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3.0 DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

The purpose of structures, systems, and components (SSCs) is to ensure safety of the SHINE irradiation facility (IF) and radioisotope production facility (RPF) and protection of the public. The SSCs, identified by the analyses in the SHINE Medical Technologies, Inc. (SHINE) Preliminary Safety Analysis Report (PSAR), should be designed using the appropriate architectural and engineering design criteria.

This chapter of the SHINE construction permit (CP) safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) of the preliminary design of the SHINE IF and RPF SSCs as presented in Chapter 3, “Design of Structures, Systems, and Components,” of the SHINE PSAR, as supplemented by the applicant’s responses to requests for additional information (RAIs).

3.1 Areas of Review

SHINE PSAR Section 3, “Design of Structures, Systems and Components,” identifies the SSCs considered to ensure facility safety and protection of the public. SHINE PSAR Sections 3.1 through 3.5 are applicable to both the SHINE IF and RPF. SSCs that are unique to either the IF or RFP are covered in SHINE PSAR Sections 3.5a, “Irradiation Facility” or 3.5b, “Radioisotope Production Facility,” respectively.

The staff reviewed PSAR Section 3 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design criteria of the SHINE facility SSCs. As part of this review, the staff evaluated descriptions and discussions of the SHINE facility SSCs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the SHINE facility SSCs were evaluated to ensure the design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions is sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed SHINE’s identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design.

Areas of review for this section included both SHINE IF and RPF SSCs. Within these review areas, the staff assessed the following:

- The capability of the SSCs to ensure safe facility operation, safe facility shutdown and continued safe conditions, response to anticipated transients, response to potential accidents analyzed in PSAR Chapter 13, “Accident Analysis,” and control of radioactive material discussed in PSAR Chapter 11, “Radiation Protection Program and Waste Management.”
- The capability of the SSCs to withstand wind and other meteorological conditions (e.g., wind loading, pressure and back pressure effects of potential wind conditions, snow and ice loads) as discussed in PSAR Chapter 2, “Site Characteristics.”
- The capability of the SSCs to withstand predicted hydrological conditions at the site, including a postulated inadvertent Fire Protection System (FPS) discharge.

- The capability of the SSCs to maintain function in the case fo a seismic event at the site.
- The capability of the SSC design bases to ensure required electromechanical systems and components function.

3.2 Summary of Application

As stated above and described in SHINE PSAR Section 3, the design bases of SSCs for the IF and RPF are established to ensure facility safety and protection of the public. With the exception of discussion related to IF- or RPF-specific systems, the summary provided below applies to both the IF and RPF.

PSAR Section 3.1 discusses the use of defense-in-depth practices in the SHINE facility and system design. PSAR Section 3.1 also discusses the facility and provides a “road map” where the specifics of the design criteria are discussed in detail. PSAR Section 3.2, “Meteorological Damage,” includes historical data and predictions as specified in PSAR Chapter 2, “Site Characteristics,” and discusses the criteria used to design the SHINE facility to withstand wind, tornado, snow and ice, and water damage. The combinations of the meteorological loads with other loads (i.e., dead loads and earthquake loads) for the structural analysis are provided in PSAR Section 3.4, “Seismic Damage.” PSAR Chapter 3.3, “Water Damage,” provides information on the hydrological conditions found at the facility. PSAR Sections 3.4.1 and 3.4.2 provide information on seismic input and analysis, including the following items Design Response Spectra, Design Time Histories, Critical Damping Values, Seismic Analysis Methods, Soil-Structure Interaction Analysis (includes meteorological loads), Combination of Earthquake Components, Seismic Analysis Results, Assessment of Structural Seismic Stability (includes meteorological loads), Structural Analysis of Facility (includes meteorological loads). PSAR Section 3.4.3 presents the seismic qualification of systems and equipment. PSAR Section 3.4.4 discusses seismic instrumentation. PSAR Section 3.4.5.1, “Aircraft Impact Analysis,” provides an aircraft impact analysis since the SHINE facility is located near the Southern Wisconsin Regional Airport (SWRA). PSAR Section 3.4.5.2, “External Explosions,” provides an assessment of external explosions. PSAR Section 3.5, “Systems and Components,” discusses SSCs that are considered either safety related (SR) or nonsafety-related (NSR) and what criteria were used to make this determination. Additionally, SSCs were classified by three seismic categories (i.e., SC I, SC II, and SC III) and two quality levels (i.e., QL-1 and QL-2). Safety related SSCs are classified QL-1 and SC I; and NSR SSCs are classified QL-2 and either SC II or SC III. PSAR Sections 3.5a, “Irradiation Facility,” and 3.5b, “Radioisotope Production Facility,” lists systems that are part of the IF and RPF, respectively. Specifically, SSCs required to operate during and/or after design basis accidents or a design basis earthquake (DBEQ) are discussed in these sections or in the system’s PSAR section and include relevant requirements, standards, and documentation.

Additionally, the following PSAR tables list facility systems and provide references to guidance, codes, and standards.

- Table 3.1-1, “Systems List.”
- Table 3.1-2, “Codes and Standards Used to Guide the Design of the SHINE Facility.”
- Table 3.1-3, “NRC Guidance Used in the Design of the SHINE Facility.”

3.3 Regulatory Basis and Acceptance Criteria

As previously stated and described in SHINE PSAR Section 3, the design bases of SSCs for the IF and RPF are established to ensure facility safety and protection of the public. Therefore, the regulatory basis and acceptance criteria provided below applies to both the IF and RPF.

The staff reviewed SHINE PSAR Section 3 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design criteria for the SHINE facility SSCs in support of the issuance of a construction permit. In accordance with paragraph (a) if 10 CFR 50.35, “Issuance of Construction Permits,” a construction permit authorizing SHINE to proceed with construction may be issued once the following findings have been made:

(1) SHINE has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.
(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.
(3) Safety features or components, if any, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.
(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

The staff’s evaluation of the preliminary design criteria for SHINE’s SSCs does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE facility SSCs as described in the FSAR as part of SHINE’s operating license application.

3.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE’s SSC design criteria are as follows:

> 10 CFR 50.34, “Contents of applications; technical information,” paragraph (a), “Preliminary safety analysis report.”

3.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated SHINE’s SSC design criteria against the applicable regulatory requirements listed above primarily using the guidance and acceptance criteria contained in Chapter 3, “Design of Structures, Systems, and Components,” of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 4), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 5), as well as the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 6), and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 7).

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers [IEEE] standards, American National Standards Institute/American Nuclear Society [ANSI/ANS] standards) has been utilized in the review of SHINE's SSC design criteria. The use of additional guidance is based on the technical judgement of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG Augmenting NUREG-1537, Parts 1 and 2; and the SHINE PSAR.

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 3.4, "Review Procedures and Technical Evaluation," of this SER. Additional guidance documents used to evaluate SHINE's SSC design criteria are provided as references in Appendix B.

3.4 Review Procedures, Technical Evaluation, and Evaluation Findings

As described in SHINE PSAR Section 3, the design bases of SSCs for the IF and RPF are established to ensure facility safety and protection of the public. The technical evaluation provided below in Sections 3.4.1 through 3.4.4 applies to both the SHINE IF and RPF, in Section 3.4.5.1 applies to the SHINE IF, and in Section 3.4.5.2 applies to the SHINE RPF. The staff's review considers the interface of SSCs between the IF and RPF as part of the technical evaluation.

The staff performed an evaluation of the technical information presented in SHINE PSAR Section 3, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of the SHINE facility's SSC design criteria in support of the issuance of a construction permit, in accordance with 10 CFR 50.35(a). Sufficiency of the preliminary design criteria for SHINE's SSCs is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 3.3, "Regulatory Basis and Acceptance Criteria," of this SER. The results of this technical evaluation are described in SER Section 3.5, "Summary and Conclusion."

For the purposes of issuing a CP, the preliminary design of the SHINE facility SSCs may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the SHINE facility SSCs based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of the SHINE facility SSCs does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the

SHINE facility SSCs, as described in the FSAR, as part of SHINE's operating license application.

3.4.1 Design Criteria

The staff evaluated the sufficiency of the design criteria, as described in SHINE PSAR Section 3.1, "Design Criteria," using the guidance and acceptance criteria from Section 3.1, "Design Criteria," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG 1537, Part 2, Section 3.1, the staff compared the specified design criteria with the proposed and analyzed normal operation, response to anticipated transients, and consequences of accident conditions applicable to the appropriate SSCs assumed to function in SHINE PSAR 3.1 and other relevant chapters of the PSAR.

As stated in Section 3.1 of NUREG-1537, Part 2, the design criteria should be specified for each SSC that is assumed in the PSAR to perform an operational or safety function. Additionally, design criteria should include references to applicable up-to-date, standards, guides, and codes. The design criteria should be stipulated for those features as outlined below:

- Design for the complete range of normal facility operating conditions.
- Design to cope with anticipated transients and potential accidents.
- Design redundancy to protect against unsafe conditions in case of single failures of facility protective and safety systems.
- Design to facilitate inspection, testing, and maintenance.
- Design to limit the likelihood and consequences of fires, explosions, and other potential manmade conditions.
- Quality standards commensurate with the safety function and potential risks.
- Design bases to withstand or mitigate wind, water, and seismic damage to reactor systems and structures.
- Analysis of function, reliability, and maintainability of systems and components.

SHINE PSAR Section 3.1 states the SHINE facility and system design are based on defense-in-depth practices. Defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. PSAR Section 3.1 also provides sufficient information to guide the staff to the appropriate section of the PSAR where the design criteria for specific SSCs are discussed in detail. Additionally, PSAR Section 3.1 outlines the standards, guides, and codes applied to the design of the SSCs.

On the basis of its review, the staff finds that the level of detail provided demonstrates an adequately established design criteria in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.1, allowing the staff to make the following relevant findings: (1) the design criteria are based on applicable standards, guides, codes, and criteria and provide reasonable assurance that the facility SSCs can be built and will function as designed and as required by the SAR; (2) the design criteria provide reasonable assurance that the public will be protected from radiological risks from operation.

Therefore, the staff finds that the design criteria of the SHINE facility SSCs meets the applicable regulatory requirements and acceptance criteria of NUREG-1537 in support of the issuance of a construction permit in accordance with 10 CFR 50.35.

3.4.2 Meteorological Damage

The staff evaluated the sufficiency of the facility design features to cope with meterological damage, as described in SHINE PSAR Section 3.2, “Meteorological Damage,” using the guidance and acceptance criteria from Section 3.2, “Meteorological Damage,” of NUREG-1537, Part 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 3.2, the staff considered the description of the site meteorology to ensure that all SSCs that could suffer meteorological damage are considered, as presented in PSAR Section 3.2 and other relevant chapters of the PSAR. The design criteria and the potential for meteorological damage compare with local applicable architectural and building codes for similar structures. The design specifications for SSCs are compatible with the functional requirements and capability to retain function throughout the predicted meteorological conditions. The methods for determining the wind, tornado, and snow and ice loadings are summarized. In PSAR Section 3.4.2.6.3, “Site Design Parameters,” these loads are provided as site design parameters rather than as structural design loads. The combinations of the meteorological loads with other loads (i.e., dead loads and earthquake loads) for the structural analysis are provided in PSAR Section 3.4, “Seismic Damage.”

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

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

Therefore, in RAI 3.2-1 (Reference 14), staff asked the appliant to 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, and to calculate the design loads on the roof of the reactor building, and compare them with local building codes for similar types of structures. The applicant was also asked to provide additional information explaining why PSAR Section 3.2.3, “Snow, Ice, and Rain Loading,” does not utilize the data developed under PSAR Section 2.3.1.2.9, “Snowpack and Probably Maximum Precipitation (PMP),” or update PSAR Section 3.2.3 with the data in PSAR Section 2.3.1.2.9, accordingly.

In response to RAI 3.2-1 (Reference 21), the applicant pointed out the location of this information in the PSAR and stated that a rain-on-snow surcharge load is not considered in the structural analysis because the SHINE facility is located in an area where the ground snow load (determined from Figure 7-1 of American Society of Civil Engineers [ASCE] 7-05, "Minimum Design Loads for Buildings and Other Structures") is greater than 20 lb/ft^2. The applicant also stated that PSAR Sections 2.3.1.2.9 and 19.3.2.3.6 contain an administrative error stating the units for the 50 and 100-year interval snowpacks are inches. In accordance with Figure 7-1 of ASCE 7-05, the units for the 50 and 100-year interval snowpacks are lb/ft^2. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds this response is consistent with an applicable industry standard and, therefore, satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.2 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on meterological damage is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.2, allowing the staff to make the following relevant findings: (1) the design criteria and designs should provide reasonable assurance that SSCs would continue to perform their safety functions as specified in the SAR under potential meteorological damage conditions; and (2) the design criteria and designs should use local building codes, standards, or other applicable criteria, at a minimum, to ensure that significant meteorological damage at the facility site is very uilikely.

Therefore, the staff finds that the facility design features to cope with meterological damage is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35.

3.4.3 Water Damage

The staff evaluated the sufficiency of the facility design features to cope with predicted hydrological conditions, as described in SHINE PSAR Section 3.3, "Water Damage," using the guidance and acceptance criteria from Section 3.3, "Water Damage," of NUREG-1537, Part 2.

In accordance with the review procedures of Section 3.3 of NUREG-1537, Part 2, the staff considered the site description to ensure that all SR SSCs with the potential for hydrological (water) damage, including the damage due to a potential inadvertent FPS discharge, are considered in this PSAR section. For any such SR SSC, the staff reviewed the design bases to verify consequences are addressed and described in detail in appropriate chapters of the SHINE PSAR.

SHINE PSAR Section 3.3 provides the design basis precipitation level (at grade), flood level (below grade), and maximum ground water level (below grade) for the SHINE facility. These levels are associated with the local probable maximum precipitation (PMP) and the local probable maximum flood (PMF) and are quantified in PSAR Section 2.4, "Hydrology." In SHINE PSAR Section 2.4.2.3, "Effect of Local Intense Precipitation," a local PMP event creates a water level about level with grade. The first floor of the building is at least 4 inches (in.) above grade; therefore, water will not infiltrate the door openings in the case of a local PMP event. In SHINE PSAR Section 2.4.3, "Probable

Maximum Flood on Streams and Rivers," a local PMF event creates a water level approximately 50 feet (ft) (15.2 meters [m]) below grade. The lowest point of the facility is 29 ft (8.8 m) below grade; therefore, flooding does not cause any structural loading in the case of a local PMF event. The PMF elevation is approximately 50 ft (15.2 m) below grade. There is no dynamic force on the structure due to precipitation or flooding. The lateral surcharge pressure on the structures due to the design PMP water level is calculated and does not govern the design of the below grade walls. The load from water due to discharge of the fire protection system in the radiologically controlled area (RCA) is supported by slabs on grade. Drainage is provided for the mezzanine floor in the RCA to ensure that the mezzanine slab is not significantly loaded. The mezzanine floor slab is designed to a live load of 125 pounds per square foot (610 kilograms per square meter). Therefore, the mezzanine floor slab is capable of withstanding any temporary water collection that may occur while water is draining from the mezzanine floor.

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

While SHINE PSAR, Section 3.3, 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 FPS, there is no discussion of the effects of discharge of the FPS on SSCs.

Therefore, in RAI 3.3-1 (Reference 14), staff asked the applicant to provide information on the effects of discharge from the FPS on SSCs.

In response to RAI 3.3-1 (Reference 21), the applicant stated, in part, that "[t]he safety-related function(s) of structures, systems, and components (SSCs) that are subject to the effects of a discharge of the fire suppression system will be appropriately protected by redundancy, separation, and a fail-safe design of each SSC." The applicant also stated, in part, that "electrical equipment may be protected from unacceptable damage if wetted by fire sprinkler system discharge by sprinkler water shields or hoods, in accordance with National Fire Protection Association (NFPA) 13 [Reference 34]." Additionally, the applicant indicated that fire suppression system discharge in one fire area will not impact safety-related SSCs in adjacent fire areas.

The staff finds this response is consistent with an applicable industry standard and, therefore, satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.3 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on hydrological damage is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.3, allowing the staff to make the following relevant findings: (1) the design criteria and designs should provide reasonable assurance that SSCs would continue to perform required safety functions under water damage conditions; and, (2) the design should use local building codes, as applicable, to help ensure that water damage to SSCs at the facility site would not cause unsafe facility operation, would not prevent safe shutdown of the facility, and would not cause or allow uncontrolled release of radioactive material.

Therefore, the staff finds that the facility design features to cope with hydrological damage is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35.

3.4.4 Seismic Damage

The staff evaluated the sufficiency of the facility design features in the case of a seismic event, as described in SHINE PSAR Section 3.4, “Seismic Damage,” using the guidance and acceptance criteria from Section 3.4, “Seismic Damage,” of NUREG-1537, Part 2.

In accordance with the review procedures of Section 3.4 of NUREG-1537, Part 2, the staff considered the site description and historical data to ensure that the appropriate seismic inputs have been considered. For any SSC damage, the staff considered the extent to which a seismic event would impair the safety function of the SSC.

SHINE PSAR Section 3.4.4 discusses that seismic instrumentation will be solid-state triaxial time-history accelerometers at essential locations that enable the prompt processing of the data. Additionally, the accelerometers will operate during all modes of facility operation. Maintenance and repair procedures will be developed to keep the maximum number of accelerometers in service during facility operation. In addition, the accelerometers will include provisions for in-service testing, the capability of periodic channel checks during normal facility operation, and the capability for in-place functional testing.

SHINE PSAR Section 3.4.5.1, “Aircraft Impact Analysis,” provides an aircraft impact analysis since the SHINE facility is located near the SWRA.

SHINE PSAR Section 3.4.5.2, “External Explosions,” provides an assessment of external explosions even though the SHINE facility is not licensed as an operating nuclear reactor. Since SHINE is not a reactor, the NRC Regulatory Guide 5.69, “Guidance for the Application of Radiological Sabotage Design-Basis Threat in the Design, Development and Implementation of a Physical Security Program that Meets 10 CFR 73.55 Requirements,” postulated explosions are not considered. Notwithstanding the above, SHINE was assessed for accidental explosions due to chemical reactions inside the facility, accidental explosions due to storage of hazardous materials outside the facility, and accidental explosions due to external transportation.

SHINE PSAR Section 2.2.3.1.1, “Explosions,” provides the maximum overpressure at any safety-related area of the facility from any credible external source is less than 1 pounds per square inch (psi) (6.9 kilopascal [kPa]). This safety-related area is within the facility’s seismic boundary, and is thus protected by outer walls and roofs consisting of reinforced concrete that is strong enough to withstand the postulated external explosions defined in Regulatory Guide 1.91, Revision 1, “Evaluations of Explosions Postulated to Occur on Transportation Routes Near Nuclear Power Plants.”

NUREG-1537, Part 1, Section 3.4, “Seismic Damage," states that the applicant should include information on the facility seismic design to provide reasonable assurance that the reactor could be shut down and maintained in a safe condition or that the consequences of accidents would be within the acceptable limits in the event of potential seismic events. To verify that seismic design functions are met, the applicant should give the bases for the technical specifications. NUREG-1537, Part 2, Section 3.4, “Seismic Damage,” states that the reviewer should find sufficient information to conclude that the design to protect against seismic damage provides reasonable assurance that the facility structures, systems, and components will perform the necessary safety functions described and analyzed.

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

Therefore, In RAI 3.4-1 (Reference 14), the staff asked the applicant to provide: (a) the reference manual and revision used for SASSI; (b) additional information explaining whether the geotechnical investigations requested above also determined the dynamic soil properties used for the Soil-Structure Interaction analyses; and (c) the report with details and results for the Soil-Structure Interaction analyses.

In response to RAI 3.4-1 (Reference 21), the applicant stated, in part, that "the soil-structure interaction analysis . . . was performed using the SASSI2010 software, Version 1.0. The SASSI2010, Version 1.0 User's Manual contains proprietary information and, therefore, is available for NRC review at Sargent and Lundy's offices." The soil-structure interaction analysis used equivalent linear elastic material properties because the frequency domain analysis method in SASSI requires the use of elastic material properties. The applicant used the following approach to determine the equivalent linear material properties for the dynamic analyses:

1. Shear wave and compression wave test results from Table A-1 of the Preliminary Geotechnical Engineering Report . . . were obtained and considered as the best estimate (mean) soil properties (G_{BE}). The soil test results provided mechanical properties at low shear strain level.

2. Free field site response analyses were conducted for input seismic motions using the SHAKE2000 computer program to determine the shear strain compatible shear modulus and damping values for the design basis seismic input motion. SHAKE2000 uses an iterative nonlinear procedure to determine strain compatible soil properties from the geotechnical investigation results.

3. The strain compatible soil properties obtained from the above procedure were input to SASSI and the seismic analyses using the frequency domain method were conducted to determine seismic responses of the structure and to develop in-structure response spectra.

Additionally, the applicant stated, in part, that "[o]nly the best estimate soil case is reported for the seismic analysis in [PSAR Section 3.4]. The variation of the soil properties will be considered in the final seismic analysis. Upper bound and lower bound soil properties (G_{UB} and G_{LB}) . . . and the coefficient of variation (COV) will be determined in accordance with [NUREG-0800 Section 3.7.2], and the results of the final seismic analysis will be provided in the FSAR." The applicant also provided Calculation 2013-02413, "Soil-Structure Interaction Analysis of Shine Medical Isotope Production Facility for Design Seismic Event," Revision 0. Following the receipt of SHINE's FSAR, staff will confirm that the issue described above has been resolved in the final seismic analysis.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.4 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 1, Section 3.4, "Seismic Damage," states, in part, 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 . . . 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, in part, 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.

Therefore, in RAI 3.4-2 (Reference 14), the staff asked the applicant to provide a comprehensive description of the SHINE facility structures required to maintain necessary safety functions should a seismic event occur.

In response to RAI 3.4-2 (Reference 21), the applicant described the SHINE IF and RPF structures necessary to provide safety functions. These structures included the supercells and tank farm, which make up the Radiologically Controlled Area (RCA). Thick concrete walls and roofs encase each Iradiation Unit (IU) in a concrete vault, which is seismically designed. Additionally, IUs are housed within the IF and are separated from the RPF within the seismic boundary as shown in SHINE PSAR Figure 1.3-2. SHINE PSAR Figure 1.3-2 also shows the control room, battery rooms, uninterruptable power supply rooms, and other miscellaneous support rooms to the west. The RCA and these areas to the west of the RCA are part of the seismic boundary and are classified as Seismic Category I. These areas contain the safety-related SSCs. The applicant described the construction of these structures and stated that the concrete walls and slabs are designed for axial, flexural, and shear loads in accordance with American Concrete Institute (ACI) 349-06. The applicant stated other areas of the facility contain nonsafety-related equipment and, therefore, those areas are not Seismic Category I.

Further, the applicant stated that during a seismic event, the forces will be transmitted through the structural reinforced concrete shear walls to the foundation mat and, ultimately, the soil. SHINE PSAR 3.4.2.6.4.7 describes how sub-grade walls of the facility are designed to resist the dynamic soil pressure loads that may occur during as seismic event.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.4 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

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

SHINE PSAR, Section 3.4.2.6.5, "Structural Analysis Model," reports that a three-dimensional finite element Structural Analysis Model of the SHINE Facility structure was created using the SAP2000 computer program. Additionally, SHINE PSAR, Section 3.4.2.6.6, "Structural Analysis Results," reports Structural Analysis Results were obtained from the SAP2000 model.

Therefore, in RAI 3.4-3 (Reference 14), the staff asked the applicant to provide the reference manual and revision for the SAP2000 computer program that was used. In RAI 3.4-4 (Reference 14), the staff asked the applicant to provide the report with details and results for the SAP2000 finite element structural analyses.

In response to RAI 3.4-3 (Reference 21), the applicant stated that "Version 14.1 of the SAP2000 computer program was used to develop the three-dimensional finite element model of the SHINE facility structure. The SAP2000 reference manual contains proprietary information and, therefore, is available for NRC review at Sargent and Lundy's offices."

In response to RAI 3.4-4 (Reference 21), the applicant provided Calculation 2013-01989, "Conceptual Design of Hardened SHINE Facility Structural Elements," Revision 0, which contains the details and results of the SAP2000 finite element analysis.

The staff finds these responses satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.4 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

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

NUREG-1537, Part 2, Section 3.5, "Systems and Components," states, in part, that the reviewer should conclude there is sufficient information to support the design bases of the electromechanical systems and components to give reasonable assurance that the facility systems and components will function as designed to ensure safe operation and safe shutdown of the facility.

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

Therefore, in RAI 3.4-5, the staff asked the applicant to provide the details and results for seismically qualifying the SHINE facility subsystems and components. The staff also requested the applicant 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, [Reference 35]) are used for the dynamic analyses of equipment.

In response to RAI 3.4-5 (Reference 21), the applicant stated that seismic qualification of piping systems classified as safety-related will be analyzed using the method identified in SHINE PSAR Section 3.4.3. The details of this analysis will be provided in the SHINE FSAR. Additionally, the applicant stated that seismic qualification of components with one of the following methods: (1) qualification by analytical methods (including static analysis, simplified dynamic analysis, or detailed dynamic anaylsis); (2) qualification by testing (e.g., pull testing); or (3) a combination of the analytical and testing methods. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds these responses satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.4 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 1, Section 3.4, "Seismic Damage," states that in order to verify that seismic design functions are met, the applicant should give the technical specifications necessary to ensure operability, testing, and inspection of associated systems, including instrumentation and controls. NUREG-1537, Part 2, Section 3.4, "Seismic Damage," states that the reviewer finds the surveillance activities proposed provide reasonable assurance that the safety-related functions of the structures, systems, and components that are required to respond to, or mitigate the consequences of, seismic damage to the facility will be maintained.

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

Therefore, in RAI 3.4-6 (Reference 14), the staff asked the applicant to: (a) provide a summary description of the data these instruments record in the event of felt earthquake motions (i.e., acceleration time histories); and, (b) provide an explanation of the data retrieval and processing procedure(s). Additionally, the staff asked the applicant to clarify whether a separate computer is required to view the digitized acceleration time histories, and generate response spectra.

In response to RAI 3.4-6 (Reference 20), the applicant stated, in part, that:

> . . .neither NUREG-1537 nor the ISG augmenting NUREG-1537 require seismic instrumentation for research reactors or isotope production facilities. Seismic instrumentation is not required as referenced under Section IV(a)(4) of Appendix S to 10 CFR 50 or Section VI(a)(3) of Appendix A to 10 CFR 100, since the SHINE facility is not a nuclear power plant. Therefore, SHINE has decided to not install seismic instrumentation. An IMR has been initiated to remove the reference to installed seismic instrumentation from Subsection 3.4.4. Should a seismic event be felt at the SHINE facility . . . as stated in the SHINE Preliminary Emergency Plan [Reference 3]. The operators will place the plant in a safe condition until the event can be evaluated and the determination is made that safe operations can be commenced. Facility procedures will be used to systematically assess the operability and functionality of the plant SSCs. The magnitude of the event will be determined using information available from the U.S. Geological Survey (USGS) or other authoritative source.

NUREG-1537, Part 2, Section 3.4, "Seismic Damage," states that "[t]he applicant should demonstrate that all potential consequences from a seismic event are within the acceptable limits considered or bounded in the accident analyses of Chapter 13 to ensure that conditions due to a seismic event will not pose a significant risk to the health and safety of the public." The SHINE site location is near the Southern Wisconsin Regional Airport. SHINE PSAR, Section 3.4.5.1, "Aircraft Impact Analysis," outlines the methodology for conducting and evaluating small aircraft impact analyses in support of the seismic envelope design for external hazards. The potential locations for 25 aircraft impact analyses of the SHINE facility are listed.

SHINE PSAR Table 3.4-4, "Aircraft Impact Analysis Results," show that the performance of all barriers are acceptable to prevent transport of radioactive materials to unrestricted areas. However, staff note the engineering report that describes the analyses' details states that all of the results are not referenced.

Therefore, in RAI 3.4-7 (Reference 14), the staff asked the applicant to provide the engineering report that describes the aircraft impact analyses' details that reports the results. Additionally, the staff asked the applicant to provide a summary of the results.

In response to RAI 3.4-7 (Reference 21), the applicant provided Calculation 2013-01911, "Evaluation for Aircraft Impact," Revision 0, which contains the details and results of the aircraft impact analyses. The applicant stated that:

> Calculation 2013-01911 evaluates the initial design of the SHINE Medical Isotope Production Facility at Janesville, Wisconsin for effects of an accidental aircraft crash by aircraft operating through the SWRA. As described in Calculation 2013-01911, Section 4.1, the Challenger 605 is selected as the design basis aircraft for performing the evaluations. Calculation 2013-01911, Figures 4.4.1-1 (A) and 4.4.1-1 (B), show the walls and roof slabs evaluated for the facility. Roof panels and walls are two-foot thick reinforced concrete with a design strength of 5000 psi. Roof slabs are supported on trusses spanning in the east-west direction. These trusses are supported on external walls and either on an internal wall running in the north-south direction or on a plate girder spanning in the north-south direction.
>
> Evaluations are made for local damage and overall damage in Calculation 2013-01911, Sections 5.2 and 5.3, respectively. Local damage evaluation results show that the two-foot thick reinforced concrete panels do not scab under the impact from the engine of the impacting aircraft. Calculation results for perforation margin show that the condition of ACI 349-06, Paragraph F.7.2.3 is satisfied. Therefore, a punching shear evaluation in the overall response assessment is not necessary.
>
> The overall damage evaluation is performed in Section 5.3 of the calculation, considering 25 cases of impact. Calculation 2013-01911, Section 4.4.4 describes the impact cases. Calculation 2013-01911 Table 6-1 and SHINE PSAR Table 3.4-4 summarize the acceptability of the 25 impact cases, provided stated conditions for reinforcement size and spacing, including shear ties, and provisions for truss members, including a non-linear analysis in the future to show acceptability of inelastic deformation, are met.

The staff finds these responses satisfiy the acceptance criteria of NUREG-1537, Part 2, Section 3.4 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 1, Section 3.4, "Seismic Damage," states that the applicant should include information on the facility seismic design to provide reasonable assurance that the reactor could be shut down and maintained in a safe condition or that the consequences of accidents would be within the acceptable limits in the event of potential seismic events. NUREG-1537, Part 2, Section 3.4, "Seismic Damage," states that the reviewer should find sufficient information to conclude that the design to protect against seismic damage provides reasonable assurance that the facility SSCs will perform the necessary safety functions described and analyzed.

While SHINE's response to RAI 3.4-1(b) (Reference 21) provided additional information on free field site response analyses using the SHAKE2000 computer program, the response did not include a reference for the version of the SHAKE2000 computer program used in SHINE's seismic
analysis.

Therefore, in RAI 3.4-8 (Reference 16), the staff asked the applicant to provide the reference for the version of the SHAKE2000 computer program used in SHINE's seismic analysis.

In response to RAI 3.4-8 (Reference 24), the applicant provided that Version 3.5 of the SHAKE2000 computer program was used in the SHINE seismic analysis.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.4 and demonstrates adequate design criteria in support of a preliminary design.

NUREG-1537, Part 1, Section 3.4, "Seismic Damage," states that in order to verify that seismic design functions are met, the applicant should give the technical specifications necessary to ensure operability, testing, and inspection of associated systems, including instrumentation and controls. NUREG-1537, Part 2, Section 3.4, "Seismic Damage," states that the reviewer find that the surveillance activities proposed provide reasonable assurance that the safety-related functions of the SSCs that are required to respond to, or mitigate the consequences of, seismic damage to the facility will be maintained.

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

However, in response to RAI 3.4-6 (Reference 20), SHINE states that seismic instrumentation will not be installed at the SHINE facility, citing no regulatory requirement for such instrumentation under 10 CFR Part 50 or Part 100. SHINE instead stated, in part, that "procedures will be used to systematically assess the operability and functionality of the plant SSCs. The magnitude of the event will be determined using information available from the U.S. Geological Survey (USGS) or other authoritative source."

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

Therefore, in RAI 3.4-9 (Reference 16), the staff asked the applicant to provide a discussion of the methodology that will be used to develop procedures for post-earthquake evaluations and re-qualifications of Seismic Category I and Seismic Category II SSCs without onsite seismic instrumentation recording information such as acceleration time histories and response spectra.

In response to RAI 3.4-9 (Reference 24), the applicant stated that seismic instrumentation is not required as referenced under Section IV(a)(4) of Appendix S to 10 CFR 50 or Section VI(a)(3) of Appendix A to 10 CFR 100, since the SHINE facility is not a nuclear power plant. However, SHINE has decided that for asset protection and business operations purposes, nonsafety-related seismic instrumentation could assist with the timely determination of the accelerations experienced at the plant following a seismic event. Therefore, SHINE will acquire and install a nonsafety-related seismic monitoring system to help establish the acceptability of continued operation of the plant following a seismic event. This system will provide acceleration time histories or response spectra experienced at the facility to assist in verifying that SSCs important to safety at the SHINE facility can continue to perform their safety functions. SHINE will provide an explanation of the data retrieval and processing procedure(s) and state whether or not a separate computer is required to view the digitized acceleration time histories and generate response spectra in the FSAR. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds these responses satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.4 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on seismic damage is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.4, allowing the staff to make the following relevant findings: (1) the design criteria and designs should provide reasonable assurance that structures, systems, and components would continue to perform required safety functions following a seismic event; and (2) the design to protect against seismic damage provides reasonable assurance that the consequences of credible seismic events will be considered and adequately protect public health and safety.

Therefore, the staff finds that the facility design features to cope with seismic damage is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35.

3.4.5 Systems and Components

The staff evaluated the sufficiency of the facility design features for systems and components, as described in SHINE PSAR Section 3.5, "Systems and Components," using the guidance and acceptance criteria from Section 3.5, "Systems and Components," of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

In accordance with the review criteria of NUREG-1537, Part 2, Section 3.5, the staff verified the design bases for the SSCs that are required to function are described in detail in this or other PSAR sections in sufficient detail.

Additionally, SHINE PSAR Section 3.5 states the following:

> Sections 3.5a and 3.5b discuss the conditional application of Appendix A to 10 CFR 50, "General Design Criteria for Nuclear Power Plants," and 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities," as good design practice. Although not mandatory, these design criteria provide a rational basis from which to proceed.

Based on this statement, the staff review also included 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," and PSAR Table 3.5b-1, "Baseline and General Design Criteria for Radioisotope Production Facility."

Further, in accordance with the guidance in the ISG augmenting NUREG-1537, Part 2, Section 3.5, while compliance with 10 CFR 70.64 is not required for this type of facility, if applicant can adequately address the baseline design criteria in 10 CFR 70.64, it would be found acceptable by the staff. Therefore, since the SHINE PSAR compares the facility against the baseline design criteria of 10 CFR 70.64, the additional basis of NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Section 3.4.3.2 was included in the review which encompassed how the design of the facility addresses each baseline design criterion.

The regulations in 10 CFR 50.2, "Definitions," provide definitions including that for safety-related SSCs. The definition states:

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

The regulations in 10 CFR 70.4, "Definitions," provide the definition for "items relied on for safety" (IROFS)." The definition states:

> Items relied on for safety mean structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a

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

SHINE PSAR, Section 3.5.1, "Classification of Systems and Components Important to Safety," discusses the classification of SSCs. SHINE PSAR, Section 3.5.1.1, "Nuclear Safety Classifications for SSCs," states: SHINE uses a modified definition from 10 CFR 50.2, "Definitions," to develop the definition of SR SSCs, where appropriate, and utilizes a portion of 10 CFR 70.4, "Definitions," for the definition of IROFS SSCs. SHINE PSAR, Section 3.5.1.2, "Quality Assurance (Quality Group Classifications for SSCs)," discusses how SR SSCs will be classified as QL-1 and IROFS SSCs will be classified as QL-2. The section goes on to state that SR SSCs shall have "the full requirements of the Quality Assurance Program Description (QAPD) in accordance with an approved Quality Assurance Plan (QAP)," and that IROFS SSCs shall have requirements "in conformance with an approved QAP...." In addition, SHINE PSAR, Section 3.5.2, "Seismic Classification," states, in part, that SR SSCs and IROFS SSCs are both Seismic Category I. The staff noted that this appeared to infer that IROFS SSCs shall not have "the full requirements of the QAPD in accordance with an approved Quality Assurance Plan (QAP)."

Therefore, in RAI 3.5-1 (Reference 14), the staff asked the applicant to: 1) provide the basis referencing the definition of SR SSCs in 10 CFR 50.2, "Definition," the basis for using a modified definition of SR SSCs, the basis for utilizing only a portion of the requirements of 10 CFR 70.61, "Performance requirements," and the basis for why the 10 CFR 70.61 requirements do not encompass the SHINE's modified definition of SR SSCs; and 2) define and provide the basis for the difference between QL-1 and QL-2. Additionally, 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, the staff asked the applicant to describe how they will be physically different. Finally, with respect to Seismic Category I, the staff asked the applicant to clarify what the differences are in Seismic Category I acceptance criteria under QL-1 and QL-2.

In response to RAI 3.5-1 (Reference 20), the applicant stated that the 10 CFR 50.2 definition of safety-related was referenced because it incorporates specific, measurable attributes that are at least equivalent to the definition of safety-related items contained in ANSI/ANS-15.8-1995 (R2013).

Section 1.3 of ANSI/ANS-15.8-1995 (R2013) states:

> Safety-related items. Those physical structures, systems, and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents.

The applicant stated that the reference of the 10 CFR 50.2 definition of SR SSCs for the IF results in a clear demarcation of safety-related equipment, principally the boundary necessary to contain fissile material, the ability to terminate the fission process and ensure its safe condition after shutdown, and ensure that releases of materials in accidents are limited to ensure 10 CFR 20 regulations are met. Further, the applicant asserted when considering the 10 CFR 50.2 definition as written, items (1) and (2) of the definition do not apply to any SSCs in the facility, as SHINE does not have a reactor. Components would be classified according to item (3) alone. Therefore, by modifying items (1) and (2) of the definition, the applicant has incorporated additional SSCs into the safety-related classification. The applicant stated that this modified definition and the accident analysis process detailed in PSAR Chapter 13 ensures that the health and safety of the worker and the public off-site are adequately protected through proper selection of safety-related SSCs to prevent accidents and control and mitigate their consequences and by ensuring that worker and public doses are less than the limits of 10 CFR 20 during potential accidents. Finally, the applicant determined that a modification of the definition of safety-related will ensure that SSCs important to safety in the RPF are completely encompassed by the safety-related definition, and will eliminate the classification of SHINE SSCs as items relied on for safety (IROFS). SHINE has incorporated chemical and criticality-safety aspects into the classification of safety-related SSCs. SHINE is proposing this alternate methodology for designating SSCs important to safety for both the IF and RPF based on the SHINE definition of safety-related.

The applicant identified a complete set of initiating events and accidents for the entire facility in the ISA performed for the preliminary design. The ISA will be updated as part of detailed design with any necessary changes and will be renamed the "SHINE Accident Analysis" following issuance of the OL. The applicant states the ISA and the SHINE facility design achieve the following objectives: (1) ensures that the complete set of initiating events has been considered; (2) categorizes the initiating events and accidents by type, and determines the limiting cases in each group to be quantitatively analyzed; (3) meets 10 CFR 20 acceptance criteria (i.e., 5 rem total effective dose equivalent (TEDE) to the worker and 100 mrem TEDE to a member of the public off-site) for the consequences of each postulated event; (4) ensures the necessary SSCs are included in the design to prevent criticality; and (5) ensures the necessary SSCs are included in the design to prevent undue risk to the health and safety of workers and the public from accidents involving chemicals produced from licensed material.

The applicant states analyses are performed to identify the SSCs in the facility that are necessary to prevent or mitigate the accidents, in accordance with applicable acceptance criteria. Those SSCs would be designated safety-related. The results of the analyses and the designations of safety-related SSCs would be included in the PSAR and FSAR. SSCs meeting the provisions of 10 CFR 50.36 will be included in the Technical Specifications (TS) and subject to the provisions of 10 CFR 50.90. The term IROFS will no longer be used in the PSAR and FSAR.

The applicant also provides that a configuration management program will be established to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel that affects the safety analysis or licensing basis. The applicant also states that following issuance of the OL, changes to the SHINE facility that affect the accident analysis will be resolved using the failure modes and effects analysis (FMEA) or another suitable accident analysis technique in order to assure that the SHINE facility configuration is maintained in accordance with the licensing basis. Changes to the accident analysis will be evaluated under 10 CFR 50.59 to determine if NRC approval is required. If NRC approval is required, 10 CFR 50.90 will be used.

The applicant also provided the following updated definition of safety-related:

> Safety-Related SSCs: Those SSCs that are relied upon to remain function during normal conditions and during and following design basis events to assure:
>
> 1. The integrity of the primary system boundary (PSB);

2. The capability to shut down the TSV and maintain the target solution in a safe shutdown condition;
3. The capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20;
4. That the potential for an inadvertent criticality accident is not credible;**
5. That acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area; or,
6. That an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur.

   ** - The applicant updated this part of the definition in a response to RAI 3.5-6, which is discussed below.

Related to quality levels, the applicant provided a revised QAPD, which included an updated discussion on the graded approach to quality. The QAPD realigns and redefines the quality levels as follows:

- QL-1 shall implement the full measure of the QAPD and shall be applied to safety-related SSCs.
- QL-2 will include the nonsafety-related quality activities performed by the licensee, that are deemed necessary by SHINE to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements.

The applicant stated that as a result of further design work and this response, they will review and update the ISA and ISA Summary. Further, the applicant will incorporate additional changes into to the PSAR, as a result of updates to the ISA and ISA Summary.

As discussed above, the applicant modified the definition of safety-related in the PSAR to encompass those SSCs that are required for safety in both the IF and the RPF. Coincident with this change, the applicant modified the SHINE QAPD and the QL-2 classification to eliminate IROFS components. The components meeting the revised safety-related definition are classified as QL-1, and therefore, there will be no difference in regards to the quality classification or Seismic Category I acceptance criteria for two SSCs that must meet the same performance characteristics.

With the exception of item 4 in the definition of safety-related SSCs (item 4 was changed in the applicant's response to RAI 3.5-6), the staff accepted this response. The staff finds this response is consistent with the guidance provided in ISG augmenting NUREG-1537, Part 1 by using ISA methodologies as described in 10 CFR 70 and NUREG-1520, applying the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designating items relied on for safety, and establishing management measures. Additionally, the staff finds this response consistent with the following guidance in ISG augmenting NUREG-1537, Part 1, which stated, in part, that "[a]pplicants 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."

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

SHINE PSAR, Section 3.5.2, “Seismic Classifcation,” states, in part, that SSCs that have “[t]he capability to prevent or mitigate potential accidents at the facility that could exceed the performance requirements in 10 CFR 70.61,” are designated Seismic Category I. The performance requirements include mitigating the effects of an “acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material….” SHINE PSAR, Figure 1.3-2, “Production Building Floor Plans Preliminary Arrangement,” has the following notation: “Heavy Outline Denotes Seismic Boundary.” In addition, SHINE PSAR, Table 3.5-1, “System and Classifications” (pages 3-52 – 3-55), states that the facility structure is safety-related, Seismic Category I, and QL-1. There is no mention of the seismic classification of the north and south portions of the building outside the seismic boundary, which include chemical storage facilities. The staff noted that this statement appeared to infer that these portions of the building are nonseismic and in a postulated design basis earthquake, they would collapse. If all of the access points into the “seismic boundary” are located on the north and south sides of the building, it is possible that personnel would not be able get in or out of the building after a design basis earthquake and individuals could be exposed to licensed material and/or hazardous chemicals.

Therefore, in RAI 3.5-2 (Reference14), the staff asked the applicant to 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.

In response to RAI 3.5-2 (Reference 20), the applicant stated the production building seismic portion will be provided with at least two safety-related seismic access points in the final design, enabling personnel to exit the building following a seismic event. These exits will ensure that personnel will be able to exit the building and, therefore, will not be exposed to licensed material, a chemical exposure from licensed material, or hazardous chemicals produced from licensed material in excess of the guidelines described in the PSAR. Following the receipt of SHINE’s FSAR, staff will confirm that this issue has been resolved.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 3.5 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE’s FSAR.

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

SHINE PSAR, Table 3.5-1, “System and Classifications,” states that

> Radiologically Controlled Area Ventilation Zone 1 is safety-related, QL-1, and Seismic Category I;
>
> Radiologically Controlled Area Ventilation Zone 2 is IROF, QL-2, and Seismic Category I; and

Radiologically Controlled Area Ventilation Zone 3 is nonsafety-related, QL-3, and Seismic Category III.

SHINE PSAR, Section 9a.2.1.1, “Radiologically Controlled Area Ventilation System,” does not state that one normally goes through Radiologically Controlled Area Ventilation Zone 3 to get to Radiologically Controlled Area Ventilation Zones 1 or 2, but such a pathway can be inferred from PSAR Section and Figure 1.3-2. Thus, Radiologically Controlled Area Ventilation Zone 3 would be used for access and egress after a postulated event with a LOOP or a design basis earthquake with a LOOP.

Therefore, in RAI 3.5-3 (Reference 14), the staff asked the applicant to provide the basis for designating the Radiologically Controlled Area Ventilation Zone 3 nonsafety-related, QL-3, and Seismic Category III or provide a discussion of the alternate method of access/egress of the Radiologically Controlled Area Ventilation Zones 1 and 2, without causing outside contamination.

In response to RAI 3.5-3 (Reference 21), the applicant stated that RCA Ventilation Zone 3 (RVZ3) is designated as nonsafety-related and QL-2 because it does not meet the SHINE definition of a safety-related SSC (See also RAI 3.5-1 response), as follows:

1. RVZ3 is not relied upon to maintain the integrity of the primary system boundary (PSB).
2. RVZ3 is not relied upon to shut down the target solution vessel (TSV) or maintain the target solution in a safe shutdown condition.
3. RVZ3 is not relied upon to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20. This function, as it relates to ventilation, is accomplished by RCA Ventilation Zone 1 (RVZ1) and RCA Ventilation Zone 2 (RVZ2), the ventilation systems used in areas containing radiological material.
4. RVZ3 is not relied upon to assure that an inadvertent criticality accident is not credible.
5. RVZ3 is not relied upon to assure that acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area. This function, as it relates to ventilation, is accomplished by RVZ1 and RVZ2, the ventilation systems used in areas containing licensed material.
6. RVZ3 is not relied upon to ensure that an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur. This function, as it relates to ventilation, is accomplished by RVZ1 and RVZ2, the ventilation systems used in areas containing uranium in soluble form.

   RVZ3 is classified as Seismic Category III because it is a nonsafety-related system, and does not adversely impact SSCs important to safety that are designed to withstand the effects of a design basis earthquake and remain functional.

The applicant further states that contamination would not be expected with a loss-of-off-site power because there are no external events that result in both a loss-of-off-site power and a radiological release. However, if the RVZ3 fans are not operating during a radiological event, then emergency response in accordance with the SHINE Preliminary Emergency Plan will evaluate and control contamination.

The staff has the following concerns with the applicant's responses to RAI 3.5-3:

> Safety Classification of RCA Ventilation Zone 3 (RVZ3) - While in its response to RAI 3.5-3, the applicant uses the revised safety-related definition determining that RVZ3 is NSR, the staff cannot concur at this time based on the response to RAI 9a2.1-3, which is discussed in detail in Section 9a2.1 of this SER. In that response to this RAI, the applicant stated that RVZ3's supply and exhaust are provided by RVZ2, that RVZ3 is within the Seismic Category I RCA boundary, and that RVZ3 is the RCA tertiary confinement zone.

Therefore, while this issue is still unresolved, the staff feels that based on the information provided in the RAI 9a2.1-3 response, that the applicant can provide further justification for this safety classification in the FSAR at the OL stage.

As required by 10 CFR 50.34(a)(4), "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

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

Therefore, in RAI 3.5-4 (Reference 14), the staff asked the applicant to provide a discussion that addresses how facility personnel will be able to determine that the facility is in a safe condition (or put the facility in a safe condition) and how the facility will be maintained in a safe condition, in the event of a postulated design basis earthquake with a LOOP and unavailability of the systems above.

In response to RAI 3.5-4 (Reference 20), the applicant stated that in the event of a postulated design basis earthquake with a loss-of-off-site power, facility personnel will be able to determine if the facility is in a safe condition and maintain it in such a state as necessary using safety-related equipment. The SHINE Facility Control Room is part of a safety-related, Seismic Category I structure. The applicant also stated that PSAR Table 3.5-1 contains an administrative error, stating the Facility Control Room is an NSR, Seismic Category III structure and that designation of the Facility Control Room will be corrected in the FSAR. The Control Room contains the necessary SR controls and indicators to maintain the facility in a safe condition. In the event of a loss-of-off-site power, SR equipment either fails to its safe condition or is powered by the Uninterruptible Electrical Power Supply System (UPSS). The automatic safety systems designed to protect the public and maintain the facility in a safe shutdown condition operate without operator intervention. The SR RCA ventilation isolates, as necessary, to contain radioactive releases. The isolation components are fail-safe and move to their safe position upon a loss of power. The applicant's response to RAI 3.5-1 provided the SHINE definition of SR SSCs. The following systems are not necessary for personnel to determine that the facility is in a safe condition or to place the facility in a safe condition, and are not defined as SR using the SHINE definition of SR SSCs:

- Facility Instrument Air System,
- Stack Release Monitoring System,
- Health Physics Monitors,
- Facility Breathing Air System,
- Facility Data and Communication System,
- Lighting System,
- Emergency Lighting System, and
- Facility Ventilation Zone 4, Standby Diesel Generator System.

The applicant noted that none of these systems are used to prevent or mitigate the consequences of accidents, as presented in PSAR Chapter 13.

The staff finds the response addresses the how the applicant will meet the requirements in 10 CFR 50.34(a)(4) and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

As required by 10 CFR 50.34(a)(4), "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

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

> General Design Criterion 1 provides that structures, systems, and components important to safety are to be designed, fabricated, erected, and tested to quality standards. Thus, General Design Criterion 1 applies to Seismic II/I since the Seismic II structures, systems, and components should be properly designed, fabricated, and installed to reduce the likelihood of a Seismic Category II structure, system, or component coming loose and falling on and damaging a Seismic Category I structure, system, or component.
>
> General Design Criterion 2 provides that structures, systems, and components important to safety are to be designed to resist the effects of natural phenomena like earthquakes. General Design Criterion 2 applies to Seismic II/I because it specifies the natural phenomenon (i.e., earthquake) that must be considered in

> the design of these structures, systems, and components. If not considered, an earthquake could loosen a Seismic Category II structure, system, or component to the extent that it could cause an unsafe condition (i.e., fall on and damage a Seismic Category I structure, system, or component).
>
> General Design Criterion 4 provides that structures, systems, and components important to safety are to be protected against the effects of internally-generated missiles. General Design Criterion 4 applies to Seismic Category II structures, systems, and components because it specifies protection against the effects of internally-generated missiles (i.e., fall on and damage of a Seismic Category I structure, system, or component).

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

Therefore, in RAI 3.5-5 (Reference 14), the staff asked the applicant to 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.

In response to RAI 3.5-5 (Reference 21), the applicant referred to PSAR Subsection 3.5.2, which states structures, components, equipment, and systems designated as safety-related are classified as Seismic Category I. The applicant put criteria in place for Seismic Category II SSCs to ensure that they do not interfere with Seismic Category I SSCs as described below:

> Criteria for Seismic Category II Structures
>
> Nonsafety-related structures are designed with the following two general criteria:
>
> 1. SSCs in nonsafety-related structures attached to a safety-related structure or separated from a safety-related structure by a distance less than or equal to the height of the nonsafety-related structure are designed for abnormal and extreme environmental loads if the failure of the nonsafety-related SSC could result in damage to safety-related SSCs. However, if the failure of the nonsafety-related SSC will not result in damage to safety-related SSCs, the nonsafety-related SSC need not be designed for abnormal and extreme environmental load combinations.
>
> 2. Nonsafety-related SSCs separated from a safety-related structure by a distance greater than the height of the nonsafety-related structure need not be designed for abnormal and extreme environmental load combinations.
>
> Criteria for Nonsafety-Related SSCs in Safety-Related Structures
>
> > Nonsafety-related SSCs within safety-related structures (i.e., within the seismic boundary) are evaluated for II/I interaction. Seismic interaction effects to be considered include proximity, differential displacements, structural failure and falling, water spray or flood, and fire.

The applicant stated that depending on the type of component, NSR SSCs categorized as II/I are evaluated or qualified using the following methods to demonstrate that they do not impact SR SSCs:

(1) detailed evaluation using structural analysis or consideration of seismic loading in the development of allowable spans and support configurations;

(2) anchorage design and analysis to assure that the components do not interact with adjacent SR SSCs or become missiles during a seismic event;

(3) qualitative evaluation using considerations such as weight to assess the potential impact on SR components (e.g., a lightweight object impacting a large diameter pipe, or a small bore pipe impacting the rugged casing of a pump); or

(4) specifications for commodity or architectural items can include requirements for performance during a seismic event (e.g., cabinet door swing limits and lighting supports designed for seismic loads).

The staff finds the response addresses how the applicant will meet the requirements in 10 CFR 50.34(a)(4) and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The regulations in 10 CFR 50.2, "Definitions," provide definitions including that for safety-related SSCs. The definition states:

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

The regulations in 10 CFR 70.4, "Definitions," provide the definition for "items relied on for safety" (IROFS)." The definition states:

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

The regulations in 10 CFR 21.3, "Definitions," define a "basic component." As it would apply to the SHINE facility, the definition states:

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

SHINE PSAR, Section 3.5.1, "Classification of Systems and Components Important to Safety," discusses the classification of SSCs. SHINE PSAR, Section 3.5.1.1, "Nuclear Safety Classifications for SSCs," states in part, that "SHINE uses a modified definition from 10 CFR 50.2, "Definitions," to develop the definition of SR SSCs, where appropriate," and utilizes a portion of 10 CFR 70.4, "Definitions," for the definition of IROFS SSCs.

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

Additional information is needed for the NRC staff to evaluate the adequacy of SHINE's modified definition of safety-related structures, systems, and components. Furthermore, additional information is needed for NRC staff to determine the relationship between definition of basic component in 10 CFR 21.3 to SHINE's proposed definition of SR SSCs. Additionally, the NRC staff notes that despite SHINE's statement that this revised definition of SR SSCs eliminates the classification of certain SSCs as items relied on for safety, the term "IROFS" still appears in several places in the SHINE PSAR.

Therefore, in RAI 3.5-6 (Reference 16), the staff asked the applicant to:

(1) Provide a performance-based definition for the fourth part (i.e., with respect to the credibility of an inadvertent criticality accident) of the six-part definition of SR SSC or to provide a discussion of why it is not necessary;

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

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

In response to RAI 3.5-6 (Reference 24), the applicant referred to the definition of SR SSCs was provided in the response to RAI 3.5-1 regarding implementation of the requirements of 10 CFR 70.61(d). The applicant further stated that the fourth part of definition of SR SSCs was updated to be performance-based and readily applicable to SSCs as follows:

> 4. That all nuclear processes are subcritical, including use of an approved margin of subcriticality;

Regarding basic components, the applicant responded that they consider SR SSCs to be basic components, as defined in 10 CFR 21.3.

The applicant stated that the SSCs at the SHINE facility will not bear the classification of IROFS. PSAR Subsection 1.3.3 inadvertently retains references to IROFS. Additionally, the Acronyms and Abbreviations list for PSAR Chapter 14 inadvertently retains a definition for the IROFS acronym, which is not used elsewhere in the chapter. The applicant provided a revised PSAR to remove the inadvertent references to IROFS. However, PSAR Table 3.5b-1 of the PSAR will continue to refer to "items relied on for safety" in the context of a direct quotation from 10 CFR 70.64. The applicant stated that these items are referred to as SR SSCs.

The staff finds the response addresses the how the applicant will use the aforementioned definitions from 10 CFR 50.2, 10 CFR 70.4, and 10 CFR 21.3 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

As required by 10 CFR 50.34(a)(4), the information in the PSAR shall contain "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents." In response to RAI 3.5-4 SHINE stated, in part, that the Control Room is part of a safety-related, Seismic Category I structure, but that the other SSCs are not defined as safety-related based on SHINE's definition of safety-related structures, systems, and components.

While SHINE's response to RAI 3.5-4 also states that safety-related systems are automatic and would put the facility in a safe condition without operator intervention, there is no discussion on how control room operators or other facility personnel will determine the facility is in a safe condition or how personnel will maintain the facility in a safe condition. Under the conditions of a postulated design basis earthquake and a loss-of-offsite power (LOOP), conditions could exist which would inhibit facility personnel from determining that the facility is in a safe condition and maintaining the facility in a safe condition utesing necessary safety-related equipment:

- SHINE PSAR Tables 2.3-2 and 2.3-3 show that the outdoor temperature can vary between -37°F and 104°F. While Control Room ventilation is supplied via Facility Ventilation Zone 4 (FVZ4), which is nonsafety-related, the Control Room has no heating, ventilation, and air conditioning (HVAC) system, which could impact Control Room habitability and equipment operability.
- The SHINE facility does not include emergency lighting, which could impact the ability of facility personnel to assess the facility status and to staff the Control Room.
- Since the Stack Release Monitoring System is not defined as safety-related, its unavailability could impact the ability of facility personnel to determine that there are no releases going up the stack.
- Since the Health Physics Monitors are not defined as safety-related, their unavailability could impact the ability of facility personnel to assess levels of contamination during egress from the facility.
- Since the Facility Data and Communication System is not defined as safety-related, its unavailability could impact the ability of control room personnel to determine the facility status and communicate with other facility personnel and offsite agencies.

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

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

Therefore, in RAI 3.5-7 (Reference 16), the staff asked the applicant to provide additional information describing how the design of the SHINE control room and other SSCs will allow control room operators or other facility personnel to determine the facility is in a safe condition or how personnel will maintain the facility in a safe condition in the event of a postulated design basis earthquake with a loss-of-off-site power.

In response to RAI 3.5-7 (Reference 25), the applicant discussed how that the facility is designed to be maintained in a safe configuration through the use of SR equipment during normal operations and as required to prevent or mitigate the consequences of abnormal operational transients or design basis accidents.

The applicant stated that during detailed design they will demonstrate that the Control Room will be within reasonable temperatures that will ensure SR equipment operability and that the Control Room Operators can monitor plant conditions. The applicant will describe the method chosen to ensure the Control Room remains within a reasonable temperature range, and define the reasonable temperature range, in the FSAR.

The applicant stated that the Control Room will have access to information on the status of safety-related plant systems through the display and interface panels for the Target Solution Vessel (TSV) Reactivity Protection System (TRPS) and Radiological Integrated Control System (RICS), the Engineered Safety Features Actuation System (ESFAS) operator panel, the radiation monitor displays from the Radiation Area Monitoring System (RAMS), the displays and alarms for the Criticality Accident Alarm System (CAAS), and the neutron fluxes measured by the Neutron Flux Detection System (NFDS) and relayed to the TRPS. These systems are safety-related and powered by the UPSS. These systems provide sufficient information to allow personnel in the Control Room to determine that the plant is in a safe condition and maintained in a safe condition.

The applicant described how the Control Room will have adequate lighting following a seismic event or LOOP, which included: 8 hours of battery backup power; charging capability by the standby diesel generator (SDG) and Normal Electrical Power Supply System (NPSS); and, the availability of handheld lights. Additionally, the Emergency Lighting System (ELTG) was added to the systems list provided in PSAR Table 3.1-1.

The applicant stated that, in addition to the monitoring of the plant conditions through the Control Room instrumentation, personnel will be able to assess releases through the facility stack. The primary means of monitoring the facility stack will be with the Stack Release Monitoring (SRM) system. This system will provide monitoring of noble gases, aerosols, iodine, and tritium effluents. Although NSR, SHINE will add the SRM system to the loads powered by the UPSS, and therefore the SRM system will likely be available after a LOOP. The nominal connected load and the nominal demand load for the SRM system will be determined during detailed design. SHINE will update the UPSS load list provided in PSAR Table 8a2.2-1 in the FSAR to include the SRM system.

The applicant stated that as described in Section 7.2.3 of the SHINE Preliminary Emergency Plan, if the SRM system or Health Physics Moniors becomes unavailable due to a design basis earthquake or LOOP, there will be other methods and equipment to perform the functions of those system. These methods and equipment will be maintained by inventory and surveillances to ensure availability when required.

The applicant stated that the Control Room Operators and other SHINE personnel will be able to communicate with each other and off-site agencies during a seismic event or LOOP by having multiple independent communication subsystems available that use different technologies to ensure at least one method is available for on-site and off-site communication.

The applicant stated that as described in PSAR Section 13b.3, potential chemical hazards from on-site chemicals associated with licensed materials have been evaluated, which included appropriate safety controls to prevent or mitigate the consequences to an acceptable level. Offsite chemical hazards have been evaluated in PSAR Subsection 2.2.3 and in the response to RAI 2.2-3.

The applicant stated that fire areas in the SHINE IF and RPF are separated by three-hour rated fire barriers to prevent the spread of a fire throughout the facility. While one fire zone may become uninhabitable, the majority of the facility will not be affected. SHINE also has a diesel-driven fire pump, which is expected to be available following a LOOP. The SHINE fire protection systems and programs are further described in PSAR Section 9a2.3.

The applicant stated the design of the Control Room and other SSCs will ensure that SHINE personnel can assess the safe condition of the facility and ensure that it is maintained in a safe shutdown condition following a design basis earthquake or LOOP.

The staff finds the response addresses the how the applicant will meet the requirements in 10 CFR 50.34(a)(4) and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

As required by 10 CFR 50.34(a)(4), an applicant needs to submit "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

SHINE PSAR, Table 3.5b-1, "Baseline and General Design Criteria for Radioisotope Production Facility" (pages 3-102 - 3-106), under the first column, "Baseline Design Criteria 10 CFR 70.64," lists the following criterion:

(7) Utility services. The design must provide for continued operation of essential utility services.

Under the second table column, "As Applied to SHINE," the stated applicability is: "As Applied and Means of Compliance - The SHINE facility provides a standby diesel generator for asset protection of selected systems. Refer to SHINE PSAR, Section 8b for detailed information." The staff notes that while SHINE PSAR, Table 3.5b-1 refers to PSAR, Section 8b, PSAR, Section 8b essentially refers to PSAR, Section 8a.

However, the SDG is classified nonsafety-related and does not have to function after a design basis earthquake. In addition, SHINE PSAR, Section 8a2.1.4, "SHINE Facility Loads Supported by SDG," references Table 8a2.1-2, "Standby Diesel Generator Load List" (Reference 36), but unlike Section 8a2.2.3, "SHINE Facility Systems Served by the Class 1E UPSS ," which provides a list of what systems are supported by the Class 1E UPSS, does not provide a list of systems supported by the SDG system.

Therefore, in RAI 3.5b-1 (Reference 14), the staff asked the applicant to provide a list of systems supported by the SDG and provide clarification on how Criterion 7 is met for the case of a postulated design basis earthquake with a LOOP.

In response to RAI 3.5b-1 (Reference 20), the applicant stated that the following systems are supported by the standby diesel generator (SDG):

- Tritium Purification System (TPS),
- Radiologically Controlled Area Ventilation Zone 1 (RVZ1),
- Facility Instrument Air System (FIAS),
- Facility Ventilation Zone 4 (FVZ4),
- Emergency Lighting System (ELTG),
- Uninterruptible Electrical Power Supply System (UPSS),
- Radioactive Drain System (RDS), and
- Facility Fire Detection and Suppression (FFPS).

Additionally, the applicant stated that following are additional loads on the SDG that are not listed as systems in the PSAR:

- Security System,
- Freeze Protection,
- Raw Material Storage Area Heaters, and
- Emergency Operating Center.

The applicant stated that during a loss of normal AC power, Criterion 7 is met by the UPSS. The safety-related UPSS feeds two 120 VAC UPS Class 1E buses, which provide power to essential equipment and instrumentation. The systems served by the Class 1E UPSS are identified in PSAR Subsection 8a2.2.3. The UPSS is capable of delivering required emergency power for the required duration during normal and abnormal operation. The UPSS battery chargers associated with the UPSS Class 1E battery subsystem are connected to the bus fed by the SDG. The battery chargers provide the required isolation between the non-1E Normal Electrical Power Supply System (NPSS) and Class 1E 250 VDC. The AC input breakers on both battery chargers and voltage regulating transformers are qualified as isolation devices using guidance from the Institute of Electrical and Electronics Engineers (IEEE) 384, "IEEE Standard Criteria for Independence of Class 1E Equipment and Circuits."

The staff finds the response addresses the how the applicant will meet the requirements in 10 CFR 50.34(a)(4) and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

As required by 10 CFR 50.34(a)(4), an applicant needs to submit "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

In response to RAI 3.5b-1, SHINE provided the information on the systems supported by the SDG, and stated that Criterion 7 of 10 CFR 70.64 is met by the Uninterruptible Power Supply Chain. Additional information is needed for the NRC staff to evaluate the SDG's ability to meet Criterion 7 of 10 CFR 70.64 to determine the adequacy of SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents.

Therefore, in RAI 3.5b-2 (Reference 16), the staff asked the applicant to provide additional information stating how the standby diesel generator meets Criterion 7 of 10 CFR 70.64, given that it and the systems it powers are classified as non-safety-related and how the Uninterruptible Power Supply Chain meets Criterion 7 of 10 CFR 70.64 during a loss of normal AC power.

In response to RAI 3.5b-2 (Reference 24), the applicant stated PSAR Table 3.5b-1 provides SHINE's general evaluation of the design bases of the RPF against the baseline design criteria specified under 10 CFR 70.64 and general design criteria (GDC) 61, 62, 63, and 64 of Appendix A to 10 CFR 50 as a good design practice. Criterion 7, "Utility services," of the baseline design criteria specified under 10 CFR 70.64 states, "[t]he design must provide for continued operation of essential utility services." The applicant states that while the SDG provides an additional source of power should off-site power be lost, it is not safety-related and is not used to meet Criterion 7 of 10 CFR 70.64. The applicant stated that they plan to use the UPSS to power safety-related equipment should off-site power be lost and the SDG not be available. The UPSS provides continued operation of essential electrical utility service at the SHINE facility, and no other essential utilities are identified for the facility. The applicant will revise the "As Applied and Means of Compliance" discussion provided for Criterion 7 in PSAR Table 3.5b-1 in the FSAR to be consistent with the discussion provided for Criterion 17, "Electric power systems," in PSAR Table 3.5a-1.

The staff finds the response addresses the how the applicant will meet the requirements in 10 CFR 50.34(a)(4) and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on systems and components, with the exception of the issue described above regarding the Safety Classification of RCA Ventilation Zone 3 (RVZ3) in applicant's response to RAI 3.5-3, is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.5, allowing the staff to make the following relevant findings: (1) the design criteria included consideration of the conditions required of the SSCs to ensure safe facility operation, including response to transient and potential accident conditions analyzed in the PSAR; and (2) the design of the SSCs addressed the applicable baseline design criteria of 10 CFR 70.64.

Therefore, the staff finds that the facility design features to cope with seismic damage is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration.

3.5 Summary and Conclusion

The staff evaluated the descriptions and discussions of the SHINE facility's SSC design criteria, as described in Chapter 3 of the SHINE PSAR and supplemented by the applicant's responses to RAIs, and finds that the preliminary design criteria of SHINE's SSCs, including the principle design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in NUREG-1537 and the ISG augmenting NUREG-1537. Based on these findings, the staff has made the following conclusions to support the issuance of a construction permit in accordance with 10 CFR 50.35:

(1) SHINE has described the proposed design criteria of SSCs, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Further technical or design information required to complete the safety analysis of the IF ESFs may reasonably be left for later consideration the FSAR.

(3) Safety features or components, if any, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.