3.0 DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

This chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) reviews the structures, systems, and components (SSCs) considered in the final design of the SHINE facility for its safe operation and for the protection of the public. The U.S. Nuclear Regulatory Commission (NRC, the Commission) staff evaluated these SSCs for their protective functions and related design features to ensure the adequacy of the facility defense-in-depth against uncontrolled release of radioactive material to the environment. The bases for the design criteria for some of the SSCs discussed in this chapter may have been developed in other chapters of the SHINE final safety analysis report (FSAR) and were considered in this chapter's review as deemed necessary.

This chapter of the SER describes the NRC staff's review and evaluation of the final design of the SHINE main production facility structure (FSTR), with its irradiation facility (IF) and radioisotope production facility (RPF), non-radiologically controlled seismic area, relevant non-safety areas, and the nitrogen purge system (N2PS) structure. In addition to the information in SHINE FSAR chapter 3, "Design of Structures, Systems, and Components," this review also includes additional relevant information from other chapters of the FSAR and the applicant's responses to staff requests for additional information (RAIs).

3.1 Areas of Review

SHINE FSAR sections 3.1, "Design Criteria," through 3.6, "Nitrogen Purge System Structure," are the applicable areas for the NRC staff's safety review of the SHINE FSTR, its IF, RPF, and safety and non-safety areas, and the N2PS structure as discussed below.

The NRC staff reviewed SHINE FSAR chapter 3 and other chapters for material and information regarding the final design of SSCs to safely operate the SHINE facility in response to transient and potential accident conditions analyzed in the FSAR. Sections 3.4.2, 3.4.3, and 3.4.5 of the SER specifically discuss the FSTR design features for protection during and/or after meteorological, water, and seismic events. The review considered applicable regulatory requirements and appropriate regulatory guidance and acceptance criteria.

The NRC staff reviewed the description and analysis of the SSCs of the SHINE facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The staff also reviewed the final analysis and evaluation of the design and performance of SSCs with the objective of assessing the risk to public health and safety resulting from the operation of the SHINE facility and the adequacy of the SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents. The staff reviewed whether there is reasonable assurance that the final design is adequate to remain safe during operation and capable of safe shutdown, as defined in SHINE technical specification (TS) 1.3, "Definitions," during environmental events and accident conditions. Special attention was provided to facility design and operating characteristics having unusual or novel design features to ensure that they remain safe and functional so that they can fulfill their intended function during facility operation.

3.2 Summary of Application

SHINE FSAR chapter 3 describes the principal design criteria and design bases of SSCs for the IF and RPF established to ensure facility safety and protection of the public. With the exception of discussions related to IF- or RPF-specific systems, the following summary applies to both the IF and the RPF.

SHINE FSAR section 3.1, "Design Criteria," discusses areas of the SHINE facility and its SSCs subject to this review for its safe operation to ensure that the SSCs within the facility demonstrate adequate protection against the hazards present for the range of normal operations, anticipated transients, and design-basis accidents (including during and/or after meteorological or hydrological events, water impact, abnormal loads, or a design-basis earthquake). This section includes relevant information to demonstrate that the design criteria are based on applicable standards, guides, and codes and to support that the SSCs will function as designed and required by the SHINE safety analyses. It also includes references to where the specifics of the design criteria are discussed in detail.

SHINE FSAR section 3.2, "Meteorological Damage," includes historical data and predictions as specified in SHINE FSAR chapter 2, "Site Characteristics," and discusses the criteria used to design the SHINE facility to withstand the site characteristics of wind, tornado, snow, and ice. The combination of meteorological loads with other loads (i.e., dead loads and earthquake loads) essential for the facility structural analysis is provided in SHINE FSAR section 3.4, "Seismic Damage," and further outlined below.

SHINE FSAR section 3.3, "Water Damage," provides information on the hydrological conditions found at the SHINE facility and discusses the criteria used to design against flooding. The combination of water-related loads with other loads (i.e., dead loads and earthquake loads) essential for the facility structural analysis is provided in SHINE FSAR section 3.4, and further outlined below.

SHINE FSAR section 3.4 includes an outline of the FSTR layout and describes its safety-related SSCs in the IF, RPF, the non-radiologically controlled seismic area, and a non-safety-related area and describes their performance to seismic and abnormal (e.g., aircraft impact) loadings. safety-related and non-safety-related SSCs, which are classified in two seismic categories, Seismic Category I and Seismic Category II, are reviewed. SHINE FSAR section 3.4 includes descriptions of the overall facility, its response to site seismicity, and analyses of potential accidents and hazards internal and external (e.g., damage analysis due to aircraft accidents from the nearby airport) to the FSTR. SHINE FSAR section 3.4 refers to SHINE FSAR chapter 2, which includes several sections on site seismicity, seismic input, and hazards essential to soil-structure interaction (SSI) analysis.

SHINE FSAR section 3.5, "Systems and Components," includes a high-level discussion on the design basis (e.g., separation, isolation, redundancy) and operation (e.g., condition of operation, setpoints, design features) of SHINE SSCs.

SHINE FSAR section 3.6, "Nitrogen Purge System Structure," discusses the N2PS structure and its SSCs. It also describes their design attributes, capacity, and performance associated with meteorological, water, and seismic events.

Additionally, this chapter of the SER includes the NRC staff's review of the SHINE facility safety-related SSCs and those SSCs that are non-safety-related but that perform functions that may impact safety-related SSCs. These SSCs are identified in SHINE FSAR tables 3.1-1 and 3.1-2, "Safety-Related Structures, Systems, and Components," and "Nonsafety-Related Structures, Systems, and Components," respectively.

Tables in SHINE FSAR chapter 3 list the applicable design criteria for the SSCs discussed in other FSAR chapters but that are referenced in chapter 3 for consideration as those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public and to control or mitigate the consequences of such accidents.

3.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 3 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the principal design criteria and design bases and the information provided by SHINE for the issuance of an operating license.

3.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE principal design criteria and design bases are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report"

- 10 CFR 50.40, "Common standards"

- 10 CFR 50.57, "Issuance of operating license"

- 10 CFR Part 20, "Standards for Protection Against Radiation"

3.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.

- 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.

- "Final Interim Staff Guidance 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.

- “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.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, American Society of Civil Engineers (ASCE) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment 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 FSAR. Following such guidance as well as local building codes and recognized industry practices, as applicable, provides reasonable assurance that any potential damage would not cause unsafe operations, prevent safe shutdown, or allow uncontrolled release of radioactive material. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

In its review, the NRC staff also noted the applicant’s voluntary adoption of guidance in specific sections of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [Light-Water Reactor] Edition,” including section 3.7.1, “Seismic Design Parameters,” and section 3.7.2, “Seismic System Analysis,” for developing seismic input and performing seismic analysis of the FSTR. The approach taken by SHINE is acceptable because the guidance of NUREG-0800 regarding seismic input and analysis is more stringent than that of NUREG-1537.

3.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR chapter 3, as supplemented, to assess the sufficiency of the principal design criteria and design bases for the SHINE facility and its safety-related SSCs for the protection of the public and the environment in support of the issuance of an operating license. The sufficiency of the principal design criteria and design bases is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 3.3, “Regulatory Requirements and Guidance and Acceptance Criteria,” of this SER. The findings of the staff review are described in section 3.5, “Review Findings,” of this SER.

3.4.1 Design Criteria

The NRC staff evaluated the sufficiency of the principal design criteria and design bases, as presented in SHINE FSAR section 3.1, using the guidance and acceptance criteria from section 3.1, “Design Criteria,” of NUREG-1537, Parts 1 and 2, and section 3.1, “Design Criteria,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The principal design criteria for the SHINE facility provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. The design bases identify the specific functions to be performed by an SSC and the specific values or ranges of values chosen for controlling parameters as reference bounds for the design. The principal design criteria for the SHINE facility were established in the preliminary safety analysis (PSAR) as required by 10 CFR 50.34(a)(3). This regulation also required SHINE to provide the design bases and the relation of the design bases to the principal design criteria for the facility.

Subparagraph 50.34(b)(2) of 10 CFR requires a description and analysis of the SSCs of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description must be sufficient to permit understanding of the system designs and their relationship to safety evaluations. Subparagraph 50.34(b)(4) of 10 CFR requires a final analysis and evaluation of the design and performance of SSCs with the objective stated in 10 CFR 50.34(a)(4) and consideration of any pertinent information developed since the submittal of the PSAR.

The NRC staff’s analysis of the SHINE facility SSCs evaluated whether the design bases and principal design criteria for the SHINE systems and subsystems are met and if the FSAR describes how the principal design criteria for the facility are achieved.

SHINE included the discussion of principal design criteria and design bases for SSCs in the applicable FSAR section describing those SSCs. For each SSC, SHINE FSAR tables 3.1-1 and 3.1-2 identify the applicable FSAR section or sections that describe the SSC. Similarly, the NRC staff evaluation, as applicable to the specific principal design criteria and design bases, is included within the chapter of this SER where the staff evaluated those SSCs.

The discussion in this section of the NRC staff’s evaluation discusses the acceptability of SHINE’s chosen principal design criteria identified in SHINE FSAR table 3.1-3, “SHINE Design Criteria,” and of the Nuclear Safety Classification, as described in SHINE FSAR section 3.1, established by SHINE to ensure that the risk of events is highly unlikely or that the consequences are mitigated to acceptable levels.

3.4.1.1 SHINE Facility Design Criteria

Generally, the SHINE facility design criteria adapt 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” Appendix A, “General Design Criteria for Nuclear Power Plants,” for a medical isotope production facility. Since the SHINE facility uses low-enriched uranium in the form of a uranyl sulfate target solution that is irradiated in a subcritical assembly by neutrons produced by a fusion neutron source, many of the general design criteria of 10 CFR Part 50, Appendix A do not apply to it. Additionally, as discussed in chapter 7, “Instrumentation and Control Systems,” of this SER, the application specific action items (ASAIs) specified in the NRC topical report on the highly integrated protection system (HIPS) platform are intended for power reactor applications and, therefore, some of the ASAIs do not apply to the application of the HIPS platform at the SHINE facility for the target solution vessel (TSV) reactivity protection system and engineered safety features actuation system (ESFAS).

The SHINE FSAR lists 39 design criteria for the SHINE facility. The majority of the design criteria have specific application to individual SSCs within the IF's irradiation units (IUs) and the RPF as listed in SHINE FSAR tables 3.1-1 and 3.1-2. The SHINE FSAR further states that Design Criteria 1 through 8 from SHINE FSAR table 3.1-3 are not specifically listed as applicable design criteria in tables 3.1-1 and 3.1-2 but are generally applicable to all SSCs.

Consistent with the guidance in NUREG-1537, the SHINE FSAR includes the following eight generally applicable design criteria:

Design Criterion 1 – Quality standards and records

> Safety-related structures, systems, and components (SSCs) are designed, fabricated, erected, and tested to quality standards commensurate with the safety functions to be performed. Where generally recognized codes and standards are used, they are identified and evaluated to determine their applicability, adequacy, and sufficiency and are supplemented or modified as necessary to ensure a quality product in keeping with the required safety function.
>
> A quality assurance program is established and implemented in order to provide adequate assurance that these SSCs satisfactorily perform their safety functions.
>
> Appropriate records of the design, fabrication, erection and testing of safety-related SSCs are maintained by or under the control of SHINE throughout the life of the facility.

The adequacy of the SHINE quality assurance program is reviewed and found acceptable in section 12.9 of this SER. The SHINE TSs assign the Operations Manager (Level 2) overall responsibility for the development and implementation of the quality assurance program. Additionally, SHINE TS 5.2.4.1.f requires a biannual audit of the quality assurance program records by an independent review and audit committee and TS 5.4.4 requires that specific facility procedures be developed in accordance with the program. The NRC oversight and inspection program conducts inspections of program records to ensure that required records are maintained and audits were conducted in accordance with the TS requirements.

Design Criterion 2 – Natural phenomena hazards

> The facility structure supports and protects safety-related SSCs and is designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches as necessary to prevent the loss of capability of safety-related SSCs to perform their safety functions.
>
> Safety-related SSCs are designed to withstand the effects of earthquakes without loss of capability to perform their safety functions.

The NRC staff found SHINE's design for natural phenomena hazards acceptable in sections 2.4.3, 2.4.4, 2.4.5, 3.4.2, 3.4.3, and 3.4.4 of this SER. Also, the evaluation of the safety systems against the effects of natural phenomena is documented in sections 7.4.4.2.1

and 7.4.5.2.1 of this SER. Sections 8a.4 and 8b.4 of this SER evaluate the electrical system offsite power service; power distribution system; standby diesel generator and supported loads; distribution equipment; facility grounding system; lightning protection system; cathodic protection system; freeze protection; and cable and raceway components and routing.

Criterion 3 – Fire protection

> Safety-related SSCs are designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.
>
> Noncombustible and heat resistant materials are used wherever practical throughout the facility, particularly in locations such as confinement boundaries and the control room.
>
> Fire detection and suppression systems of appropriate capacity and capability are provided and designed to minimize the adverse effects of fires on safety-related SSCs. Firefighting systems are designed to ensure that their rupture or inadvertent operation does not significantly impair the safety capability of these SSCs.

The NRC staff found SHINE's design for fire protection acceptable in sections 2.4.2.3, 9a.4.3, and 9b.4.3 of this SER. The staff's evaluation of fire protection for the safety systems is provided in sections 7.4.4.2.1 and 7.4.5.2.1 of this SER. Additionally, combustible gas management is reviewed and found acceptable in sections 6a.4.2, 13a.4.9, 13a.5.1, and 13b.4.8 of this SER.

Criterion 4 – Environmental and dynamic effects

> Safety-related SSCs are designed to perform their functions with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. These SSCs are appropriately protected against dynamic effects and from external events and conditions outside the facility.

The NRC staff found SHINE's design for environmental and dynamic effects acceptable in section 2.4.2 of this SER. The staff also found SHINE's protection system independence and equipment qualifications acceptable in sections 7.4.4.2.1 and 7.4.5.2.1 of this SER. Additionally, credible facility-specific events related to operations and maintenance, including heavy load drop events, are found acceptable in section 13a.4.12 of this SER. For the RPF, the staff found SHINE's analyses for mishandling or malfunction of RPF equipment acceptable in section 13b.4.6 of this SER.

Criterion 5 – Sharing of structures, systems, and components

> Safety-related SSCs are not shared between irradiation units unless it can be shown that such sharing will not significantly impair their ability to perform their safety functions.

The NRC staff evaluated the design and performance of the SSCs of the SHINE facility, including those SSCs shared by both the IF and the RPF. The staff found acceptable SHINE's design with respect to the sharing of SSCs, including the interface between the IF and the RPF and common systems shared between those facilities, as discussed in section 1.4 of this SER. Additionally, although all IUs share the ESFAS and the control room and although three separate tritium purification systems are shared by the eight IUs, as discussed in sections 7.4.4.2.1 and 7.4.5.2.1 of this SER, the NRC staff found that the sharing of these systems does not impair the ability to perform the associated safety functions.

Criterion 6 – Control room

> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

The NRC staff found SHINE's control room design acceptable in section 7.4.9.1 of this SER. Additionally, the operator's role to perform required actions is reviewed and found acceptable in section 7.4.9.2 of this SER. The adequacy of specific controls and displays is evaluated in section 7.4.6 of this SER.

Criterion 7 – Chemical protection

> The design provides for adequate protection against chemical risks produced from licensed material, facility conditions that affect the safety of licensed material, and hazardous chemicals produced from licensed material.

The NRC staff found SHINE's evaluation of hazardous materials or activities on the SHINE site and in the vicinity of the SHINE site acceptable in section 2.4.2.3 of this SER. SHINE evaluated onsite toxic chemicals in SHINE FSAR section 13b.3, "Analyses of Accidents with Hazardous Chemicals," and SHINE FSAR table 13b.3-2, "Hazardous Chemical Source Terms and Concentration Levels." The staff found acceptable SHINE's evaluation for adequate protection against chemical risks in section 13b.4.9 of this SER.

Criterion 8 – Emergency capability

> The design provides emergency capability to maintain control of:
>
> 1) licensed material and hazardous chemicals produced from licensed material;
>
> 2) evacuation of on-site personnel; and
>
> 3) on-site emergency facilities and services that facilitate the use of available off-site services.

The NRC staff evaluated SHINE document EMG-01-01, Revision 1, "Emergency Plan," to assess the sufficiency of SHINE's emergency capability. The staff found SHINE's design for emergency capability acceptable in section 12.4.7 of this SER.

The remaining 31 SHINE facility design criteria are specifically assigned to systems and subsystems as detailed in SHINE FSAR tables 3.1-1 and 3.1-2. The NRC staff evaluations of those specific design criteria are provided in the corresponding sections of this SER.

3.4.1.2 SHINE Facility Nuclear Safety Classification

To demonstrate that the principal design criteria are adequate, SHINE FSAR section 3.1 provides that acceptable risk is achieved by ensuring that all postulated events are highly unlikely or by reducing the consequences to less than the SHINE safety criteria. The SHINE safety criteria are listed below followed by the NRC staff's evaluation of their acceptability as constraints to meet NRC regulations and ensure public health and safety.

> SHINE Safety Criterion: An acute worker dose of five rem [roentgen equivalent man] or greater total effective dose equivalent (TEDE).

A dose of 5 rem TEDE is the regulatory occupational dose limit for adults under 10 CFR 20.1201, "Occupational dose limits for adults." It is also the basis for the derived annual limit on intake (ALI) for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rem. SHINE defines the control room operator as the "worker" receptor for calculating radiological consequences.

> SHINE Safety Criterion: An acute dose of 1 rem or greater TEDE to any individual located outside the owner-controlled area.

As discussed in section 13a.4.1 of this SER, no radiological accident dose criterion is set forth in the NRC's regulations or in applicable guidance to assess the risk to public health and safety and control room operators for non-power production or utilization facilities (NPUFs). As a matter of comparison, the NRC staff has used the public dose limits of 10 CFR Part 20 (i.e., 0.1 rem TEDE) as the accident dose criteria to license NPUFs (e.g., Safety Evaluation Report Related to Renewal of the Facility Operating License for the University of Massachusetts Lowell Research Reactor," dated February 2022 (Agencywide Documents Access and Management System Accession No. ML21168A054)). For a research reactor, the results of the accident analysis have generally been compared with 10 CFR 20.1001 through 20.2402 consistent with the guidance in chapter 13 of NUREG-1537, Part 2. However, the NRC staff described in the *Federal Register*, Volume 82, Number 60, dated March 30, 2017 (82 FR 15643), a proposal to amend the NRC's regulations that govern the license renewal process for non-power reactors, testing facilities, and other production or utilization facilities, licensed under the authority of section 103, section 104a, or section 104c of the Atomic Energy Act, as amended, that are not nuclear power reactors. In this proposed rule, the NRC collectively refers to these facilities as NPUFs, which would include the SHINE facility. The staff stated that it had determined that the 10 CFR Part 20 public dose limit of 0.1 rem TEDE is unduly restrictive to be applied as accident dose criteria for NPUFs not subject to 10 CFR Part 100, "Reactor Site Criteria," which would include the SHINE facility, and proposed, instead, an accident dose criterion of 1 rem. In addition to being consistent with the proposed accident dose criterion in 82 FR 15643, the staff also finds SHINE's accident dose criterion to be acceptable based on the early phase protective action guides (PAGs) established by the U.S. Environmental Protection Agency (EPA), which were published in the EPA document EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents," dated January 2017, to provide reasonable assurance of adequate protection of the public from unnecessary exposure to radiation. The maximum hypothetical accident at the SHINE facility, which would result in a maximum public dose of 0.727 rem, is reviewed and found acceptable in section 13.5.4.7 of this SER.

SHINE Safety Criterion: An intake of 30 milligrams or greater of uranium in a soluble form by any individual located outside the owner-controlled area.

As discussed in the "Introduction to the Interim Staff Guidance," of the ISG augmenting NUREG-1537, Part 2, the NRC staff has determined that the use of integrated safety analysis methodologies, as described in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications," application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for medical isotope production facilities. As noted in the ISG, this is just one acceptable way of demonstrating the safety of a medical isotope production facility and is not required. Further, the ISG does not require licensees that would not otherwise have to follow the regulations in 10 CFR 70.61 to do so. Under 10 CFR 70.61(b), licensees must use engineered controls, administrative controls, or both to reduce the likelihood of occurrence of each credible high consequence event such that the events are highly unlikely or their consequences are less severe than those described in 10 CFR 70.61(b)(1)-(4). Further, 10 CFR 70.61(b)(3) defines events resulting in an intake of 30 milligrams or greater of uranium in soluble form by any individual located outside the controlled area identified pursuant to 10 CFR 70.61(f) as high consequence events. Finally, 10 CFR 70.61(f) requires licensees to establish a controlled area, as defined in 10 CFR 20.1003, "Definitions," and notes that licensees must retain the authority to exclude or remove personnel and property from this area.

Although 10 CFR 70.61 does not apply to SHINE, SHINE proposed to adopt the following safety criterion: an intake of 30 milligrams or greater of uranium in a soluble form by any individual located outside the owner-controlled area. As an initial matter, SHINE FSAR section 2.1.1.2, "Boundary and Zone area Maps," defines an owner-controlled area consistent with the definition of controlled area in 10 CFR 20.1003. Additionally, SHINE retains the authority to exclude or remove personnel and property from this area. Consequently, SHINE proposes to use this criterion from the radiological and chemical consequences and likelihood criteria contained in the performance requirements of 10 CFR 70.61 as a safety criterion.

Consistent with the ISG augmenting NUREG-1537, Part 2, SHINE has chosen to adopt the 30 milligrams or greater soluble uranium criterion from the radiological and chemical consequences and likelihood criteria contained in the performance requirements of 10 CFR 70.61 as a safety criterion. The NRC staff finds this acceptable because, as discussed in the ISG augmenting NUREG-1537, Part 2, doing so presents an acceptable means of demonstrating adequate safety for a medical isotope production facility.

SHINE Safety Criterion: An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could lead to irreversible or other serious, long-lasting health effects to a worker or could cause mild transient health effects to any individual located outside the owner-controlled area.

SHINE FSAR section 13a2 states that the SHINE safety analysis (SSA) applies a methodology based on NUREG-1520 to identify and evaluate credible accident scenarios, including hazardous chemical accidents. The NRC staff evaluated the SSA using the guidance and acceptance criteria from the ISG augmenting NUREG-1537, Parts 1 and 2, which endorses as one acceptable method the use of integrated safety analysis methodologies as described in 10 CFR Part 70 and NUREG-1520. As discussed in section 13a.4.2 of this SER, the staff found SHINE's analysis of radiological consequences as well as chemical consequences for chemical hazards directly associated with NRC licensed radioactive material acceptable.

> SHINE Safety Criterion: Criticality where fissionable material is used, handled, or stored (with the exception of the target solution vessel).

SHINE analyzed inadvertent nuclear criticality in the RPF in SHINE FSAR section 13b.1.2.5. SHINE stated that nuclear criticality safety is achieved through the use of preventative controls throughout the RPF, which reduces the likelihood of a criticality accident to highly unlikely. The NRC staff reviewed this and found SHINE's analysis of inadvertent nuclear criticality in the RPF acceptable in section 6b.4.3 of this SER.

> SHINE Safety Criterion: Loss of capability to reach safe shutdown conditions.

SHINE defines "Safe Shutdown" in proposed TS 1.3 as:

> An IU is in a Safe Shutdown condition if the following performance criteria are achieved and maintained:
>
> A. Target solution is not present:
>
> No target solution is present in the IU
>
> AND
>
> TSV fill valves are closed.
>
> OR
>
> B. Target solution is present:
>
> Target solution is drained from the TSV
>
> AND
>
> Hydrogen is controlled:
>
> Nitrogen purge system (N2PS) is Operable
>
> OR
>
> Target solution hydrogen generation rates are below those requiring preventive controls.

The NRC staff evaluated the specified conditions identified by SHINE for safe shutdown. If target solution is not present within an IU, the IU is stated to be in Mode 0, as defined in proposed TS table 1.3, "IU Modes of Operation." The additional requirement that the TSV fill valves be closed helps ensure that the IU is in a safe shutdown condition. Alternately, the facility is in safe shutdown if target solution is present (but not present in the TSV) and hydrogen is controlled. This implies that the IU is in either Mode 3 (post-irradiation (shutdown)) or Mode 4 (transfer to RPF). Although the hydrogen generation rate of the irradiated target solution is minimized by stopping irradiation activities, hydrogen generation continues in facility tanks containing irradiated target solution or radioactive liquid waste via radiolysis generated by radioactive decay. Control of hydrogen minimizes the risk of reaching a flammable concentration and is assured by either operating the N2PS or when hydrogen generation rates are below levels of concern. The draining of the target solution to the TSV dump tank results in safe shutdown since the target solution is drained to the favorable geometry TSV dump tank. The staff evaluated the subcritical assembly and phenomena that are expected to impact the changes in target solution composition in sections 4a.4.2 and 13a4.1 of this SER and found that the target solution design and its interface with the pressure boundary offer reasonable assurance that the health and safety of the public can be assured during normal operation and that the SHINE safe shutdown safety criterion ensures that the facility is designed to automatically shut down the irradiation process, place the target solution into a safe condition, and stabilize accident conditions without immediate operator actions.

3.4.1.3 Review Findings for SHINE Facility Design Criteria and Nuclear Safety Classification

The NRC staff reviewed the descriptions and discussions of the SHINE facility design criteria and nuclear safety classification, as described in SHINE FSAR section 3.1, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE FSAR, the staff determined that:

- SHINE specified design criteria for each SSC that is assumed in the FSAR to perform an operational or safety function.

- SHINE design criteria include references, where appropriate, to applicable up-to-date standards, guides, and codes. The descriptions of the design are included in the section of the FSAR that corresponds to the specific SSC and generally include the following:

    - Design for the complete range of normal expected operating conditions.

    - Design to cope with anticipated transients and potential accidents, as discussed in Chapter 13, "Accident Analysis" of the FSAR.

    - Design for redundancy, so that any single failure of any active component will not prevent safe shutdown or result in an unsafe condition.

    - Design to facilitate inspection, testing, and maintenance.

    - Design with provisions to avoid or mitigate fires, explosions, and potential man-made or natural conditions.

    - Quality standards commensurate with the safety function and the potential risks.

    - Analysis and designs for meteorological, hydrological, and seismic effects (see sections 3.2, 3.3, and 3.4 of the staff's SER)

    - Design bases necessary to ensure the availability and operability of required SSCs.

The principal design criteria are the criteria that SHINE established to ensure, in part, that the SHINE safety criteria are met. The SHINE safety criteria are the criteria that SHINE established to ensure that the principal safety considerations of the facility are adequately addressed. The SHINE safety criteria are derived from the performance requirements in 10 CFR 70.61(b) and (c). These are not required to be applicable to SHINE's 10 CFR Part 50 license, but were adopted by SHINE to provide controls, to the extent needed, to reduce the likelihood of occurrence and consequences of events. The SHINE nuclear safety classification states that the components that are relied upon to achieve SHINE's safety criteria are classified as safety-related. The NRC staff finds that the safety-related SSCs identified by SHINE are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents to within acceptable limits. Therefore, the staff concludes that the SHINE discussion regarding nuclear safety classification is acceptable.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE facility design criteria and nuclear safety classification are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.4.2 Meteorological Damage

The NRC staff evaluated the sufficiency of the SHINE facility design features to cope with meteorological damage, as presented in SHINE FSAR section 3.2, using the guidance and acceptance criteria from section 3.2, "Meteorological Damage," of NUREG-1537, Parts 1 and 2, and section 3.2 of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 3.2 of NUREG-1537, Part 2, the NRC staff considered the description of the site meteorology to ensure that all SSCs that could suffer meteorological damage are considered, as presented in SHINE FSAR sections 3.2 and 3.6 and other relevant chapters of the FSAR. The design criteria are compatible with local architectural and building codes for similar structures. The design specifications for SSCs are compatible with the functional requirements and capability to maintain their function throughout the predicted meteorological conditions. The methods for determining the wind, tornado, and snow and ice loadings are summarized. In SHINE FSAR 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 discussed in SHINE FSAR section 3.4.2.6.4, "Design Loads and Loading Combinations."

In its review of SSCs considered for meteorological damage, the NRC staff noted that SHINE FSAR sections 3.2 and 3.4.2.6.3 describe the design criteria, methodology, and parameters used for the main production facility structure. However, based on the staff review of SHINE FSAR section 1.4, "Shared Facilities and Equipment," and audited documents, the staff noted that other structures that may support and protect safety-related SSCs from meteorological damage may have not been properly described in the FSAR. The staff also noted that the FSAR inconsistently used the term "SHINE facility" to either refer to the main production facility structure (alone) or to refer to all of the structures within the SHINE facility, as described in SHINE FSAR section 1.4.

During its evaluation of the applicant's response to NRC staff RAI 3.2-1 (ML21029A103), the staff noted that SHINE stated that the N2PS structure is the only structure described in SHINE

FSAR section 1.4 that is not part of the main production facility structure, and that it performs a safety-related function. Since this structure is not considered part of the main production facility structure, SHINE added section 3.6 to its FSAR to incorporate the design criteria, parameters, and methodology for evaluating meteorological damage that is applicable to the N2PS structure and to describe how that structure is designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, and floods. The staff also noted that the design criteria applicable to the N2PS structure are SHINE Design Criteria 1 through 4, as described in SHINE FSAR table 3.1-3. During its review of SHINE FSAR section 3.6, the staff noted that the N2PS structure is designed to withstand the same potential meteorological damage described in SHINE FSAR section 3.2 for the main production facility structure. Therefore, the staff's evaluation of the main production facility structure also applies to the N2PS structure.
The NRC staff finds the applicant's response, addition of section 3.6 to the SHINE FSAR, and changes to SHINE FSAR table 3.1-1 acceptable because SHINE: (a) confirmed that the N2PS structure is the only structure described in SHINE FSAR section 1.4 that has a safety-related function and is not part of the main production facility structure and (b) provided a description, included in the FSAR, of the design criteria, parameters, and methodology applicable to the N2PS structure.

During its review of the design criteria and parameters considered for coping with meteorological damage, the NRC staff noted that some of the criteria, parameters, and methodology defined in SHINE FSAR sections 3.2 and 3.4 were not sufficiently described to understand how the structures were designed for protection from the meteorological condition. To ensure that the applicable design criteria, parameters, and methodology to cope with meteorological damage are sufficiently described in the FSAR, and to provide reasonable assurance that SSCs would continue to perform necessary operational and safety functions throughout the predicted meteorological conditions, the staff issued RAIs 3.2-2 and 3.2-3.

During its evaluation of the applicant's response to RAI 3.2-2 (ML21011A240), the NRC staff noted that SHINE FSAR sections 3.2 and 3.4 were revised to also include the following design criteria/parameters:

(1) the exposure coefficient and other factors used in SHINE FSAR Equation 3.2-1 for the wind loading, including the gust factor and pressure coefficient;

(2) the basic wind speed for Wisconsin, including a description of the applied factor to account for a 100-year recurrence interval;

(3) the values applicable to the site for the tornado rotational speed, translation speed, differential pressure, and rate of differential pressure, including additional discussion of the site's design basis tornado missile spectrum and maximum horizontal speed, used for the tornado loading; and

(4) the values applicable to the site for the factors used in SHINE FSAR Equation 3.2-3 for snow, ice, and rain loading, including the snow load and recurrence interval.

During its evaluation of the applicant's response to RAI 3.2-3, the NRC staff noted that SHINE clarified that the methodology and acceptance criteria described in NUREG-0800, section 3.5.3, "Barrier Design Procedures," were used to transform the tornado generated missile impacts into an effective or equivalent static load on the structures. In its response, SHINE also stated that SHINE FSAR section 3.2.2.2 had been revised to correct the reference to NUREG-0800, section 3.5.3 and to add additional information related to the tornado missiles considered in the analysis.

The NRC staff finds the applicant's response and changes to SHINE FSAR sections 3.2.1, 3.2.2, 3.2.3, and 3.4.2.6.3 acceptable because the additional design criteria provided by the applicant for meteorological damages: (a) are consistent with applicable local building codes, national standards, guidelines, and recognized industry practices and (b) are sufficient to provide reasonable assurance that SSCs would continue to perform necessary operational and safety functions throughout the predicted meteorological conditions. The staff also finds the applicant's response and changes to SHINE FSAR section 3.2.2.2 acceptable because they clarify that the methodology used by SHINE is consistent with NUREG-0800, section 3.5.3, which provides an acceptable methodology and criteria for transforming tornado generated missile impacts into an effective or equivalent static load on the structures.

In its review of the methodology used for determining loading and its design, the NRC staff noted that potential meteorological conditions are considered in the design of the SHINE facility by analyzing the pressure effects of wind loads, tornado loads (including tornado generated missiles), snow loads, ice loads, and rain loads using a 100-year return period, as described in SHINE FSAR sections 3.2 and 3.4.2.6.3. These loads are determined by the methodology and guidelines provided in ASCE Standard 7-05, "Minimum Design Loads for Building and Other Structures," and the NRC Regulatory Guide (RG) 1.76, "Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants" (ML070360253). As stated in SHINE FSAR sections 3.2.3 and 3.4.2.6.3.9, rain loading was not considered to be a potential concern because the SHINE facility is designed with a sloped roof and a building configuration that precludes the accumulation of rainwater. Also, as stated in its previous response to RAI 3.2-1 for the construction permit application, by letter dated December 3, 2014 (ML14357A345), rain-on-snow surcharge load was not considered in the structural analysis because the SHINE facility is located in an area where the ground snow load (as determined from figure 71 of ASCE 7-05) is greater than 20 pounds per square foot. The NRC staff also noted that SHINE FSAR section 3.4.2.6.2 states that the following codes and standards are used for the design of the SHINE facility: (a) American Concrete Institute (ACI) 349-13, "Code Requirements for Nuclear Safety-Related Concrete Structures and Commentary," and (b) ANSI/American Institute of Steel Construction (AISC) N690-12, "Specification for Safety-Related Steel Structures for Nuclear Facilitates." Based on the information provided, the NRC staff finds that the design, methodology, and parameters used are consistent with local applicable architectural and building codes for similar structures and are compatible with the SHINE facility functional requirements and capability to retain function throughout the predicted meteorological conditions.

Based on its review, the NRC staff determined that the level of detail provided on meteorological damage is adequate and supports the applicable acceptance criteria of section 3.2 of NUREG-1537, Part 2. The staff concludes that the design criteria and the design for protection from meteorological damage conditions are based on applicable local building codes, standards, and criteria, which provides assurance that SSCs will continue to perform their safety functions as specified in the SHINE FSAR. Therefore, the SHINE facility design features for coping with meteorological damage meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.4.3 Water Damage

The NRC staff evaluated the sufficiency of the SHINE facility design features to cope with predicted hydrological conditions, as presented in SHINE FSAR section 3.3, using the guidance and acceptance criteria from section 3.3, "Water Damage," of NUREG-1537, Parts 1 and 2, and section 3.3 of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of section 3.3 of NUREG-1537, Part 2, the NRC staff considered the site description and facility designs to ensure that all safety-related SSCs with the potential for water damage, including damage due to external and internal flood hazards, are considered in the SHINE FSAR. For any such safety-related SSCs, the staff reviewed the design bases to verify that the consequences are addressed and described in detail in the appropriate chapters of the FSAR.

3.4.3.1 Flood Protection from External Sources

SHINE FSAR section 3.3 describes that the design basis precipitation level is at site grade, the design basis flood level is at 50 feet below grade, and the maximum ground water level is at 50 feet below grade. These levels are associated with the local probable maximum precipitation (PMP) and the local probable maximum flood (PMF) and are quantified in SHINE FSAR section 2.4.2.3, "Effect of Local Intense Precipitation," and section 2.4.3, "Probable Maximum Flood on Streams and Rivers."

SHINE FSAR section 2.4.2.3 states that the effect of the local PMP on the areas adjacent to the safety-related structures of the SHINE facility, including the drainage from the roofs of the structures, was evaluated. The maximum water levels due to the PMP were estimated near the safety-related structures of the facility based on the site topographic survey map. A drainage system designed to carry runoff from the site consists of conveying water from roofs, as well as runoff from the site and adjacent areas, to peripheral ditches. The facility is surrounded by berms with interior ditches along the berms and the grade around the structures slopes towards the peripheral ditches. However, during a PMP event, the stormwater drainage system is conservatively assumed to be nonfunctional. During a PMP event, the water level is estimated to be at grade and the top of the finished foundation elevation is at least 4 inches (in.) above grade.

SHINE FSAR section 2.4.3 notes that a local PMF event creates a water level approximately 50 feet below grade. The lowest point of the facility is 29 feet below grade; therefore, flooding would not cause any structural loading in the case of a local PMF event and 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.

In its response to RAI 3.2-1 (ML21029A103), the applicant noted that the N2PS structure performs a safety function and, therefore, added section 3.6 to the SHINE FSAR to discuss the design of this structure. The applicant also noted that the external flooding assumptions (i.e., PMP and PMF water levels) are the same for the N2PS structure as for the main production facility and that the N2PS structure has been designed to ensure that water does not infiltrate the structures and cause damage to safety-related SSCs.

The NRC staff reviewed the information on the site PMP and PMF provided in SHINE FSAR sections 2.4.2.3, 2.4.3, 3.3, and 3.6.2. The staff noted that the design PMP elevation is at plant grade and that the PMF is approximately 50 feet below grade and approximately 21 feet below the lowest point of the facility. In addition, the staff noted that the finished foundation level is at least 4 in. above site grade. Based on its review, the staff finds that there is no dynamic force applied to the structures due to precipitation or flooding, and that a PMP or a PMF event will not cause water to infiltrate the structures and result in damage to safety-related SSCs.

3.4.3.2 Flood Protection from Internal Sources

SHINE FSAR section 3.3.1.1.2, "Flood Protection from Internal Sources," states that the bounding flood volume in the radiologically controlled area (RCA) is from the fire protection system (FPS). The credible volume of discharge from the FPS is due to a manual fire-fighting flow rate of 500 gallons per minute (1893 liters per minute) for a duration of 30 minutes, in accordance with the guidance in section 5.10 of National Fire Protection Association (NFPA) 801, "Standard for Fire Protection for Facilities Handling Radioactive Materials." Therefore, the total discharge volume is 15,000 gallons (56,782 liters). The resulting flooded water depth in the RCA from this fire protection discharge is less than 2 in., which bounds the total water available in the process chilled water system (PCHS) and the radioisotope process facility cooling system (RPCS) that could cause internal flooding. The floors of the uranium receipt and storage system/target solution preparation system rooms are elevated to prevent water intrusion in the event of an internal flood and water sensitive safety-related equipment in the RCA is raised 8 in. from the floor. Safety-related functions of systems that are subject to the effects of a discharge of the fire suppression system are appropriately protected by redundancy and separation. SHINE FSAR section 3.3.2 notes that the load from build-up of water due to FPS discharge is supported by slabs on grade except for the mezzanine floor. However, the mezzanine floor includes openings that will ensure that the slab is not significantly loaded and it is designed with a live load value of 250 pounds per square foot.

SHINE FSAR section 3.3.1.1.2 also notes that flood scenarios have been considered for the pipe trenches and vaults. Process piping, vessels, and tanks containing special nuclear material or radioactive liquids are seismically qualified. There is no high-energy piping within these areas and any pipe or tank rupture in the RPF vaults is routed to the radioactive drain system (RDS). The RDS is sized for the maximum postulated pipe or tank failure as described in SHINE FSAR section 9b.7.6. The design of the shield plugs over the pipe trenches and vaults prevents bulk leakage of liquid into the vaults from postulated flooding events within the remainder of the RCA.

The NRC staff reviewed the information provided in SHINE FSAR section 3.3.2 and noted that the loads due to possible water build-up are supported by slabs on grade, which will be able to support the additional water load. The mezzanine floor is not on grade; however, it has been designed to limit the possible water load to less than the design live load of the floor. Therefore, the staff determined that the structures have been properly designed to support any additional loads from water due to FPS discharge. The staff also reviewed SHINE FSAR section 3.3.1.1.2 and noted that the bounding volume of water in the RCA was due to a manual discharge of the FPS. As part of its review of internal flooding, the staff conducted an audit, during which it reviewed calculations associated with postulated flooding depths in the RCA. The staff identified locations in the RCA that appeared to have flooding depths greater than 8 in. To understand how equipment in these areas would be protected from flooding, the staff issued RAI 3.3-1. The staff also noted in the audit that manual flood barriers will be used to control flooding.

In its response to NRC staff RAI 3.3-1 (ML21011A240), the applicant stated that the bounding internal flood volume of 15,000 gallons distributed over the minimum open floor space in the IF results in a maximum flood height of approximately 11.7 in. Therefore, the design was revised to raise the minimum height of water-sensitive, safety-related equipment in the RCA to 12 in. above the floor. The RAI response also describes that the bounding flood scenario in the RPCS room results in a flood height of approximately 22.9 in. In this room, the minimum height for water-sensitive, safety-related equipment is 24 in. above the floor. The RAI response further notes that the manual flood barrier in the RPCS room is not relied on in the safety analysis to keep leakage from leaving the room.

The NRC staff reviewed the information in SHINE FSAR section 3.3.1.1.2 and finds it acceptable because the applicant clearly identified the maximum flood heights in the building and that the minimum heights of water-sensitive, safety-related equipment ensures that the equipment remains above the postulated internal flood levels.

While reviewing the information provided in SHINE FSAR section 3.3.1.1.2, the staff also noted that the uninterruptible electrical power supply system has two redundant and isolated trains to prevent both trains from being damaged by discharge of the FPS.

In its response to NRC staff RAI 3.3-2 (ML21011A240), the applicant stated that safety-related equipment subject to discharge of the FPS are protected by redundancy and separation, where practicable. Where equipment cannot be effectively separated, fire response plans are established to ensure that redundant trains are not simultaneously damaged from activation of the FPS.

The NRC staff reviewed the information in SHINE FSAR section 3.3.1.1.2 and finds it acceptable because it describes that water-sensitive, safety-related equipment is protected from discharge of the FPS either by redundancy and separation, or with an appropriate fire response plan.

The NRC staff reviewed SHINE FSAR section 3.6, which describes the design of the N2PS structure. The staff reviewed the information provided in SHINE FSAR section 3.6.2 related to water damage of the N2PS structure and noted that there are no water sources internal to the N2PS structure and so there is no risk of internal flooding. Since there are no internal water sources, the staff finds that there is no potential internal flooding hazard that would cause damage to safety-related SSCs in the N2PS structure.

Based on its review, the NRC staff finds that the safety-related SSCs are adequately protected from internal flooding hazards and that the structures are adequately designed to withstand additional loads from postulated internal flooding.

3.4.3.3 Water Damage Evaluation Summary

Based on its review, the NRC staff determined that the level of detail provided on water damage is adequate and supports the applicable acceptance criteria of Section 3.3 of NUREG-1537, Part 2. The staff concludes that the design criteria and the designs would protect against potential water damage and provide reasonable assurance that SSCs would continue to perform their required safety functions, 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 SHINE facility design features for coping with postulated water damage meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.4.4 Seismic Damage

SHINE FSAR section 3.4 describes the general arrangement of the SHINE FSTR, its IF, RPF, the non-radiologically controlled seismic area, and a non-safety-related area. The IF, RPF, and non-radiologically controlled seismic area are within the seismic boundary of the facility and are classified as Seismic Category I SSCs.

The NRC staff evaluated the sufficiency of the FSTR design and its features to cope with potential seismic damage, as presented in SHINE FSAR section 3.4. The staff's review used the guidance and acceptance criteria from section 3.4, "Seismic Damage," of NUREG-1537, Parts 1 and 2, and section 3.4 of the ISG augmenting NUREG-1537, Parts 1 and 2, applicable references listed in SHINE FSAR section 3.7, and, when and where applicable and as deemed necessary, the additional guidance from sections 3.7.1 and 3.7.2 of NUREG-0800. Consistent with the review procedures of section 3.4 of NUREG-1537, Part 2, the staff also considered the site description and facility design to ensure that all safety-related SSCs with a potential for seismic damage were considered.

SHINE described the FSTR as a reinforced concrete box shear wall system on soil. Its major structural elements include the foundation mat, mezzanine floor, roof slab, and shear walls. Steel roof trusses support the concrete roof slab of the IF and RPF. The mezzanine floor is made of reinforced concrete on metal deck. The floor is vertically supported by structural steel beams and columns, and laterally restrained by reinforced concrete partition walls. A large section of the basemat in the RPF is recessed below-grade to accommodate a series of tanks, valve pits, and other mechanical systems. The tanks are separated by cast-in-place reinforced concrete walls and are covered by precast concrete shield plugs. Depending on their function, interior FSTR walls are made of cast-in-place reinforced concrete, reinforced masonry, or gypsum boards mounted to metal studs. Additional details of facility SSCs and equipment that include an exhaust stack, supercells, and below grade reinforced concrete vaults and tanks are also found in other FSAR chapters (e.g., sections 1.2.1, 2.1.1.2, 3.4.2.6.4.1, and 4b.2.2.2 and tables 7.7-2 and 7.7-3).

To ensure that all applicable design criteria, parameters, and methodology to cope with seismic/transient and other abnormal loads are sufficiently addressed in the FSAR, and to obtain reasonable assurance that SSCs would continue to perform their operational and safety functions during seismic events and for abnormal loads, the NRC staff issued RAIs. The staff reviewed SHINE's response to RAI 3.4-7 (ML21011A240), and finds it acceptable because consistent with NUREG-1537, the applicant's design follows the applicable guidance of RGs, NUREGs, local building codes, and national codes and standards that include provisions for materials testing. The staff also finds the applicant's revisions to SHINE FSAR sections 3.4 and 3.7 acceptable because they reflect references to RGs, NUREGs, local building codes, and national codes and standards that are applicable to the facility design.

To further clarify how various FSTR SSCs (e.g., the stack, walls, tanks, vaults, supercells, etc.) are configured and integrated into the seismic design and because of concern that potential future internal rearrangement of FSTR SSCs and relocation of equipment could alter the intent of the original structural design and to ensure that the facility would continue to maintain its defense-in-depth, the NRC staff issued RAIs. The NRC staff reviewed the applicant's response to RAI 3.4-8 (ML21011A240), and finds its discussion of configuration control acceptable because proposed SHINE TS 5.5.4, "Configuration Management," includes an oversight and controls program that addresses changes made to the facility design, to its physical configuration, and to its documentation so that these are in accordance with the 10 CFR 50.59, “Changes, tests and experiments,” process.

The NRC staff noted that although SHINE updated its FSAR to include additional FSTR design details such as its size and seismic isolation, other key design information on the FSTR (e.g., its height, thickness of its walls, materials used for its construction) and its SSCs (e.g., anchorage) was still lacking. This level of detail is needed to sufficiently evaluate future changes that may be made to the facility or its reconfiguration consistent with the 10 CFR 50.59 process and to confirm the conservatisms in the FSTR design and that of its SSCs. Therefore, the NRC staff issued RAIs.

The NRC staff reviewed SHINE’s response to RAI 3.4-18 (ML21208A135), and noted that the applicant expanded upon the FSAR description of the FSTR and clarified that the collapse of the exhaust stack would not endanger the FSTR, its safety-related SSCs, or the N2PS facility, as these are either designed to withstand substantial loads, such as aircraft impacts, or are removed from harm’s way. In its RAI response, the applicant also clarified that the collapse of the stack on the non-safety-related portion of the facility or on the Seismic Category II interior partitions, would not affect safety-related SSCs or create a risk exceeding established facility safety criteria. Furthermore, the applicant clarified that supercells are integrated in the FSTR design and that the concrete shield plugs are properly sized and accounted for in the design. The staff finds that the applicant’s finalized facility configuration description and statement that safety-related SSCs are qualified to be functional during and after a transient or abnormal loadings is adequate and consistent with the regulatory framework and, therefore, acceptable. The staff also finds that SHINE’s revisions to FSAR sections 3.4, 3.7, 9a2.1.1.1, and 4b.2.2.2.1 are adequate as they provide more detailed descriptions of the facility and of its SSCs and, therefore, are acceptable.

3.4.4.1 Seismic Input

SHINE FSAR section 3.4.1, “Seismic Input,” provides an overview of the site seismicity and seismic input for the seismic analysis of the facility. It provides information for the peak ground acceleration for the safe shutdown earthquake (SSE), its design response spectra, synthetic time histories for SSI analyses, and critical damping values for structural components. SHINE FSAR 3.4.1.1, “Design Response Spectra,” states that the SSE is defined by a maximum ground acceleration of 0.2 g (seismic acceleration, rate of change of velocity per unit time, e.g., feet per second^2 (ft/s^2)) and design response spectra in both vertical and horizontal directions, as per RG 1.60, Revision 2, “Design Response Spectra for Seismic Design of Nuclear Power Plants” (ML13210A432). The ground motion response spectrum (GMRS) is defined as an outcrop motion at a depth of 2.3 meters (m) (7.5 feet (ft)) below the grade, the location of competent materials with a minimum shear wave velocity of 305 meters per second (m/s) (1,000 ft/s) at the site. This approach follows section 3.7.1 of NUREG-0800. The peak ground acceleration (PGA) of 0.2 g for both vertical and horizontal directions is developed for the site and exceeds the designated minimum free-field PGA value of at least 0.1 g to be used, per acceptance criterion 1.A. of section 3.7.1 of NUREG-0800. For these reasons, the NRC staff finds that the design response spectra used for analyzing the FSTR are acceptable.

To ensure that the SHINE FSAR provides sufficient information that conditions due to a seismic event will not pose significant risk to the health and safety of the public and to conclude that the facility design will perform adequately during a design basis seismic event with its SSCs performing the necessary safety functions as described in the application, the NRC staff issued RAIs 3.4-1 and 3.4-2. Through its responses to RAIs 3.4-1 and 3.4-2 (ML21011A240), SHINE supplemented SHINE FSAR section 3.4.1, as noted above, and section 3.4.2, "Seismic Analysis of Facility Structures," which the staff reviewed and evaluated as noted below.

Synthetic acceleration-time histories are generated enveloping the design response spectra in three mutually orthogonal directions, using the seed recorded time histories from the El Centro earthquake in 1940, for SSI analysis and developing the in-structure response spectra (ISRS). They are shown in figures 3.4-1-1 through 3.4-1-3 of the applicant's response to RAI 3.4-1. The NRC staff finds this approach to be consistent with acceptance criterion 1.A(ii) of section 3.7.2 of NUREG-0800. Based on this observation, the staff concludes that the approach to generate synthetic acceleration-time histories is acceptable. These artificial time histories are used in site response analysis to develop strain-compatible soil properties and in-profile ground motions for seismic analysis.

Each of the time histories meets the design response spectra consistent with Option 1, "Single Set of Time Histories," Approach 2 of section 3.7.1 of NUREG-0800 and, therefore, is acceptable. The calculated correlation coefficient between any pairs of the two horizontal and one vertical SSE motions generated, as given in the applicant's response to RAI 3.4-1, is significantly smaller than the maximum allowable correlation coefficient of 0.16 given in acceptance criterion 1.B, "Design Time Histories," of Section 3.7.1 of NUREG-0800. This shows that the generated acceleration spectrum in one direction is independent of those in the other two mutually orthogonal directions. Additionally, the duration of the generated pulse is approximately 40 seconds long, as stated in the applicant's response to RAI 3-4-1 and as provided in figures 3.4-1-1 through 3.4-1-3, which is significantly larger than the 20 seconds as stated in acceptance criterion 1.B.ii.(a) of section 3.7.1 of NUREG-0800. In addition, the NRC staff finds that the duration of the strong motion portion in each orthogonal direction is significantly longer than the minimum 6 seconds given in acceptance criterion 1.B of section 3.7.1 of NUREG-0800. Based on these observations, the staff concludes that the generated SSE design spectra are acceptable to conduct the SSI analysis.

3.4.4.2 Seismic Analysis of Facility Structures

SHINE FSAR section 3.4.2 addresses modeling and analysis of the FSTR performed by the SASSI2010 and SAP2000 finite element analysis (FEA) codes. It includes applied loads to the structure (e.g., dead, live – including meteorological, crane, fluid, soil pressure, and seismic, etc.), discussions of structural response to multidirectional seismic input, structural seismic stability, etc.

SHINE FSAR section 3.4.2.4, "Seismic Analysis Results," includes seismic loads that have been applied to the structural analysis model and used to develop the ISRS for use in sizing equipment and structural components. As stated in section 3.4.2.1, "Seismic Analysis Methods," and further confirmed by SHINE in its response to NRC staff RAI 3.4-2, the seismic analysis of the FSTR used SASSI2010 (version 1.0) and SAP2000 (version 17.2) computer programs. The staff's RAI 3.4-2 questions on seismic analysis methods and soil-structure modeling and SHINE's public responses are documented in ML21011A240. The staff finds the use of SASSI2010 and SAP2000 for estimating the SSI response and for the structural analysis, respectively, of the FSTR acceptable for the following reasons:

(1) The SASSI2010 and SAP2000 codes are commercially available and widely used for analyses in the nuclear industry.

(2) The SASSI2010 software performs a complex frequency response analysis using the input acceleration time histories, consistent with the defined SSE response spectra, to determine the response of the structure and to generate the ISRS, element force and moments, maximum seismic acceleration (zero-period acceleration (ZPA)), and nodal accelerations for different damping values.

(3) SAP2000 (version 17.2) is a finite element (FE) code commercially available and widely used for analyses in the nuclear industry. By using the earthquake-generated forces as static loads, it performs an equivalent static analysis to determine in-plane shear force in a wall (diaphragm), wall overturning, and stability of the FSTR.

The SHAKE2000 program (version 3.5) was used to generate the strain-dependent soil properties. The SHAKE2000 program is commercially available and widely used for analyses in the nuclear industry.

In addition to the information provided on the structure, the SSI analysis also includes detailed information of the soil layers supporting the structure obtained in the site geotechnical investigation, as summarized in SHINE FSAR section 2.5.2.3, “Site Soil Conditions,” and section 2.5.7.1, “Site Soil Conditions.” The NRC staff reviewed and evaluated the applicant’s information on the SSE ground motion response spectra for the SHINE site in section 2.5 of this SER and found it to be acceptable, because it is consistent with the United States Geological Survey (USGS) Hazards Map. However, the staff noted that soil parameters necessary for SSI analysis and foundation assessment were not sufficiently clear to determine soil bearings at specific elevations, settlements, and stability of the FSTR discussed in SHINE FSAR sections 3.4.2.5 and 3.4.2.6.3.1 and, therefore, issued RAIs 3.4-5 and 3.4-6. The staff conducted a regulatory audit (ML21089A334), to review the analysis supporting the geotechnical evaluation. As a result of the audit, the applicant revised its FSAR and supplemented its response to RAI 3.4-6. The RAIs and SHINE’s public responses are documented in ML21011A240 and ML21106A136, respectively. The staff reviewed the applicant’s RAI responses and finds them acceptable because the computed factors of safety against sliding and overturning are greater than the minimum values required, the allowable soil bearing capacity is higher than the maximum foundation contact pressures, and the differential and total settlements are accounted for in the FSTR FEA through the resulting generalized forces, so the facility structure is designed to accommodate the potential differential and total settlements.

Horizontal soil layers in SASSI2010 model the soil column down to an elastic half-space representing the bedrock. Strain-dependent soil properties are determined from geotechnical investigations and free-field site response analysis using the SHAKE2000 program (version 3.5). The free-field site response analysis is performed using the mean or best estimate (BE), the upper bound (UB), and the lower bound (LB) soil properties to represent potential variations of the in-situ soil conditions. The NRC staff finds this approach to be consistent with section 3.7.2 of NUREG-0800 and ASCE 4-16, “Seismic Analysis of Safety-Related Nuclear Structures” (section 5.1.7, “Uncertainties in SSI Analysis”), to treat potential variation in soil properties and, therefore, it is acceptable.

The UB and LB soil properties are generated from the mean soil properties (BE) assuming a coefficient of variation of 0.5, because the site is well investigated, which the NRC staff acknowledges to have occurred during the site characterization phase. Additionally, this approach is consistent with section 3.7.2 of NUREG-0800 and section 5.1.7 of ASCE 4-16 and, therefore, is acceptable.

The SSI analysis was performed using LB, BE, and UB soil columns with strain-compatible properties and the corresponding SSE earthquake motion. Major structural elements of the FSTR were modeled with appropriate mass and stiffness properties to analyze the SSI effects using SASSI2010, as stated in SHINE FSAR section 3.4.2.2. SHINE FSAR section 3.4.2.2 considers loads as mass equivalents for seismic analysis. This approach is consistent with NRC guidance (i.e., section 3.7.2 of NUREG-0800) and industry standards and, therefore, is acceptable.

The nature of miscellaneous dead weights as equivalent masses and those associated with hydrodynamic and crane masses is further discussed in the applicant's response to RAI 3.4-3 (ML21011A240). The NRC staff's acceptance of the applicant's response is detailed next. The structural model of the FSTR accounts for the self-weight of the structure. In addition, mass equivalent of 25 percent of the floor live loads and 75 percent of the roof design snow loads are included in the model. In addition, following section 3.7.2 of NUREG-0800, a mass equivalent of 50 pounds per square foot floor load is added to represent the dead load from minor equipment, etc. Floor loads and equipment loads, as previously noted, are converted to mass and included in the model along with the self-weight of the structure. Additionally, 100 percent of the hydrodynamic mass of the water in the IU cells and 100 percent of the crane mass are included in the model. The staff finds that the SSI model of the FSTR appropriately accounts for different dead and live loads including loads from major equipment or other major components (e.g., water in IU cells). Because the loads are consistent with acceptance criterion 3.D of section 3.7.2 of NUREG-0800, the staff finds that the applicant has appropriately included all different load types in the SSI model of the FSTR.

In addition, a cracked case is analyzed with BE soil profile and assumed cracked structural components from an SSE, as stated in the applicant's response to RAI 3.4-9 (ML21011A240). The modulus of elasticity of the modeled concrete elements is reduced by 50 percent of its nominal values, based on ASCE/Structural Engineering Institute (SEI) 43-05, "Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities." The NRC staff finds that the reduction of modulus is also consistent with table 3-2, "Effective Stiffness of Reinforced Concrete Element," of ASCE 4-16 and section 3.7.2 of NUREG-0800. Based on this discussion, the staff finds that the applicant has followed the recommended approach for degradation of stiffness of modeled structural components following acceptable national standards for use in the seismic analysis; hence, the degraded modulus value is acceptable. The staff finds that the applicant's modeling approach satisfies acceptance criterion 3.C of section 3.7.2 of NUREG-0800 and, therefore, is acceptable.

Damping values of concrete and steel components of the FSTR for LB, BE, and UB analyses (uncracked cases) are given in table 2 of RG 1.61, Revision 1, "Damping Values for Seismic Design of Nuclear Power Plants" (ML070260029), with the Operating Basis Earthquake (OBE). As no cracking is expected in an OBE excitation, the corresponding damping values excitation (4 percent for concrete and 3 percent for steel) have been used to analyze the uncracked LB, BE, and UB scenarios. In the cracked case, cracking of components is assumed to occur. The cracked case uses increased values for damping (7 percent for concrete and 4 percent for steel), consistent with those given in table 1 of RG 1.61, Revision 1, for an SSE. Based on this discussion, the NRC staff finds that the damping values used for uncracked scenarios are acceptable as they are from RG 1.61, Revision 1, and, therefore, concludes that acceptance criterion 2 of section 3.7.1 of NUREG-0800 is satisfied. In addition, the cracked case uses damping values associated with an SSE excitation contained in RG 1.61, Revision 1. As the damping values used are consistent with RG 1.61, Revision 1 and ASCE/SEI 43-05, the staff concludes that that appropriate structural damping values have been used in conducting the SSI of the FSTR and, therefore, that acceptance criterion 3.C.iv of section 3.7.2 of NUREG-0800 is satisfied as well, in addition to acceptance criterion 2 of section 3.7.1 of NUREG-0800.

Major openings within the walls and slabs are incorporated in the SSI model. Thick shell elements are used to model the concrete walls, slabs, and basemats. Three-dimensional beam elements are used to model the steel structural elements, such as trusses. Thick shell elements are used to model the interior partition walls made of concrete. Interior partition walls made of masonry or gypsum are not explicitly modeled as they are isolated from the lateral load-resisting system; however, their mass is accounted for in the analysis. Beam elements are used to model the steel truss components. These modeling practices are outlined in the applicant's response to NRC staff RAI 3.4-9 (ML21011A240). The excavated soil volume is modeled with solid elements in the SSI model to assess the SSI effects as described in the applicant's response to RAI 3.4-2. The vertical dimension of the elements matches the thickness of the corresponding soil layers. The equivalent linear strain-compatible soil properties determined at the site are assigned to these solid elements. The maximum dimension of these elements is small enough to propagate the highest frequency of interest in the model used in the analysis, as stated in the applicant's response to RAI 3.4-9 (ML21011A240). The FE model is acceptable because it was developed following regulatory guidance (section 3.7.2 of NUREG-0800) and accepted engineering practice.

The SASSI2010 SSI analysis of the FSTR produces acceleration response in three mutually orthogonal directions from the input motion in each direction, for example, acceleration response in X, Y, and Z directions from input motion only in X direction, Y direction, or Z direction. These codirectional response values were calculated at selected nodes (points) located on different structural elements/locations of the FSTR. The selected response spectra locations are as shown in figures 3.4-4-1 through 3.4-4-9 of the applicant's response to NRC staff RAI 3.4-4 (ML21011A240). Output from the SASSI 2010 SSI analysis includes response spectra accelerations at the 75 standard frequencies between 0.2 hertz (Hz) and 34 Hz, consistent with table 2 of RG 1.122, Revision 1, "Development of Floor Design Response Spectra for Seismic Design of Floor-Supported Equipment or Components" (ML003739367). In addition, output also includes response spectra accelerations at 37 Hz, 40 Hz, 43 Hz, 46 Hz, and 50 Hz frequencies, as given in SHINE FSAR section 3.4.2.4. These spectra are generated at six critical damping ratios: 2 percent, 3 percent, 4 percent, 5 percent, 7 percent, and 10 percent, as stated in the applicant's response to RAI 3.4-4. The ordinate of the calculated response spectrum is at frequencies sufficiently close to produce an accurate response spectrum following RG 1.122, Revision 1. In addition, several high frequencies are included in developing the ISRS. These codirectional responses are combined using the square-root of the sum of the squares method following RG 1.92, Revision 3, "Combining Modal Responses and Spatial Components in Seismic Response Analysis" (ML12220A043), and is consistent with acceptance criterion 5.A of section 3.7.2 of NUREG-0800. Therefore, the NRC staff finds that the method used to develop the ISRS of the FSTR is acceptable.

As stated previously, the ISRS from the SSI analysis for each soil model is calculated at various nodes/locations shown in figures 3.4-4-1 through 3.4-4-9 of the applicant's response to NRC staff RAI 3.4-4, with figures 3.4-4-3 through 3.4-4-9 withheld from public disclosure as they also contain security-related information. The combined response from the LB, BE, UB, and cracked seismic analysis cases at each node are enveloped to develop the bounding response at that node. The output response spectra are combined into 39 groups, given in table 3.4-4-1 of the applicant's response to RAI 3.4-4. Responses of nodes in each group are enveloped to determine the bounding response spectra at these structural elements/locations. The resulting bounding response spectra are smoothed, and the peaks of the spectra are broadened by ± 15 percent to account for approximations in the modeling techniques and uncertainties in the parameters used in structural analysis. The resulting ISRS plots for each of the 39 groups are shown in figures 3.4-4-10 through 3.4-4-48 of the applicant's response to RAI 3.4-4. The peak acceleration or ZPA for each of the 39 groups is taken from the corresponding ISRS plot at the maximum frequency point and is given in table 3.4-4-2 of the applicant's response to RAI 3.4-4. As the response has been calculated on different structural components and major facility equipment of the FSTR, the NRC staff finds that the analysis is acceptable because it satisfies acceptance criterion 2.B of section 3.7.2 of NUREG-0800. The approach to smoothing and broadening the spectra to account for uncertainty follows RG 1.122, Revision 1, and the staff finds that the approach is consistent with acceptance criterion 5.C of section 3.7.2 of NUREG-0800. Therefore, based on the above discussion, the method used to develop the bounding ISRS is acceptable.

SHINE FSAR section 3.4.2.6, "Structural Analysis of Facility," and section 3.4.2.6.2, "Applicable Codes and Standards," provide a succinct listing of applicable codes and standards used for the structural design of the facility. SHINE FSAR section 3.4.2.6.2 states that the facility concrete design is based on ACI 349-13, and for structural steel design on ANSI/AISC N690-12. RG 1.142, Revision 2, "Safety-Related Concrete Structures for Nuclear Power Plants (Other than Reactor Vessels and Containments") (ML013100274), endorses ACI 349 with certain exceptions and modifications so that defense-in-depth is maintained in the design of nuclear concrete facilities.

During its review of SHINE FSAR section 3.4.2.6.2, the NRC staff noted that there is no information in the FSAR regarding whether the applicant considered the guidance of RG 1.142 to further enhance its ACI 349-13 based concrete design so that the defense-in-depth philosophy included in NUREG-1537 is maintained. Concerned that such modifications and omissions from the structural design may have resulted in an overall nonconservative structural design, the staff issued RAI 3.4-10. The staff finds the applicant's response to RAI 3.4-10 (ML21011A240), acceptable because the design of the FSTR concrete box and its structural concrete SSCs to transient and/or abnormal loads: (a) is in accordance with the ACI 349-13 as modified by the RG 1.142, Revision 2, regulatory positions for successive levels of protection to act as direct or indirect barriers against the release of radioactive material to the environment and (b) ensures that failure of a single SSC would not impair protection of the health and safety of the public or from the uncontrolled release of radioactive material to the environment.

SHINE FSAR section 3.4.2.6.2 also states that the FSTR structural steel design follows ANSI/AISC N690-12. The NRC staff noted that the limited information provided in this section was not adequate to demonstrate that the requirements of the steel design code ANSI/AISC N690-12 are met, including those related to fire. The staff was concerned with the potential for fires, particularly those associated with an aircraft impact, to generate elevated temperatures and how this could damage the safety-related structural steel used in the FSTR SSCs and issued RAI 3.4-11. The staff's RAI and the applicant's public response are in (ML21011A240), and are discussed below.

The NRC staff reviewed the applicant's response to RAI 3.4-11 and noted that SHINE clarified that the safety-related FSTR structural steel SSCs (i.e., the mezzanine and roof trusses) are designed in strict accordance with ANSI/AISC N690-12 to applicable loads/loading conditions. SHINE also clarified that it used the stepwise screening approach detailed in U.S. Department of Energy (DOE) Standard DOE-STD-3014-2006, “Accident Analysis for Aircraft Crash into Hazardous Facilities,” to programmatically reduce the risk for facility damage and to eliminate the need to further examine consequences of elevated temperatures due to aircraft impact generated fires on the safety-related FSTR structural steel SSCs. The staff finds SHINE’s design approach based on national standards and building codes to be consistent with NUREG-1537 and, therefore, it is acceptable. Additional concerns regarding postulated aircraft impact locations on the FSTR external envelope were resolved through RAI 3.4-19, which is discussed below in section 3.4.4.5, “Seismic Envelope Design of External Hazards,” of this SER.

To ensure that: (a) the consequences of elevated temperatures to FSTR structural steel would be minimal (if any) from postulated aircraft crash fires, (b) the facility would continue to maintain its defense-in-depth, and (c) the DOE-STD-3014-2006 limits to active fire and/or suppression systems following such events had been considered, the NRC staff also reviewed SHINE FSAR section 9a2.3, “Fire Protection Systems and Programs,” and the associated applicant responses to RAIs in ML21364A055. In particular, the staff noted that the applicant’s response to RAI 9-5 outlines facility passive design features to limit fire consequences. The staff also noted that the facility is designed with protective systems such as 1, 2, or 3 hours of fire-resistant barriers separating individual fire areas consistent with NUREG-1537, Part 1, section 9.3, “Fire Protection Systems and Programs,” to prevent the uncontrolled release of radioactive material to the environment, should a fire occur. The applicant’s response to RAI 9-5 clarifies the basis for the fire barrier ratings (e.g., analysis, regulatory requirements, assessments of fire area contents, means of egress considerations, equipment separation, area considerations). The staff notes that additional safety measures exist, such as manual firefighting capability from nearby fire brigades including those from the adjacent airport. Based on the above, the staff finds the applicant’s response regarding fires in RAI 3.4-11, as supplemented by the applicant’s responses to RAIs regarding SHINE FSAR section 9a2.3.1, “Fire Protection Plan and Program,” adequate and, therefore, acceptable for its safety determination.

For the review of SHINE FSAR section 3.4.2.6, “Structural Analysis of Facility,” consistent with the guidance of NUREG-1537, the NRC staff also reviewed other sections of the FSAR to determine how the effects of irradiated environments could affect the performance of structural materials (i.e., concrete and steel) under normal and overload conditions such as those encountered during earthquakes, aircraft impact, and blast loads. Such reviews included discussions on neutron driver assembly system (NDAS) irradiated structural support beams in SHINE FSAR sections 1.3.3.3 and 4a2.3 and neutron and gamma fluxes in the subcritical assembly in SHINE FSAR section 4a2.5.3.2. The staff reviewed the structural performance of irradiated concrete and structural steel affected by radiation exposure exceeding the threshold limits of NUREG/CR-7171, “A Review of the Effects of Radiation on Microstructure and Properties of Concretes Used in Nuclear Power Plants” (ML13325B077), and ACI 349.3R, “Report on Evaluation and Repair of Existing Nuclear Safety-Related Concrete Structures,” in these areas during facility operation and issued RAI 3.4-12.

The NRC staff reviewed the applicant’s response to RAI 3.4-12, Revision 1 (ML21271A076), and noted that the applicant’s analyses indicated that FSTR fluence is below the threshold acceptance limits of NUREG/CR-7171 and those of ACI 349.3R for concrete and its steel embedments, respectively. For gamma heating on concrete, although the analyses indicated an elevated exposure below the TSV, the staff finds its effects on concrete pool acceptable because pool light water surrounding the TSV provides significant shielding, thereby reducing the temperature rise in the general and local concrete areas to below the threshold values allowed in ACI 349.3R.

In its response to RAI 3.4-12, the applicant also determined, based on UB effects of fluence on the austenitic stainless steel used in the subcritical assembly support structure (SASS), that safety-related austenitic stainless steel SASS components in the IU cells, near the TSV and NDAS, also exhibit adequate ductility and strength to resist anticipated transients and abnormal loads. In addition, the NRC staff noted that stainless steel used in the design (see SHINE FSAR sections 4a2.4.1.1 and 4a2.4.1.5) was tested for radiation and corrosion at Oak Ridge National Laboratory. Furthermore, the staff noted that the FSAR states that the surveillance and inspection program ensures that the integrity of the primary system pressure boundary components (PSB) is not degraded below acceptable limits due to radiation. The staff finds the capacity of the aforementioned components adequate to perform their intended functions because their evaluation was based on recognized industry practices, as noted in SHINE FSAR section 4a2.4.1.5. The staff also finds that the FSAR surveillance and inspection measures for the effects of fluence on safety-related austenitic stainless steel SASS components are adequate. Based on the above, staff finds the evaluation and measures taken to ensure that the aforementioned austenitic stainless steel components perform their intended functions during the facility operating life to be consistent with the regulatory framework and, therefore, acceptable.

The NRC staff, in its review of SHINE FSAR section 3.4.2.6.4 noted that this section addresses several loads including dead, live, and earthquake loads. For dead loads, the FSAR includes concrete cover blocks for below grade tanks and trenches. The staff noted that this FSAR section considers the concrete blocks to be live loads, which may indicate that they are not integrated in the facility seismic design. To clarify and resolve the size and anchorage of these blocks, whether the facility incorporates them into its design precast vaults in the RPF, what the “minimum” live loads are, and whether the roof live loads align with those referenced in ASCE 7-05 or International Building Code (IBC) 1607, the staff issued RAIs 3.4-7 and 3.4-8. Earthquake loads in the seismic analysis are addressed in RAI 3.4-4.

Further, in its review of SHINE FSAR section 3.4.2.6.4.6, “Crane Load,” the NRC staff noted that crane loading was evaluated in accordance with American Society of Mechanical Engineers (ASME) NOG-1, “Rules for Construction of Overhead and Gantry Cranes (Top Running Bridge, Multiple Girder).” The staff also noted the limited description of how crane loads were defined and subsequently incorporated in the crane systems designs. The staff reviewed the applicant’s response to RAIs 3.4-13 and 3.4-21 (ML21011A240 and ML21208A135, respectively) and noted the following:

(1) For crane loads and loading conditions, SHINE clarified that the IF and RPF crane systems design loads (seismic, dead, impact, stop, lift capacities) are conservatively calculated deterministically consistent with ASME NOG-1. Additionally, SHINE clarified that it used the calculated loads also for the FSTR design but ensured that for crane loading there was conservatism in the building design consistent overall with ASCE 7-05 or IBC 1607 building codes and requirements. Specifically, SHINE calculated the crane seismic loads as distributed loads based on ISRS peak acceleration, crane mass, and full lift load. For the facility crane runway system horizontal impactive design loads, SHINE used those considered for a design basis earthquake, which are more conservative than those of ASME NOG-1 and those required by the aforementioned building codes. The NRC staff finds these approaches based on local building codes, standards, and recognized industry practices to be consistent with NUREG-1537 and, therefore, acceptable.

(2) For crane runway systems design, SHINE clarified that for the SSI analysis, consistent with ASME NOG-1, it decoupled the IF and RPF crane responses from their runways. SHINE also clarified that all building facility sections, including walls supporting the IF and RPF cranes, are designed with a minimum of 10 percent margin for all loading conditions and modes of failure. It also stated that a minimum 7 percent design margin exists for any of the designed IF and RPF crane runway systems components. SHINE then stated that the conservatism used in the estimated deterministic loads further increases the aforementioned two design margins. It then described how the crane runway systems are attached to the facility external walls to help isolate external impact or base induced shear loads. Although the cranes are not considered to be critical or safety-related equipment, as noted in the applicant's RAI response (see also SHINE FSAR section 9b.7.2.3), nonetheless a failure of their runway systems could potentially affect safety-related SSCs. The NRC staff finds that there is reasonable assurance that such a failure would be highly unlikely because the design of the runways has adequate margins and follows the conservatisms of local building codes, national standards, and recognized industry design practices consistent with NUREG-1537 and, therefore, is acceptable.

Based on the above, the NRC staff finds the revised SHINE FSAR section 9b.7.2.1 clarifying that the IF and RPF cranes are designed to remain in-place and on the runway girder, with or without a load, during and after a seismic event, acceptable.

The NRC staff also reviewed SHINE FSAR section 9b.7.2 and noted that the cranes meet ASME B30.2, "Overhead and Gantry Cranes (Top Running Bridge, Single or Multiple Girder, Top Running Trolley Hoist)," and Crane Manufacturers Association of America, Inc. (CMAA) 70, "Multiple Girder Cranes," service level (class) B requirements. The staff noted that both cranes serve the RCA of the FSTR and are used to move or manipulate radioactive material within the RCA. The staff also noted that CMAA-70 Class B cranes are limited to light service requirements (e.g., repair shops, light assembly operations, light warehousing) and limited in height of lifts. In addition, the staff noted that the RPF crane is a 15-ton ASME NOG-1 Type II, double girder bridge style crane with no single failure-proof features to support its lift during a seismic event. However, there was a limited discussion on the effects of radiation and usage of cranes and crane systems during the operating life of the facility. Therefore, the staff issued RAI 3.4-14 regarding the potential detrimental effects of radiation on each crane's structure and increased usage that could affect crane performance, such as dropped lifts on safety-related SSCs and potentially challenge the facility's defense-in-depth and the radiological release limits of 10 CFR Part 20 during facility operating life.

In its response to RAI 3.4-14 (ML21011A240), SHINE clarified that the crane purchase specifications included environmental conditions in their design criteria that account for radiation exposure to 30 years. SHINE also stated that the IF and RPF cranes are constructed consistent with ASME NOG-1 Type I and Type II design requirements for seismic loads, fracture toughness, and radiation hardening, as applicable. SHINE further clarified that load cycle limits are those of CMAA 70-2004 and inspection, testing, and maintenance are in accordance with ASME B30.2 and/or ANSI N14.6-1993, "Radioactive Materials - Special Lifting Devices for Shipping Containers Weighing 10000 Pounds (4500 kg) or More," as applicable. The NRC staff finds the applicant's approach for the design of cranes with respect to radiation resistance and usage to be in accordance with national codes and standards consistent with NUREG-1537 and, therefore, it is acceptable.

In its review of SHINE FSAR section 3.4.2.6.4.8, “Fluid Load,” the NRC staff noted the existence and application of hydro loads to critical equipment. Additional details for this fluid loading condition are in SHINE FSAR chapter 4, which details the fluid-structure interaction of water with submerged or semi-submerged equipment containing uranyl sulfate solution within the light water pool during seismic/abnormal loading events. SHINE FSAR chapter 3 references ASCE 4-98, which provides guidance for hydrostatic and hydrodynamic analysis of equipment or structures loaded with hydrostatic and hydrodynamic pressures/forces, assessments of fluid-structure interaction, and the stability of structures in a fluid (water) basin. Although the applicant referenced this standard, it is not clear to what extent the standard was used for the water (fluid), pool (basin), and equipment interactions, and whether the analyses were extended to include comingling of uranyl sulfate solution into the pool in the event of a breach of the TSV tank containing this solution. Material Data Sheets indicate that uranyl sulfate in its solid form has a specific gravity considerably higher than that of water. Consistent with these data, in this case the calculated hydrodynamic loads and stability analyses would differ from a hydrodynamic analysis using solely water as a fluid load.

To clarify what methodology was used to derive the hydrodynamic loads and their effects on submerged equipment/structures/pool and to identify the echelons of defense considered against the release of uranyl sulfate solution into the pool and the subsequent consequences if such a release were to occur, the NRC staff determined the need for additional information and issued RAI 3.4-15.

The NRC staff reviewed the applicant’s response to RAI 3.4-15 (ML21011A240), and noted that SHINE evaluated the IU structure and its light water pool submerged or semi-submerged safety-related equipment to hydrodynamic loads composed of sloshing forces and those attributed to added masses during seismic excitation consistent with applicable national standards (i.e., ASCE 4-98, TID-7024, ACI 350.3-06, and ANSI/AISC N690-12). In its response, SHINE also clarified the defense-in-depth echelons against the release of uranyl sulfate target solution and associated fission material, including the TSV and the light-water pool as barriers, which are part of the PSB. SHINE further clarified that it did not consider the release of uranyl sulfate solution into the pool to be a postulated event, nonetheless it designed the PSB to withstand seismic/abnormal loadings. Furthermore, SHINE observed that a potential leakage into the pool would insignificantly increase the density of the large body of water in the pool and the associated hydrodynamic loads and their effects on submerged/semi-submerged equipment during a seismic event. The NRC staff finds the applicant’s response to the RAI to be acceptable for the following reasons: (a) the calculation of the hydrodynamic forces was done in accordance with national standards, codes, and recognized industry practice, (b) the PSB was designed to resist transient and abnormal loads and with a defense-in-depth philosophy to contain the release of radioactive material, and (c) the calculated increase in the hydrodynamic forces resulting from an increased water density due to uranyl sulfate solution released into the light water pool was insignificant. The staff also finds the revision to SHINE FSAR sections 3.4.2.6.4.8 and 4a2.2.5 regarding hydrodynamic loading and its effects on the SASS acceptable as the methodologies considered in the analyses are in accordance with national standards, codes, and recognized industry practices consistent with NUREG-1537.

3.4.4.3 Seismic Classification and Qualification

SHINE FSAR section 3.4.3, “Seismic Classification and Qualification,” identifies categories of SSCs and presents the seismic qualification of the SHINE facility’s systems and equipment. It includes the definition of category I and category II SSCs and details of the methodologies used for their seismic qualification. The NRC staff reviewed the methodologies that the applicant used for seismic qualification of equipment/components achieved with analytical methods (including static analysis, simplified dynamic analysis, or detailed dynamic analysis), testing (e.g., material qualification testing), or a combination of the analytical and testing methods and found them acceptable. These are discussed in section 3.4.4 of this SER.

3.4.4.4 Seismic Instrumentation

SHINE FSAR section 3.4.4, “Seismic Instrumentation,” summarizes the seismic instrumentation at the facility. The NRC staff reviewed the summary and noted that SHINE has in place non-safety-related seismic instrumentation to assess the effects of accelerations experienced at the facility following a seismic event so that the facility and its safety-related SSCs continue to operate safely. The measurement of seismic acceleration at the facility using non-safety-related instrumentation is reasonable and acceptable because the NRC’s regulations do not require seismic instrumentation for this facility.

3.4.4.5 Seismic Envelope Design of External Hazards

SHINE FSAR section 3.4.5, “Seismic Envelope Design for External Hazards,” provides input for an aircraft impact analysis, which is necessary because the SHINE facility is located near the SWRA. It also discusses external facility explosions. SHINE FSAR section 3.4.5.1, “Aircraft Impact Analysis,” outlines the effects of global and local small aircraft crashes (impact loadings) on the facility from the nearby SWRA. It states that the Challenger 605 was selected as a “design basis aircraft” for global impact response analysis based on airport operations data. It also states that the analysis used the energy balance method of DOE-STD-3014-2006 while taking into consideration the ductility limits of ACI 349-13 and ANSI/AISC N690-12 for reinforced concrete and steel truss elements, respectively. For local impacts, it states that the Hawker and the Challenger 605 were the two aircraft considered as design basis aircrafts. SHINE FSAR section 3.4.5.1 then references DOE-STD-3014-2006, which provides guidance for functional assessments, screening, and evaluating global, local, and vibration damage to the FSTR and its SSCs. The NRC staff notes that the applicant’s statement in SHINE FSAR section 1.2.2, claiming design robustness of the building structure, stems from a postulated aircraft impact analysis based on criteria and guidance of DOE-STD-3014-2006.

In evaluating SHINE FSAR section 3.4.5.1, the NRC staff sought clarifications through its RAIs 3.4-16 and 3.4-20 on how the two aircrafts were selected, what was the perceived mode of impact, and how potential global and local impact loads, damage estimates, and resulting consequences on the FSTR and its SSCs were assessed.

The NRC staff reviewed SHINE’s responses to RAIs 3.4-16 and 3.4-20 (ML21011A240 and ML21208A135, respectively) and noted that the selected aircraft for local and global impact analysis was the Challenger 605 aircraft based on SWRA operations data and because it had the heaviest engines of all aircraft frequenting the airport. The staff also noted that SHINE’s analyses used national standards and codes to assess the effects of postulated impacts (e.g., DOE-STD-3014-2006 and ACI 349-13, appendix F) on the design of the entire exterior envelope of the FSTR as well as on several of its interior walls that act as barriers to exterior wall openings. Regarding potential skidding of the aircraft on the roof, SHINE stated that while this was not explicitly accounted for in the impact analysis, the seismic qualification of the roof slab bounds the skidding aircraft impact scenario. The staff finds SHINE's approach for the aircraft selection based on airport historical data and the analysis performed that conservatively addresses the entire external facility envelope and internal walls for local and global impacts based on national standards and codes adequate and consistent with the guidance of NUREG-1537 and, therefore, acceptable. The staff accordingly finds the revision to SHINE FSAR section 3.4.5.1 clarifying that the FSTR seismic loading bounds any aircraft impact scenario that produces lateral forces acceptable.

Aside from aircraft impacts on the external facility envelope, the NRC staff also examined potential effects of such impacts on safety-related SSCs attached to the facility envelope. The staff followed-up on the applicant's response to RAI 3.4-11, which stated that there was no safety-related equipment supported from the building in the vicinity of postulated impacts and that the risk to damage and resulting consequences were "deemed small and the results are documented." To better assess SHINE's response, the staff issued RAI 3.4-19 requesting that the applicant provide additional clarifications on the analysis methodology used to evaluate the structural behavior at critical areas of the impacted structure and on the overall robustness and structural integrity of the facility based on the structural response at postulated impact locations.

In its response to RAI 3.4-19 (ML21029A103), SHINE clarified that the only components attached to facility exterior walls are the crane runways, with the cranes classified as non-safety-related SSCs. SHINE also clarified that the impact analysis methodology used to evaluate the response of the facility structure is in accordance with DOE-STD-3014-2006 with critical facility areas (e.g., exterior and labyrinth walls, missile barriers, roof, wall corners, etc.) of impacted concrete sections designed to ACI 349-13. The NRC staff finds the applicant's response acceptable because it reaffirmed that there is no safety-related equipment on the facility envelope and that the methodology used to assess the response, robustness, and structural integrity of the facility due to aircraft impacts is based on national standards, building codes, and recognized industry practices consistent with the guidance of NUREG-1537. The NRC staff also finds SHINE's revision to SHINE FSAR section 3.4.5.1 acceptable because it clarifies the reason why punching shear damage was not considered in the analysis.

SHINE FSAR section 3.4.5.2, "Explosion Hazards," discusses external explosions/blast effects on the FSTR and references SHINE FSAR section 2.2.3 for details on the source and derivation of blast overpressures, including the regulatory guidance and software used for the hazards evaluation. The NRC staff had questions concerning the validity of software and uncertainties in the methodologies used for the design of the FSTR with respect to blast effects, and whether the external nitrogen tank in the proximity to the FSTR was designed to code for potential accidental explosions and, therefore, issued RAI 3.4-17.

The NRC staff reviewed the applicant's response to RAI 3.4-17 (ML21029A103), and noted that SHINE followed the methodology described in RG 1.91, Revision 2, "Evaluations of Explosions Postulated to Occur at Nearby Facilities and on Transportation Routes Near Nuclear Power Plants" (ML12170A980), to determine that potential explosions would not have adverse effects on facility operations or prevent a safe shutdown of the facility. SHINE also clarified that potential explosive materials are located at a safe distance from the FSTR and that those that are located closer have an explosion incident rate of 1E-6 per year. SHINE further stated that the externally located liquid nitrogen tanks are designed in accordance with the ASME Boiler and Pressure Vessel Code, Section VIII, Division 1 to prevent their accidental explosion and fragmentation. The staff finds that these approaches based on the guidance in RG 1.91, Revision 2, and national codes are consistent with NUREG-1537 and, therefore, acceptable.

3.4.4.6 Seismic and External Hazards Damage Evaluation Summary

Based on its review, the NRC staff finds that the applicant used acceptable methods to perform the SSI analyses, assess transient and abnormal loads, and evaluate conditions and external hazards that could challenge the defense-in-depth of the facility and its SSCs. Based on its review, the staff determined that the level of detail provided in the SHINE FSAR, as supplemented, regarding damage due to earthquakes, abnormal loads, and internal/external hazards is adequate and supports the final design and satisfies the applicable acceptance criteria of section 3.4 of NUREG-1537, Part 2. The staff concludes that the applicant's design criteria and designs would protect against potential seismic or abnormal loads damages and provide reasonable assurance that SSCs would continue to perform their required safety functions, would not cause unsafe facility operation, would not prevent safe shutdown of the facility, and would not cause or allow the uncontrolled release of radioactive material. Therefore, the staff finds that the SHINE facility design is adequate to cope with postulated seismic or external hazards damages and meets the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

3.4.5 Systems and Components

The NRC staff evaluated the sufficiency of the SHINE facility design features for systems and components, as presented in SHINE FSAR section 3.5, using the guidance and acceptance criteria from section 3.5, "Systems and Components," of NUREG-1537, Parts 1 and 2, and section 3.5, "Systems and Components," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 3.5 summarizes the design philosophy that SHINE applied to the facility design. The SHINE design philosophy includes defense-in-depth practices, use of engineering controls over administrative controls, physical separation and electrical isolation of safety systems, and system redundancy. The NRC staff considered these design philosophies in its evaluation of the SSCs described in the SHINE FSAR in the corresponding sections of this SER.

3.4.6 Nitrogen Purge System Structure

SHINE FSAR section 3.6 discusses the N2PS structure. It addresses design considerations to avert potential damages due to meteorological, water (flooding), and seismic events. Meteorological and water (flooding) related design considerations are addressed in sections 3.4.2 and 3.4.3 of this SER. Design considerations for seismic damage are discussed below.

The N2PS structure contains a portion of the N2PS system, which is a high-pressure nitrogen gas system. In its response to NRC staff RAI 3.2-1 (ML21029A103), SHINE explained that the seismic analysis is based on the equivalent static load method and uses the seismic analysis of the FSTR. The seismic loads are calculated using the FSTR grade level in-structure-response spectra with an amplification factor of 1.5.

The NRC staff reviewed the information provided in SHINE FSAR section 3.6.3 related to seismic damage of the N2PS structure and finds it acceptable because the equivalent static load method with an amplification factor of 1.5 provides a conservative seismic response and accounts for possible SSI effects between the FSTR and the N2PS structure. SHINE FSAR section 9b.6.2.3 describes that the N2PS structure, and the associated supports, are designed to withstand Seismic Class I seismic events. Therefore, the staff finds that the N2PS structure and pipe and high-pressure tube supports are seismically qualified.

3.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE design of SSCs, as described in chapter 3 of the SHINE FSAR, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) The SHINE facility adequately protects against potential meteorological, water, and seismic or external hazards damages.

(2) The SHINE facility provides reasonable assurance that its SSCs would continue to perform their required safety functions, would not cause unsafe facility operation, and would not prevent safe shutdown of the facility.

(3) The SHINE facility provides adequate levels for defense-in-depth against uncontrolled release of radioactive material to the environment.

(4) The issuance of an operating license for the SHINE facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE design of SSCs are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.