12.0 CONDUCT OF OPERATIONS

The conduct of operations involves the administrative aspects of facility operation, the organizational structure, the functional responsibilities, levels of authority, and interface for establishing, executing, and verifying the organizational structure, staffing, and selection and training of personnel.

This chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the NWMI production facility conduct of operations, as presented in Chapter 12.0, "Conduct of Operations," of the NWMI preliminary safety analysis report (PSAR), Revision (Rev.) 3, and as supplemented by the applicant's responses to requests for additional information (RAIs). As explained in 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 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.

12.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 12.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary aspects of the NWMI production facility operation, the organizational structure, the functional responsibilities, levels of authority, and interface for establishing, executing, and verifying the organizational structure, staffing, and selection and training of personnel for the purposes of issuing a construction permit under 10 CFR Part 50.

Specific areas of review for this chapter included the organizational structure, responsibilities of individuals and groups, selection and training of personnel, organizational aspects of radiation protection, and the facility safety program; the composition and qualification of the NWMI audit committee members, charter and rules of the audit committees, conduct of the review functions, and conduct of the audit functions; procedures, and procedural controls, to include the minimum topics for which procedures are required, the process for the review and approval of procedures, and the process for making substantive, minor, and temporary changes to procedures; preliminary emergency plan; and quality assurance (QA) program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility.

In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items, which are determined to be probable subjects of technical

specifications (TSs) for the facility, with special attention given to those items which may significantly influence the final design of the facility. The staff documented its review of NWMI's probable subjects of TSs for the facility in Chapter 14, "Technical Specifications," of this SER.

The staff did not review certain administrative information, procedures, plans, or programs that are related to the operation of the facility and do not affect construction. This includes information related to the actions to be taken after a reportable event or a violation of the facility safety limits; submission of timely information to the NRC in the form of annual reports and special reports (e.g., reportable events, violations of safety limits, changes in key personnel, changes in transient or accident analysis); facility records, including review and retention guidelines; security planning; operator training and requalification plan; proposed tests to determine operability of the facility and the timing of a report that summarizes the results of the startup tests; or proposed material control and accounting (MC&A) plan.

The staff also did not review environmental information as described in Section 12.12, "Environmental Reports," of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content" (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" (Reference 9). The staff's evaluation of NWMI's environmental information, submitted as Chapter 19.0, "Environmental Review" (Reference 1), of the NWMI PSAR, is documented in NUREG-2209, "Environmental Impact Statement for the Construction Permit for the NWMI Medical Radioisotope Production Facility" (Reference 22).

12.2 Summary of Application

NWMI PSAR Section 12.1, "Organization," describes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure. The organizational structure includes internal and external functions for NWMI, including interface responsibilities for multiple organizations.

NWMI PSAR Section 12.2, "Review and Audit Activities," discusses review and audit activities. The Plant Manager is responsible to establish review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. Committee activities will be summarized and reported to the Chief Operating Officer (COO). Independent audits of the facility will be conducted periodically and will be specified in the final safety analysis report (FSAR).

NWMI PSAR Section 12.3, "Procedures," provides a description of the operating procedures. As described by NWMI, the operating procedures will provide appropriate direction to ensure that the NWMI production facility is operated normally within its design basis, and in compliance with TSs. Operating procedures will be written, reviewed, and approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct and the wording and format are clear and concise. Procedures will be prepared, approved, canceled and implemented in accordance with the NWMI procedure program. The extent of detail in a procedure will be dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error. The process for making changes and revisions to procedures will be documented. A controlled copy of all operations procedures will be maintained in the control room or equivalent area. Activities and tasks will be performed consistent with approved implementing procedures.

NWMI PSAR Sections 12.4, “Required Actions,” 12.5, “Reports,” 12.6, “Records,” 12.8, “Security Planning,” 12.10, “Operator Training and Requalification,” 12.11, “Startup Plan,” and 12.13, Material Control and Accountability Program,” states that the information regarding these sections will be provided in the operating license (OL) application.

NWMI PSAR Section 12.7, “Emergency Planning,” provides a draft emergency preparedness plan, which is identified as Appendix A, “Northwest Medical Isotopes, LLC Radioisotope Production Facility Emergency Response Plan,” to Chapter 12 of the NWMI PSAR. NWMI states that this information will be updated in the FSAR as part of the OL application.

NWMI PSAR Section 12.9, “Quality Assurance,” provides a description of the NWMI QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. The applicant provided the NWMI Quality Assurance Program Plan (QAPP) in Chapter 12.0, Appendix C, “Quality Assurance Program Plan for the Design, Construction, and Operation of the Radioisotope Production Facility,” of the NWMI PSAR.

12.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 12.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary NWMI organization, review and audit activities, procedures, actions, plans, and programs 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 FSAR.

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program 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 production facility. However, the staff evaluated the NWMI production

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," (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," (Reference 9) and "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," (Reference 10) and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors" (Reference 11). The staff's review in Chapter 2.0, "Site Characteristics," 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 will not be inimical to public health and safety.

12.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the preliminary NWMI organization, review and audit activities, procedures, actions, plans, and programs are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.40, "Common standards."
- 10 CFR Part 50, Appendix E, Part II, "Preliminary Safety Analysis Report."

12.3.2 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).

- ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research and Test Reactors" (Reference 45).

- Regulatory Guide (RG) 2.5, "Quality Assurance Program Requirements for Research and Test Reactors" (Reference 95).

The ISG Augmenting NUREG-1537, Parts 1 and 2 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, Parts 1 and 2, 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" (Reference 24), 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 RPF 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, and American National Standards Institute/American Nuclear Society (ANSI/ANS) 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.

12.4 Review Procedures and Technical Evaluation

The staff evaluated the technical information presented in NWMI PSAR Chapter 12.0 to assess the sufficiency of the preliminary plan for the NWMI production facility conduct of operations for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary plan for the NWMI conduct of operations is determined by ensuring the preliminary plan for the NWMI conduct of operations meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in SER Section 12.3, "Regulatory Basis and Acceptance Criteria." A summary of the staff's technical evaluation is described in SER Section 12.5, "Summary and Conclusions."

12.4.1 Organization

NWMI PSAR Section 12.1 describes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure for the NWMI production facility. The organizational structure includes internal and external functions for NWMI, including interface responsibilities for multiple organizations. The organization structure facilitates the execution of the conduct of operations program.

The staff evaluated the sufficiency of the preliminary plan for the NWMI organization, as described in NWMI PSAR Section 12.1, in part by reviewing the organizational structure, the responsibilities of individuals and groups, the staffing for operations, the selection and training of personnel, the organizational aspects of radiation protection, and the facility safety program, using the guidance and acceptance criteria from Section 12.1, "Organization," of the ISG Augmenting NUREG-1537, Parts 1 and 2, and of NUREG-1537, Parts 1 and 2.

Consistent with the review criteria in Chapter 14, "Technical Specifications," of NUREG-1537, Part 2, Section 12.1, and ANSI/ANS-15.1-2007, "The Development of Technical Specifications for Research Reactors" (Reference 43), Reaffirmed in 2013, the staff evaluated the description of the NWMI review and audit activities to ensure that the PSAR provides a basis for the TS requirements for the organization activities.

The review procedures of NUREG-1537, Part 1, Section 12.1.1, "Structure," state that the description of the organizational structure should include the radiation safety function and indicate how the staff implementing that function interacts with the staff responsible for reactor operations and the top administrative officials. The multilevel chart should show the relationship of the review and audit function to the organizational structure. The persons implementing the review and audit function should communicate with the management of the reactor facility, but should report to an organizational level above this management to ensure independence of the review and audit function.

The NWMI PSAR provides the functional organization in Figure 12-1, "Northwest Medical Isotopes, LLC Organization Chart," and NWMI PSAR, Section 12.1, states that the staff implementing the radiation safety function supports on-shift plant operations and interacts with Executive Management through the chain of command. In addition, the NWMI QA Manager reports directly to the COO and will have the independent oversight responsibility for the implementation of the QAPP. Oversight activities include auditing for compliance with regulatory requirements and conformance with organizational processes and procedures.

NWMI PSAR Section 12.1.3, "Staffing," states, that "NWMI will provide sufficient resources in personnel and materials to safely conduct operations. Facility staffing considerations, including minimum staffing levels, allocation of control functions, overtime restrictions, facility status updates during turnover between shifts, procedures, training, and availability of senior operators during routine operations, will be defined in the Operating License Application." The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it is not expected to impact construction of the facility.

NWMI PSAR Section 12.1.6, "Production Facility Safety Program," states, in part, that "[th]e RPF safety program will be developed and integrated with the radiological safety and other facility safety programs and will use the methods described in 10 CFR 50, [']Domestic Licensing of Production and Utilization Facilities;['] 10 CFR 70.61 , [']Performance Requirements;['] and 10

CFR 70.62, [']Safety Program and Integrated Safety Analysis,['] as appropriate. Further details of the facility safety program will be provided in the Operating License Application." The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it is expected to be based on the final design and is not expected to impact construction of the facility.

Based on its review, the staff finds that the level of detail provided on the NWMI preliminary plan for organization activities is adequate and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.1, allowing the staff to make a finding that the applicant's commitments to develop and conduct organization activities are consistent with guidance and provide reasonable assurance that the NWMI organization activities will comply with applicable requirements.

Therefore, the staff finds the information in NWMI PSAR Section 12.1 is sufficient and meets the applicable guidance and regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. Further information as may be required to complete the review of NWMI's organization (e.g., staffing considerations and production facility safety program) can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

12.4.2 Review and Audit Activities

NWMI PSAR Section 12.2 discusses review and audit activities. The Plant Manager is responsible to establish review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. These activities are summarized and reported to the COO. Independent audits of the NWMI facility operations will be conducted periodically and their scope will be specified in the NWMI OL application.

The staff evaluated the sufficiency of the preliminary NWMI review and audit activities, as described in NWMI PSAR Section 12.2, in part, by reviewing the composition and qualification of the committee members, charter and rules of the committee, conduct of the review function, and conduct of the audit function, using the guidance and acceptance criteria from Section 12.2, "Review and Audit Activities," of NUREG-1537, Parts 1 and 2.

Consistent with the review criteria in Chapter 12 of NUREG-1537, Part 2, Section 12.2, and ANSI/ANS-15.1-2007, the staff evaluated the description of the NWMI review and audit activities to ensure that the PSAR provides a basis for the TS requirements for the review and audit function.

NUREG-1537, Part 1, Section 12.2 states that the applicant should explicitly state who holds the approval authority and should specify how the review and audit committees communicate and interact with facility management and corporate management.

NWMI PSAR Section 12.2 discusses the establishment of the review and audit committees and states they report to the COO. However, NWMI PSAR Section 12.2.1, "Composition and Qualifications," states, in part, that "[t]he minimum number and qualifications of the committee members and the potential use of members from outside the organization will be identified in the Operating License Application." NWMI PSAR also states in Section 12.2.2, "Charter and Rules," that details on the charter and rules for the Review and Audit Committee will be provided in the FSAR. The staff finds it reasonable for the applicant to defer the submission of

this information until the OL application since it is not expected to impact construction of the facility.

NUREG-1537, Part 2, Section 12.2, Acceptance Criteria, states, in part, that "[t]he applicant should give the details of the review function…The reviews should include 10 CFR 50.59 ["Changes, tests, and experiments"] safety reviews." NWMI PSAR, Section 12.2.3, "Review Function," include this in the minimum list of items that will be reviewed by the Review and Audit Committee.

In addition, NUREG-1537, Part 1, Section 12.2.4, "Audit Function," states, in part, that "[t]he applicant should list and discuss the items that must be audited by the committee. In addition to audits by the facility committee, the licensee may consider entering into an auditing agreement with other non-power reactor facilities to bring in staff members from other non-power reactors to perform an audit."

NWMI PSAR, Section 12.2.4 includes audit frequency, areas of the facility operation subject to audits, logistics, responsibilities and a list of examples of activities to be audited.

Based on its review, the staff finds that the level of detail provided on the NWMI plan for review and audit activities is adequate and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.2, allowing the staff to make a finding that the applicant's commitments to develop and conduct review and audit activities provide reasonable assurance that the NWMI review and audit activities will comply with applicable requirements.

Therefore, the staff finds the information in NWMI PSAR Section 12.2 is sufficient and meets the applicable guidance and regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. Further information as may be required to complete the review of NWMI's review and audit activities (e.g., details on the Review and Audit Committee) can reasonably be left for later consideration since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

12.4.3 Procedures

The staff evaluated the sufficiency of the preliminary NWMI production facility procedures, as described in NWMI PSAR Section 12.3, using the guidance and acceptance criteria from Section 12.3, "Procedures," in NUREG-1537, Parts 1 and 2.

Consistent with the review criteria of Chapter 12 of NUREG-1537, Part 2, Section 12.3, and ANSI/ANS 15.1-2007, the staff evaluated the description of the NWMI procedure activities to ensure that the PSAR provides a basis for the TS requirements for procedures.

NUREG-1537, Part 1, Section 12.3, states, in part, that "[t]he applicant should discuss the basic topics that the procedures do or will cover…The applicant should discuss the methodology used for developing procedures, including the approval process. The applicant should also discuss the process required to make changes to procedures including substantive and minor permanent changes, as defined in ANSI/ANS-15.1-1990, and temporary deviations to deal with special or unusual circumstances during operation. The applicant should note that 10 CFR 50.59 may apply to changes to procedures."

NUREG-1537, Part 2, Section 12.3, Acceptance Criteria, states, in part, that "[t]he applicant should discuss the method for the review and approval of procedures. The method should involve staff from reactor operations, radiation protection, and reactor administration and the review committee, as appropriate to the procedure under review and approval." NUREG-1537, Part 2, Section 12.3 also states, in part, that "[t]he applicant should propose a method for making changes to procedures. This method should cover minor changes with little or no safety significance, substantive changes that are safety significant, and temporary deviations caused by operational needs."

NWMI PSAR, Section 12.3 discusses operating procedures and the procedure program. It generally discusses the use of procedures and that the process for making changes and revisions is documented as follows. Operating procedures will be written, reviewed, approved by appropriate management, controlled, and monitored to ensure that the content is technically correct and the wording and format are clear and concise. Procedures will be prepared, approved, revised, canceled, and implemented in accordance with the NWMI procedure program. Procedure changes, including substantive and minor changes and temporary deviations to deal with special or unusual circumstances during facility operations, will comply with ANSI/ANS-15.1-2007 requirements. The details of the NWMI production facility operating procedures will be specified in the FSAR. The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it is expected to be informed by the final design and is not expected to impact construction of the facility.

Based on its review, the staff determined that the level of detail provided on the NWMI procedure development and review activities is adequate for the issuance of a construction permit because it meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.3.

Therefore, the staff finds the information included in NWMI PSAR Section 12.3, is sufficient to meet the guidance and applicable regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. Further information as may be required to complete the review of NWMI's operating procedures can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

12.4.4 Required Actions

The staff evaluated the sufficiency of the preliminary plan for NWMI required actions, as described in NWMI PSAR Section 12.4, using the guidance and acceptance criteria from Section 12.4, "Required Actions," in NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.4 states that required actions to be taken in the event of a violation of a facility safety limit or the occurrence of a reportable event will be developed for submission in the FSAR.

Using the guidance in NUREG-1537, Part 2, the staff finds it reasonable for the applicant to provide this information in the OL application since it is expected to be based on the final design and is not expected to impact construction of the facility.

Therefore, further information as may be required to complete the review of NWMI's required actions can reasonably be left for later consideration in the FSAR since this information is not

necessary for the review of a construction permit application. NWMI will provide this information in the FSAR to be submitted as part of an OL application.

12.4.5 Reports

The staff evaluated the sufficiency of the preliminary NWMI plans for submitting reports to the NRC, as described in NWMI PSAR Section 12.5, using the guidance and acceptance criteria from Section 12.5, "Reports," in NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.5, states, in part, that "A list of reports to be submitted to the NRC, and associated frequency, will be provided in the Operating License Application."

Using the guidance in NUREG-1537, Part 1, the staff finds it acceptable for the applicant to provide its plans for submitting reports to the NRC in the OL application since it is not expected to impact construction of the facility.

Therefore, further information as may be required to complete the review of NWMI's plan for submitting reports to the NRC can reasonably be left for later consideration since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application. Detailed information regarding reports during the design and construction phase is described in the NWMI PSAR Chapter 12.0, Appendix C.

12.4.6 Records

The staff evaluated the sufficiency of the preliminary NWMI plan for its records management program, as described in NWMI PSAR Section 12.6 and Appendix C, using the guidance and acceptance criteria from Section 12.6, "Records," in NUREG-1537, Parts 1 and 2 and ANSI/ANS-15.8-1995.

NWMI PSAR Section 12.6, states, "[t]he records management program will define the process for managing facility records and will be consistent with the requirements of the applicable regulations." The records management program includes the identification, generation, authentication, maintenance, and disposition of records. A detailed discussion of records management regarding operations will be provided in the FSAR.

Using the guidance in NUREG-1537, the staff finds it acceptable for the applicant to provide this information in the OL application since it is not expected to impact construction of the facility.

Therefore, further information as may be required to complete the review of NWMI's plan for records management can reasonably be left for later consideration since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application. The detailed discussions on type of records, retention period and procedure adherence during the design and construction phase of the facility are described in NWMI PSAR Chapter 12.0, Appendix C.

12.4.7 Emergency Planning

The regulations in Part II to Appendix E of 10 CFR Part 50 state that the PSAR should address the site layout and location, consideration of access routes, surrounding population distribution, land

use, and jurisdictional boundaries. The ISG Augmenting NUREG-1537, Part 2, Section 12.7.1, "Introduction," provides the guidelines for reviewing applications and references in NUREG-0849 "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors" for the review and evaluation of emergency plans at non-power reactors (Reference 79). The guidance provided in NUREG-0849, Section 1.0, "Introduction," calls for the emergency plan to provide a description of the facility, including authorized power level, location, and access routes to the facility. In addition, the owner and operator of the facility should be identified, and the objectives of the emergency plan explained. The staff notes that the NWMI Emergency Response Plan (ERP), Rev. 1 is contained within Rev. 3 of the NWMI PSAR.

Section A1.0, "Introduction," of the NWMI ERP, states that the NWMI production facility is located on Lot 15 in Discovery Ridge, which is a research park development in Columbia, Missouri. The facility owner and operator is identified as being Northwest Medical Isotopes, LLC, of Corvallis, Oregon. The objectives of the NWMI ERP is to describe NWMI's response to radiological and other emergencies occurring at the facility and to minimize the consequences of such emergencies. There is no specific power level identified for this facility, as there is no reactor located at the NWMI production facility.

In an RAI dated January 25, 2017 (Reference 14), the staff requested that the applicant provide a legible figure of the facility, or an electronic copy that could be manipulated to facilitate resolution of building names, numbers, and labels, roads and parking lots, site boundaries showing fences and gates, major site features, access routes, and water bodies within approximately 1 mile (1.6 kilometers (km)) of the NWMI production facility site. The staff also asked the applicant to provide a general area map covering a radius of approximately 10 miles (16.1 km) from the NWMI production facility, which included the location of sensitive facilities near the site, such as hospitals, schools, nursing homes, nearest residence, fire department, prisons, environmental sampling locations, and other structures and facilities that are important to emergency management as described in the NWMI ERP as described in the PSAR.

In a March 6, 2017, letter (Reference 18), and an amended response dated April 28, 2017 (Reference 19), to RAI 12A-1a and RAI 12A-1b, the applicant provided a replacement for Figure A-3, which is referred to as Figure 1 in the RAI response. The applicant also provided new Figures 2, 3, 4 and 5 in the RAI response, which provide building names, numbers, and labels, roads and parking lots, site boundaries showing fences and gates, and major site features, including access routes, and bodies of water within one mile of the NWMI site. New Figure 4 also shows the location of sensitive facilities near the site. Due to the small size of Figure 4 and Figure 5, the staff noted the low resolution provided limited usefulness. A larger version of Figures 4 and 5 should be made available at the time of the OL application. The staff reviewed the responses to RAI 12A-1a and RAI 12A-1b and concluded that the information provided is consistent with the guidance in NUREG-0849, and ISG Augmenting NUREG-1537, Part 2. Therefore, the staff finds the RAI responses acceptable. The staff noted that in the PSAR, Rev. 1, the applicant has incorporated Figures 1, 4, and 5 of the RAI response as Figures A-3, A-4, and A-5 in Rev. 1 of the PSAR. The applicant did not incorporate Figures 2 and 3 of the RAI response into Rev. 1 of the PSAR.

The staff finds the information in the application, as supplemented by the response to the RAIs, and as partially incorporated into PSAR Rev. 1, concerning the site layout and location, consideration of access routes, surrounding population distribution, land use, and jurisdictional boundaries, authorized power level, and the identification of the owner and operator of the facility, and the explanation of the objectives of the NWMI ERP are acceptable and meet the

relevant requirements of 10 CFR Part 50, Appendix E, Part II, and the guidance and criteria provided in the applicable guidance. The staff concludes that this preliminary information meets the applicable regulatory requirements and acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. In addition, 10 CFR 50.34(a)(10) requires a discussion of preliminary plans for coping with emergencies in accordance with 10 CFR Part 50, Appendix E. Further information can reasonably be left for consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application in accordance with 10 CFR 50.34(b)(6)(v).

While there are no specific regulatory requirements in 10 CFR Part 50, Appendix E, Part II related to definitions, ISG Augmenting NUREG-1537, Part 2, Section 12.7.2, "Definitions," provides the guidelines for reviewing applications and references in NUREG-0849 for the review and evaluation of emergency plans at non-power reactors. Section 2.0, "Definitions," of NUREG-0849, states that the emergency plan should provide definitions for terms that are unique to the facility and should include phrases with meanings specific to the facility. As such, the staff reviewed the terms defined as having special meaning and the list of acronyms and abbreviations provided in the NWMI ERP. The staff finds the defined terms, acronyms, and abbreviations to be complete and used consistently throughout the document. The staff also finds the information acceptable and determined that the definitions, acronyms, and abbreviations are consistent with the guidelines provided in NUREG-0849, Section 2.0. The staff concludes that the preliminary information provided meets the applicable acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. Further information can reasonably be left for consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section A, require a description of the onsite and offsite organizations for coping with emergencies and the means for notification in the event of an emergency, and of persons assigned to the emergency organization. 10 CFR Part 50, Part II, Section B calls for the emergency plan to describe contacts and arrangements made with local, State, and Federal governmental agencies with responsibilities for coping with emergencies. Section G, of Appendix E, Part II of 10 CFR Part 50, calls for the emergency plan to describe the time and means to be employed to notify local and State governments in the event of an emergency. The guidance in NUREG-0849 Section 3.0, Organization and Responsibilities," and ISG Augmenting NUREG-1537, Part 2, Section 12.7.3, "Organization and Responsibilities," identifies criteria for evaluating the emergency organization including the onsite emergency organization and any augmentation from offsite groups, and the identification, by normal everyday title, of all persons or groups that will fill positions in the emergency organization.

The staff reviewed Section A3.0, "Organization and Responsibilities," of the NWMI ERP contained within the PSAR, to evaluate the applicant's proposed emergency organization, and in an RAI letter dated January 25, 2017, submitted six RAIs related to this subsection. The applicant responded to RAIs 12A-2a, 12A-2b and 12A-2c, RAI 12A-3, RAI 12A-4, and RAI 12A-5 by letter dated March 6, 2017 (Reference 18), as supplemented by a letter dated April 28, 2017 (Reference 19).

In RAI 12A-2a, the staff requested that the applicant describe what contacts and arrangements have been made and documented with local, State, and Federal governmental agencies with responsibility for coping with emergencies at the NWMI production facility site. In response, the applicant stated, in part, that no formal agreements have been made. The applicant indicated

that only introductory conversations have taken place with supporting organizations. Continued interactions with these organizations and the development of appropriate agreements are anticipated in the development of the OL application.

In RAI 12A-2b and 12A-2c, the staff requested that the applicant clarify the organizational responsibility for the support function of the Missouri Office of Emergency Coordination, as stated in Section A3.1.2, "State Agencies," to the NWMI ERP, as it relates to the formal radiological emergency preparedness program. Also, in RAI 12A-2c, the staff requested that the applicant clarify whether the Missouri State Emergency Management Agency, under the Missouri Department of Public Safety, has responsibility for the State's formal radiological emergency preparedness program. In its response (References 18 and 19), the applicant indicated that the Missouri Office of Emergency Coordination will be replaced with the Missouri State Emergency Management Agency, and Section A3.1.2 and Section A3.3.3, "Interfaces Between the Facility Emergency Organization, Off-Site Local Support Organizations, and State and Federal Agencies," of Appendix A to the NWMI ERP will be updated to include the organizational responsibilities for this agency. The staff noted that these changes have been incorporated into NWMI ERP as described in the PSAR.

In RAI 12A-3, the staff requested that the applicant identify the 24-hour on-shift staff positions designated and trained to perform the initial responsibilities for the Emergency Director, Emergency Coordinator, Radiation Safety Officer, and Radiological Assessment Team positions, until these positions are filled by responding emergency personnel. In response (References 18 and 19), the applicant stated the staff positions were intended to be by title, not by individual. The positions would be staffed as 24-hour on-shift positions. Individuals who fill these staff positions will be identified in the emergency plan implementation procedures (EPIPs), which will be developed and submitted as part of the NWMI OL application.

In RAI 12A-4, the staff requested that the applicant confirm if the specified notification times are included in the NWMI ERP for: (1) prompt notification of off-site response authorities, normally within 15 minutes of the declaration of an emergency classification, and (2) notification of the NRC Operations Center, as soon as possible but no later than 1 hour after a declared emergency. In response to RAI 12A-4, the applicant stated that Section A4.2, "Notice of Unusual Events," and Section A4.3, "Alert," of the NWMI ERP would be revised in the PSAR to include the specified notification times. The staff noted that these changes have been incorporated into NWMI ERP as described in the PSAR.

In RAI 12A-5, the staff requested clarification of what position would be responsible for authorizing reentry to the facility after an evacuation. In response to RAI 12A-5, the applicant indicated the NWMI ERP would be revised to clarify this was the responsibility of the Emergency Coordinator.

The staff reviewed the responses to RAIs 12A-2a, 12A-2b, 12A-2c, 12A-3, 12A-4, and 12A-5 and finds that the information provided is consistent with the guidelines in NUREG-0849, and the ISG Augmenting NUREG-1537. Therefore, the staff concludes that the responses to these RAIs are acceptable. The staff verified that the proposed changes in the RAI responses have been incorporated in the ERP Rev. 1 of the PSAR.

Based on the discussion above, the RAI responses, and the PSAR as revised in Rev. 3, the staff finds that the information provided in the NWMI ERP, Section A3.0, meets the applicable regulatory requirements and acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. Further information can be reasonably left for later consideration in, and

the information, as amended will be evaluated following the receipt of, the FSAR and ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section C requires that protective measures be taken within the site boundary to protect health and safety in the event of an accident.

The acceptance criteria in NUREG- 0849, Section 4.0, “Emergency Classification System,” and from the ISG Augmenting NUREG-1537, Part 2, Section 12.7.4, “Emergency Classification System,” states, in part, that the emergency plan should contain an emergency classification system consistent with the planning standard and EPIPs in an appendix to the emergency plan.

The staff reviewed Section A4.0, “Emergency Classification System,” of the NWMI ERP, which provides for classification of personnel or operational emergencies which are less severe events. Events associated with personnel injuries, radiation doses greater than occupational doses, skin doses, internal contamination, area radiation monitors, air radiation monitors, and events that cause significant damage to the NWMI production facility complex are included in the classification system. The classification system also describes other more severe events which would lead to classification as a notification of unusual event or higher classifications.

The NWMI ERP does not at this time include references to emergency plan implementing procedures. These procedures are not needed because 10 CFR 50.34(a)(10) requires that only a discussion of preliminary plans be included in an application for a construction permit.

The staff finds that the information provided in the NWMI ERP, Section A4.0, is sufficient to meet regulatory requirements and acceptance criteria for the issuance of a construction permit. Further information can reasonably be left for later consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section H require a preliminary analysis reflecting the need to include methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations within and outside the site boundary and assessing recommended protective actions. The acceptance criteria in NUREG-0849, Section 5.0, “Emergency Action Levels,” and from the ISG Augmenting NUREG-1537, Part 2, Section 12.7.5, “Emergency Action Levels,” states, in part, that the emergency action levels (EALs) should be appropriate to the specific facility and consistent with the emergency classes discussed in Section 12.7.4, and to the extent possible, specify the effluent monitors used to project dose rates and radiological effluent releases at the site boundary. In addition, the EALs should be comparable to the U.S. Environmental Protection Agency’s (EPA) early phase protective action guides (PAGs) described in EPA 400-R-92-001.

The staff reviewed Section A5.0, “Emergency Action Levels,” of the NWMI ERP and submitted four RAIs (Reference 14) related to EALs. The applicant provided its responses to RAI 12A-8, RAI 12A-9a, RAI 12A-9b, and 12A-9c by letter dated April 28, 2017 (Reference 19).

In RAI 12A-8, the staff requested that the applicant specify the effluent monitors used to project dose rates and radiological effluent releases, and include the set points in the EALs to initiate protective actions as per the guidance in NUREG-0849. In response to RAI 12A-8, the applicant stated it will provide the information related to the instrumentation, manufacturer, detection methodology, and set points in the NWMI OL application. The staff reviewed the

response to RAI 12A-8 and concluded that the information concerning effluent monitors is acceptable because the requested information is not needed for the issuance of a construction permit, particularly since the design of the facility is not final. Therefore, the staff finds that the response to this RAI is acceptable.

In RAIs 12A-9a, 12A-9b and 12A-9c, the staff requested that the applicant: (a) clarify the basis for the inclusion of a general emergency classification in NWMI PSAR Chapter 12, Appendix A, Section 5.0; (b) explain why the site area emergency and general emergency EALs are identical in Table A-1 of the NWMI ERP, and (c) explain why there is no security-related action level as discussed in ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors" (Reference 96) associated with an alert. In response to RAIs 12A-9a, 12A-9b and 12A-9c, the applicant stated that NWMI-2013-021, Chapter 13, "Accident Analysis," in NWMI PSAR Rev. 3, shows that maximum dose to the general public will not reach the EALs defined for a site area emergency or a general emergency in ANSI/ANS-15.16-2015. Accordingly, these two classifications will be removed from the NWMI ERP. The applicant also stated that NWMI ERP Table A-1 will be amended such that the EAL descriptions are consistent with the guidance in ANSI/ANS-15.16-2015, to include security related classifications as appropriate. The staff noted that these changes have been incorporated into PSAR Rev. 1.

The staff reviewed the response to RAIs 12A-9a, 12A-9b and 12A-9c, and finds that information provided meets the requirements of Appendix E to 10 CFR Part 50, and conforms to the guidance of NUREG-0849, Section 5.0; ISG Augmenting 1537, Part 2, Section 12.7.5; EPA 400-R-92-001, and ANSI-ANS-15.16-2015. Therefore, the staff concludes that these RAI responses acceptable. The staff verified that the proposed changes in the RAI responses have been incorporated in Rev. 1 of the NWMI ERP as described in the PSAR.

The staff concludes that the information provided in the NWMI ERP, Section A5.0, as amended by the response to RAIs, meet regulatory requirements and acceptance criteria for the issuance of a construction permit. Further information can reasonably be left for later consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section H require a preliminary analysis reflecting the need to include methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations within and outside the site boundary, including the capabilities for dose projection and dispatch of radiological monitoring teams within the emergency planning zone (EPZ).

The acceptance criteria from NUREG-0849, Section 6.0 for the "Emergency Planning Zones," the ISG Augmenting NUREG-1537, Part 2, Section 12.7.6, "Emergency Planning Zones," and in RG 2.6, "Emergency Planning For Research and Test Reactors and Other Non-Power Production and Utilization Facilities" (Reference 97), supplementing ANSI/ANS-15.16-2015, Section 3.6, "Emergency Planning Zones," state, in part, that the emergency plan should identify the EPZ, the emergency plan should provide an acceptable basis for the EPZ, and the size of the EPZ should be established so that the dose to individuals beyond the EPZ is not projected to exceed the early phase EPA PAGs. The guidance only calls for the identification of an area that would be impacted by a plume exposure exceeding the early phase EPA PAGs. No ingestion pathway EPZ is needed to meet established guidance.

The staff reviewed Section A6.0, "Emergency Planning Zone," of the NWMI ERP, which states that the EPZ for the NWMI facility is the area within the operations boundary as indicated in

Figure A-3. The applicant stated that NWMI-2013-021, PSAR Chapter 13, Rev. 2, shows that the maximum dose to the general public will not reach the EALs defined for a site area emergency or a general emergency in ANSI/ANS-5.16-2015.

The staff finds that the applicant has identified an EPZ, and sized the EPZ such that doses to individuals beyond the EPZ are not projected to exceed the PAGs, and provides an acceptable basis as discussed in Rev. 2 of Chapter 13, of NWMI-2013-021. As such, the staff concludes that the information provided in the NWMI ERP, Rev. 1, Section A6.0, "Emergency Planning Zones," meet regulatory requirements and acceptance criteria for the issuance of a construction permit. Further information can reasonably be left for later consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50 Appendix E, Part II, Section C require a description of the protective measures to be taken to protect health and safety in the event of an accident, procedures by which these measures are to be carried out, and expected response of offsite agencies in the event of an emergency. ISG Augmenting NUREG-1537, Part 2, Section 12.7.7, "Emergency Response," provides the guidelines for reviewing applications and references NUREG-0849, which provides the guidelines for the review and evaluation of emergency plans at non-power reactors. In particular, NUREG-0849, Section 7.0, "Emergency Response," provides criteria for emergency response measures that should be identified for each emergency.

The staff reviewed Section A7.0, "Emergency Response," of the NWMI ERP, which provides the activation process, assessment actions, corrective actions, and protective actions to be taken for each class of emergencies. The plan identifies the Emergency Coordinator as the position responsible for mobilizing that part of the facility emergency organization appropriate for the emergency and notifying offsite support agencies. Specific procedures have not been developed, however, the information can reasonably be left for development to support an OL application.

The staff finds that the information provided in the NWMI ERP, Section A7.0, meets the regulatory requirements and acceptance criteria for the issuance of a construction permit. Further evaluation of this information, as amended, will occur following the receipt of the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50 Appendix E, Part II, Sections D and E, require a description of the features of the facility to provide for: (a) onsite first aid and decontamination; (b) emergency transportation of onsite individuals to offsite treatment facilities, and (3) provisions to be made for emergency treatment at offsite facilities of individuals injured as a result of licensed activities. The ISG Augmenting NUREG-1537, Part 2, Section 12.7.8, "Emergency Facilities and Equipment," and NUREG-0849, Section 8.0, "Emergency Facilities and Equipment," provide criteria for evaluating plans for providing first aid, decontamination, and transportation of injured personnel.

The staff reviewed Section A7.0, Section A8.3, "First Aid, Decontamination, and Medical Facilities," and Section A3.1.4, "Local Agencies," of the NWMI ERP, which identifies the University of Missouri Health Systems Ambulance Service as providing transportation services, and the University Hospital and Boone Hospital, both in Columbia, as available to provide offsite medical treatment. The plan also states that first aid and decontamination kits will be provided

in the facility complex. A shower room will be provided in the facility complex and personnel decontamination facilities are also available at the University Hospital.

The staff finds that the information provided in the NWMI ERP meets the regulatory requirements and acceptance criteria in applicable guidance documents for the issuance of a construction permit. Further evaluation of this information, as amended, will occur following the receipt of the FSAR and the ERP revision submitted with the NWMI OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section H require a preliminary analysis reflecting the need to include facilities, systems and methods to identify the degree of seriousness and potential scope of radiological consequences within and outside the site boundary. Additionally, there is to be an onsite facility for use in assessing the consequences of a potential radiological accident. ISG Augmenting NUREG-1537, Part 2, Section 12.7.8 and NUREG-0849, Section 8.0, “Emergency Facilities and Equipment,” provides criteria for evaluating plans for providing an emergency support center (ESC), representative types of monitoring and sampling equipment, and communication equipment.

The staff reviewed Section A8.0, “Emergency Facilities and Equipment,” of the NWMI ERP to evaluate what emergency facilities and equipment will be available. This section describes the ESC as being the production facility Control Room, it identifies various portable and fixed radiological monitors located throughout the facility, sampling equipment, instruments for specific radionuclide identification and analysis, personnel monitoring equipment and smoke and fire detection equipment. Communications equipment include installed telephones and a public address system, both with backup power supplies, portable radios, a building intercom system, and the expectation that individuals may also have cell phones.

The staff finds that the information provided in the NWMI ERP, Rev. 1 of the PSAR, meet regulatory requirements and acceptance criteria in applicable guidance documents for the issuance of a construction permit. Further evaluation of this information, as amended, will occur following the receipt of the FSAR and the ERP revision submitted with the NWMI OL application.

There are no specific regulatory requirements in 10 CFR Part 50, Appendix E, Part II, related to recovery. ISG Augmenting NUREG-1537, Part 2, Section 12.7.9 “Recovery,” provides the guidelines for reviewing applications and references NUREG-0849 for the review and evaluation of emergency plans at non-power reactors. Section 9.0, “Recovery” of NUREG-0849, states that the emergency plan specify that recovery procedures will be written and approved as needed.

The staff reviewed Section A9.0,” Recovery,” of the NWMI ERP and determined that it outlines a task group to be formed to support recovery actions, including the development and approval of procedures as necessary, and preparation of a report after any event.

The staff finds the recovery process as identified in the NWMI ERP to be consistent with the guidelines provided in NUREG-0849, Section 9.0. The staff concludes that the preliminary information provided meets the applicable acceptance criteria and is therefore sufficient for the issuance of a construction permit. Further evaluation of this information, as amended, will occur following the receipt of the FSAR and the ERP revision submitted with the NWMI OL application.

Under 10 CFR Part 50, Appendix E, Part II, Section F describes the requirement for both employee training for those employees required to respond to an emergency and for non-employees who might be called upon in the event of an emergency. The acceptance criteria for information on training from the ISG Augmenting NUREG-1537, Part 2, Section 10.0, "Maintaining Emergency Preparedness," and NUREG-0849, Section 10.0, "Maintaining Emergency Preparedness," calls for a description of training, the review and updating of emergency plans and procedures, and the inventory of supplies that would be used in emergencies.

The staff reviewed Section A10.0, "Maintaining Emergency Preparedness," of the NWMI ERP, to evaluate the applicant's maintenance of emergency preparedness, and in an RAI letter dated January 25, 2017 (Reference 14), submitted two RAIs related to this subsection. The applicant's responses to RAIs 12A-6a and 12A-6b are contained in Reference 18.

In RAI 12A-6a, the staff requested that the applicant provide details of the training program to include the criteria stated in ISG Augmenting NUREG-1537, Part 2, Section 10.0, to include administration of the training program, frequency of training, estimated hours of initial and retraining, and training on the use of protective equipment. In response to RAI 12A-6a, the applicant stated it will amend Section A10.1, "Initial Training and Periodic Retraining Program," Section A3.3.1, "Normal Facility Organization," and Section A3.3.2, "Authorities and Responsibilities of Facility Emergency Personnel," of the NWMI ERP, to clarify responsibilities for administering the training program. The applicant indicated planned frequencies of training, and the project hours of training to be provided. The applicant also specified that training on the use of protective equipment would be included.

In RAI 12A-6b, the staff requested that the applicant describe the training to be provided for first aid and rescue personnel. In response to RAI 12A-6b, the applicant stated training for first aid responders is described in Section A8.3.1, "First Aid Training," of the NWMI ERP, which includes training such as the American National Red Cross Standard Multimedia Course. Additionally, as members of the RPF emergency organization, first aid personnel would participate in annual training, as described in Section A10.1 of the NWMI PSAR.

The staff reviewed the responses to RAIs 12A-6a and 12A-6b and finds that the information as amended concerning the training program is acceptable and meets the guidance in NUREG-0849. Therefore, the responses to these RAIs are acceptable. The staff verified that the proposed changes in the RAI responses are incorporated in Rev. 1 of the NWMI ERP as described in the PSAR.

The staff reviewed the information provided in NWMI PSAR Chapter 12, Appendix A, Section A10.2, "Emergency Drills," pertaining to emergency drills. ISG Augmenting NUREG-1537, Part 2, Section 12.7.10, states that an adequate emergency plan should demonstrate several criteria related to emergency drills and qualifications. In RAI 12A-7, the staff requested that the applicant clarify how the conduct of drills, as described in PSAR Chapter 12, Appendix A, Section A10.2, demonstrates the guidance in Section 12.7.10 of ISG Augmenting NUREG-1537, Part 2. In response to RAI 12A-7, the applicant stated it would amend Section A10.2 to address the criteria in Section 12.7.10 of ISG Augmenting NUREG-1537, Part 2. The applicant also indicated that Section A10.4.2 (1) in NWMI PSAR Chapter 12, Appendix A, would be revised to include quarterly checks to verify the ability to communicate with off-site response agencies. The staff verified that the proposed changes in the RAI responses are incorporated in Rev. 1 of the NWMI ERP as described in the PSAR.

The staff reviewed the response to RAI 12A-7 and concluded that the information in the NWMI ERP as described in the PSAR concerning conductance of emergency drills is in accordance with the applicable guidance and is acceptable. Therefore, the response to RAI 12A-7 is acceptable.

The staff finds that the preliminary information provided in the NWMI ERP as described in the PSAR, and in the applicant's responses to RAIs meets the acceptance criteria identified in the ISG Augmenting NUREG-1537, Part 2, Section 12.7, "Emergency Planning," NUREG-0849, ANSI/ANS-15.16-2015, and EPA 400-R-92-001, and therefore, meets the requirements of 10 CFR Part 50, Appendix E, Part II, and is sufficient for the issuance of a construction permit. Further evaluation of this information will occur following the receipt of the NWMI FSAR and the NWMI ERP revision submitted with the NWMI OL application.

In conclusion, the staff concludes that the preliminary information provided meets the applicable regulatory requirements and acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. Further information can reasonably be left for later consideration in, and the information, as amended, will be evaluated following the receipt of, the FSAR and the ERP revision submitted with the NWMI OL application.

12.4.8 Quality Assurance

Chapter 12.0, Appendix C, of the NWMI PSAR states that the NWMI QAPP is based on ANSI/ANS-15.8-1995 and 10 CFR 70.64(a)(1), "Quality standards and records." NWMI concluded that these standards and requirements are sufficient for use in the development of the NWMI QAPP, which is to be applied to the design, fabrication, construction, operation, and decommissioning of the NWMI production facility.

The staff evaluated the sufficiency of the NWMI QAPP, as described in Appendix C of NWMI PSAR Chapter 12.0, in part, by determining whether the applicant satisfied the relevant requirements of 10 CFR 50.34(a)(7) and by using the guidance from Section 12.9, "Quality Assurance," of NUREG-1537, Parts 1 and 2. This guidance refers QA reviewers to ANSI/ANS-15.8, as endorsed by RG 2.5, for the review of an applicant's QA program. The following is an evaluation of the NWMI QAPP as described in Appendix C of NWMI PSAR Chapter 12.0. Since the staff's review of the NWMI construction permit is limited to those activities licensed under 10 CFR Part 50, the staff did not evaluate NWMI's QAPP against the requirements of 10 CFR 70.64(a)(1).

In Section C1.0, "Introduction," of the NWMI QAPP, the applicant describes the applicability, scope, and its consistency with ANSI/ANS 15.8-1995. NWMI states that its QA program described in Section C1.2, "Application," of the NWMI QAPP, will be applied to NWMI activities, consistent with their importance to safety and reliability. NWMI states it will apply a graded approach to those items and activities that could affect the quality of safety related SSCs and other components not specifically designated as safety related. NWMI activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

The staff finds that NWMI provided an adequate description of the QAPP that follows the standard. NWMI commits to the full standard and describes the applicability of the standard to its facility with a graded quality approach. The graded approach is a process established to determine the level of analysis, documentation, and the actions necessary to comply with

specific requirements, commensurate with the safety significance. The staff finds that the description of the NWMI QA program application meets the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and is therefore acceptable.

Section C1.4, "Definitions," of the NWMI QAPP provides a list of key definitions used throughout the document. The NWMI QAPP defines safety-related, non-safety-related, safety-related IROFS, and non-safety related IROFS. The staff finds that the definitions are in accordance with ANSI/ANS-15.8-1995 and consistent with definitions for safety-related and non-safety related SSCs provided in NWMI PSAR Section 3.5.1.3, "Nuclear Safety Classifications for Structures, Systems, and Components."

Section C2.0, "Design, Construction, and Modifications," and its associated subsections described below, of the NWMI QAPP describe the QA program developed by NWMI to provide the safety and reliability during the design and construction of the NWMI production facility.

Section C2.1, "Organization," of the NWMI QAPP describes the NWMI organizational structure, functional responsibilities, levels of authority, and lines of communication for establishing, executing, and verifying implementation of activities within the scope of the QAPP. NWMI QAPP Section C2.1 states that the Quality Assurance Manager will have an independent oversight responsibility of the QAPP. The Quality Assurance Manager will report directly to the COO, who will have overall responsibility for the NWMI QA program.

The NWMI QAPP also specifies that the COO will report directly to the president CEO for operational aspects of the company, including safety, quality, security and safeguards, environmental stewardship, and regulatory licensing affairs. The COO will be responsible for all the external operations of NWMI, including supplier organizations, and integrating all quality requirements as defined in the QAPP across the internal and external organizations.

The NWMI QAPP provides for independence between the organization responsible for performing an activity or function and the organization responsible for quality oversight activities (i.e., QA and quality control).

The staff finds that the NWMI organizational controls in NWMI QAPP Section C2.1 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable.

Section C2.2, "Quality Assurance Program," of the NWMI QAPP documents the requirements for establishing, implementing, and managing the QA program. The program implements a graded approach to quality, as described in Section C2.2.2, "Requirements," of the NWMI QAPP. Quality Level (QL)-1 classification implements the full measure of the NWMI QAPP and will be applied to all safety-related SSCs. QL-2 includes the quality activities performed by NWMI, generally on a continuing basis, that are applied to ensure that the items are available and reliable to perform their safety functions when needed that are not QL-1. QL-3 includes non-safety related quality activities performed by NWMI that are deemed necessary. As described in NWMI PSAR Section 3.5.1, "General Design Basis Information," safety-related IROFS are classified QA Level 1. At a minimum, safety-related non-IROFS are classified as QA Level 2, and non-safety-related SSCs are classified as QA Level 3.

As described in NWMI QAPP Section C2.2.1, "Program Hierarchy," the QAPP is implemented on all NWMI work activities that include safety-related components. In addition, the QAPP may be supplemented by project-specific QA plans. The NWMI QA program is inclusive of this

QAPP and applicable implementing procedures as necessary to effectively address requirements. All NWMI activities and tasks will be performed consistent with approved implementing procedures. NWMI procedures will be delineated, managed, and maintained by the Quality Manager, with support from NWMI staff.

Additionally, NWMI QAPP Section C2.2, describes provisions for the appropriate and necessary indoctrination and training of personnel who perform activities affecting quality, to ensure that suitable proficiency is achieved and maintained. When required, qualification and selection of personnel will be conducted consistent with requirements established in applicable NWMI procedures. The scope of indoctrination will include administrative and technical objectives, as well as the requirements of applicable codes, standards, and the NWMI QAPP. Records of personnel training and qualification will be maintained. NWMI also stated that the full QAPP applies to all QL-1 components and all IROFS are considered QL-1.

The staff finds that the NWMI PSAR Appendix C definitions for QL-1, QL-2, and QL-3 classifications, are adequate to represent a graded approach to quality, as described in NWMI QAPP Section C2.2. The staff further finds that the NWMI programmatic controls are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and are therefore acceptable for the issuance of a construction permit.

Section C2.3, “Design Control,” of the NWMI QAPP establishes a design control process to control the design, design changes, and modifications subject to the provisions of the QAPP. The NWMI QAPP states that procedures will identify the process and include the provisions for the control of design documents, control of software, and implementation of required rules, regulations, codes, and standards. In addition the section describes specific procedures and responsibilities for the implementation of this section of the QAPP.

Section C2.3.2, “Requirements,” of the NWMI QAPP establishes that applicable design inputs, including design bases, performance requirements, regulatory requirements, codes, and standards, are to be identified and documented.

Section C2.3.1, “Responsibility,” of the NWMI QAPP states that NWMI personnel have responsibility for identifying and controlling the design interfaces and will coordinate activities among participating organizations. This section states that the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, will be verified for each application. Deviations from the established design inputs will be documented and controlled. The design organization will ensure that the final design is relatable to the design input by adequate documentation. Computer design programs used to develop any portion of the facility design or to analyze the design will be controlled. When a design program must be developed, the program will be controlled to ensure that it is fully documented and validated. When changes to previously validated computer programs are made, documented re-validation will be performed for the change and include appropriate benchmark testing.

This section also states that design verification will be performed by competent persons other than those who designed the item. Design verification will be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations. Qualification testing will be defined in formal test plans and will include appropriate acceptance criteria. Testing will demonstrate the adequacy of performance that simulates the most adverse design conditions. Test results will be documented and verified to have met the test requirements. Such documents and records will be collected, stored, and maintained for the life of the safety-related item.

Section C2.3.2 describes how changes to design inputs for final designs, field changes, and temporary and permanent modifications to SSCs or computer codes shall be documented, justified, and subject to design control measures commensurate with those applied to the original design. These measures include evaluation of effects of those changes on the overall design and on any analysis on which the design is based. NWMI states in QAPP Section C2.3.2 that qualification testing will be performed to demonstrate the adequacy of performance of SSCs under conditions that simulate the most adverse design conditions. NWMI also stated in NWMI QAPP Section C2.3.3, "Design Changes," that engineering change control procedures have been developed for the RPF design and construction to ensure that modifications to safety related SSCs, IROFS, or computer codes, will be based on a defined design and safety function of the component.

The staff finds that the NWMI programmatic and design change controls in NWMI QAPP Section C2.3 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support issuance of a construction permit.

Section C2.4, "Procurement Document Control," of the NWMI QAPP establishes controls necessary to ensure that correct quality requirements will be formally and effectively communicated to NWMI suppliers of items and services. The NWMI QAPP stipulates that procurement documents at all procurement levels identify the documentation required to be submitted for information, review, or approval by NWMI. The procurement documents control include sufficient technical and quality requirements to ensure that the items or services will satisfy the needs of the purchase and all documents at all procurement levels require the documentation to be reviewed by the purchaser. Procurement documents will require the supplier to report non-conformances associated with the items or services being procured.

The staff finds that the NWMI procurement document controls described in NWMI QAPP Section C2.4 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.5, "Procedures, Instructions, and Drawings," describes the NWMI measures to ensure that quality activities are based on documented instructions, procedures, or drawings, as appropriate. These documents will include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

The staff finds that the NWMI controls for instructions, procedures, and drawings described in NWMI QAPP Section C2.5 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.6, "Document Control," describes the NWMI process to control the review, approval, and distribution of documents, including changes thereto, which prescribe activities affecting quality. It states that the program and implementing procedures will establish the requirements for identification, review and approval, and distribution of documents. Major changes to controlled documents will be reviewed and approved by the same organizations that performed the review of the original issue.

The staff finds that the NWMI document controls described in NWMI QAPP Section C2.6 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.7 describes the NWMI measures to ensure that purchased items and services conform to procurement documents. These measures include supplier evaluation and selection, source surveillance and inspection, and audits and review of supplier documents, as applicable.

As described in Section C2.7.2.2, "Supplier Selection," the NWMI QAPP requires that the selection of suppliers be based on evaluation of their capabilities to provide items or services consistent with the requirements of the procurement documents.

Section C2.7.2.4, "Supplier's Performance," of the NWMI QAPP requires that measures be established to control the supplier's performance. Evaluation methods will include review of supplier plans and procedures, source surveillance or inspection, QA assessments, receipt inspections deviations, waivers, and corrective actions. NWMI states that it will require that suppliers verify and provide evidence of the quality of their products.

In NWMI QAPP Section C2.7.2.5, "Supplier-Generated Documents," NWMI states that it will establish methods to control and approve supplier-generated documents. Based on the complexity of the product and importance to safety, NWMI states that it will independently verify the quality of supplier's product using source surveillances, inspections, audits, or review of supplier's non-conformances, dispositions, waivers, and corrective actions.

NWMI QAPP Section C2.7.2.6, "Item or Service Acceptance," describes the NWMI process to ensure that purchased items and services conform to procurement specifications. NWMI states that it will use one or more of the following methods to accept an item or service: supplier Certificate of Conformance, source verification, receipt inspection, or post-installation testing. Receipt inspection will include, as appropriate, verification by objective evidence such features as proper configuration, identification and cleanliness, shipping damage, and indication of fraud or counterfeit. Documented evidence of acceptability must be completed prior to placing an item in service, and these controls are also applicable to software.

The staff finds that the NWMI controls for purchased items and services described in NWMI QAPP C2.7 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.8, "Identification and Control of Items," describes the NWMI measures to ensure that only correct and accepted items are used or installed. Identification will be maintained on the items or in documents traceable to the items, or in a manner that ensures identification is established and maintained as described in this section.

The staff finds that the NWMI controls for identification and control of items described in NWMI QAPP Section C2.8 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.9, “Control of Special Processes,” describes the NWMI measures to ensure that approved special process procedures are used by qualified personnel, and consistent with specified codes and standards, including acceptance criteria for the process. NWMI states that special processes will be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Records for qualified personnel, processes, and equipment associated with special processes will be maintained, as appropriate.

The staff finds that the NWMI controls for special processes described in NWMI QAPP Section C2.9 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.10, “Inspections,” describes the NWMI inspection process to verify the quality and conformance of the item to specified requirements. The inspection process will be applicable to procurement, construction, modification, maintenance, and experiment fabrication. Inspections will be performed by persons other than those who performed the work being inspected, but may be from the same organization. The inspection process requires that to verify conformance of an item or activity to specified requirements or the continued applicability of an item in service, the inspection shall be planned, executed, and implemented. Inspection activities require that such activities shall be documented and controlled by instructions, procedures, drawings, checklist, travelers, or other appropriate means.

The staff finds that the NWMI controls for inspection described in NWMI QAPP Section C2.10 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.11, “Test Control,” describes the NWMI requirements for planning, conducting, and documenting tests to specific requirements that provide evidence of product or computer program acceptability. Test results will be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Computer programs to be used for operational control will be tested consistent with an approved verification and validation plan and will demonstrate required performance over the range of operation of the controlled function or process. NWMI also stated that testing activities will be completed under the QA program of the organization that is completing the work.

NWMI states in the PSAR that all suppliers of computer software will be required to verify and provide evidence of the quality of their software products. In addition, methods to control and approve supplier generated documents will be established. Based on the complexity of the product and importance to safety, NWMI states that it will independently verify the quality of supplier products. NWMI-QA-PRO-029 Testing Procedure, identifies the process by which computer testing will be completed.

The staff finds that the NWMI controls for testing described in NWMI QAPP Section C2.11 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

NWMI QAPP Section C2.12, “Control of Measuring and Test Equipment [M&TE],” describes the NWMI measures to ensure that tools, gauges, instruments, and other M&TE used for activities affecting quality are controlled, calibrated, or adjusted at specified periods, to maintain accuracy

within specified limits. Frequency of the calibration of M&TE shall be defined and based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions that might affect measurement control.

Out-of-calibration devices will be tagged and segregated, until calibration has been restored. Records of calibration and repair, including as-found conditions, shall be maintained to indicate calibration and the capability of the M&TE.

The staff finds that the NWMI controls for M&TE described in NWMI QAPP Section C2.12 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

In Section C2.13, “Handling, Storage, and Shipping,” the NWMI QAPP requires that handling, storage, and shipping of items be performed consistent with work and inspection instructions, drawings, specifications, shipping instructions, or other pertinent documents specified for the use in the conducting the activity.

The staff finds that the NWMI controls for handling, storage, and shipping described in NWMI QAPP Section C2.13 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and are therefore acceptable to support the issuance of a construction permit.

Section 2.14, “Inspection, Test, and Operating Status,” of the NWMI QAPP requires that the status of inspection and test activities be identified on the items or in documents traceable to the items. Identification of inspection and test status will ensure that required inspection and test activities were performed and will prevent inadvertent installation or operation of items that have not passed the required inspections or tests.

The staff finds that the NWMI controls for inspection, test, and operating status described in NWMI QAPP C2.14 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

Section C2.15, “Control of Nonconforming Items,” of the NWMI QAPP describes the necessary measures to control nonconforming items, to prevent their inadvertent use or installation. These controls include measures for identification, documentation, evaluation, segregation (as appropriate), and disposition of nonconforming items. Recommended dispositions, such as “use-as-is,” “reject,” “repair,” or “rework,” will be identified, documented, and approved.

In Section C2.15.2.2, “Disposition,” of the NWMI QAPP, NWMI states that it will document the technical justification for the acceptability of a nonconforming item dispositioned as “repair,” or “use-as-is.” Non-conformances to design requirements of items dispositioned as “repair,” or “use-as-is,” will be subject to design control measures commensurate with those applied to the original design. Nonconforming items dispositioned as “repair,” or “rework,” will be re-examined consistent with applicable procedures and appropriate acceptance criteria. In response to RAIC2.15-1 (Reference 31), NWMI described the procedures and applicability of non-conforming items and 10 CFR Part 21, “Reporting of Defects and Noncompliance,” evaluations. The applicant also described the applicability of regulations during the design and constructions phases of the facility via procedures.

The staff finds that the NWMI controls for nonconforming items and services described in NWMI QAPP Section C2.15 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

Section C2.16, "Corrective Actions," of the NWMI QAPP requires that conditions adverse to quality be identified promptly and corrected as soon as practical. The corrective actions will be consistent with the design requirements, unless those requirements were faulty.

In the case of a significant condition adverse to quality, the cause of the condition will be investigated and corrective action to prevent recurrence will be taken. NWMI states that it will perform the evaluation of significant conditions adverse to quality for reporting to the NRC when required in accordance with 10 CFR Part 21 reporting requirements.

The staff finds that the NWMI controls for corrective actions described in NWMI QAPP Section C2.16 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

Section C2.17, "Quality Records," of the NWMI QAPP specifies procedures that describe the necessary measures to ensure that, at minimum, sufficient records of the following activities be maintained and appropriately stored: inspection and test results, results of QA reviews, QA procedures, and engineering reviews and analyses for design or changes and modifications. The NWMI records management will be implemented, and enforced consistent with written procedures, instructions, or other documentation.

NWMI QAPP Section C2.17 also states that records shall be classified as "lifetime," or "non-permanent," by NWMI customers as applicable. Both kind of records will be delineated with implementing procedures. As for the design and construction phase of the facility, all records are maintained according to procedure requirements. Records will be stored in a location that provides damage prevention from moisture, temperature, and pestilence. Provisions will be specified for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage. NWMI requires that records that be maintained by a supplier be accessible to NWMI. However, the staff needed clarification on what is defined as a quality record. In response to RAI C2.17-1 (Reference 31), NWMI stated that the Quality Records procedures identify the process by which quality records are identified and maintained. NWMI QAPP C2.17.2, "Requirements," states that NWMI's Quality Records procedure describes the quality documents relevant to the final design and construction (including modifications).

NWMI stated in the PSAR that lifetime records will be classified consistent with the recommendations found in ANSI/ANS-15.8.

The staff finds that the NWMI controls for quality records described in NWMI QAPP Section C2.17 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support the issuance of a construction permit.

Section C2.18, "Assessments," of the NWMI QAPP describes the process and expectations to implement a system of audits, assessments, and surveillance of activities affecting quality during the design and construction phase for the production facility. The assessments will be

completed during design, construction, and modification to evaluate the effectiveness of the quality program implementation in those areas.

NWMI QAPP Section C2.18 also states that assessments will be performed consistent with written procedures or checklists. Assessment results will be documented and reviewed by the management personnel responsible for the area assessed. Management of the assessed organization will investigate adverse findings and schedule corrective actions. The adequacy of the responses will be evaluated by the assessing organization. Assessment records will include plans, reports, written replies, and records of completion of corrective actions.

NWMI requires that personnel conducting assessments have the requisite training and experience in the area of the assessment.

The staff finds that the NWMI controls for assessments described in NWMI QAPP Section C2.18 are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, and are therefore acceptable to support a construction permit.

Section C3, “Facility Operations,” of the NWMI QAPP outlines the elements of a QA program for conduct of operation at the NWMI production facility. NWMI states in this section that additional detail on its QA program for the conduct of operations will be submitted as part of its OL application. The staff finds it acceptable for the applicant to defer the submission of this information until the OL application since it relates to the administration and conduct of activities related to operation of the facility and is not expected to impact construction of the facility. The NWMI QAPP also states that some requirements of the QA program for operations may be found in other documents, such as the training program, emergency preparedness plan, security plan, and TSs, and would not be duplicated in the QA program.

The information provided in NWMI QAPP Section C3 including its subsections, pertains to the operations of the NWMI production facility, and specific details are not necessary for the issuance of a construction permit since 10 CFR 50.34(a)(7) only requires that an applicant for a construction permit provide a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Therefore, further information as may be required to complete the review of NWMI’s QA program for the conduct of operations can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

NWMI has included a section heading for the future inclusion of NWMI QAPP Section C5.0, “Decommissioning,” in its OL application. The staff finds it reasonable for the applicant to defer the submission of this information until the OL application since it relates to the administration and conduct of activities related to facility decommissioning and is not expected to impact construction of the facility.

Since the proposed NWMI QAPP Section 5.0 pertains to the decommissioning of the NWMI production facility, specific details are not necessary for the issuance of a construction permit because 10 CFR 50.34(a)(7) only requires that an applicant for a construction permit provide a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Therefore, further information as may be required to complete the review of NWMI’s QA program for decommissioning can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a

construction permit application. NWMI will supply this information in the FSAR to be submitted as part of an OL application.

Based on its review, the staff finds that the information in NWMI PSAR Chapter 12.0, Section 12.9 in conjunction with Appendix C1, is sufficient and meets the guidance in ANSI/ANS-15.8-1995 and the QA requirements in 10 CFR 50.34(a)(7), which requires that an applicant for a construction permit provide a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Therefore, the staff finds that NWMI has met the applicable guidance and regulatory requirements for the issuance of a construction permit, and, as such, is acceptable for implementation during the design and construction of the NWMI production facility. Further information as may be required to complete the review of NWMI's QA program for the conduct of operations and decommissioning can reasonably be left for later consideration in the FSAR since this information is not necessary for the review of a construction permit application. Further evaluation of the NWMI QAPP will occur following the receipt of the NWMI FSAR. The staff will also review any updates to the NWMI QAPP submitted by NWMI to the NRC prior to or after the issuance of a materials license under 10 CFR Part 70, as described in Section C2.20 of the NWMI QAPP.

The staff will review NWMI's design changes and design control process to verify that the construction and design process effectively implements NRC requirements and other licensing design commitments made by NWMI, including implementation of the NWMI QAPP, as part of the staff's construction inspection program, as described in NRC Inspection Manual Chapter (IMC) 2550, "Non-Power Production and Utilization Facilities Licensed Under 10 CFR Part 50: Construction Inspection Program (CIP)."

The objectives of IMC 2550, include: (1) verification of the development of QA procedures, instructions, and other documents that are consistent with the NWMI QAPP; and (2) verification of the effective implementation of the NWMI QAPP, including timely implementation of organizational staffing, procedures, instructions, QA activities, design controls, engineering controls, and administrative controls necessary to achieve quality objectives.

In order to provide reasonable assurance that regulatory requirements and licensee commitments for QA are adequately included in the design, procurement, and construction of the NWMI production facility, the staff recommends that the construction permit include the following condition:

NWMI shall implement the QA program described, pursuant to 10 CFR 50.34(a)(7), in Rev. 3 of the NWMI PSAR , including revisions to the quality QA program in accordance with the provisions below.

NWMI may make a change to its previously accepted QA program description initially included in Rev. 3 of the NWMI PSAR, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the QA program description that do not reduce the commitments must be submitted to the NRC within 90 days. Changes to the QA program description that do reduce the commitments must be submitted to the NRC and receive NRC approval before implementation, as follows:

- **Changes made to the previously accepted QA program description must be submitted as specified in 10 CFR 50.4.**

- **The submittal of a change to the QA program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the QA program description commitments previously accepted by the NRC. The letter need not provide the basis for changes that correct spelling, punctuation, or editorial items.**

- **A copy of the forwarding letter identifying the changes must be maintained as a facility record for three years.**

- **Changes to the QA program description included in the NWMI PSAR shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.**

12.4.9 Operator Training and Requalification

The staff evaluated the sufficiency of the NWMI operator training and requalification program, as described in NWMI PSAR Section 12.10, using the guidance and acceptance criteria from Section 12.10b, "Production Facility Operator Training and Requalification," in the ISG Augmenting NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.10 states that the NWMI production facility operator training and requalification program will be described in the FSAR.

The staff finds that the information provided regarding NWMI's operator training and requalification program, can reasonably be left for later consideration in the NWMI FSAR since it is not expected to impact construction of the production facility.

12.4.10 Startup Plan

The staff evaluated the sufficiency of the preliminary NWMI startup plan, as described in NWMI PSAR Section 12.11, using the guidance and acceptance criteria from Section 12.11, "Startup Plan," in the ISG Augmenting NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.11 states that the startup plan will be developed and described in the FSAR.

Using the guidance in NUREG-1537, Part 1, the staff considered this statement in the PSAR and concluded that further information regarding the operation of the NWMI production facility is not necessary for the issuance of a construction permit given that a startup plan should be based on a final design.

Therefore, the staff finds that the information provided is adequate, and further information regarding the startup plan, as described in NWMI PSAR Section 12.11, can reasonably be left for later consideration in the NWMI FSAR.

12.4.11 Environmental Reports

The staff did not review environmental information as described in Section 12.12, "Environmental Reports," of NUREG-1537, Parts 1 and 2. Parts 1 and 2 of the ISG Augmenting NUREG-1537, state that this section of Chapter 12.0 has been superseded by Chapter 19.0, "Environmental Review." The staff's evaluation of NWMI's environmental information, submitted as Chapter 19.0, "Environmental Review," of the NWMI PSAR, is documented in NUREG-2209.

12.4.12 Material Control and Accounting Plan

The staff evaluated the sufficiency of the preliminary NWMI MC&A plan, as described in NWMI PSAR Section 12.13, using the guidance and acceptance criteria from Section 12.13, "Material Control and Accounting Plan," in the ISG Augmenting NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 12.13 states that the MC&A program will be described in the FSAR.

The staff considered the statement in the PSAR and concludes that, since NWMI has not requested a license to possess special nuclear material (SNM) during construction, a MC&A plan is not necessary at this time. A MC&A plan will be necessary when NWMI applies for a license to possess SNM under 10 CFR Part 70.

Therefore, the staff finds that the information on NWMI's MC&A plan, as described in NWMI PSAR Section 12.13, is acceptable and that further information can reasonably be left for later consideration in the evaluation of the NWMI FSAR or if NWMI applies for a license to possess SNM.

12.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI organization, including probable subjects of TSs, as described in Chapter 12.0 of the NWMI PSAR, and finds that the preliminary plan for the NWMI conduct of operations meets the applicable guidelines of the ISG Augmenting NUREG-1537, Part 2 and NUREG-1537, Part 2, as follows:

- The staff finds that the level of detail provided on NWMI's organization activities is adequate and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.1, allowing the staff to make a finding that the applicant's commitments to develop and conduct organization activities provide reasonable assurance that the NWMI organization activities will comply with applicable requirements and be consistent with guidance.

- The staff finds that the level of detail provided on the NWMI review and audit activities is adequate and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.2, allowing the staff to make a finding that the applicant's commitments to develop and conduct review and audit activities provide reasonable assurance that the NWMI review and audit activities will comply with applicable requirements.

- The staff finds that the level of detail provided for the NWMI procedure development and review activities is adequate for the issuance of a construction permit and meets the applicable acceptance criteria of NUREG-1537, Part 2, Section 12.3.

- The staff finds that further information on required actions, reports, and records can reasonably be left for later consideration in the FSAR.

- The staff finds that the preliminary information on emergency planning provided meets the applicable regulatory requirements and acceptance criteria, and therefore, is sufficient for the issuance of a construction permit. Further information can reasonably be left for later consideration in the FSAR and revised ERP, and evaluation of this information will occur following the receipt of the NWMI FSAR and the NWMI ERP revision submitted with the NWMI OL application.

- The staff finds that further information on security planning can reasonably be left for later consideration in the FSAR.

- The staff finds that the information to be included in NWMI PSAR Section 12.9 is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit. Further information on NWMI QA program requirements during operations and decommissioning can reasonably be left for later consideration in the FSAR, and further evaluation of the NWMI QAPP will occur following the receipt of the NWMI FSAR. The staff will also review any updates to the NWMI QAPP submitted by NWMI to the NRC prior to or after the issuance of a materials license under 10 CFR Part 70, as described in Section C2.20 of the NWMI QAPP. The staff will review NWMI's design changes and design control process to verify that the construction and design process effectively implements NRC requirements and other licensing design commitments made by NWMI, including implementation of the NWMI QAPP, as part of the staff's construction inspection program, as described in NRC IMC 2550. In order to provide reasonable assurance that regulatory requirements and licensee commitments for QA are adequately included in the design, procurement, and construction of the NWMI production facility, the staff recommends that the construction permit include the condition described in Proposed Permit Condition 3 in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions And Final Safety Analysis Report Commitments," of this SER.

- The staff finds that information on the operator training and requalification program, startup plan, and MC&A plan can reasonably be left for later consideration in the FSAR.

Based on these findings and subject to the condition referenced above, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) 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.

(2) There is reasonable assurance: (i) that the construction of the NWMI production facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations.

(3) The issuance of a permit for the construction of the production facility would not be inimical to the common defense and security or to the health and safety of the public.

(4) The applicant is technically qualified to engage in the proposed activities in accordance with the Commission's regulations.