locations that could be occupied as well as to the unrestricted environment; and (2) 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 staff to determine the adequacy the shielding design of the irradiation unit 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 (i.e., the source term). For each component included in (a) above, describe the key assumptions included in the radiation transport modeling using MCNP (or other computer codes) used to determine shield wall thickness.

PSAR Section 4a2.6 – Nuclear Design

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

The ISG to 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 system and maintain it in a shutdown condition.”

RAI 4a2.6-1 PSAR Section 4a2.6.1 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 on this subject for the 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 analysis that supports the adequacy of operator action response times. Additionally, discuss why there is not an automated protection system.

RAI 4a2.6-2 PSAR Section 4a2.6.1 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 was intentional. 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 to 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. The discussion on this topic in the SHINE PSAR is insufficient in relation to SHINE maintaining subcriticality under all phases of operation. While some

information is presented on coefficients of reactivity in PSAR Section 4a2.6.4, additional information is needed to verify that the SHINE irradiation units will not become critical under any condition.

RAI 4a2.6-3 Compare the reactivity worths of all components in the irradiation unit (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 is the fuel solution is over-moderated. A pipe break or other means of introducing voids, lowering the coolant density in the system, would result in a reactivity insertion if that was the case. It is important to know if voiding out the cooling system can 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 to NUREG-1537, Part 2, Section 4a2.5.2, "Reactor Core Physics Parameters," states that the applicant should present information on "core physics parameters that determine reactor operating characteristics…"

RAI 4a2.6-5 The 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 to 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. PSAR Section 4a2.6.3.6 states that the dump system has redundant dump valves.

RAI 4a2.6-7 There are important attributes to redundancy and diversity beyond just 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; and

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

RAI 4a2.6-9 The ISG to NUREG-1537, Part 2, Section 4a2.5.1, "Normal Operating Conditions," states 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." This analysis should also include the evaporation of water.

PSAR Section 4a2.6.1.1, "Gas Management System Effects," states that the "radiolysis of water in the system causes an anticipated increase in reactivity during operation…"

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.

PSAR Section 4a2.7 – Thermal-Hydraulic Design

RAI 4a2.7-1 The ISG to NUREG-1537, Part 2, Section 4a2.6, "Thermal-Hydraulic Design," states that the applicant should discuss possible "system instability following a 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 establishes "standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission."

PSAR Section 4a2.7.2 states that "Plating out of chemicals on the TSV surfaces is not expected ..." However, should plating out occur, increased local dose rates could occur that 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 to NUREG-1537, Part 2, Section 4a2.6, "Thermal-Hydraulic Design," states that "the 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…"

PSAR Section 4a2.7.5.1, "Target Solution Conditions," states that "void formation in the target solution is expected, and will be factored into the nuclear calculations (void coefficients of reactivity) and thermal hydraulic calculations for the final design."

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

PSAR Section 4a2.8 – Gas Management System

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

The ISG to NUREG-1537, Part 2, Section 4a2.7, "Gas Management System," states that "the 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." PSAR Section 4a2.8 discusses the SHINE 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% and automatic shutdown of the neutron driver at 3%. 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 PSAR Table 4a2.8-1states that the condenser in the TSV Off-Gas Condenser has a greater than 15% heat transfer margin. The vapor pressure of water changes rapidly with temperature in the vicinity of 140F. For example, increasing the water temperature from 140F to 150F increases the vapor pressure by

approximately 33%. Non-condensable 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% margin.

RAI 4a2.8-5 A pressure safety valve is connected to the TOGS piping to passively prevent an overpressurization within the primary system boundary (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.

RAI 4a2.8-6 PSAR Section 4a.8.5, "Abnormal Conditions," states that no significant amount of 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 SOx gas and scenarios related to SOx gas.

PSAR 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 PSAR page 4b-9 contains a typographical error: "usanium oxide" should be "uranium oxide".

Correct this error.

RAI 4b-2 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."

RAI 4b-3 ISG to NUREG-1537, Part 2, Section 4b.1 states that "the license application should include a list of byproduct materials (identity and amounts) in the process solutions, finished products, and wastes from the process."

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.

Chapter 5 – Cooling Systems

PSAR Section 5a2 – Irradiation Unit Cooling System

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

Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, Section 5a2, "Aqueous Homogeneous Reactor Cooling System," states that the applicant should provide the design bases, descriptions, and functional analyses of the aqueous homogeneous reactor 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 PSAR Chapters 5a2.2.9, "Secondary Cooling System Interaction," 5a2.3.5, "RPCS Cooling Functions and Operation," and 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. However, the information provided in the PSAR is insufficient.

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 The level of detail on instrumentation for the cooling system functions throughout the chapter is insufficient.

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

RAI 5a2.2-3 ISG to NUREG-1537, Part 2, Section 5a2.2, "Primary Cooling System" states that "the 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. PSAR Section 5a.2.2.2, "PCLS 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. Many additives used to maintain water quality are toxic.

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

Chapter 6 – Engineered Safety Features

PSAR Section 6a2 – Irradiation Facility Engineered Safety Features

PSAR 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 [safety analysis report], 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 Engineered Safety Features 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 Engineered Safety Feature. 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."

Interim Staff Guidance Augmenting NUREG-1537, Part 1, Section 6a2, "Aqueous Homogeneous Reactor [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 engineered safety features are provided to ensure that operations are conducted within safe limits."

PSAR Section 6a2.1 contains a description of the Engineered Safety Features for the irradiation facility but does not contain enough information for an overall understanding of the functions of the Engineered Safety Features and the conditions under which the equipment or systems must function.

a) Provide a description of the conditions under which each engineered safety feature (ESF) must function.

b) Provide block diagrams and drawings to show the location, basic function, and relationship of each the Engineered Safety Feature 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.

PSAR 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,” Paragraph 1, states: “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 PSAR, Section 6a2.2.1, discusses a system called the “TPS [tritium purification system] confinement system,” but the section did not provide sufficient information for the reviewer to gain a complete understanding of the entire system.

Provide additional information to completely describe and define the "TPS confinement system," including system boundaries and interfaces and a reference to the appropriate diagram(s).

RAI 6a2.2-2 PSAR, Section 6a2.2.1.2, states, in part: "This ESF effectively reduces the amount of ductwork in the confinement volume that needs to remain intact to achieve IU [irradiation unit] cell, TOGS [TSV [target solution vessel] off-gas system] shielded cell, or TPS glovebox confinement."

The meaning of this sentence is not clear to the reviewer. Provide clarification.

RAI 6a2.2-3 SHINE PSAR, Section 6a2.2.1.2, 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."

This PSAR statement regarding this Engineered Safety Feature and its function has insufficient detail to enable the reviewer to draw a reasonable conclusion regarding the adequacy of this aspect of the design of this ESF.

Provide additional information to describe this Engineered Safety Feature.

RAI 6a2.2-4 SHINE PSAR, Section 6a2.2.1.3, 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 PSAR did not list and define the adverse environments and did not explain how the design withstands and mitigates them.

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, 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."

The meaning of the second sentence of this section is not clear to the reviewer.

Provide clarification. 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 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, indicates that the details of the TPS confinement system will be left to the Final Safety Analysis Report (FSAR). However, this does not provide sufficient information for the reviewer to draw a reasonable conclusion regarding the adequacy of the design of this ESF for the purpose of issuance of a construction permit.

Explain why it is acceptable to leave the development of the details of TPS confinement to the FSAR.

RAI 6a2.2-8 SHINE PSAR, Section 6a2.2.1.4, 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, is called "Isolation valves on piping system," 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, “Acceptance Criteria,” states, in part: “To be considered an ESF, design features must exist to mitigate the consequences of specific accident scenarios.”

In PSAR Section 6a2.2, a list of initiating events (IEs) is provided, which were included for the design-basis accident (DBA) review. A subsequent list gives IEs which do not have radiological consequences that require mitigation by Engineered Safety Features. However, Section 6a2.2 did not explain the basis for the determination of which Initiating Events do not have radiological consequences.

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

RAI 6a2.2-11 NUREG-1537 Part 1, Section 6.2.1, 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, “Evaluation Findings,” states: “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."

PSAR, Section 6a2.2.1, does not contain the confinement Engineered Safety Feature effectiveness comparison in the discussion of mitigative effects.

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

RAI 6a2.2-12 NUREG-1537 Part 1, Section 6.2.1, 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."

PSAR, Section 6a2.2.1, 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, 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, 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."

PSAR, Section 6a2.2.1, discusses the confinement Engineered Safety Feature 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 PSAR Chapter 7.

RAI 6a2.2-14 NUREG-1537 Part 1, Section 6.2.1, 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, states, in part: "The reviewer should evaluate… [Thus, this section should describe]… Surveillance 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, states, in part: "Engineered safety features are tested to ensure that ESF components maintain operability." However, plans for testing ESF functionality as well as technical specification operability were not fully described.

   Describe planned tests of Engineered Safety Features 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, 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."

   This statement does not provide the prescribed information, nor does it provide discrete references to sections of Chapter 14. Provide the information on the 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.

PSAR Section 6b – Radioisotope Production Facility Safety Features

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

RAI 6b.1-1 NUREG-1537 Part 1, Section 6.1, 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 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."
Interim Staff Guidance Augmenting NUREG-1537, Part 1, Section 6b.1, "Summary Description," states: "The current version of this section of NUREG-1537 applies, provided the term 'reactor' is understood to mean 'radioisotope production facility."

PSAR Section 6b.1 contained a description of the Engineered Safety Features for the Radiation Production Facility but did not contain enough information for an overall understanding of the functions of the Engineered Safety Features 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 Engineered Safety Feature 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.

PSAR 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," Paragraph 1, states: "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 PSAR, Section 6b.2.1.3, 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 PSAR, Section 6b.2.1.3, 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."

The meaning of the second sentence of this section is not clear to the reviewer. Provide clarification of this statement. Also 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 6b.2-3 PSAR, Section 6b.2.1.4, 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 PSAR, Section 6b.2.1.4, 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, 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, "Acceptance Criteria," states, in part: "To be considered an ESF, design features must exist to mitigate the consequences of specific accident scenarios."

In PSAR, Section 6b.2, a list of Initiating Events is provided which were included for the Design Basis Accident review. A subsequent list shows a list of Initiating Events, which do not have radiological consequences that require mitigation by the Engineered Safety Features, but the basis for this determination or categorization was not provided.

Provide the basis for this determination or categorization of Initiating Events 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, 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, “Evaluation Findings,” states: “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 does not contain the confinement ESF effectiveness comparison in the discussion of mitigative effects. Provide the comparative study or reference the section of the SHINE PSAR which provides the information.

RAI 6b.2-7 NUREG-1537 Part 1, Section 6.2.1, 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.”
PSAR, Section 6b2.1 does not contain or reference the confinement Engineered Safety Feature HVAC system schematic diagram. Provide the prescribed schematic diagram(s) for this system.

RAI 6b.2-8 NUREG-1537 Part 1, Section 6.2.1, 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, 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.”

PSAR, Section 6b.2.1, discusses the confinement Engineered Safety Feature 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 PSAR Chapter 7.

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

NUREG-1537 Part 1, Section 6.2.1, 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, states, in part: “The reviewer should evaluate… [Thus, this section should describe]… Surveillance methods and intervals included in the technical specifications that ensure operability and availability of the confinement ESFs, when required.”

RAI 6b.2-9 PSAR, Section 6b.2.2.1.6, 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."

However, this statement does not provide the prescribed information, nor does it provide discrete references to the applicable sections of Chapter 14.

Provide the information on 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 6b.2 that is specified in NUREG-1537 Part 1, Chapter 14.

RAI 6b.2-10 SHINE PSAR, Section 6b.2.1.2, 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.2.1.4, states, in part: "Engineered safety features are tested to ensure that ESF components maintain operability…" However, plans for testing ESF functionality as well as technical specification operability were 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, states, in part: “The RV [radiologically controlled area ventilation system] serving the RCA [radiologically controlled area], outside

of the Irradiation Facility, includes components whose functions are designated as non-safety-related and IROFS" [items relied on for safety].

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

PSAR Section 6b.3 – Nuclear Criticality Control

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

10 CFR 50.34(a)(4), "Contents of applications; technical information," 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."

As stated in ISG to NUREG-1537, Chapter 13, NRC staff have 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 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 ISG to NUREG-1537, Part 2, Section 6b.3, states that "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 "and that "NCS 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 the PSAR (e.g., pg 1-4, 6b-17, and 14b-2), the applicant implies safety limits are determined utilizing MCNP and validated methods. Also, while that 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 ISG to NUREG-1537, Part 2, Section 6b.3 states 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."

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

Provide either the relevant passages in the PSAR that address applicable management measures or revise the PSAR to discuss management measures. Of particular interest to the staff are the 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 the 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 ISG to NUREG-1537, Part 2, Section 6b.3, states that the reviewer should determine "whether the margin of subcriticality for safety is sufficient to provide reasonable assurance of subcriticality."

While statements are present in the PSAR, including Section 6b.3, regarding a subcritical margin, there is no text justifying a subcritical margin and addressing how it will be utilized.

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. Staff notes that this may be information that is included in the summary of the NCS reference manual referred to previously.

RAI 6b.3-5 ISG to NUREG-1537, Part 2, Section 6b.3 states that the reviewer should determine whether the applicant has committed 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, was not clearly delineated in the PSAR.

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

RAI 6b.3-6 ISG to NUREG-1537, Part 2, Section 6b.3, 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.

Section 6b.3, page 6b-12, states that heterogeneous 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 ISG to 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.

PSAR Section 6b.3 includes minimal apparent discussion about the configuration management program (e.g., pages 6b-15 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 ISG to NUREG-1537, Part 2, Section 6b.3, states that the reviewer should determine whether the applicant's use of moderator as a controlled parameter is acceptable.

The 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.

RAI 6b.3-9 ISG to NUREG-1537, Part 2, Section 6b.3, 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).

The 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 ISG to NUREG-1537, Part 2, Section 6b.3 states, in part, that:

- Criticality management measures should ensure that the reliability and availability of the safety controls are adequate to maintain subcriticality,
- Criticality process safety controls should be provided for criticality safety, and adescription 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
- 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.

On page 13b-29, the PSAR 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 engineered safety features. In addition, on page 6b-11, the PSAR 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 design basis accident that does not have consequences requiring mitigation by engineered safety features. Include a discussion demonstrating that under all normal and abnormal credible conditions, subcriticality will be maintained.

RAI 6b.3-11 ISG to NUREG-1537, Part 2, Section 6b.3, states 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-11, 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.3-12 ISG to NUREG-1537, Part 2, Section 6b.3, 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.3-13 ISG to NUREG-1537, Part 2, Section 6b.3, 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 the PSAR Section 6b.3 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.3-14 ISG to NUREG-1537, Part 2, Section 6b.3, states that the reviewer should determine if the applicant's use of mass as a controlled parameter is acceptable under stated circumstances, i.e., 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 PSAR Section 6b.3, page 6b-18.

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

RAI 6b.3-15 ISG to NUREG-1537, Part 2, Section 6b.3, states that the reviewer should determine whether the applicant's use of density as a controlled parameter is acceptable.

PSAR Section 6b.3 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.3-16 ISG to NUREG-1537, Part 2, Section 6b.3, states that the reviewer should determine whether the applicant's use of enrichment as a controlled parameter is acceptable.

PSAR Section 6b.3 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.3-17 ISG to NUREG-1537, Part 2, Section 6b.3, states that the reviewer should determine whether the applicant's use of reflection as a controlled parameter is acceptable.

PSAR Section 6b.3 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.3-18 ISG to NUREG-1537, Part 2, Section 6b.3, 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, PSAR Section 6b.3 does not explicitly state the use of interaction as a controlled parameter.

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

RAI 6b.3-19 ISG to NUREG-1537, Part 2, Section 6b.3, states that the reviewer should determine whether the applicant's use of volume as a controlled parameter is acceptable.

PSAR Section 6b.3 does not appear to address volume as a controlled parameter.

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

RAI 6b.3-20 ISG to NUREG-1537, Part 2, Section 6b.3, states that 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.

PSAR Section 6b.3.1 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

PSAR Section 7a2 – Irradiation Facility Instrument and Control Systems
PSAR 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 that the design bases for the instrumentation and control 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, and
- The specification of precision and accuracy requirements for the instruments, control subsystems, or components.

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.

PSAR Section 7a2.3 – TSV Process Control Description

RAI 7a2.3-1 NUREG-1537, Part 2, Section 7.3, "Reactor Control System," states that the acceptance criteria for this section include the following: "The Reactor Control System should give continuous indication of the neutron flux from subcritical source multiplication level through the licensed maximum power range."

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.

PSAR Section 7a2.4 – TSV Reactivity Protection System

RAI 7a2.4-1 NUREG-1537, Part 2, Section 7.4, "Reactor Protection System," states that the acceptance criteria for this section include the following: "The reactor should have operable protection capability in all operating modes and conditions, as analyzed in the SAR."

PSAR Section 7a2.4.1, "TRPS 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.

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

RAI 7b.3-1 ISG to NUREG-1537, Section, 7b.3, "Process Control Systems," states that the acceptance criteria for this section include: "The system should be designed with sufficient control of reactivity for all required production and SNM fuel reconditioning process operations…"

PSAR Section 7b.3, "Production Facility Process Control Systems," states that the radiological integrated control system monitors and controls inter-equipment process fluid transfers in the radioisotope production facility. For transport requiring a pump, the radiological integrated control system 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.

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

RAI 7b.4-1. NUREG-1537, Section 7.5, "Engineered Safety Features Actuation Systems," states that "the range and sensitivity of ESF actuation system sensors should be sufficient to ensure timely and accurate signals to the actuation devices."

PSAR Section 7b.4.1.2.3, “Uranyl Nitrate Conversion System Over-Temperature Alarm,” states that the radiological integrated control system monitors the temperature of each uranyl nitrate conversion system in the radioisotope production facility with independent redundant sensors. These sensors measure the temperature at the outlet of the uranyl nitrate conversion system.

Justify why the sensor location at the outlet is appropriately representative of the process.

Chapter 8 – Electrical Power Systems

PSAR Section 8a2 – Irradiation Unit Electrical Power Systems

PSAR 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, that 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. In a related provision, NUREG-1537, Part 2, Section 8.2, "Acceptance Criteria," one acceptance criterion is that any non-safety-related uses of an emergency electrical power system should not interfere with performance of its safety-related functions.

The second paragraph in PSAR Section 8a2.2.1, "Class 1E UPSS," references PSAR Figure 8a2.2-1, "One-Line Diagram – Uninterruptible Electrical Power Supply System," for uninterruptible power supply system components configuration. The second paragraph of PSAR Section 8a2.1.11, "Raceway and Cable Routing," states, "Non-Class 1E circuits are electrically isolated from Class 1E circuits by isolation devices in accordance with IEEE 384 (IEEE, 2008)."

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 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-1E 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

PSAR Section 9a2 – Irradiation Facility Auxiliary Systems

PSAR 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," states that "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 PSAR Section 9a2.1.1, "Radiologically Controlled Area Ventilation System," discusses the following systems: Radiological Controlled Area Zone 2 Supply Air, Radiological Controlled Area Ventilation Zone 1 Exhaust, Radiological Controlled Area Ventilation Zone 2 Exhaust, and Radiological Controlled Area Ventilation Zone 3. In reviewing this section with Figures 9a2.1-1, "RVZ1 Ventilation Flow Diagram," and 9a2.1-2, "RVZ2SA and RVZ2 Ventilation Flow Diagram," the following was noted during the review of this section:

a) The section states that Radiological Controlled Area Zone 2 Supply Air supplies air to Radiological Controlled Area Ventilation System Zone 2 and Radiological Controlled Area Ventilation System Zone 3, but there is no mention of where Radiological Controlled Area Ventilation System Zone 1 gets its supply air from. 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 Radiological Controlled Area 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) PSAR Section 9a2.1.1 states that Radiological Controlled Area Ventilation System Zone 3 supplied by the Radiological Controlled Area Zone 2 Supply Air Subsystem, is exhausted to Radiological Controlled Area Ventilation System Zone 2, and is maintained at a higher pressure than Radiological Controlled Area 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 Radiological Controlled Area Ventilation System Zone 3: an arrow after the supply fans that states - "Supply Air Flows To Additional Rooms" but provides no clarification as to what rooms/air receive the air; an arrow to the exhaust fans that states - "Exhaust Flows From Additional Zone 2 Rooms" which seems to

preclude any air from Radiological Controlled Area Ventilation System Zone 3; and at the two Zone 3 airlocks an “Offset Airflow” from Zone 3 to Zone 2, which is probably not sufficient total exhaust airflow for Radiological Controlled Area Ventilation System Zone 3.

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

RAI 9a2.1-2 PSAR Section 9a2.1.2 discusses Facility Ventilation Zone 4, and although this is a non-radiological controlled area ventilation system, since it is part of the facility, there is the potential of contamination appearing in this area. There is no flow diagram and no indication as to where the system exhausts and if there are any radiation detectors on the exhaust.

Provide additional information on the Facility Ventilation Zone 4 ventilation system, including a Facility Ventilation Zone 4 flow diagram.

PSAR 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 2, 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 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*.

In reviewing PSAR Section 9a2.3, “Fire Protection Systems and Programs,” Fire Area 6 (PSAR Section 9a2.3.4.4.6.7, Figure 9a2.3-1, “Fire Area and Fire Zone Boundaries”) is the corridor in the facility structure that wraps around the north, west, and south sides of the building. A fire in this area would 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 1 and 3 utilize gaseous fire suppression systems, as described in 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 any release (needed or accidental).

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," states that "methods 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 may be affected. Photoelectric smoke detector capability can be affected in areas of dust/particulates.

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

RAI 9a2.3-5 While the neutron moderation capability of water is discussed, the neutron moderation capability of firefighting foam is not (some foams are better neutron moderators than water). This is relevant when it comes additional help being provided by local fire departments, who 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," states that "the fire protection plan should discuss the prevention of fires, including limiting the types and quantities of combustible materials."

As part of the building and adjacent (i.e., sharing a common wall) to the Fire Brigade/Hazmat Room (FA-16), containing the Fire Zone Panels, is the Boiler Room (FA-17) which has a natural gas pipeline supplying the boiler.

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," states that "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."

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.

PSAR Section 9b.7 – Other Auxiliary Systems

RAI 9b.7-1 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 PSAR Section 9b.7.2, "RCA Material Handling," information is provided as to the equipment used to move or manipulate radioactive material within the Radiological Controlled Area. And it is stated that "the overhead cranes meet the requirements of ASME B30.2 and CMAA 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, ensuring 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.

Chapter 11 – Radiation Protection Program and Waste Management

PSAR 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.

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." More 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, "[Target Solution Vessel] TSV Noble Gas and Iodine Production Rates, Annual Releases, and [Effluent Concentration Limits] ECL Fraction at the Site Boundary after 960 Hours of [Noble Gas Removal System] NGRS Holdup.
   (ii) A description leakage pathways (including holdup and filtration/adsorption) from the point of production to the point of worker exposure.
   (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 ISG to NUREG-1537, Part 2, Section 11.1, "Radiation Protection," states that the application should identify trained radiation workers.

PSAR Section 9b.7.2, "RCA Material Handling," provides information on the equipment used to move or manipulate radioactive material within the Radiological Controlled Area, 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, 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)

Title 10 of the *Code of Federal Regulations*, Section 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" states that "…The highest levels of facility management should be committed to the ALARA program."

RAI 11.1-3 PSAR Section 11.1.2, "Radiation Protection Program," and Section 11.1.3, "ALARA Program," discuss the applicant's commitment to 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 the applicant'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 PSAR Section 11.1.3 states 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 required on the radiation zones 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 PSAR 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 11.1-4 Title 10 of the *Code of Federal Regulations*, Section 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.

PSAR Section 11.1.5.1.1.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. If Very High Radiation Areas were intended to be included in the plant design, certain accommodations may be necessary to include the controls associated with such areas, which is the reason that the question is being raised at this time.

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 11.1-5 through 7)

NUREG-1537, Part 2, Section 11.1.7, "Environmental Monitoring," states that "the 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."

The applicant's proposed radiological environmental monitoring program for plant operation is provided in PSAR Section 11.1.7, "Environmental Monitoring." The staff notes that it is important to evaluate the radiological environmental monitoring program at this time because of the need to conduct a pre-operational radiological environmental monitoring program (baseline measurements). Additional information is needed from the applicant regarding several elements of the proposed operational radiological environmental monitoring program.

RAI 11.1-5 PSAR Section 11.1.7.2.2.1 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, continuous air monitors 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 was cited by the applicant did not specify continuous air monitors 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 11.1-6 PSAR Section 11.1.7.2.3 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, the staff believes that routine milk sampling as part of the radiological environmental monitoring program is warranted for the following reasons: (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 in-plant 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 staff comments, whether it is appropriate to add milk sampling to the radiological environmental monitoring program.

RAI 11.1-7 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 PSAR Section 11.1.7.2.1, 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 has proposed nine direct radiation-monitoring locations, based on the smaller source term compared to nuclear power plants. The staff believes that the number of direct monitoring locations should not be based on source term alone. Consideration must 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 has 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.

PSAR Section 11.2 – Radioactive Waste Management

(Applies to RAIs 11.2-1 through 2)

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. The applicant has committed to compliance with 10 CFR Part 20.

NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," states that "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. PSAR Sections 9b.7.2, "[Radiologically Controlled Area] RCA Material Handling," and PSAR Section 11.2, "Radioactive Waste Management," provide no criteria on the handling of this waste stream and contain insufficient and conflicting information regarding extraction column handling in and from the supercells to the shielded vaults and further to packaging and shipping for disposal. The information provided is insufficient to ascertain safety, the ability to meet regulatory requirement regarding hazardous material identification in shipping papers (10 CFR 20, Subpart K), 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. 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 six 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 PSAR Chapter 1, “The Facility.”

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

Note: The applicant should consider removing either PSAR Table 4a2.2-2, “Irradiated Target Solution Activity for Select Radionuclides Following Shutdown,” or PSAR Table 11.1-3, “Irradiated Target Solution Activity for Select Radionuclides [ ].” Best practice for licensing documents is to provide such data in only one location, referring to that location in other sections as needed. This minimizes the potential for revision leading to inconsistency if the same changes are not made in multiple locations.

RAI 11.2-2 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 labeled 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 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.

RAI 11.2-3 NUREG-1537, Part 1, Appendix A describes the applicability of 10 CFR 50.9, “Completeness and accuracy of information,” to non-power reactors. 10 CFR 50.9 requires that information provided by the applicant must be complete and accurate.

PSAR Table 11.2-5, “Waste Methodology for Consolidated Liquids,” contains errors, and at least one inconsistency, as addressed below.

- The requirement to sample the influent waste stream should be changed to obtain a representative waste tank sample. PSAR Section 11.2.3.2.1, "Solid Wastes," 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 required for accurate characterization. Regulatory Guide 1.21, "Measuring, Evaluating, and Reporting Radioactive Material in Liquid and Gaseous Effluents and Solid Waste," contains guidance regarding sampling liquid radioactive waste.

- The basis for the requirement to provide a means to evaporate waste contains a basic 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 a basic 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.

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. Examples follow:

- 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.

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

b) 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 11.2-4 NUREG-1537, Part 2, Section 11.2, “Radioactive Waste Controls,” states “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

PSAR Section 12.1 – Organization

RAI 12.1-1 NUREG-1537, Part 2, Section 12.1, "Organization," states, "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, "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 organization 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, and states, "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 under PSAR Section 12.1.2, "Responsibility." Additionally, ensure that the responsibility for the safe operation of the facility and for the protection of the health and for safety of the staff and the public is clearly shown in this section.

RAI 12.1-2 NUREG-1537, Part 2, Section 12.1 states that "the 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."

NUREG-1537, Part 1 states, "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."

PSAR Section 12.1.4, “Selection and Training Of Personnel,” states, “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 is responsible to the Plant Manager for the development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety.”

However, PSAR Section 12.1.4 does not include:

- a reference to the operator requalification program
- a review of 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 training of personnel:

a) Include a reference to the operator training program and the operator requalification program in this section.

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

c) Discuss the selection and training of personnel in this section.

d) Indicate if minimum requirements exist for the facility staff.

PSAR Section 12.2 – Review and Audit Activities

RAI 12.2-1 NUREG-1537, Part 2, Section 12.2, “Review and Audit Activities,” states, “The 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.”

PSAR Section 12.2, “Review and Audit Activities,” states, “The [Plant Manager] 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 required 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, states, “The applicant should give the details of the review function…The reviews should include 10 CFR 50.59 safety reviews.”

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,” states, “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, 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, “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.”

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.

PSAR Section 12.3 - Procedures

RAI 12.3-1 NUREG-1537, Part 1, Section 12.3, “Procedures,” states, “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,” states, “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."

The PSAR 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, as addressed below:

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

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

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

* Please note that 10 CFR 50.59 may apply to changes to procedures.

PSAR Section 12.7 – Emergency Planning

RAI 12.7-1 NUREG-0849, 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, Rev. 0, 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 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 "the 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 "The 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 “The 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 Preliminary Emergency Plan, Rev. 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.

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

RAI 12.7-4 The Preliminary Emergency Plan, Rev. 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 “the 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 Preliminary Emergency Plan, Rev. 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 Shift Supervisor if the Shift Supervisor is absent filling the roll of the Emergency Director or explain why this information is not necessary.

(Applies to RAIs 12.7-6 through 7)

NUREG-0849, Section 3.0, Evaluation Item 1.f, 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 Preliminary Emergency Plan, Rev. 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 Preliminary Emergency Plan, Rev.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 that "each 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 that each licensee's emergency plan should contain "emergency action levels which are 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. NRC staff believes that an unshielded criticality event would have 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 Table 5.1 of the SHINE Preliminary Emergency Plan, Rev. 0, 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 Final Safety Analysis Report (FSAR).

RAI 12.7-11 Section 5.0, Emergency Action Levels," of the SHINE Preliminary Emergency Plan, Rev. 0, 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.

To the extent possible, 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.

RAI 12.7-12 NUREG-0849, Section 6.0, "Emergency Planning Zones," 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."

Section 6.0, Emergency Planning Zone (EPZ), of the Preliminary Emergency Plan, Rev. 0, 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 or NUREG-0849, include an acceptable basis for the selection of the EPZ or explain why an EPZ is not necessary.

RAI 12.7-13 NUREG-0849, Section 7.0, "Emergency Response," states that the emergency plan should cover the actions to notify and mobilize the emergency organization and the applicable offsite support organizations for each emergency class."

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," states that "the emergency plan should provide a summary description of those actions that could be taken to mitigate or correct the problem for each emergency class."

Section 7.3 of the SHINE Preliminary Emergency Plan, Rev. 0 addresses corrective actions for taking control of an emergency, however the information provided is insufficient.

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 Preliminary Emergency Plan, or explain why this information is not necessary.

RAI 12.7-15 NUREG-0849, Section 7.0, 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 items relied on for safety, or 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, Evaluation Item 4.a, states that the emergency plan should describe "conditions 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 the SHINE Preliminary Emergency Plan, Rev. 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 "methods to ensure personnel accountability and the segregation of potentially contaminated personnel."

RAI 12.7-17 Describe the "contaminations controls," as mentioned in Section 7.4.5 of the SHINE Preliminary Emergency Plan, Rev. 0, that will be in place throughout the facility and in close proximity to the contaminated area, or 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 the SHINE Preliminary Emergency Plan, Rev. 0 or explain why this is not necessary.

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

Section 7.4.7 of the SHINE Preliminary Emergency Plan, Rev.0, 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, Evaluation Item 4.e, states that the emergency plan should describe "the 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 Section 7.2.1 of the SHINE Preliminary Emergency Plan, Rev. 0 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 or describe where this information can be found in the Safety Analysis Report. Alternatively, 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 and clear description of the ESC such as its primary location, back-up location, capabilities, equipment, size, or 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, states that the 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, Rev. 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, states that "the 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, Rev. 0, Section 8.4. 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 "written 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, Rev. 0, Section 8.5.2, confirm that a description of the backup off-site communications system will be provided with the FSAR.

RAI 12.8-28 NUREG-0849, states that "an emergency plan shall be prepared that addresses the necessary provisions for coping with radiological emergencies."

SHINE Preliminary Emergency Plan, Rev. 0, Section 8.6, "Contingency Plan," 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 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, Rev. 0, Section 9.0, 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 revise the emergency plan to reflect conditions, as stated in the approved guidance.

RAI 12.7-30 The staff could not find in the SHINE Preliminary Emergency Plan, Rev. 0, where 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 are located.

Identify the section within the SHINE Preliminary Emergency Plan, Rev. 0, where this information can be found or 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. Alternatively, explain why this information is not necessary.

RAI 12.7-31 NUREG-0849, Section 9.0, "Recover," states that the emergency plan should specify "that the recovery procedure(s) will be written and approved as needed."

Explain who will write and who will 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," states that the 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 included in 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, Rev. 0, will be 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," states that the emergency plan should provide for annual 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, or 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 the licensee will provide to workers. Include in the emergency plan the following, or explain why this information is not necessary:

a) The topics and general content of training programs for the licensee'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 the licensee would offer to fire, police, medical, and other non-licensee emergency personnel 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 (QAPD)

PSAR Appendix 12C Section 1 - Introduction

RAI 12C.1 ANSI/ANS-15.8-1995, Section 1.3 defines safety-related items and 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 last paragraph of the QAPD Executive Summary and Section 1, Introduction, state that SHINE utilizes a definition of safety-related systems, structures, and components (SSCs) for the Quality Level 1 SSCs from 10 CFR 70.4, "Definitions". 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.

Clarify (a) how the QAPD definition for safety-related SSCs is 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.

PSAR Appendix 12C Section 1.2 - Application

RAI 12C.1.2-1 ANSI/ANS-15.8-1995, Section 1.2 states, in part, that activities 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.

Section 1.2 of the QAPD states that activities 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 the activities related to protection systems are included for the safety systems listed above in the quality assurance program.

RAI 12C.1.2-2 ANSI/ANS-15.8-1995, Section 1.2 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 QAPD Section 3, Facility Operations, states that this section provides the elements of a quality assurance program for conduct of operations at the SHINE facility. The last paragraph of the QAPD Section 1.2 states that the 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.

PSAR Appendix 12C Section 2.1 - Organization

RAI 12C.2.1-1 ANSI/ANS-15.8-1995, Section 2.1 states that persons 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 QAPD Section 2.1, subsection titled “Chief Operating Officer (COO)” states that authority 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 states that the 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 QAPD Section 2.1, subsection titled “Chief Operating Officer (COO)” states that the Chief Operating Officer 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 report to the COO on all matters concerning quality. The SHINE Functional Organizational Chart, as provided in Enclosure 1, 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 QAPD Section 2.1, subsection titled “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 report to the Chief Executive Officer (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 Section 2.1.2 of the QAPD states that independence 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.

PSAR Appendix 12C Section 2.3 – Design Control

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

Section 2.3 of the QAPD states that this 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 Section 3.10 of ANSI/ANS-15.8-1995, 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 states that applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented.

Section 2.3.1 of the QAPD states that 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 states that in 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.

Section 2.3.3 of the QAPD states that, in 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 systems, structures, and components 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 states that when 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.

Section 2.3.4 of the QAPD 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."

RAI 12C.2.3-5 10 CFR 50.34(a)(7) requires "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."

Section 2.3.1 of the QAPD states that "applicable design inputs, such as, performance requirements, regulatory requirements, codes and standards, shall be identified and documented."

The QAPD does not provide an adequate description of the management measures established to ensure compliance with the performance requirements, and does not provide an adequate discussion of what Quality Levels will be applied to passive engineered and active engineered items relied on for safety (IROFS) to ensure they are available and reliable to perform their safety function when needed.

Describe quality assurance measures that will be applied to the design, procurement, construction, operation, maintenance, inspection, testing, and modification of IROFS, as presented elsewhere in the PSAR. NUREG-1520, Section 11.4.3.8, provides additional guidance for quality assurance elements related to IROFS.

PSAR Appendix 12C Section 2.4 – Procurement Document Control

RAI 12C.2.4-1 ANSI/ANS-15.8-1995, Section 2.4 states that at each level of procurement, the procurement documents shall provide for access to supplier's plant facilities and records, for inspection or audit by the purchaser, the designated representative, or other parties authorized by the purchaser.

The QAPD Section 2.4 states that at 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 further states that the procurement documents shall include purchaser’s requirements for reporting and approving disposition of supplier nonconformances associated with the items or services being procured.

The second paragraph of the QAPD Section 2.4 states that procedures 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.

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

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

The second paragraph of the QAPD Section 2.5 states that 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.

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

RAI 12C.2.7 ANSI/ANS-15.8-1995, Section 2.7.3 states that based 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 QAPD Section 2.7.3 states that based 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.

PSAR Appendix 12C Section 2.10 – Inspections

RAI 12C.2.10 ANSI/ANS-15.8-1995, Section 2.10 states that records of the inspection personnel's qualification shall be established and maintained by the employer.

The second paragraph of the QAPD Section 2.10 states that records of the 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).

PSAR Appendix 12C Section 3 – Facility Operations

RAI 12C.3 ANSI/ANS-15.8-1995, Section 3 states that many 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.

Section 3 of the QAPD states that many 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."

PSAR Appendix 12C Section 3.3 – Performance Monitoring

RAI 12C.3.3 ANSI/ANS-15.8-1995 states that management shall document periodical observations and identify any deficiencies. It also states that management should assess deficiencies to ensure the execution of corrective actions that will prevent recurrence.

Section 3.3 of the QAPD states 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).

PSAR Appendix 12C Section 5 – Decommissioning

RAI 12C.5 ANSI/ANS-15.8-1995, Section 5 states that 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.

Section 5 of the QAPD states that the quality assurance requirements for the SHINE facility during the decommissioning phase are addressed by the appropriate sections of this QAPD and the 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.

PSAR Appendix 12C Enclosure 2 – Graded Approach to Quality

RAI 12C.E2 ANSI/ANS-15.8-1995, Section 1.3, defines safety-related items and 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 QAPD Enclosure 2, Graded Approach to Quality, 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. It further states that QL-2 will include quality activities performed by the licensee, generally on a continuing basis that is applied to ensure that the items are available and reliable to perform their safety functions when needed.

Provide clarification for the following:

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

(b) as to the meaning of the phrase “generally on a continuing basis,” as used in the definition of QL-2 in Enclosure 2; and

(c) as to why items that “are available and reliable to perform their safety functions when needed” are not considered safety-related.

Chapter 13 – Accident Analysis

Generic Information Request

RAI 13a2-G 10 CFR 50.34(a)(4), “Contents of applications; technical information,” 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.”

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, section 13a2.2.1.4 states that “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 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; and

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 power 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.

PSAR Section 13a2.1 – Irradiation Facility Accident Analysis

RAI 13a2.1-1 ISG to 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 (MHA).

PSAR Section 13a2.1.1.1 states, “Because 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 7 and RAIs 13a2.2-1 through 2)

ISG to NUREG-1537, Part 2, Section 13a2, 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 PSAR Section 13a2.1.1.1 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 The applicant may have to analyze several events in a particular accident category to determine the limiting event.

PSAR Section 13a2.1.2.1 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 PSAR Section 13a2.1.2.2.3 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 PSAR Section 13a2.1.2.2.1 discusses increases in the target solution density during operations and concludes that "this even causes a positive reactivity addition, but not large enough to reach a critical condition…" However, additional information is needed for the review staff to verify 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 keff 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 keff value.

RAI 13a2.1-6 Scenario C- Loss of or Reduced PCLS and light water pool system (LWPS) Flow is the most limiting of the reduction of cooling events, as described in PSAR Section 13a2.1.3.1. 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 PSAR Section 13a2.1.8.2 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."

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

RAI 13a2.2-1 PSAR Section 13a2.2.1.5 defines factors related to the radiation source term.

Provide the technical basis for these quantities for each specific scenario considered.

RAI 13a2.2-2 PSAR Section 13a2.2.2.1 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.

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

(Applies to RAIs 13b.1-1 through 2 and 13b.2)

10 CFR 50.34(a)(4), "Contents of applications; technical information," 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."

As set forth in Interim Staff Guidance (ISG) augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, October 17, 2012, Part 1, Section 13b, U.S. Nuclear Regulatory Commission (NRC) staff have determined that the "use of Integrated Safety Analysis (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 items relied on for safety (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 ISG to NUREG-1537, Part 2, Section 13b.1 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, (ML13172A361), states that the ISA Summary will be provided in the Operating License Application. Based on the process descriptions and hazards identified in the preliminary safety analysis report (PSAR), the staff believes that certain engineered safety features should be identified and described in the PSAR, because 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 Section 70.61.

RAI 13b.1-2 ISG to 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 the PSAR, specifically 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 PSAR states are bounding, but does not describe all accident scenarios that could result in high or intermediate consequences. The preliminary safety analysis report should describe all accident scenarios that could result in high or intermediate consequences, and then designate the IROFS that prevent or mitigate the consequences. The preliminary safety analysis report should also describe all accident sequences that could result in high or intermediate chemical consequences, and should identify the structures, systems, and components provided for their prevention and mitigation.

Additionally, PSAR Section 13b.2 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. All passive engineered and active

engineered IROFS that prevent or mitigate the accident scenarios with high or intermediate consequences should be described as well. For accident sequences involving chemical consequences, identify the structures, systems, and components 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 Interim Staff Guidance to 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.

The applicant should note 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 staff. Chemical exposure criteria different from those described in this ISG will be acceptable, if an adequate basis for the staff is provided to make the determination needed to issue or continue a license.

The preliminary safety analysis report 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)

PSAR Section 19.2 – Proposed Action

RAI 19.2-1 ISG to 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 of the ER provides proposed equipment to be used in the construction, preoperational, and decommissioning phases. By letter dated October 4, 2013, SHINE's response to Request for Additional Information (RAI) Transportation Request #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 whether a concrete batch plant would be located on the proposed SHINE site. Additionally, provide the following information if a concrete batch plant would be located on site:

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, and

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 ISG to 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 ER identifies a 12-month construction period and the response to RAI Proposed Action Request # 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 #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 #5 states that the duration of decommissioning activities would be 12 months, however the response to Proposed Action Request # 3 states that SHINE assumed a 6-month decommissioning period, which was used to estimate diesel fuel usage.

Clarify 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 ER 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 off-site 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 ISG to 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 molybdenum-99 product.

RAI 19.2-4 ISG to 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.

Provide additional information on the following topics:

a) Footprint of the Production Facility Building: Section 19.4.1.2 of the ER states that the production facility building would have a bounding length of 416 ft. and width of 167 ft. (which equals a footprint of 69,472 sq. ft.). However, the PSAR Section 2.2.2.5.1 assumes bounding dimensions of 316 ft. in length and 316 ft. 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 #5 provides a footprint for the production facility building of 54,000 sq. ft.

   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 #5 provides a total footprint of 350,000 sq ft, which accounts for buildings, parking lots, roads, and the stormwater swale. However, Table 19.4.1-1 of the ER states that 25.85 ac. (10.46 ha) would be permanently disturbed. 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 sq ft (8 ac) footprint, would be permanently converted.

c) Total Temporarily Impacted Acres: The ER, Section 19.2, states that construction activities would affect 51 ac (20.6 ha), of which 25.1 ac (10.2 ha) would be temporarily disturbed. However, Table 19.4.1-1 of the ER states that 14.54 ac (5.88 ha) would be temporarily disturbed.

   Clarify the number of temporarily disturbed acres during construction, operations, and decommissioning.

RAI 19.2-5 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 to 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.

Section 19.2 of the ER identify a maximum of 420 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 #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 #10 states that SHINE assumed 150 vehicles per day during operations.

a) Clarify 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 these numbers within the ER (e.g., Table 19.4.7-1).

b) Clarify and provide the approximate number of vehicles assumed during construction, operation, and decommissioning. Please identify and distinguish between worker vehicles, truck deliveries, and off-site 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 these numbers within the ER.

PSAR Section 19.3 – Description of the Affected Environment

RAI 19.3 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 non-proprietary 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.

PSAR Section 19.4 – Impacts of Proposed Construction, Operations, and Decommissioning

RAI 19.4-1 ISG to NUREG-1537, Part 1, Section 19.4.3, “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 #1 and Air Quality Request #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 ac (10.5 ha) of agricultural land would be permanently converted to industrial use and 0.18 ac (0.07 ha) of open land would be permanently converted to industrial use, for a total of 25.85 (ac) (10.46 ha) of permanently converted land.

Clarify and address why SHINE used an estimate of 25.67 ac (10.39 ha) or 25.85 ac (10.46 ha) of permanently converted land to estimate fugitive dust emissions.

Financial Analysis

RAI FA-1 10 CFR 50, Appendix C.I.A.1 presents the format for including the estimate of construction costs in an application for a CP. In addition, 10 CFR 50, Appendix C.I.A.1 states that the cost estimate should be accompanied by the bases from which the estimate is derived.

However, the application did not include the bases for the total production plant costs, support facility costs, plant equipment, and a one year supply of uranium inventory.

Address the providing the bases from which the estimates were derived.

RAI FA-2 10 CFR 50.33(f)(2) requires licensees to submit information related to obtaining funds to cover costs of operations for the first five years of facility operations.

SHINE provided information related to operating revenues and costs projected for 2017-2021. SHINE indicated that revenues from operations will be used to cover costs of operations. NUREG-1713, Revision 1, informs NRC staff to review relevant information related to the source of revenues to cover facility operations costs.

The application did not indicate the bases for their revenue projections or the bases for the plant operation costs.

Provide the bases for which the estimates of operation costs are derived. Additionally, provide similar information for the revenue estimates provided in the CP application.