

3.0 DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

The purpose of the Northwest Medical Isotopes, LLC (NWMI or the applicant) production facility's structures, systems, and components (SSCs) is to ensure the safety of the facility and the protection of the public and workers. The material presented in this chapter of the NWMI preliminary safety analysis report (PSAR) should discuss the safety and protective functions and related design features of the SSCs that help provide protection against uncontrolled releases of radioactive material and chemical related exposures. The bases for the design criteria for some of the SSCs discussed in this chapter may be developed in other chapters of the PSAR.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility's SSCs as presented in Revision 3 of Chapter 3.0, "Design of Structures, Systems, and Components," of the NWMI PSAR. As explained in SER Section 1.1.1, "Scope of Safety Review," the NWMI construction permit application generally refers to the building that will house all activities, including SSCs related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility," or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

3.1 Areas of Review

NWMI PSAR Chapter 3.0 identifies and describes the design criteria for the SSCs for the NWMI production facility. The information presented emphasizes safety and protective functions, items relied on for safety (IROFS) used by NWMI to demonstrate compliance with 10 CFR Part 50 requirements for a production facility, and related design features that help provide defense-in-depth against releases of radioactive material and chemical exposures to workers and the public. The bases for the design criteria for some of the SSCs discussed in this chapter are developed in other chapters of the PSAR and are cross-referenced, when appropriate.

The staff reviewed NWMI PSAR Chapter 3.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design criteria of the NWMI production facility SSCs for the purposes of issuance of a construction permit under 10 CFR Part 50. As part of this review, the staff evaluated descriptions and discussions of the NWMI production facility SSCs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI production facility SSCs was evaluated to ensure the design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions are sufficient to provide reasonable

assurance that the final design will conform to the design basis. In addition, the staff reviewed NWMI's identification of credible events and IROFS that demonstrate reasonable assurance that the performance requirements of 10 CFR 70.61, "Performance requirements," can be met for the NWMI production facility.

Areas of review for this chapter included the NWMI production facility SSCs. Within these review areas, the staff assessed the capability of the SSCs to ensure safe facility operation, safe facility shutdown and continued safe conditions, response to anticipated transients, response to potential accidents analyzed in PSAR Chapter 13.0, "Accident Analysis," and control of radioactive material described in PSAR Chapter 11.0, "Radiation Protection Program and Waste Management."

3.2 Summary of Application

NWMI PSAR Chapter 3.0 describes the design bases of SSCs for the NWMI production facility established to ensure production facility safety and protection of the public and workers.

NWMI PSAR Section 3.1, "Design Criteria," describes the design criteria applied to the NWMI production facility and SSCs within the production facility. The PSAR states that the principal design criteria for a production facility establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs. The SSC systems associated with the NWMI production facility are identified. The IROFS for the facility that are discussed in NWMI PSAR Section 3.1 are further evaluated in NWMI PSAR Chapter 6.0, "Engineered Safety Features," and Chapter 13.0.

NWMI PSAR Section 3.2, "Meteorological Damage," includes a discussion of NWMI production facility meteorological accidents with radiological or chemical consequences, which was derived from an NWMI evaluation of natural phenomena and manmade events on engineered safety features and IROFS. This section also discusses the criteria used to design the NWMI production facility to withstand wind, tornado, snow, ice, and water damage. The combinations of the meteorological loads with other loads (i.e., dead loads and earthquake loads) for the structural analysis are provided in NWMI PSAR Section 3.4, "Seismic Damage."

NWMI PSAR Section 3.2.8, "External Hazards," discusses NWMI's evaluation of external events including aircraft impacts, external explosions, and external fires.

NWMI PSAR Section 3.3, "Water Damage," identifies the requirements and guidance for the water damage design of the NWMI production facility SSCs. The applicant used NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," and American Society of Civil Engineers (ASCE) 7, Chapter 5, which provide guidance on flood protection of nuclear SSCs. Updates and development of technical specifications (TSs) associated with the design of the NWMI production facility SSCs for water damage will be provided in Chapter 14.0 of the operating license (OL) application.

NWMI PSAR Sections 3.4.1, "Seismic Input," and 3.4.2, "Seismic Qualification of Subsystems and Equipment," provides information on design response spectra, soil-structure interactions and dynamic soil pressures, seismic input and analysis, equivalent-static analyses, dynamic analyses, and seismic qualification of subsystems and equipment.

NWMI PSAR Section 3.4.3, "Seismic Instrumentation," discusses the instrumentation that will be used to record accelerations during a seismic event. The purpose of the instrumentation is to

(1) permit a comparison of measured responses of structures and selected components with predetermined results of analyses that predict when damage might occur, (2) permit facility operators to understand the possible extent of damage within the facility immediately following an earthquake, and (3) permit determination of when a safe-shutdown earthquake event has occurred that would require emptying of the process tank(s) for inspection, as specified in National Fire Protection Association (NFPA) 59A, "Standard for the Production, Storage, and Handling of Liquefied Natural Gas," Section 4.1.3.6(c).

NWMI PSAR Section 3.5, "Systems and Components," states that certain systems and components of the NWMI production facility are considered safety-related because they perform safety functions during normal operations or are required to prevent or mitigate the consequences of abnormal operational transients or accidents. This PSAR section also defines the safety classifications for the NWMI production facility. This section also summarizes the design basis for design, construction, and operating characteristics of safety-related SSCs of the NWMI production facility. The NWMI production facility systems and components are also classified by three seismic categories (i.e., Seismic Category I, Seismic Category II, and non-safety-related SSCs) as defined in Section 3.5.1.3.2, "Seismic Classification for Structures, Systems, and Components," of the NWMI PSAR and three quality levels (i.e., QL-1, QL-2, and QL-3) as defined in Section 3.5.1.3.1, "Quality Group Classifications for Structures, Systems, and Components," of the NWMI PSAR.

NWMI evaluated the general design criteria from 10 CFR 70.64, "Requirements for new facilities or new processes at existing facilities," and 10 CFR Part 50, Appendix A (general design criteria 60-64) consistent with the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," (Reference 11) to inform the production facility design basis. This evaluation is presented in NWMI PSAR Table 3-22, "Design Criteria Requirements." NWMI PSAR Section 3.5.2, "Radioisotope Production Facility," states that these general design criteria provide a rational basis from which to initiate the production facility design but are not mandatory. Since the general design criteria were derived from 10 CFR Part 70 and Appendix A of 10 CFR Part 50, which are not regulatory requirements for a production facility licensed under 10 CFR Part 50, NWMI states in PSAR Section 3.5.2 that there are some cases where conformance to a particular criterion is not directly measurable. For each of the criteria, a specific assessment of the NWMI production facility design is made, and a list of references is included to identify where detailed design information pertinent to each criterion is treated. The accident sequences in Chapter 13.0 define the credible events as determined by NWMI for the production facility. NWMI states that the safety-related parameter limits ensure that the associated design basis is met for the events presented in Chapter 13.0.

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

- Table 3-2, "Summary of Items Relied on for Safety Identified by Accident Analyses"
- Table 3-3, "Relevant U.S. Nuclear Regulatory Commission Guidance"
- Table 3-4, "Other Federal Regulations, Guidelines, and Standards"
- Table 3-5, "Local Government Documents"
- Table 3-6, "Discovery Ridge/University of Missouri Requirements"
- Table 3-7, "Design Codes and Standards"

3.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 3.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design criteria for the NWMI production facility SSCs for the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

- (1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.
- (2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).
- (3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.
- (4) Based on the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI facility site. However, the staff evaluated the NWMI facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 9). The staff's review in this SER chapter evaluated the design criteria, meteorological damage, water damage, seismic damage and systems and components to ensure that issuance of the construction permit for the production facility will not be inimical to public health and safety.

3.3.1 Applicable Regulatory Requirements

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

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

10 CFR 50.40, "Common standards."

3.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with NRC regulations, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 9).
- "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 (Reference 10).
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 11).
- NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," dated June 2015 (Reference 24).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility," as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria,

alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term “performance requirements” when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a radioisotope production facility license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff’s use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society standards) has been used in the staff’s review of NWMI’s PSAR. The use of additional guidance is 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 NWMI PSAR. Additional guidance documents used to evaluate NWMI’s PSAR are provided as references in Appendix B, “References,” of this SER.

3.4 Review Procedures, Technical Evaluation, and Evaluation Findings

NWMI PSAR Chapter 3.0 describes the design bases of SSCs for the NWMI production facility established to ensure facility safety and the protection of the public. The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 3.0. The purpose of the review was to assess the sufficiency of the preliminary design and performance of the NWMI production facility’s SSC design criteria for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). Sufficiency of the preliminary design criteria for the NWMI production facility’s SSCs is determined by ensuring the design meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in SER Section 3.3, “Regulatory Basis and Acceptance Criteria.” The staff also evaluated the potential impacts of events that may cause radiological or chemical exposures exceeding the thresholds in 10 CFR 70.61, from the 10 CFR Part 70 target fabrication activities, on the 10 CFR Part 50 production facility. A summary of the technical evaluation is described in SER Section 3.5, “Summary and Conclusions.”

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility’s SSCs may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility’s SSCs based on the applicant’s design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff’s evaluation of the preliminary design of the NWMI production facility’s SSCs does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the NWMI production facility’s SSCs as described in the FSAR submitted as part of NWMI’s OL application.

3.4.1 Design Criteria

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

Consistent with the review procedures of NUREG-1537, Part 2, Section 3.1, the staff compared the specified design criteria with the proposed normal operation of the NWMI production facility,

response to anticipated transients, and consequences of accident conditions applicable to the appropriate SSCs assumed to function in NWMI PSAR Section 3.1 and other relevant chapters of the PSAR.

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

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

In addition, NUREG-1537, Part 2 also states that the applicant should identify the SSCs by function(s), modes of operation, location, type(s) of actuation, relative importance in the control of radioactive material and radiation, applicable design criteria, and the chapter and section in the PSAR where these design criteria are applied to the specific SSC.

NWMI PSAR Tables 3-3, 3-4, 3-5, 3-6, and 3-7, present the design inputs that were used in the development of the design. The PSAR notes in Section 3.1.7, "Codes and Standards," that codes and standards are used as guidance for the design of the facility SSCs. The technical evaluation performed by the staff assumed that the production facility will be constructed consistent with the design inputs in PSAR Section 3.1. The staff expects that NWMI will document changes to design inputs following its quality assurance (QA) program as shown in NWMI PSAR Chapter 12.0, "Conduct of Operations." The staff will examine the detailed final design and design inputs as part of an OL application review.

NWMI PSAR Section 3.0 states that the NWMI production facility and system design are based on defense-in-depth practices. Defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that

will exhibit greater tolerance to failures and external challenges. PSAR Section 3.1 also provides sufficient information to guide the staff to the appropriate section of the PSAR where the design criteria for specific SSCs are discussed in detail including a crosswalk. Additionally, PSAR Section 3.1 outlines the standards, guides, and codes that were used as design inputs for the NWMI production facility.

Based on its review, the staff finds that the level of detail provided in NWMI PSAR Section 3.1 demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.1, allowing the staff to find that: (1) the design criteria are based on applicable standards, guides, codes, and criteria and provide reasonable assurance that the facility SSCs can be built and will function as designed and as required by the PSAR; and (2) the design criteria provide reasonable assurance that the public will be protected from radiological risks from operation. As noted above, NWMI should keep the staff informed of changes to design inputs that impact the construction of the facility to support the NRC's construction inspection program of the facility.

Therefore, the staff concludes that the design criteria of the NWMI production facility's SSCs are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information, based on the final design, that is required to complete the safety analysis can reasonably be left for later consideration. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR submitted as part of the OL application.

3.4.2 Meteorological Damage

The staff evaluated the sufficiency of the NWMI production facility's preliminary design features to cope with wind or other meteorological damage, as described in NWMI PSAR Section 3.2, for the issuance of a construction permit using the guidance and acceptance criteria from Section 3.2, "Meteorological Damage," of NUREG-1537, Part 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 3.2, the staff considered the description of the site meteorology to ensure that all SSCs that could suffer meteorological damage are considered, as presented in NWMI PSAR Section 3.2 and other relevant chapters of the PSAR. 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 retain function throughout the predicted meteorological conditions. The staff also reviewed (a) design load definitions; (b) design load combinations for the SSCs; (c) the detailed determination of applicable design loads, including the wind loadings and tornado wind loadings; (d) tornado generated missile impact effects; and (e) rain, snow, and ice loadings for SSCs from Section 3.4.2 of the NWMI PSAR, for the adequacy and completeness of content and compliance with regulatory requirements and guidance in accordance with the review procedures and acceptance criteria of NUREG-1537, Part 2, Section 3.2. The applicant has specifically considered and described the approach to comply with NUREG-1537, Part 1, Section 2.3.1, "General and Local Climate," as discussed in NWMI PSAR Section 3.2.5.2, "Snow Load," Section 3.2.5.2.1, "Normal Snow Load," and Section 3.2.5.3, "Atmospheric Ice Loads."

NWMI PSAR Section 3.2.3.1.3, "Live Loads," and Table 3-13, "Floor Live Loads," state that some of the loads that may affect the global structural response and the local structural element

designs are “To Be Determined” (TBD). The applicant further states that a conservative load value is assumed in the preliminary design for all unknown loads and these are marked as “Hold.” All “Holds” are removed as the design matures, and no final design is issued with any remaining “Holds.” NWMI states that all TBD loads will be provided in the FSAR as part of the OL application.

NWMI PSAR Section 3.2.4.2 states that the regulatory basis used for the tornado winds and generated missile characteristics used in the design is Regulatory Guide (RG) 1.76, Revision 1, “Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants,” for Region 1. The tornado load criteria will be updated by using tornado loading in accordance with 10^{-5} annual probability of exceedance in the OL application which is consistent with NUREG-1520, Part 3, Appendix D, “Natural Phenomena Hazards.”

Based on its review, the staff finds that the level of detail provided on meteorological damage for the preliminary design demonstrates an adequate design basis and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.2, allowing the staff to find that: (1) the design criteria and designs provide reasonable assurance that SSCs would continue to perform their safety functions as specified in the PSAR under potential meteorological damage conditions; and (2) the design criteria and designs use local building codes, standards, or other applicable criteria to ensure that significant meteorological damage at the production facility site is minimized.

Therefore, the staff concludes that the NWMI production facility design features for coping with meteorological damage are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis, based on the final design, can reasonably be left for later consideration. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI’s FSAR submitted as part of the OL application.

3.4.3 Water Damage

The staff evaluated the sufficiency of the NWMI production facility’s preliminary design features to cope with predicted hydrological conditions, as described in NWMI PSAR Section 3.3, for the issuance of a construction permit using the guidance and acceptance criteria from Section 3.3, “Water Damage,” of NUREG-1537, Part 2.

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

NWMI PSAR Section 3.3.1.1.1, “Flooding from Precipitation Events,” describes the flood protection measures for the NWMI production facility’s SSCs and states the following:

The site will be graded to direct the storm-water from localized downpours with a rainfall intensity for the 100-year storm for a 1-hr duration around and away from the RPF. Thus, no flooding from local downpours is expected based on standard

industrial design. Rainwater that falls on the waste management truck ramp and accumulates in the trench drain has low to no consequence for radiological, chemical, and criticality hazards.

Situated on a ridge, the RPF will be located above the 500-year flood plain according to the flood insurance rate map for Boone County, Missouri, Panel 295.... The site is above the elevation of the nearest bodies of water (two small ponds and a lake), and no dams are located upstream on the local streams. This data conservatively provides a 2×10^{-3} year return frequency flood, which can be considered an unlikely event according to performance criteria. However, the site is located at an elevation of 248.4 m (815 ft), and the 500-year flood plain starts at an elevation of 231.6 m (760 ft), or 16.8 m (55 ft) below the site. Since the site, located only 6.1 m (20 ft) below the nearest high point on a ridge (relative to the local topography), is well above the beginning of the 500-year flood plain, and is considered a dry site, the probable maximum flood from regional flooding is considered highly unlikely, without further evaluation.

NWMI PSAR Section 3.3.1 also states that, per NUREG-1520, Section 3.2.3.4(1)(c), and ASCE 7, Chapter 5, flood loads will be based on the water level of the 100-year flood (one percent probability of exceedance per year). NWMI has determined the NWMI production facility to be above both the 100-year and the 500-year flood plain. Chapter 2.0, Section 2.5.3, "On-site Soil Types," of the NWMI PSAR, provides additional detail related to flood protection measures.

NWMI PSAR Section 3.3.1.1, "Flood Protection Measures for Structures, Systems, and Components," and Section 3.3.1.2, "Flood Protection from External Sources," state that the flood loads on the SSCs are considered highly unlikely based on the elevation above the 100-year and 500-year flood plain and are not considered in the design loads. Section 3.3.1.2 further states that the SSCs located below grade will be protected using the hardened protection approach, where systems and components are enclosed in a robust reinforced concrete structure. Water stops at expansion and construction joints will be installed and waterproofing of the NWMI production facility will be provided to protect external surfaces from exposure to water. The level of waterproofing to be used will be contained in the OL application.

NUREG-1537, Part 1, Section 3.3, "Water Damage," states, in part, that "the applicant should specifically describe ... (2) the impact on systems resulting from instrumentation and control electrical or mechanical malfunction due to water, and (3) the impact on equipment, such as fans, motors, and valves, resulting from degradation of the electromechanical function due to water." NUREG-1537, Part 2, Section 3.3, states, in part, that "The design criteria and designs should provide reasonable assurance that structures, systems, and components would continue to perform required safety functions under water damage conditions. For the design the applicant should use local building codes, as applicable, to help ensure that the water damage to structures, systems, and components at the [NWMI] production facility site ... would not cause or allow uncontrolled release of radioactive material."

NWMI PSAR Section 3.3 discusses water damage and Section 3.3.1.3, "Compartment Flooding from Fire Protection Discharge," and Section 3.3.1.4.1, "Potential Failure of Fire Protection Piping," deal with flooding due to malfunction of the FPS. The applicant stated, in part, that sensitive systems and components, whether electrical, optical, mechanical or chemical, are typically protected within the enclosure designed for the anticipated adverse environmental conditions resulting from these types of inadvertent water discharges. These critical

components will be installed within appropriate severe-environment rated enclosures consistent with relevant industry standards (e.g., NFPA, etc.). The applicant also stated that the final comprehensive NWMI production facility design will include any design elements, and sensitive equipment protection measures that will be included in the FSAR as part of the OL application. The applicant also stated that the OL application will include the identification of or commitments to codes, standards, and other referenced documents that make up the design bases. The flood protection measures described by the applicant are designed to guard against flooding from the rupture of an on-site fire protection tank if the final design determines that feature is necessary.

Per NWMI PSAR Section 3.3.1.4, "Compartment Flooding from Postulated Component Failures," Section 3.3.1.5, "Permanent Dewatering System," and Section 3.3.1.6, "Structural Design for Flooding," the flood water depth due to a rupture of water containing components and its consequences will be included in the FSAR as part of the NWMI OL application. The applicant stated that there is no impact of flood water on structural systems, and no dewatering system is required.

Based on its review, the staff finds that the level of detail provided on hydrological damage demonstrates an adequate design basis and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.3 because the applicant's design should allow for SSCs to continue to perform their safety functions based on the use of applicable codes and standards including local building codes. This allows the staff to find that the design criteria and preliminary design would protect against potential hydrological (water) damage and would provide reasonable assurance that the NWMI production facility's SSCs would continue to perform their required safety functions, would not cause unsafe production facility operation, would not prevent safe shutdown of the production facility, and would not cause or allow uncontrolled releases of radioactive material or chemical exposures.

Therefore, the staff concludes that the NWMI production facility design features for coping with hydrological damage are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis, based on the final design, can reasonably be left for later consideration. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will confirm that the final design conforms to this design basis during its review of the NWMI FSAR submitted as part of the OL application.

3.4.4 Seismic Damage

The staff evaluated the sufficiency of the NWMI production facility's preliminary design features in the case of a seismic event, as described in NWMI PSAR Section 3.4, for the issuance of a construction permit using the guidance and acceptance criteria from Section 3.4, "Seismic Damage," of NUREG-1537, Part 2.

Consistent with the review procedures of Section 3.4 of NUREG-1537, Part 2, the staff considered the site description and historical data to ensure that the appropriate seismic inputs have been considered. For any SSC damage, the staff considered the extent to which a seismic event would impair the safety function of the SSCs for the NWMI production facility. NWMI PSAR in Section 3.4 discusses the seismic inputs, soil-structure interaction, methods of seismic analysis, seismic qualification of subsystems and equipment, and seismic instrumentation. The PSAR section discusses NWMI's use of the methodology from RG 1.60,

“Design Response Spectra for Seismic Design of Nuclear Power Plants,” as the basis for the NWMI production facility seismic design.

NUREG-1537, Part 1, Section 3.4, “Seismic Damage,” states, in part, that “the applicant should specify and describe the SSCs that are required to maintain the necessary safety function if a seismic event should occur.” The NWMI production facility seismic design should provide reasonable assurance that the NWMI production facility could be shut down and maintained in a safe condition. To verify that seismic design functions are met, the applicant should give the bases for TSs necessary to ensure operability, testing, and inspection of associated systems, including instrumentation and control portions, as applicable.

NUREG-1537, Part 2, Section 3.4, “Seismic Damage,” states that the review should include the designs and design bases of SSCs that are required to maintain function in case of a seismic event at the NWMI production facility site. The finding required is that the NWMI production facility design should provide reasonable assurance that it can be shut down and maintained in a safe condition.

NUREG-1537, Part 2, Section 2.5, “Geology, Seismology, and Geotechnical Engineering,” states, in part, that the information has been obtained from sources of adequate credibility and is consistent with other available data, such as data from the USGS or in the FSAR of a nearby nuclear power plant.

In NWMI PSAR Section 3.4, the applicant stated that the safe shutdown earthquake (SSE) design basis is the RG 1.60 ground response spectrum anchored at 0.2 g peak ground acceleration, as was adopted by the University of Missouri – Columbia Research Reactor and Callaway Nuclear Plant, which are both in the proximity of the NWMI production facility site. The regulatory guide is not indexed to any specific soil type and is sufficiently broad to cover all soil types. The composition of soil in which the NWMI production facility is embedded will be included in the soil-structure-interaction analyses as part of the building response analysis for the FSAR based on the final design. Structural damping will follow the recommendations of RG 1.61, “Damping Values for Seismic Design of Nuclear Power Plants.” Response spectra corresponding to the recommended damping values of RG 1.61 will be used to derive seismic loads. The staff expects that the applicant will analyze the final design of NWMI production facility structure with respect to the SSE and determine the impacts of high frequency (i.e., greater than 10 Hertz) ground accelerations on components that are determined to be IROFS. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. This item is being tracked in Appendix A, “Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments,” of this SER.

NWMI PSAR Section 3.4.1.2, “Method of Analysis,” discusses methods of seismic analysis and the spatial combination of three directional earthquake response effects. The applicant states in NWMI PSAR Section 3.4.1.2.1, “Equivalent-Static Analysis,” that the design of IROFS will consider seismic loads in all three directions using a combination of square-root-of-the-sum-of-squared or 100/40/40 methodologies per RG 1.92, “Combining Modal Responses and Spatial Components in Seismic Response Analysis.” The 100/40/40 methodology will be used in the development of the final NWMI production facility design and in the FSAR as part of the OL application.

NWMI PSAR Section 3.4.2 discusses seismic qualification methodologies. NWMI PSAR Section 3.4.2.1, “Qualification by Analysis,” discusses qualification by analysis, and NWMI PSAR Section 3.4.2.2, “Qualification by Testing,” discusses qualification by testing. In NWMI

PSAR Section 3.4.2.2 the applicant also states that it will define specific acceptable qualification methods in the procurement package to demonstrate seismic qualification. Seismic qualification of IROFS will include three options: (1) calculations and verification that the main structural components of the SSCs can withstand the seismic loads derived from the in-structure floor response spectra at the damping value derived from RG 1.61, (2) reference to available shake table testing that demonstrates the seismic capacity of the SSCs or of multiple similar items, and (3) demonstration of the seismic capacity through the performance of the type of SSCs in actual earthquakes.

NWMI PSAR Section 3.4.1.2.2, "Dynamic and Static Analysis," discusses the dynamic and static seismic analyses and in-structure floor response spectra generation of the NWMI production facility. Dynamic analyses are used for the evaluation of NWMI production facility structural components. A static analysis will be completed by the applicant during the final design stage using a combination of static load computations to ensure that SSCs remain in place and intact. Additionally, the applicant will consider a combination of existing shake table test data and existing earthquake experience to ensure that the equipment functions following an earthquake event. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will examine the analyses as part of the review of the final design when the FSAR is submitted as part of the OL application.

NWMI PSAR Section 3.4.2.2 discusses qualification of subsystems and equipment by testing. The applicant also stated that the capacity of the standard support system for overhead fixtures mounted above IROFS will be checked to ensure that they will withstand the seismic loads derived from the floor response spectra. The applicant also stated that the seismic analysis will include a check to ensure that pounding or sway impact will not occur between fixtures, (e.g., there is a sufficient rattle space). NWMI states that it will provide more detail in the NWMI FSAR included in the OL application based on the development of the final design. The staff finds this acceptable based on the design bases that the applicant provided in the PSAR. The staff will examine the analyses as part of the review of the final design when the FSAR is submitted as part of the OL application.

NWMI PSAR Section 3.4.3 provides a description of seismic monitoring instrumentation for the NWMI production facility. It also includes a discussion of types of seismic design categories for instrumentation which the applicant states will be in accordance with ASCE 7, Chapter 11. The applicant stated that the seismic instrumentation is not an IROFS, it provides no safety function, and therefore it is not a safety-related system. However, the applicant also stated that the seismic recorders need to be designed to withstand any credible level of shaking to ensure that the ground motion would be recorded in the event of an earthquake.

Based on its review, the staff finds that the level of detail provided on seismic damage demonstrates an adequate design basis and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.4. This allows the staff to find that: (1) the design criteria and design should provide reasonable assurance that SSCs would continue to perform their required safety functions during and following a seismic event and (2) the design to protect against seismic damage provides reasonable assurance that the consequences of credible seismic events will be considered to adequately protect public health and safety.

Therefore, the staff concludes that the NWMI production facility design features for coping with seismic damage are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR Part 50. The staff finds this acceptable based on the design bases that the applicant

provided in the PSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR submitted as part of the OL application.

3.4.5 Systems and Components

The staff evaluated the sufficiency of the NWMI production facility's preliminary design features for systems and components, as described in NWMI PSAR Section 3.5, for the issuance of a construction permit using the guidance and acceptance criteria from Section 3.5, "Systems and Components," of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria of NUREG-1537, Part 2, Section 3.5, the staff verified that the design bases for the SSCs that are required to ensure safe operation of the NWMI production facility are described in NWMI PSAR Section 3.5 or other PSAR sections in sufficient detail.

Further, consistent with the guidance in the ISG Augmenting NUREG-1537, Part 2, Section 3.5, while compliance with 10 CFR 70.64 is not required for a 10 CFR Part 50 production facility, if the applicant can adequately address the baseline design criteria in 10 CFR 70.64, the application would be found to be acceptable by the staff. Therefore, since the NWMI PSAR evaluates the production facility against the baseline design criteria of 10 CFR 70.64, the staff used additional guidance from NUREG-1520, Section 3.4.3.2, "Integrated Safety Analysis Summary and Documentation," in the review of how the design of the production facility addresses each baseline design criterion.

In NWMI PSAR Section 3.5.1.3, "Nuclear Safety Classifications for Structures, Systems, and Components," NWMI has defined terms related to SSCs as follows:

Safety-related: is a classification applied to items relied on to remain functional during or following a postulated DBE [design-basis event] to ensure the:

- Integrity of the facility infrastructure
- Capability to shut down the facility and maintain it in a safe shutdown condition
- Capability to prevent or mitigate the consequences of postulated accidents identified through accident analyses that could result in potential offsite and worker exposures comparable to the applicable guideline exposures set forth in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61 (d)
- Operation of the facility without undue risk to the health and safety of workers, the public, and the environment to meet 10 CFR [Part] 20 normal release or exposure limits for radiation doses and applicable limits for chemical exposures

Safety-related IROFS: SSCs identified through accident analyses are required to meet the performance requirements of 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d) ([see PSAR] Table 3-2)

Safety-related Non-IROFS: SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of workers, the public, and environment, and includes SSCs to meet 10 CFR [Part] 20 normal release or exposure limits

Non-safety-related: SSCs related to the production and delivery of products or services that are not in the above safety classifications

NWMI PSAR Section 3.5 is divided into two sections. Section 3.5.1, "General Design Basis Information," discusses SSCs and the criteria used to determine if SSCs are considered safety-related or non-safety-related. Additionally, SSCs were classified by three seismic categories (i.e., Seismic C-I, Seismic C-II, and non-seismic) and three quality levels (i.e., QA Level 1, QA Level 2, and QA Level 3). Safety-related IROFS are classified QA Level 1 and Seismic C-I. At a minimum, safety-related non-IROFS are classified as QA Level 2 and Seismic C-II, and non-safety-related SSCs are classified as QA Level 3 and non-seismic. QA Level 1 SSCs are controlled to the full measure of the NWMI QA plan. NWMI PSAR Section 3.5.2 lists systems that are part of the NWMI production facility. Specifically, SSCs required to operate during and/or after design-basis accidents or a design-basis earthquake are discussed in this section or in the system's PSAR section and include relevant requirements, standards, and documentation.

NWMI developed these specific definitions in order to show how the results of the integrated safety analysis and the development of IROFS allow for the designation of QA levels and seismic design criteria. The definitions are acceptable to the staff based on (a) the use of safety-related definitions that include the QA and seismic categories that have been derived for IROFS and non-IROFS; and (b) the designation of all IROFS to be QA Level 1 and Seismic Category I. The definitions and QA requirements are consistent with the NWMI QA program plan which is evaluated in Chapter 12.0 of this SER.

Further evaluations of the identification of safety-related SSCs, including IROFS can be found in Chapter 13.0 of this SER. A discussion of the development of TSs from IROFS can be found in Chapter 14.0, "Technical Specifications," of this SER.

Based on its review, the staff finds that the level of detail provided on systems and components demonstrates an adequate design basis and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 3.5 and NUREG-1520 (for review of Baseline Design Criteria). This allows the staff to find that: (1) the design criteria included consideration of the conditions required of the SSCs to ensure safe facility operation, including response to transient and potential accident conditions analyzed in the PSAR and (2) the design of the SSCs addressed the baseline design criteria of 10 CFR 70.64.

Therefore, the staff concludes that the NWMI production facility design features for systems and components are sufficient for a preliminary design and meet the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR Part 50. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR submitted as part of the OL application.

3.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility's SSC design criteria, as described in Chapter 3.0 of the NWMI PSAR and finds that the preliminary design criteria of NWMI's SSCs, including the principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provide reasonable assurance that the final design will conform to the design

basis, and (2) meet applicable regulatory requirements and acceptance criteria in NUREG-1537 and the ISG Augmenting NUREG-1537.

Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

- (1) NWMI has described the proposed design of the production facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.
- (2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.
- (3) There is reasonable assurance that, taking into consideration the site criteria contained in 10 CFR Part 100, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.
- (4) NWMI is technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.