

2.0 SITE CHARACTERISTICS

The principal purpose of this chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) is to describe why the site selected is suitable for constructing and operating the proposed NWMI production facility.

This chapter of the NWMI construction permit SER describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the NWMI production facility site characteristics as presented in Chapter 2.0, "Site Characteristics," of the NWMI preliminary safety analysis report (PSAR), Revision 3, and contained in responses to requests for additional information (RAIs). As explained in this SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and 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.

2.1 Areas of Review

NWMI PSAR Sections 2.1 through 2.6 provide the bases for the site selection and describe the applicable site characteristics, including geography, demography, meteorology, hydrology, geology, seismology, and interaction with nearby installations and facilities.

The staff reviewed NWMI PSAR Sections 2.1 through 2.6 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the site selection for the NWMI facility for the purposes of issuance of a construction permit under 10 CFR Part 50. As part of this review, the staff reviewed and evaluated descriptions and discussions of NWMI's bases for the site selection.

Areas of review for this section included the following:

- The geography and demography descriptions of the site area and facility location used to assess the acceptability of the NWMI site.
- The description of locations and routes where potential external hazards or hazardous materials are present or may reasonably be expected to be present during the projected lifetime of the NWMI site.
- The description of averages and extremes of climatic conditions and regional meteorological phenomena that could affect the safe design and siting of the NWMI site.

- The description of the NWMI site and safety-related elevations, structures, and systems from the standpoint of hydrologic considerations including the topographic map showing the proposed changes to grading and to natural drainage features.

2.2 Summary of Application

The proposed 3.0 hectares (ha) (7.4 acre (ac)) site is situated in Boone County, Missouri, within the University of Missouri (MU) Discovery Ridge Research Park (Discovery Ridge) in Columbia, Missouri. The site is north of Discovery Ridge Drive. The site is situated in central Missouri approximately 201 kilometers (km) (125 miles (mi)) east of Kansas City and 201 km (125 mi) west of St. Louis. The site is 7.2 km (4.5 mi) south of United States (U.S.) Interstate Highway 70 and just to the north of U.S. Highway 63. The Missouri River is 15.3 km (9.5 mi) to the west of the site. The site is located 5.6 km (3.5 mi) to the southeast of the main MU campus. Figure 2.1-1 below shows the relative location of the City of Columbia, Missouri with respect to Kansas City, Missouri and St. Louis, Missouri. While the topography of Boone County ranges from highly dissected hills to flat floodplains and nearly flat uplands, the NWMI facility site is primarily characterized by relatively flat surfaces at an elevation of 231 meters (m) (758 feet (ft)).

The combined resident and transient population within an 8 km (5 mi) band from the site is estimated at 68,766 persons in 2010 and 105,004 persons in 2050. The total resident population estimated for 2010 is 205 people at a distance from 0 to 1 km (0 to 0.6 mi) from the proposed site, and 1,862 people at a distance of 1 to 2 km (0.6 to 1.2 mi) from the site.

There are several major industrial and transportation facilities located within 8 km (5 mi) of the NWMI site. As shown or described in NWMI PSAR Tables 2-5, 2-12, 2-13, 2-14, and 2-15; Figures 2-4 and 2-29; and Section 2.2.2.1, "Airports," these include industrial facilities, pipelines, combustible fuel storage facilities, railroads, major highways, waterways, airports, heliports, and a hospital. There are no military bases within 8 km (5 mi) of the site.

NWMI PSAR Section 2.2.2, "Air Traffic," identifies air traffic and heliports located within 10 mi (16 km) of the NWMI facility (distance from the center of the NWMI site to the nearest edge of the airway). NWMI also describes its analysis of aircraft hazards associated with these airways, including approach and holding patterns near its proposed facility.

NWMI PSAR Section 2.2.3, "Analysis of Potential Accidents at Facilities," describes the analysis of postulated accidents and possible effects that could occur at the NWMI facility, including explosions, flammable vapor clouds, toxic chemicals, and fires.

NWMI PSAR Section 2.3, "Meteorology," describes the general and local climate, including historical averages and extremes of climatic conditions and regional meteorological phenomena. The NWMI facility location places it in the Humid Continental-Warm Summer climatic zone. This type of climate has a characteristic long, warm summer with moderate relative humidity. The winters are cool to cold and mark a period of lower precipitation than during the remainder of the year. Because of its geographical location far inland, the region is subject to significant seasonal and daily temperature variations. Air masses moving over the state during the year include cold continental polar air from Canada, warm and humid maritime tropical air from the Gulf of Mexico and the Caribbean Sea, and dry eastward flowing air masses from the Rocky Mountains located to the west. Prolonged periods of extreme hot or cold temperatures are unusual. In addition, the applicant also discusses the potential meteorological effects to the

NWMI facility and discusses the dispersion analysis of airborne releases, in both restricted and unrestricted areas, from routine releases during normal operations and from postulated releases resulting from accidents.

NWMI PSAR Section 2.4, "Hydrology," identifies the NWMI facility site surface water, groundwater aquifers, and floods. NWMI PSAR Section 2.4.3, "Floods," identifies the effects of potential floods on the proposed NWMI facility site. The site is located outside of the 500-year flood plain. The nearest Federal Emergency Management Agency (FEMA) flood zone A is located along Gans Creek located to the southeast of the site. The elevation of this zone is 242 m (795 ft). The NWMI facility site elevation is 248 m (815 ft). There are no water impoundments or dams upstream of the NWMI facility site on Gans Creek that could affect the facility. There are also two ponds located near the NWMI facility site within Discovery Ridge. These ponds include the 7.9 ha (19.6 ac) common grounds storm water management pond located to the northwest of the site. The top of the dam for this pond is 246 m (807 ft), with the spillway at 245 m (804 ft). The second, smaller pond, covers approximately 4 ha (10 ac), and is located to the northeast of the site. The elevation of the dam is approximately 244 m (801 ft). Failure of either of these two ponds would not likely affect the NWMI facility site because the elevation of the dams is lower than the elevation of the NWMI facility site.

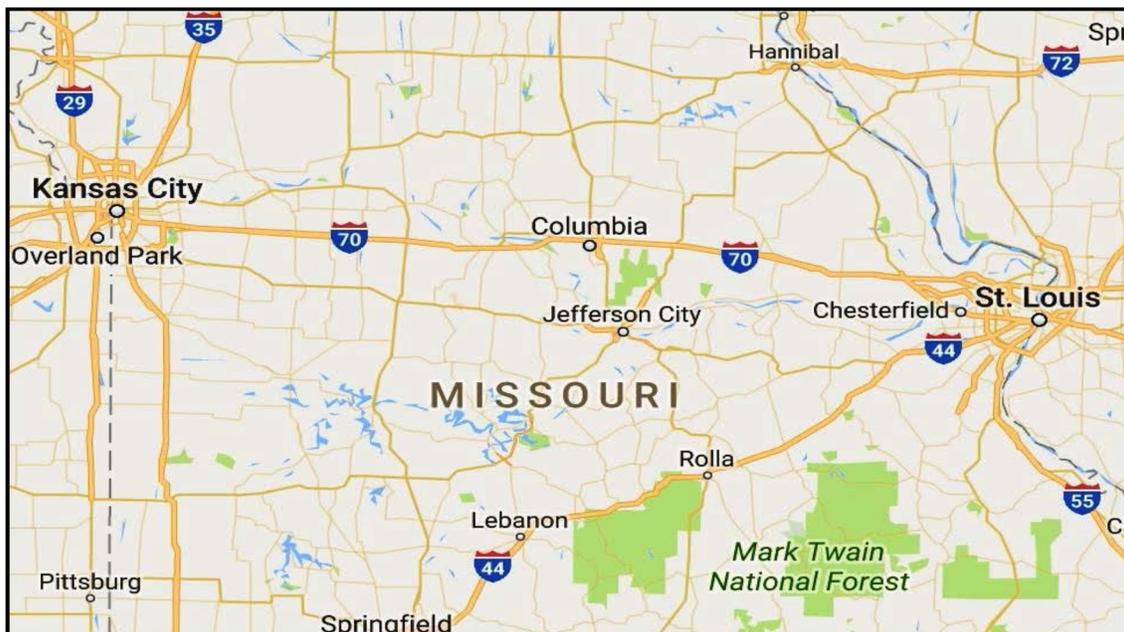


Figure 2.1-1 City of Columbia

NWMI PSAR Section 2.5, "Geology, Seismology, and Geotechnical Engineering," provides a summary description of geomorphic provinces and their tectonic development, and the glacial history responsible for surface topography features found today in the state of Missouri. These descriptions are based on a review of relevant, readily available published reports and maps and, where available, records and unpublished reports from federal and state agencies. Information on the site characteristics has been acquired from those sources and from site-specific investigations, including geotechnical field studies. NWMI PSAR Section 2.5.1, "Regional Geology," states the three geomorphic provinces of the state of Missouri, which are Interior Plains Province, Interior Highland Province, and Atlantic Plains Province, including discussion on the glacial history. The NWMI facility site is located in Boone County north of the Missouri River within the Interior Plains Province. The Interior Plains Province is characterized

by moderately dissected, glacial, flat to rolling plains that gently slope towards Missouri and Mississippi River valleys. Drainage is dendritic, and current geomorphic processes are fluvial erosion, transport and deposition, and minor mass wasting.

Precambrian metamorphic and igneous rocks now form the basement of the Interior Plains Province. The overlying sedimentary rocks are mostly composed of limestone, sandstone and shale. Several areas of Boone County contain numerous, well developed, and documented cave and sinkhole formations.

NWMI PSAR Section 2.5.2, "Site Geology," describes the geology within 8 km (5 mi) of the NWMI facility site. Specifically, this section describes the stratigraphy of the geologic units that underlie the proposed site. The section also states that highly plastic clays that exhibit volumetric change with variations in moisture content are commonly encountered near the ground surface.

NWMI PSAR Section 2.5.3, "On-site Soil Types," describes the geotechnical studies, including borings that were performed to provide preliminary geotechnical recommendations concerning earthwork and the design and construction of foundations.

NWMI PSAR Section 2.5.4, "Seismicity," describes the regional geology associated with the faults and provides the listing of historical earthquakes in a large area of the state, with magnitudes larger than 3.0. As described in NWMI PSAR Section 2.5.5, "Maximum Earthquake Potential," if an earthquake occurred along the New Madrid Seismic Zone (NMSZ) within the next 50 years, Boone County could expect a 25 to 40 percent chance of a magnitude 6.0 or greater earthquake occurring. There is also a 7 to 10 percent chance of a magnitude 7.5 to 8.0 earthquake occurring within the same time period.

NWMI PSAR Section 2.5.5 identifies the maximum expected earthquake intensity at the NWMI facility site, and concludes that a postulated 7.6 magnitude earthquake with an epicenter at the NMSZ, approximately 300 mi (483 km) away, would severely impact the site area. NWMI PSAR Table 2-42, "Projected Earthquake Hazards for Boone County," establishes the intensity as VII (very strong) for the NWMI facility site.

NWMI PSAR Section 2.5.6, "Vibratory Ground Motion," describes the development of the ground spectrum and maximum ground acceleration utilizing methodologies in various industry codes and standards.

NWMI PSAR Section 2.5.7, "Surface Faulting," identifies potential faults within 8 km (5 mi) of the NWMI facility site and identifies Fox Hollow Fault, which is approximately 5.6 km (3.5 mi) southeast of the site, as a significant but inactive and shallow normal fault.

NWMI PSAR Section 2.5.8, "Liquefaction Potential," identifies the types of underlying soils, ground water levels, and liquefaction potential, and concludes that additional geotechnical analyses are to be conducted to determine the liquefaction potential of the soils at the NWMI facility site.

2.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 2.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the bases and the information provided by NWMI for the selection of the NWMI site 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) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) 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 is 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 chapter of this SER evaluated the geography and demography of the site; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the construction permit for the production facility will not be inimical to public health and safety. The staff also evaluated structures, components, equipment, and systems designed to ensure safe operation, performance, and shutdown when subjected to extreme weather, floods, seismic events, missiles (including aircraft impacts), chemical and radiological releases, and loss of offsite power.

2.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI site characteristics are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a)(1)(i).
- 10 CFR Part 20, "Standards for Protection against Radiation."

2.3.2 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 the NRC's regulatory requirements in 10 CFR, 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 [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 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).

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, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of items relied on for safety (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 PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineer 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 PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

2.4 Review Procedures, Technical Evaluation, and Evaluation Findings

NWMI PSAR Chapter 2.0 discusses site characteristics including the geographical, geological, seismological, hydrological, and meteorological characteristics of the site and the vicinity in conjunction with present and projected population distributions, industrial facilities and land use, and site activities and controls. The staff's review of the NWMI site considers the site characteristics; design and analyses of SSCs; radiation protection and waste management programs; and accident analyses.

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 2.0, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of NWMI's site characteristics for the issuance of a construction permit, in accordance with 10 CFR 50.35. The sufficiency of the NWMI facility site characteristics is determined by ensuring the site descriptions meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 2.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the technical evaluation is described in this SER Section 2.5, "Summary and Conclusions."

2.4.1 Geography and Demography

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding geography and demography, as described in NWMI PSAR Section 2.1, "Geography and Demography," for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.1, "Geography and Demography," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 2.1, "Geography and Demography," the staff compared and verified the NWMI facility's site characteristics geography and demography with the bases for the site selection, as presented in NWMI PSAR Section 2.1.

NUREG-1537, Part 1, Section 2.1, states, in part, that the applicant should provide the descriptions of the site area and facility location to assess the acceptability of the site. The applicant should provide the following information: (1) specification of the location with respect to latitude and longitude, political subdivisions, and prominent natural and manmade features of the area; (2) site area map to determine the distance from the facility to the boundary lines of the exclusion area, including consideration of the location, distance, and orientation of plant structures with respect to highways, railroads, and waterways that traverse or lie adjacent to the exclusion area; and (3) a description of population distributions that address population in the site vicinity, including transient populations.

NUREG-1537, Part 1, Section 2.3.2, "Site Meteorology," states that sufficient information should be provided "for the dispersion analyses of airborne releases from the facility." Also, NUREG-1537, Part 2, Section 2.1, states that the staff should determine sufficient information is provided to conclude that "land use in the area of the facility is sufficiently stable or well enough planned that likely potential radiological risks to the public can be analyzed and evaluated with reasonable confidence." NUREG-1537, Part 2, Section 2.1, states that the PSAR should

contain sufficient demographic information to allow accurate assessments of the potential radiological impact on the public resulting from the siting and operation of the proposed facility. In NWMI PSAR Section 2.1.2.1, "Resident Population," the applicant provided the distance to the nearest residences in all 16 compass directions for use in its assessments of potential radiological impact on the public resulting from the siting and operation of the proposed facility.

The staff reviewed the information provided in NWMI PSAR Section 2.1 and finds that this section of the PSAR forms the basis for evaluations (e.g., dose calculations) performed in other chapters. The distance-direction relationships specified in the PSAR to area boundaries, roads, railways, waterways, and other significant features of the area were independently verified using a third-party-supplied map.

Based on its review, the staff finds that the level of detail provided on the NWMI facility's geography and demography satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.1, allowing the staff to find that: (1) the information is sufficiently detailed to provide an accurate description of the geography surrounding the facility; (2) the demographic information is sufficient to allow accurate assessments of the potential radiological impact on the public resulting from the siting and operation of the proposed facility; and (3) there is reasonable assurance that no geographic or demographic features render the site unsuitable for operation of the proposed facility.

Therefore, the staff concludes that the proposed facility's geography and demography, as described in NWMI PSAR Section 2.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35.

2.4.2 Nearby Industrial, Transportation, and Military Facilities

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding nearby industrial, transportation, and military facilities, as described in NWMI PSAR Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," of NUREG-1537, Parts 1 and 2, and Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

NUREG-1537, Part 2, does not specifically provide acceptance criteria for evaluating the aircraft accident probability posed by airports and airways. As such, to assess aircraft impact at the proposed NWMI facility, the applicant followed the guidance contained in: (1) NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [light-water reactor] Edition," Section 3.5.1.6, "Aircraft Hazards" (Reference 26), which states, in part, that accidents "with a probability of occurrence greater than an order of magnitude of 10^{-7} per year should be considered in the design of the plant," and (2) DOE-STD-3014-2006, "Accident Analysis for Aircraft Crash into Hazardous Facilities" (Reference 27).

Consistent with the review procedures in NUREG-1537, Part 2, Section 2.2, the staff confirmed that any hazards to the NWMI facility posed by normal operation and potential malfunctions and accidents at the nearby manmade stationary facilities and those related to transportation have

been described and analyzed to the extent necessary to evaluate the potential radiological risks to the facility staff, the public, and the environment.

NUREG-1537, Part 1, Section 2.2, states, in part, that “the applicant should establish whether the effects of potential accidents in the vicinity of the [facility] from present and projected industrial, transportation, and military installations and operations should be used in the safety analyses and should establish the ... facility design parameters related to accidents selected. The applicant should consider all facilities and activities within 8 kilometers of the [facility]. Facilities and activities at greater distances should be included as appropriate to their significance of accident impact on the facility.”

In NWMI PSAR Section 2.2.1, “Location and Routes,” the applicant provides maps showing locations and distances of nearby industrial facilities, pipelines, waterways, highways, railroads, fuel storage facilities, airports, and airways from the NWMI facility site. The staff confirmed that any hazards to the facility posed by normal operation and potential malfunctions and accidents at nearby manmade stationary facilities and those related to transportation have been described and analyzed to the extent necessary to evaluate the potential radiological risks to the facility staff, the public, and the environment.

NUREG-1537, Part 1, Section 2.2.2, “Air Traffic,” states that factors such as frequency and type of aircraft movement, flight patterns, local meteorology, and topography should be considered for (1) sites located with 8 km (5 mi) of an existing or projected commercial or military airport, and (2) sites located between 8 km (5 mi) and 16 km (10 mi) from an existing or projected commercial or military airport with more than approximately $200 d^2$ (where d is the distance in kilometers from the airport to the site) commercial or military aircraft movements per year.

In NWMI PSAR Section 2.2.2, the applicant describes the air traffic, including airports and airways approach and holding patterns near the proposed NWMI facility site, and the evaluation and results of its analyses of the aircraft hazards associated with this air traffic. There are three airports and three helicopter ports located within 16 km (10 mi) of the site. Because the three heliports are closer than 8 km (5 mi) to the NWMI facility site, the frequency of an aircraft crashing into the site was evaluated further using the methodology in NUREG-800, Subsection 3.5.1.6 (Reference 26). The crash frequencies that were used by the applicant were derived from the guidance in DOE-STD-3014-2006, “Accident Analysis for Aircraft Crash into Hazardous Facilities” (Reference 27). Based on the results of the analyses, the applicant determined that the crash impact frequencies from the heliports are lower than the thresholds set in NUREG-800. Since the crash frequencies are within an order of magnitude of 10^{-7} occurrences per year, no additional analysis is needed.

The calculated crash impact probabilities from other aircraft is slightly higher than an order of magnitude of 10^{-7} per year. Since the frequency of aircraft accidents exceeds the criteria for further evaluation as stated in Section 3.5.1.6 of NUREG-0800, the applicant stated that the general aviation crash will be evaluated as part of the integrated safety analysis (ISA) external event analysis and included in the operating license (OL) application. The staff concludes that the analyses of aircraft impacts that exceed the criteria can reasonably be left for further evaluation in the OL application based on the final design of the facility. Analyses at that time should reasonably be able to determine consequences and potential design changes that may be needed to demonstrate compliance with regulatory requirements.

As a result of several deficiencies identified during Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee meetings, the staff performed an independent confirmatory analysis of NWMI's aircraft impact frequencies. These deficiencies in NWMI's analysis include inconsistent flight operations, incorrect crash rates for specific aircraft, inconsistent non-airport crash frequency, transposition errors in crash impact probabilities, and incorrect runway bearings for the Columbia Regional airport. SER Table 2.4-1 presents a summary of the aircraft impact frequencies that were calculated by the staff and compares those impact frequencies to the frequencies calculated by NWMI using the non-airport crash frequencies in NWMI PSAR Table 2-19, "Effective Area Input Values and Calculated Effective Plant Area," and the Columbia Regional airport operations crash impact probabilities in NWMI PSAR Table 2-20, "Crash Impact Probabilities."

Table 2.4-1 Comparison of Aircraft Impact Frequency

Type of Aircraft	Impact Frequency (yr ⁻¹)	
	NWMI	NRC Staff
General aviation	1.78E-07	3.22E-07
Commercial air carrier	1.61E-11	2.55E-10
Air taxis	3.27E-11	4.38E-09
Military large	1.66E-08	2.60E-08
Helicopter	9.7E-07	5.1E-07
Airways	1.0E-06	1.1E-06
Total	2.2E-06	1.9E-06

The impact frequencies calculated by the staff are generally larger than the frequencies calculated by NWMI for flight operations at the Columbia Regional airport. However, the staff calculated helicopter impact frequency is smaller compared to NWMI's helicopter impact frequency. The total aircraft impact frequency calculated by the staff is of the same order of magnitude as that calculated by NWMI. Since the staff's independent calculations also support a total impact frequency greater than an order of magnitude of 10⁻⁷ per year, the staff finds that the applicant should evaluate the impact of a general aviation crash as part of the ISA in the OL application as stated in NWMI PSAR Section 2.2.2 and prescribed in Section 3.5.1.6 of NUREG-0800. The staff will further review the aircraft impact analysis in the FSAR as part of the OL application to ensure that these deficiencies are corrected.

In NWMI PSAR Section 2.2.3, the applicant identifies and describes its analysis of potential accidents to be considered design-basis events and the potential effects of those accidents on the facility, in terms of design parameters (e.g., overpressure, missile energies) or physical phenomena (e.g., impact, flammable or toxic clouds). Design-basis events, internal and external to the NWMI facility, are defined by NWMI using NUREG-1520 as those accidents that have a probability of radiological release to the public on the order of magnitude of 10⁻⁷ per year, or greater, with the potential consequences serious enough to affect the safety of the facility. The following accident categories were considered in selecting design-basis events: explosions, flammable vapor clouds (delayed ignition), toxic chemicals, and fires. Since the applicant applied methodologies for analyzing design-basis events consistent with NUREG-1520, the staff finds the applicant's preliminary calculation of the effects of potential accidents involving hazardous materials or activities on site and in the vicinity of the NWMI facility site acceptable. The staff will verify these calculations during the review of an OL.

Based on its review, the staff finds that: (1) the level of detail and analyses provided in NWMI PSAR Section 2.2 demonstrate an adequate design basis and satisfy the applicable acceptance

criteria of NUREG-1537, Part 2, Section 2.2, and (2) the applicant discusses all nearby manmade facilities and activities that could pose a hazard to its operations of the production facility. There is reasonable assurance that normal operations of such facilities would not affect the NWMI facility's operations. In addition, the analyses in NWMI PSAR Chapter 13.0, "Accident Analysis," of potential malfunctions or accidents at nearby manmade facilities and consideration of normal activities at those facilities show that safe shutdown would not be prevented, and no undue radiological risk to the public, the environment, or the operating staff is predicted. The potential consequences of these events at nearby facilities are considered or bounded by applicable accidents analyzed in Chapter 13.0 of the NWMI PSAR.

Therefore, the staff concludes that the applicant's description of operations and potential accidents at nearby manmade facilities and activities (i.e., industrial, transportation, and military) is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35.

2.4.3 Meteorology

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding meteorology, as described in NWMI PSAR Section 2.3, for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.3, "Meteorology," of NUREG-1537, Part 2.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 2.3, the staff verified that sufficient documented and referenced historical information is provided for the necessary analyses of meteorological effects at the proposed site. The staff determined that data provided address both short-term conditions applicable to accidental releases of radioactive material and long-term averages applicable to releases during normal operation. The staff also verified that the predicted frequencies of recurrence and intensities of severe weather conditions are documented.

NUREG-1537, Part 1, Section 2.3, "Meteorology," states, in part, that "the applicant should describe the meteorology of the site and its surrounding areas. Sufficient data on average and extreme conditions should be included to permit an independent evaluation by the reviewer."

NWMI PSAR Section 2.3.1, "General and Local Climate," provides a general and local climate analysis, with respect to historical and annual frequencies of severe weather for the proposed site, including the following:

- Identification of region with climate representative of the project site.
- Regional data sources
- Identification and selection for analysis of weather monitoring stations located within the site climate region
- Extreme weather
- Wind
- Tornadoes
- Humidity
- Maximum probable snowpack and precipitation
- Temperature

NWMI PSAR Section 2.3.1.2, "Precipitation," states the probable maximum precipitation (PMP) rate for the proposed site is 3.14 inches per hour. The staff examined the potential impact to the facility as a result of pond overflow during a PMP event. The staff used an independent elevation map of the site and determined that potential overflow of the ponds would not impact the facility. NWMI states in PSAR Section 3.3.1.1.1, "Flooding from Precipitation Events," that 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-hour duration around and away from the facility. The staff will evaluate the final grading of the site and the potential impact of precipitation to the facility at the final design stage (i.e., submission of an OL application). NWMI committed to accounting for precipitation and flooding in the grading of its site. The staff finds this to be an acceptable response to support the issuance of a construction permit. Following receipt of NWMI's final design (i.e., submission of an OL application), staff will confirm that this issue has been resolved. The staff is tracking this issue in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER.

In NWMI PSAR Section 2.3.2, "Site Meteorology," the applicant provides its local climate analysis for the dispersion conditions in the vicinity of the proposed site. The applicant provides the meteorological information to be used in NWMI PSAR Chapters 11.0, "Radiation Protection and Waste Management," and 13.0 for both long-term and short-term dispersion calculations. The applicant also provides several alternative sources of meteorological information and plans for access to meteorological information during the proposed license period.

Based on its review, the staff finds that the level of detail and analyses provided in NWMI PSAR Section 2.3 demonstrate an adequate design basis and satisfy the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.3, allowing the staff to find that: (1) the meteorological history and projections for the proposed site have been prepared in an acceptable form, (2) these projections have been factored into the choice of facility location and design sufficiently to provide assurance that no weather-related event is likely to cause damage to the facility during its lifetime that could release uncontrolled radioactive material to the unrestricted area, (3) the meteorological information is sufficient for analyses applicable to and commensurate with the risks of the dispersion of airborne releases of radioactive material in the unrestricted environment at the proposed site, and (4) the methods and assumptions are applied to releases from both normal operations and postulated accidents at the facility.

Therefore, the staff concludes that the applicant's description of general, local, and site meteorology is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35.

2.4.4 Hydrology

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding hydrology, as described in NWMI PSAR Section 2.4, for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.4, "Hydrology," of NUREG-1537, Part 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 2.4, the staff verified that the proposed site was selected with due consideration of potential hydrologic events and consequences, including any that could be initiated by either local or distant seismic disturbances. In addition, the staff confirmed that the design bases were incorporated into the facility design to address predicted hydrologic events and radioactive contamination of ground or surface waters.

NUREG-1537, Part 1, Section 2.4, "Hydrology," states, in part, that:

The applicant should give sufficient information to allow an independent hydrologic engineering review to be made of all hydrologically related design bases, performance requirements, and bases for operation of structures, systems, and components important to safety. Sufficient information should also be given about the water table, groundwater, and surface water features at the [facility] site to support analyses and evaluations in Chapters 11 and 13 of consequences of uncontrolled release of radioactive material from pool leakage or failure, neutron activation of soils in the vicinity of the [facility], or deposition and migration of airborne radioactive material released to the unrestricted area.

In NWMI PSAR Section 2.4, the applicant provides a detailed description of hydrological characteristics for its proposed site, including watersheds, floods, and potential dam failures.

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

The NWMI facility site is located outside of the 500-year flood plain. The nearest FEMA flood zone A is located along Gans Creek located to the southeast of the site. The elevation of this zone is 242 m (795 ft). The NWMI facility site elevation is 248 m (815 ft). There are no water impoundments or dams upstream of the NWMI facility site on Gans Creek that could affect the facility. There are also two ponds located near the NWMI facility site within Discovery Ridge. These ponds include the 7.9 ha (19.6 ac) common grounds stormwater management pond located to the northwest of the site. The top of the dam for this pond is 246 m (807 ft), with the spillway at 245 m (804 ft). The second, smaller pond, covers approximately 4 ha (10 ac), and is located to the northeast of the site. The elevation of the dam is approximately 244 m (801 ft). Failure of either of these two ponds would not likely affect the NWMI facility site because the elevation of the dams is lower than the elevation of the NWMI facility site.

Based on its review, the staff finds that the level of detail and analyses provided in NWMI PSAR Section 2.4 demonstrate an adequate design basis and satisfy the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.4, which allows the staff to find that: (1) the applicant considered hydrologic events in selecting the facility site and the site is not located where catastrophic hydrologic events are credible; (2) the applicant considered anticipated hydrologic events in developing the design bases for the facility, to mitigate or avoid significant damage so that safe operation and shutdown of the facility would not be precluded by a hydrologic event; (3) the applicant selected combinations of site characteristics and facility design bases to provide reasonable assurance that an uncontrolled release of radioactive material in the event of a credible hydrologic occurrence would be bounded by accidents analyzed in PSAR Chapter 13.0; and (4) the facility design bases give reasonable assurance that contamination of ground and surface waters at the site from inadvertent radioactive releases would not exceed the applicable limits of 10 CFR Part 20.

Therefore, the staff concludes that the applicant's description of general, local, and site hydrology is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35.

2.4.5 Geology, Seismology, and Geotechnical Engineering

The staff evaluated the sufficiency of the NWMI facility's site characteristics regarding geology, seismology, and geotechnical engineering, as described in NWMI PSAR Section 2.5, for the issuance of a construction permit using the guidance and acceptance criteria from Section 2.5, "Geology, Seismology, and Geotechnical Engineering," of NUREG-1537, Part 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 2.5, "Geology, Seismology, and Geotechnical Engineering," the staff confirmed that the information presented in the PSAR was obtained from sources of adequate credibility and is consistent with other available data, such as data from the U.S. Geological Survey (USGS) or in the FSAR of a nearby nuclear power plant. The staff also evaluated whether there is reasonable assurance that the seismic characteristics of the site are considered in the design bases of structures, systems, and other facility features discussed in NWMI PSAR Chapter 3.0, "Design of Structures, Systems, and Components."

NUREG-1537, Part 1, Section 2.5 states, in part, that the applicant should detail the seismic and geologic characteristics of the proposed site and the region surrounding the site. The degree of detail and extent of the considerations should be commensurate with the potential consequences of seismological disturbance, both to the facility and to the public from radioactive releases.

In NWMI PSAR Section 2.5, the applicant provides descriptions of the regional geologic features, the site-specific geologic features, the historical seismic information, the maximum earthquake potential, how vibratory ground motion was addressed, the surface faults in the region, and the liquefaction potential. As identified in NWMI PSAR Section 2.5.4, the most significant seismological feature in Missouri is the NMSZ, which is made up of reactivated faults. The NMSZ is the most seismically active region in the U.S. east of the Rocky Mountains and is located approximately 483 km (300 mi) southeast of the proposed NWMI facility site.

NUREG-1537, Part 1, Section 2.5.2, "Site Geology," states, in part, that "The applicant should discuss in detail the structural geology at the facility site and should pay particular attention to specific structural units of significance to the site such as folds, faults, synclines, anticlines, domes, and basins."

NUREG-1537, Part 1, Sections 2.5.3, "Seismicity," 2.5.4, "Maximum Earthquake Potential," 2.5.5, "Vibratory Ground Motion," 2.5.6, "Surface Faulting," and 2.5.7, "Liquefaction Potential," states, in part, that, "The applicant should list all historically reported earthquakes...of modified Mercalli intensity of greater than IV or magnitude (Richter) greater than 3.0...[in the list]...the applicant should evaluate the largest earthquake that could occur...and isoseismal maps for the earthquakes should be presented... the applicant should assess the ground motion at the site from the maximum potential earthquakes...and the applicant should establish the vibratory ground motion design spectrum ... [and] the applicant should discuss soil structure ... [and] prepare an appropriate state-of-the-art analysis of the potential for liquefaction at the site."

NUREG-1537, Part 2, Section 2.5 further states that, "The reviewer should confirm that the information presented 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."

NWMI PSAR Section 2.5.1.3, "Local Topography and Soils of Boone County," states that several areas of the county contain well-developed cave and sinkhole formations. NWMI PSAR Section 2.5.2.3, "Mississippian Age Osagean Series Burlington Formation (Mo)," references a report by Terracon Consultants, Inc. (Reference 62) that states that "No caves or sinkholes are known to exist ... within approximately 1 mi of [the NWMI facility site]. However, several areas of known karst activity are present...." The PSAR states that no sinkholes have occurred at the NWMI facility site since the Terracon report was issued in 2011. The most recent sinkhole formed in May 2014 at East Creek Road, approximately 0.45 km (0.73 mi) to the southwest of the NWMI facility site. The applicant also states that a site-specific investigation of the site will be conducted to ensure that the area does not have the potential for sinkhole formations. If the investigation does identify the potential for sinkholes, the design would incorporate one of the following alternatives: (1) excavate site both vertically and horizontally to remove the potential and backfill with structural fill, or (2) install piers to bedrock to support the structure if a sinkhole was to occur. If one of these alternatives needs to be implemented, it will be determined after the geotechnical investigation is complete, incorporated in the final NWMI facility design, and presented in the FSAR as part of an OL application.

NWMI PSAR Section 2.5.2.1, "Quaternary Age Holocene Series," states, in part, that "[h]ighly plastic clays that exhibit volume change with variations in moisture are commonly encountered near the ground surface (Terracon 2011)." Additionally, the applicant states in that a site-specific geotechnical investigation of the NWMI facility site will be conducted to identify the site-specific soil characteristics. If highly plastic clays are identified at the site, the design will include excavation of the clays and backfill with structural fill. The structural details will be developed in the final NWMI facility design and presented in the FSAR submitted as part of an OL application.

NWMI PSAR Section 2.5.3, states that "Soils with moisture levels above their measured plastic limits may be prone to rutting and can develop unstable subgrade conditions during general construction operations (Terracon 2011). Moderate to high plasticity clays were observed at the site. Such soils are commonly referred to as 'expansive' or 'swelling' soils.... Footings, floor slabs, and pavements supported on expansive soils often shift upward or downward causing possible distortion, cracking, or structural damage."

Consistent NUREG-1537, Part 1, Section 2.5.3, NWMI PSAR Section 2.5.4 presents a listing of recorded earthquakes with a magnitude equal to or larger than 3.0 in NWMI PSAR Table 2-41, "Recorded Missouri Earthquake History," with the last listed earthquake, with magnitude 3.0, occurred in 2016.

NWMI PSAR Section 2.5.6, states that the seismic design parameters for the proposed project are discussed in terms of the 2012 International Building Code (IBC) and associated standards. Since NUREG-1537, Part 1, Section 3.4, "Seismic Damage," as supplemented by the ISG Augmenting NUREG-1537, Part 1, Chapter 3, "Design of Structures, Systems, and Components," states that the seismic design of a radioisotope production facility should, at a minimum, be consistent with local building codes and other applicable standards, the staff finds NWMI's use of the 2012 IBC acceptable.

NUREG-1537, Part 2, Section 2.5, states that the information on potential seismic effect should be in a form suitable for developing design basis in Chapter 3 for SSCs, and that the information presented should be "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."

NWMI has committed to using the NRC Regulatory Guide (RG) 1.60, "Design Response Spectra for Seismic Design of Nuclear Power Plants" for the final seismic design adjusted to reflect the ground acceleration response of 0.2 g. The nearby University of Missouri – Columbia Research Reactor and Callaway Energy Center, used the same seismic design. The staff developed a general seismic design response spectrum incorporating site amplification factors for the proposed NWMI facility site to confirm the seismic design. Within the 1 to 10 hertz (Hz) range of the design response spectrum, the staff found the seismic response acceptable for issuance of a construction permit. This frequency range tends to impact large facility structures, components, and equipment. The staff identified a potential high-frequency (e.g., greater than 10 Hz) impact to electrical relays, piping, and instrumentation. A major factor affecting the high frequency response will be excavation depth of the site. The applicant also stated that additional information on the seismic requirements and evaluations of the NWMI facility and associated IROFS will be provided in the OL application. If an OL application is submitted, the staff will review the seismic design for both the structure and for IROFS components in order to determine whether regulatory requirements have been met. The staff concludes that these analyses on the seismic design can reasonably be left for further evaluation in the OL application when the final design is completed and IROFS components have been identified. The staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 2.5.5, states that Boone County would be severely impacted by a 7.6 magnitude earthquake with the epicenter on or near the New Madrid Seismic Zone, with an estimated intensity of VII at the site, as shown on NWMI PSAR Table 2-42. The applicant states in the PSAR that the estimated maximum ground acceleration at the NWMI facility site will meet the RG 1.60 free-field response spectrum, anchored to a peak ground acceleration (PGA) of 0.2 g, and states that, as mentioned in Chapter 3.0, the seismic design of the facility and associated IROFS will ensure the functionality and integrity of SSCs required to prevent radiological releases below the performance requirements of 10 CFR 70.61, and noted that additional information on seismic requirements and evaluations of the NWMI facility and associated IROFS will be provided in the FSAR submitted as part of an OL application. The NRC staff finds that it is acceptable for the applicant to defer the identification of specific IROFS until the OL application since NWMI has described classifications and performance requirements for the SSCs, including IROFS, at its facility in NWMI PSAR Section 3.5, "Systems and Components."

NUREG-1537, Part 1, Section 2.5.5, states that the applicant should assess the ground motion at the site from the maximum potential earthquakes associated with each tectonic province and should consider any site amplification effects. Using the results, the applicant should establish the vibratory ground motion design spectrum. The applicant states in the PSAR that that the design spectrum and estimated maximum acceleration at the NWMI facility site will meet the RG 1.60 spectrum anchored at a PGA of 0.2 g for building structural analysis and design.

The applicant stated in NWMI PSAR Section 2.5.6 that the seismic soil classification for the NWMI facility site is Class C.

NUREG-1537, Part 1, Section 2.5.7, pertains to the evaluation of soil structure, and states, in part, that, "If the foundation materials at the site adjacent to and under safety-related structures are saturated soils or soils that have a potential for becoming saturated, the applicant should prepare an appropriate state-of-the-art analysis of the potential for liquefaction at the site. The applicant should also determine the method of analysis on the basis of actual site conditions,

the properties of the ... facilities, and the earthquake and seismic design requirements for the protection of the public.”

NUREG-1537, Part 2, Section 2.5, instructs the staff to confirm that the information on the geologic features and the potential seismic activity at the site have been provided in sufficient detail and in a form to be integrated acceptably into design bases for structures, systems, and operating characteristics of the facility.

NWMI PSAR Section 2.5.8 provides information based on preliminary investigations of the NWMI facility site by Terracon, and concludes that the available data are insufficient and contradictory and that the liquefaction potential cannot be conclusively determined. It also states that additional geotechnical analysis will be conducted at the site to determine the liquefaction potential of the soils on site. The applicant states that additional information on geotechnical investigations and analyses of the site will be conducted and submitted as part of the OL application. The staff determined that the completion of the evaluation can reasonably be left for further evaluation in the OL application since the depth of soil over the bedrock is thin enough that the applicant could remove or modify the soil layer in order to address liquefaction potential if needed. The final design of the NWMI facility will need to include the actual soil characteristics of the site. The staff is tracking this issue in Appendix A of this SER.

Based on its review, the staff finds that the level of detail and analyses provided in NWMI PSAR Section 2.5 demonstrate an adequate design basis and satisfy the applicable acceptance criteria of NUREG-1537, Part 2, Section 2.5, allowing the staff to find that: (1) the information on the geologic features and the potential seismic activity at the site has been provided in sufficient detail and in a form to be integrated acceptably into the design bases for structures, systems, and operating characteristics of the facility; (2) the information in the PSAR indicates that damaging seismic activity at the proposed site during its projected lifetime is very unlikely and that, if seismic activity were to occur, any radiological consequences are bounded or analyzed in PSAR Chapter 13; and (3) the PSAR shows that there is no significant likelihood that the public would be subject to undue radiological risk following seismic activity; therefore, the potential for earthquakes does not make the site unsuitable for the proposed facility.

Therefore, the staff concludes that the applicant’s description of geology, seismology, and geotechnical engineering characteristics is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical information required to complete the safety analysis can reasonably be left for consideration, and will be provided in, the FSAR.

2.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI facility’s site characteristics, as described in Chapter 2.0 of the NWMI PSAR, and finds that the NWMI facility site characteristics: (1) provide reasonable assurance that the final design will conform to the design basis, and (2) meet all applicable regulatory requirements and NUREG-1537 acceptance criteria. 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.