11.0 RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

The purposes of the radiation protection and waste management programs are to ensure safety of the proposed Northwest Medical Isotopes, LLC (NWMI or the applicant) production facility (NWMI production facility or facility) and to provide protection to the NWMI staff, members of the public, and the environment. The radiation protection and waste management programs, identified by the analyses in the NWMI preliminary safety analysis report (PSAR), should be conducted using the appropriate methods and engineering design criteria.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary development of the NWMI radiation protection and waste management programs as presented in Chapter 11.0, "Radiation Protection and Waste Management," of the NWMI PSAR, Revision 3 (Reference 60), and contained in responses to staff 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 the 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.

11.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 11.0 against the applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of NWMI's radiation protection and waste management programs for the purposes of issuance of a construction permit under 10 CFR Part 50. As part of this review, the staff evaluated descriptions and discussions of the NWMI production facility radiation protection and waste management programs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary development of the NWMI production facility radiation protection and waste management programs was evaluated to ensure the sufficiency of the design criteria, design bases, and information relative to construction to provide reasonable assurance that the final design will conform to the design basis. 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. The staff documented its review of NWMI's probable subjects of technical TSs for the facility in Chapter 14.0, "Technical Specifications," of this SER.

Areas of review for PSAR Chapter 11.0 included the following:

- The capability of the programs to identify and discuss all expected radiation and radioactive sources, to include airborne, liquid, and solid sources, and radioactive wastes.

- The design and effectiveness of the radiation protection program required by 10 CFR 20.1101, “Radiation protection programs.”

- The ability to maintain worker and public doses and radiological releases through an as low as is reasonably achievable (ALARA) program, including: (1) a description of the methods to establish, change, and manage policy for the ALARA program; and (2) a description of how the ALARA program is implemented for all activities at the production facility to maintain radiation doses of all personnel and the public and releases of effluents to the unrestricted area ALARA.

- The procedures and equipment at the production facility for routinely monitoring and sampling workplaces and other accessible locations to identify and control potential sources of radiation exposure and releases of radioactive materials.

- The design bases for the equipment and procedures utilized for controlling radiation exposures to personnel and releases of radioactive materials from the production facility.

- The capability of the dosimetry and other methods to effectively assess exposure to radiation and radioactive materials.

- The capability of the programs for contamination control to meet all applicable requirements of the regulations and the production facility ALARA program.

- The capability of the environmental monitoring program to: (1) comply with any commitments made by the applicant; (2) establish preoperational baselines used to ascertain natural background so that the radiological impact of production facility operation on the environment can be determined; (3) promote compliance with environmental quality requirements through the production facility policy and procedures; (4) ensure that the written plans and the bases of procedures for implementing the environmental monitoring programs, including changes, are reviewed for adequacy and approved by authorized personnel; and (5) establish the environmental surveillance program, including information on the selection of sampling and other program parameters.

- The capability to manage radioactive wastes, to include: (1) philosophy of and approach to management of the wastes; (2) organization of the management function; (3) program staffing and position descriptions and program personnel responsibilities and qualifications (4) any review and audit committees related to radioactive waste management; (5) training for staff; (6) plans for shipping, disposal, and long-term storage; (7) program documentation and records, including availability and retention; (8) audits of the effectiveness of the program; (9) bases of procedures; and (10) bases of TSs.

- The effectiveness of the radioactive waste control plans at the production facility to include methods to decrease and minimize the formation of radioactive wastes.

- The methods of characterizing the possible effluents, references to the applicable regulations that establish limits for release, descriptions of the identities and amounts of radionuclides in the effluents, the release points, and the characteristics of the environment to which they are released.

11.2 Summary of Application

As relevant to the review of NWMI's proposed production facility, the preliminary design description contained in PSAR Chapter 11.0 includes an identification of the nature and magnitude of radiation sources generated as a result of facility operation, the associated shielding and ventilation system requirements that help manage occupational and public radiation exposures, the radiation protection program (including ALARA considerations, radiation monitoring, and surveillance, dosimetry, and contamination controls), and environmental monitoring activities. While all specific aspects of the program are not included, enough information has been provided for the staff to make a determination of the adequacy of the program for the purposes of the issuance of a construction permit.

NWMI PSAR, Section 11.1.1.1, "Airborne Radiation Sources," describes the production of radioactive gasses that will be produced as a result of recovery and purification of molybdenum-99 (Mo-99). Targets are to be disassembled one at a time and the target material transferred to a dissolver. The irradiated target material is loaded into the dissolver basket and lowered into the dissolver assembly, and dissolved in hot nitric acid. The production of Mo-99 through this process results in fission products, activation products, and actinides, which provide the majority of radiation sources within the NWMI facility. During normal operations, airborne radioactive materials are to be contained within closed systems. NWMI plans to contain and hold these products to allow for decay, and then allow a filtered release to ensure the airborne constraint release limit of 10 CFR 20.1101(d) is maintained.

NWMI PSAR Section 11.1.1.2, "Liquid Radioactive Sources," describes that liquid radioactive sources will be generated as a result of Mo-99 recovery and purification, recycling of low-enriched uranium LEU, and liquids resulting from treatment of offgases. During normal operations, liquid radioactive materials are to be contained within closed systems. Dissolution results in uranyl nitrate solution with Mo-99. Uranium recovery and recycle will receive the uranyl nitrate solution once the Mo-99 is removed. The Mo-99 recovery and purification system is designed to extract the Mo-99 from uranyl nitrate solution through three processing cycles of ion exchange of varying chemical processes, each producing its own liquid waste stream and passed to the waste handling system and collected in Waste Collection Tank, MR-TK-340, in the Tank Hot Cell. This section states that there will be no radioactive liquid discharges from the NWMI facility operations to the environment.

NWMI PSAR Section 11.1.1.3, "Solid Radioactive Sources," provides a summary of solid radioactive sources within the NWMI facility. Radioactive material is located in several locations within the NWMI facility, and includes fresh LEU, irradiated LEU targets, and solidified wastes. Wastes generated as a result of production will be stored to allow for radioactive decay to meet shipping and disposal requirements and then packaged in approved transportation casks and containers for transport to the appropriate disposal facility.

NWMI PSAR Section 11.1.2, “Radiation Protection Program,” addresses the following radiation protection program elements: responsibilities of key program personnel; staffing of the radiation protection program; radiation protection program independence; radiation safety committee (RSC); written radiation protection procedures; radiation protection training; and radiation safety audits. NWMI states that the radiation protection program responsibility will be vested in the Radiation Protection Manager (RPM) and that this individual will report to the Environment, Safety, and Health Manager who reports to the Chief Operating Officer (COO). A separate reporting chain to the COO is provided for the Plant Manager and his subordinates. This assures separation of the radiation safety function from the facility operating component(s), thereby facilitating independent radiation safety decisions.

NWMI PSAR Section 11.1.3, “ALARA Program,” states that the policy of NWMI is to conduct radiological operations in a manner to ensure the health and safety of its employees, contractors, and the public. The RPM is responsible for implementing the ALARA program and ensuring that adequate resources are committed to support an effective program. The RPM will prepare an annual ALARA program evaluation report that reviews: trends in radiation exposures and effluent release data; the results of audits and inspections; the use, maintenance, and surveillance of equipment used for exposure and effluent control; and, other issues that may influence program effectiveness. The Radiation Protection Program (RPP) will be independent of operations, with the RPM having direct access to the COO for radiation protection matters. The RSC will periodically review the status of projects and assess program performance.

NWMI PSAR Section 11.1.4, “Radiation Monitoring and Surveying,” provides the general framework of the NWMI facility to determine radiation levels, concentrations of radioactive material, and potential radiological hazards that could be present in the facility. This section describes the intent to detect and assess any releases of radioactive material from facility operations. Included in this section are general descriptions of instrumentation to be used and calibration commitments. This section also describes survey and personnel monitoring equipment and personnel dosimetry program implementation. The use of continuous air monitors (CAMs) for detection of airborne activity is described, as well as exhaust stack monitoring for monitoring of airborne releases.

NWMI PSAR Section 11.1.5, “Radiation Exposure Control and Dosimeter,” addresses the plan for NWMI to ensure external and internal occupational exposures are maintained ALARA. This section provides discussion of the implementation of ALARA in process design and in facility design. Access control is described, and Controlled Areas and Restricted Areas are defined. The PSAR includes definitions for a Radiation Area, High Radiation Area, Very High Radiation Areas, and Airborne Radioactivity Area, as well as the limitations on external and internal exposure. Dosimetry requirements for entry are addressed. Protective equipment and materials to be used are generally described.

NWMI PSAR Section 11.1.6, “Contamination Control,” describes general equipment and facility layout design considerations to prevent the spread of contamination to the facility and the environment. Fixed and removable contamination is defined. When establishing radiological controls for work involving potential loose or airborne contamination, the first consideration is to use techniques that will help prevent or reduce the potential for airborne radioactivity and to maintain loose surface contamination in controlled areas within ALARA levels. Access controls for contaminated areas are addressed, as well as anti-contamination techniques and the handling of potentially contaminated materials.

NWMI PSAR Section 11.1.7, “Environmental Monitoring,” discusses the applicant’s proposed radiological environmental monitoring program (REMP). NWMI will conduct a baseline environmental survey prior to construction to document radiological conditions prior to commencement of operations. This section describes the use of environmental dosimetry posted at the site boundary and lot line to monitor any dose attributable to NWMI operations. Airborne effluent is to be continuously monitored. Groundwater sampling is not planned, because NWMI does not plan to discharge any radioactive liquids directly to the environment. While biota monitoring is not planned for, NWMI intends to evaluate an ingestion exposure pathway through the evaluation of milk samples.

NWMI PSAR Section 11.2.1, “Radioactive Waste Management Program,” addresses the radioactive waste management program, including management responsibilities for the program; the quantities of gaseous, liquid, and solid wastes expected to be generated; and the manner in which waste streams will be partitioned, treated and controlled, packaged, and disposed. The applicant discusses the following aspects of the program: (1) responsibilities of management and supervisory positions; (2) operating procedures; (3) record keeping and document controls; and (4) waste management audits.

NWMI PSAR Section 11.2.2, “Radioactive Waste Management Controls,” addresses the waste NWMI foresees being produced by operations at the NWMI facility. Waste classes as described are consistent with NRC guidance and NWMI commits to generate procedures to identify, characterize, and separately treat the different waste streams in the final safety analysis report (FSAR). NWMI will implement pollution prevention and waste minimization activities that review associated processes and procedures to ensure that the kinds and amounts of waste generated are minimized.

NWMI PSAR Section 11.2.3, “Release of Radioactive Waste,” describes the approach that NWMI will use with respect to the release of radioactive waste. As previously stated, NWMI does not intend to release any liquid radioactive waste and airborne radioactive waste will be held for decay and filtered, such that release levels are less than those defined in Appendix B of 10 CFR Part 20 “Standards for Protection against Radiation.” This section states that the majority of the radioactive waste being shipped from the NWMI facility will require special containers to provide for the protection of the public and the environment. Each of these containers is designed to meet applicable NRC and U.S. Department of Transportation standards.

NWMI PSAR Section 11.3, “Respiratory Protection Program,” describes the respiratory protection program, and states that a respiratory protection program will be used only when the heating, ventilation, and air conditioning (HVAC) or other engineering controls cannot be applied to control the intake of radioactive material. The respiratory protection program includes the following elements: (1) air sampling; (2) surveys and, when necessary, bioassays; (3) performance testing of respirators for operability; (4) written procedures for all key program elements; and (5) determination by a physician that the individual user is medically fit to use respiratory protection equipment.

NWMI states in PSAR Chapter 11.0 that its radiation protection program will be designed to protect the radiological health and safety of its workers and the public. NWMI states that the program will be structured to comply with the regulatory requirements of 10 CFR Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” and 10 CFR Part 20. The program will be designed to include the elements of an ALARA program,

radiation monitoring and surveying, exposure control, dosimetry, contamination control, and environmental monitoring.

11.3 Regulatory Basis and Acceptance Criteria

The staff reviewed the NWMI PSAR Chapter 11.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility radiation protection and waste management programs for the issuance of a construction permit under 10 CFR Part 50. 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 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 facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 9). The staff's review in 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.

11.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the radiation protection and waste management programs at the proposed NWMI production facility are as follows:

- 10 CFR Part 20, "Standards for protection against radiation."
- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.35, "Issuance of construction permits."
- 10 CFR 50.40, "Common standards."

11.3.2 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, the staff used:

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

The ISG Augmenting NUREG-1537, 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, Part 2.

As appropriate, the staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards) in its 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.

11.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 11.0 to assess the sufficiency of the radiation protection and waste management programs for the issuance of a construction permit, in accordance with 10 CFR Part 50. The sufficiency of the radiation protection and waste management programs is demonstrated by acknowledgement and commitments to applicable regulatory requirements, guidance, and acceptance criteria, as discussed in SER Section 11.3, "Regulatory Basis and Acceptance Criteria." A summary of the staff's technical evaluation is described in SER Section 11.5, "Summary and Conclusions."

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

11.4.1 Radiation Sources

The staff evaluated the sufficiency of the information provided on the radiation sources, as described in NWMI PSAR Section 11.1.1 and as summarized above in SER Section 11.2, for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.1, "Radiation Sources," of NUREG 1537, Parts 1 and 2.

Consistent with the review procedures of NUREG 1537, Part 2, Section 11.1.1, the staff evaluated the discussion of potential sources of radiation in the facility, as presented in

NWMI PSAR Section 11.1.1 and other relevant chapters of the PSAR. The staff compared the description of the types of radioactive materials present with the applicable process description, including radionuclide inventories and mass balances and chemical and physical forms, to verify that all radioactive materials associated with the process have been identified. The staff reviewed the description and discussion of all sources of radiation to verify that they are described in sufficient detail to provide the bases for the design and assessment of personnel protective measures and radiation doses. The staff confirmed that all solid, liquid, and gas sources of radiation at the facility are described and discussed in sufficient detail to permit evaluation of all significant radiological exposures related to normal operation, utilization, maintenance, and radioactive waste management including processing and shipment.

NWMI PSAR Section 1.3.2.2.1, "Target Fabrication Process Description," states that LEU feed will be in the form of acid-deficient uranyl nitrate solution, consisting of fresh, scrap, and recycled LEU. The uranium target material is loaded into aluminum target elements, filled with helium or air cover gas, seal-welded, and quality checked. Following irradiation provided by a designated research reactor and return to the NWMI facility, targets are disassembled and target material transferred to a collection container, and lowered into a dissolver. Purification and separations are conducted to remove unwanted isotopes from the recovered Mo-99 product. A part of the waste solutions will contain LEU, which is processed for recovery and recycle. The nature of much of these summarized processes are carried out in hot cells, not only due to radiological and criticality concerns, but also due to containment and filtration of the associated gases. All of these processes are carried out within the biological shield of the NWMI facility, as discussed in NWMI PSAR Chapter 4.0, "Radioisotope Production Facility Description." The NWMI facility biological shield provides an integrated system of features that protects workers from the high-dose radiation generated during the processing to recover Mo-99. The primary function of the biological shield is to reduce radiation dose rates and accumulated doses in occupied areas so as to not exceed the limits expressed in 10 CFR 20.1201, "Occupational dose limits for adults."

Target fabrication processes include the storage of LEU target material and targets, production of useable LEU from fresh and recycled LEU, and assembly and loading of LEU targets for irradiation. Targets are packaged and shipped to a network of university reactors for irradiation. Once irradiation is complete, the targets are returned to the NWMI facility in a shipping cask, with a decay period of at least 8 hours prior to further processing. Receipt activities are completed in staggered fashion, with four targets processed at a time, including transfer to the disassembly hot cell. From there, targets are moved to hot cells for dissolution and then Mo-99 recovery and purification.

Confinement is used as the primary engineered safety feature (ESF) incorporated into the preliminary hazards analysis and is detailed in NWMI PSAR Chapter 6.0, "Engineered Safety Features." Confinement is designed to limit the exchange of effluents between enclosures and its external environment to controlled monitored pathways. Along with confinement, sufficient negative pressure is to be maintained to prevent uncontrolled leakage outside the confined area. In addition, IROFS associated with the confinement system were derived from the accident analysis in NWMI PSAR Chapter 13.0, "Accident Analysis." The IROFS associated with the confinement system are designed to control the release of radioactive material and maintain radiation levels below applicable radiation exposure limits, as prescribed by 10 CFR Part 20, for the protection of workers and the public.

NWMI PSAR Section 11.1.1.1 states that targets are to be disassembled one at a time and the target material transferred to a dissolver. The irradiated target material is loaded into the

dissolver basket, lowered into the dissolver assembly, and dissolved in nitric acid. The production of Mo-99 through this process results in fission products, activation products, and actinides, which provide the majority of radiation sources within the NWMI facility. Airborne radioactive sources within the NWMI facility will consist of radioactive gases released during the recovery and purification of Mo-99. Radioactive gases will originate from three areas in the RPF, shown in NWMI PSAR Figure 11-1, "Radioisotope Production Facility Airborne Radiation Source Areas." These are the Target Fabrication Area (within the RPF, but outside the NWMI production facility), Tank Hot Cell (within the production facility), and Waste Management Area (within the production facility). NWMI PSAR Table 11-1, "Gaseous Radioactive Source," provides an extensive breakdown of the gaseous radioactive sources from routine operation from the weekly throughput of eight irradiated targets, not including decay. The basis of this bounding inventory is found in NWMI-2013-CALC-006, "Overall Summary Material Balance - MURR Target Batch" (Reference 72). The offgas expected consists of nitrogen oxide, nitric acid vapors, water vapor, and fission products. Nitrogen oxide and nitric acid vapors will be removed through a treatment subsystem of condensers and absorbers.

Fission product gases are released from the targets during processing. Gases containing fission products will go through a series of cleanup columns. The primary functions of the fission gas retention equipment is to remove radioiodine from the gas stream and delay the release of noble gases to allow release from the stack. Iodine will be absorbed from the offgas stream by the iodine removal unit, an ESF. Each iodine removal unit is expected to remove a significant percentage of iodine from the inlet stream. In conjunction with the dissolver offgas primary absorber and iodine guard bed, a decontamination factor of 10^5 is anticipated. An iodine radiation detector will be placed downstream of each iodine guard bed to verify adequate iodine removal. Other gaseous fission products will be delayed by absorption beds to allow for sufficient decay. For noble gases, gas release will be delayed prior to release from the stack. Preliminary analysis indicates xenon-133 controls the required delay, with a 60-day hold planned. Following processing through the primary absorber referred to above, a secondary absorber provides the bulk of the delay of 50 to 60 days.

As stated in 10 CFR 20.1101(d), licensees are required to establish a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughter products, such that the individual member of the public likely to receive the highest dose is not expected to receive a total effective dose equivalent (TEDE) in excess of 0.1 millisievert (mSv) (10 millirem [mrem]) per year from these emissions. NWMI used the guidance of Regulatory Guide (RG) 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors" (Reference 68), to evaluate the constraint requirement. The regulatory guide states that one method of demonstrating compliance with the requirement is through the use of computer codes.

As discussed in NWMI PSAR Section 11.1.1.1.2, NWMI used Level 4 of the COMPLY computer model, Version 1.6 (Reference 42), to demonstrate compliance with 10 CFR 20.1101(d) for the NWMI facility for normal operations. NWMI PSAR Table 11-2, "Radionuclide Stack Release Source Term Input to COMPLY," was developed by combining the effluent from each of the systems that is vented to the process vessel vent system and applying appropriate decontamination factors. This source term is based on the processing of eight (8) University of Missouri-Columbia Research Reactor (MURR) targets, 8 hours after irradiation is completed. Decay of krypton and xenon is included, as indicated above. The dose analysis considered the release of airborne radionuclides and exposure to off-site individuals through direct exposure and potential environmental pathways, such as the ingestion of leafy vegetables, meat, and milk. Meteorological data for the area and planned construction dimensions were used. The

maximum dose to the public at the nearest receptor (30 feet (9.1 meter) from the NWMI facility) under normal operating conditions was determined to be 0.036 milli-Sievert per year (mSv/yr) (3.6 millirem per year (mrem/yr)). Activities in the NWMI facility are designed such that the estimated annual doses to the maximally exposed individual and the nearest resident are below the dose constraint of 10 mrem/yr (0.1 mSv/yr) as specified in 10 CFR 20.1101(d).

In NWMI PSAR Section 4.1.2.1, "Process Design Basis," NWMI indicated that the nominal process design capability was 12 targets per week from MURR for up to 52 weeks per year, and approximately 30 targets per year to be received from Oregon State University (OSU). The staff noted that this exceeded the source term used in the COMPLY code, as described above, and issued RAI 11.1-1 (Reference 13) to obtain clarification on the impact to public dose from this increased throughput. NWMI stated in response to RAI 11.1-1 (Reference 17) that this section would be updated in the FSAR as part of the OL application and that the basis would be consistent with nominal operating conditions. The staff is tracking this issue in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions And Final Safety Analysis Report Commitments," of this SER. The primary dose contributor would be the noble gas xenon, and the offgas system's planned retention for decay, which is described in NWMI PSAR Section 11.1.1.1.2, would ensure that releases of xenon would remain below release limits. The staff finds that NWMI's response to RAI 11.1-1 is acceptable because it sufficiently clarifies the basis for the source term based on number of targets. Additionally, the staff notes that NWMI stated during the August 23, 2017, Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee meeting that routine radioactive release calculations provided in the FSAR would be based on the maximum amount of targets that its license would allow to be processed.

In NWMI PSAR Section 11.1.1.3, the applicant states that the processing of 30 targets from OSU will not occur until after approximately 48 hours of decay has occurred prior to receipt of the 30 targets at the NWMI facility, resulting in less radioactivity than the eight MURR targets evaluated in the application.

NWMI PSAR Section 11.1.1.2 states that liquid radioactive sources will be generated from Mo-99 recovery and purification, recycling of LEU, and liquids resulting from treatment of process gases. Dissolution of the irradiated targets results in uranyl nitrate solution with Mo-99. Uranium recovery and recycling will receive the uranyl nitrate solution once the Mo-99 is removed. The Mo-99 recovery and purification system is designed to extract the Mo-99 from uranyl nitrate through three cycles of ion exchange of varying chemical processes, each producing its own liquid waste stream and passed to the waste handling system, collected in Waste Collection Tank MR-TK-340 in the tank hot cell.

Liquid waste is split into high-dose and low-dose streams by concentration. The high-dose fraction will be adjusted and mixed with adsorbent material. Part of the low-dose liquid fraction is expected to be suitable for recycling to selected systems as process water. Water that is not recycled will be adjusted and then mixed with adsorbent material. No radioactive liquid discharges from the NWMI facility are planned for the sewer or the environment. PSAR Table 11-3, "Liquid Radioactive Source," provides the liquid waste inventory anticipated from the generic processing scheme described above, which is the effluent from the dissolver based on eight targets, 8 hours post-irradiation in a 1-week period. Any liquid radioactive waste will be treated and/or solidified prior to being packaged and shipped to a disposal facility.

NWMI PSAR Section 11.1.1.3 states that radioactive material is located in several locations within the NWMI facility, and includes fabricated material, irradiated material, and processed

material. The process starts with LEU in the target fabrication area. NWMI PSAR Table 1-1, "Special Nuclear Material Inventory of Target Fabrication Area," identifies the approximate mass of material for the fabrication process to support the weekly throughput of eight targets processed per week. NWMI PSAR Table 1-2, "Special Nuclear Material Inventory of Irradiated Material Areas," approximates the material on return from irradiation. NWMI will specify the possession limits that it is requesting in the OL application, but these tables are representative of the materials to carry out the process defined in the construction application.

Fresh LEU, irradiated LEU target material, and solidified waste make up the solid radioactive waste sources. Normally, solid radioactive material is contained in tanks and shielded hot cells within restricted areas. NWMI PSAR Table 11-4, "Solid Radioactive Source," provides a summary of the solid radioactive source term in the NWMI facility. This is based on the projected eight MURR targets, eight hours post-irradiation, representing one work week. The table includes the eight MURR targets and accumulated high-dose and low-dose waste from processing, neglecting decay, and was further explained in NWMI-2013-CALC-006. NWMI-2013-CALC-006 uses the general inventory of radioactive material and waste from the radioisotope extraction system, described in NWMI PSAR Chapter 4.0. Each of the sub-processes of disassembly, dissolution, and purification all contribute to the inventory, and are delineated in their respective sections in Chapter 4.0, but are listed in NWMI PSAR Table 11-4.

The staff reviewed the description of expected radiation sources and associated doses including the inventories, chemical and physical forms, and locations of radioactive materials, and other facility radiation and operational parameters related to radiation safety presented in the NWMI PSAR. This review included a comparison of the bases for identifying potential radiation safety hazards with the process and facility descriptions to verify that such hazards were accurately and comprehensively identified. This review and evaluation confirm that the application identifies the potential radiation safety hazards associated with the NWMI facility and provides an acceptable basis for development and independent review of the radiation protection program.

Based on its review, the staff finds that the level of detail provided for the preliminary design satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.1. The staff finds that the applicant sufficiently identified and described in the PSAR the potential radiation sources and associated doses including the inventories, chemical and physical forms, and locations of radioactive materials, and other facility radiation and operational parameters related to radiation safety. The staff also finds that the bases for identifying potential radiation safety hazards with the process and facility descriptions have been compared to verify that such hazards were accurately and comprehensively identified in the PSAR. Furthermore, the staff finds that, as described in the PSAR, the potential radiation safety hazards associated with the NWMI production facility provide an acceptable basis for the development of the radiation protection program. The staff review also finds that analyses of system operations show that planned releases of airborne radioactive material to the unrestricted environment will not expose the public to doses that exceed the limits of 10 CFR Part 20. Further information on radiation sources can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive material throughout the facility so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that the radiation sources of the NWMI production facility meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.2 Radiation Protection Program

The staff evaluated the sufficiency of the information provided on the radiation protection program, as described in NWMI PSAR Section 11.1.2, for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.2, "Radiation Protection Program," of NUREG-1537, Parts 1 and 2. Consistent with the review procedures of NUREG-1537, Part 2, Section 11.1.2, the staff evaluated: (1) the roles, responsibilities, authorities, organization, and staffing of the radiation protection organization; (2) the roles, responsibilities, authorities, staffing, and operation of committees responsible for the review and audit of the radiation protection program; (3) the effectiveness and comprehensiveness of the radiation protection training program; (4) radiation protection plans and information that form the bases of procedures and the management systems employed to establish and maintain them; (5) the effectiveness and comprehensiveness of the program for independent oversight reviews and audits of the radiation protection program; (6) the effectiveness and comprehensiveness of the process to evaluate the radiation protection program to improve the program and the process to examine problems and incidents at the facility; and (7) the management of records relating to the radiation protection program.

The staff reviewed NWMI PSAR Section 11.1.2 to evaluate commitments by NWMI to implement the requirements of 10 CFR 20.1101 for its radiation protection program. The application includes commitments related to key program personnel, radiation protection program staffing, independence of the radiation protection program from facility operations, establishment and functioning of a RSC, development of radiation protection procedures, providing radiation protection training, conducting radiation safety audits, and record-keeping activities. In response to RAI 11.1-2a (Reference 17), NWMI states that it will provide its radiation protection program as part of its OL application. The staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 11.1.2 states that NWMI management is committed to conducting radiological operations in a manner that ensures the health and safety of employees, contractors, and the public. NWMI commits to protecting workers, the public, and the environment from unacceptable exposure to ionizing radiation sources. NWMI commits to ensuring that radiation exposure to workers and the public, and releases of radioactivity to the environment, are maintained below regulatory limits. NWMI states that the radiation protection program will protect the radiological health and safety of workers and members of the public and comply with the regulatory requirements in 10 CFR Part 19 and 10 CFR Part 20.

NWMI PSAR Section 11.1.2.1, "Responsibilities of Key Program Personnel," states that the NWMI COO has overall responsibility for the operation of the NWMI facility, including radiation protection. A detailed NWMI organization chart is provided in NWMI PSAR Chapter 12.0, "Conduct of Operations," Figure 12-1, "Northwest Medical Isotopes, LLC Organization Chart," and displays the organizational reporting hierarchy. The COO reports directly to the President and Chief Executive Officer for operational aspects of the company, including safety, quality, security and safeguards, and regulatory licensing. The organizational structure identifies internal and external functions for NWMI, including interface responsibilities for multiple organizations.

NWMI PSAR Section 11.1.2.3, "Independence of the Radiation Protection Program," states that the NWMI radiation protection program is established independent of facility operations, which helps ensure that the radiation protection program maintains its objectivity and is focused only

on implementing sound radiation protection principles necessary to achieve occupational doses and doses to members of the public that are ALARA.

NWMI PSAR Section 11.1.2.1.1, “Plant Manager,” identifies the responsibilities of the Plant Manager. The NWMI Plant Manager, another direct reporter to the COO, is responsible for the safe operation of the NWMI facility, including the protection of workers and the public against radiation exposure resulting from facility operations and materials. The Plant Manager is responsible for ensuring compliance with applicable NRC, State, and local regulations.

NWMI PSAR Section 11.1.2 states that NWMI policy is to maintain a radiation protection program commensurate with the scope of NWMI facility operations, and to the extent practical, use procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are consistent with the ALARA program. NWMI plans to perform an annual review of the content and implementation of the radiation protection program.

NWMI PSAR Section 11.1.2 states that NWMI established administrative exposure limits below the regulatory limits specified in 10 CFR Part 20 in order to ensure that those dose limits are not exceeded and to emphasize ALARA principles. The administrative occupational exposure limit is set at 2 rem/year. Constraints on atmospheric releases from the NWMI facility have been established to ensure that no member of the public would be expected to receive a TEDE in excess of 0.1 mSv/yr (10 mrem/yr).

NWMI PSAR Section 11.1.2 states that the ALARA goal and dose investigation level is set at 500 mrem/yr. In NWMI PSAR Section 11.1.2 and in its response to RAI 11.1-2d (Reference 17), NWMI described its definition of “dose investigation level,” stating that if an individual exceeded 500 mrem TEDE in a year, it would trigger an investigation by the radiation protection staff to determine the basis of the exposure, if the individual would normally not be expected to receive that dose. Additionally, NWMI explained that the routine TEDE for the workers was not expected to approach this level. Furthermore, NWMI added that the investigation process might include interviews with the individual and their immediate supervisor and a review of radiation work permits (RWPs) and procedures.

NWMI PSAR Section 11.1.2, Table 11-5, “Estimated Radioisotope Production Facility Controlled and Restricted Area Dose Rates,” provides dose rates for a variety of areas within the NWMI facility. In its response to RAI 11.1-2a, which requested the basis of the dose rates, NWMI explained that these values were either based on actual shielding calculations or were the goals and/or endpoints of the shielding analysis. NWMI indicated that the table will be updated in the FSAR. The staff finds this response acceptable because it sufficiently clarifies the basis for the dose rates. The staff is tracking this issue in Appendix A of this SER. In NWMI PSAR Section 11.1.2, NWMI stated that dosimetry is anticipated to be required in any radiologically restricted area. Additionally, NWMI plans to add information in its FSAR describing the area monitoring program to be implemented in order to demonstrate compliance with exposure limits.

NWMI PSAR Section 12.2, “Review and Audit Activities,” states that the Plant Manager establishes the Review and Audit Committee to ensure that appropriate technical expertise is available for review and audit activities. NWMI PSAR Section 12.2.1, “Composition and Qualifications,” states that the Review and Audit Committee will provide the Plant Manager and NWMI management an independent assessment of NWMI facility operations. The number and qualifications of members of the committee and potential use of members from outside the organization will be established in the FSAR as part of the NWMI OL application. With respect

to independence of auditors, NWMI PSAR Section 12.2.4, “Audit Function,” states that individuals with immediate responsibility for an area cannot perform an audit in their area of responsibility. NWMI will establish relationships with outside expertise in NWMI facility audits. With respect to operations of the Review and Audit Committee, NWMI PSAR Section 12.2.2, “Charter and Rules,” states that a charter will be established to address items such as meeting frequency, quorum for meeting, and protocols. NWMI PSAR Section 12.2 states that a report of the activities of the Review and Audit Committee will be provided to the COO. NWMI PSAR Section 12.2.3, “Review Function,” identifies a minimum list of items that will be reviewed by the committee. Included in this list are the radiation protection program, new procedures, new equipment, reportable occurrences, and operating abnormalities.

NWMI PSAR Section 11.1.2.1.2, “Safety, Health and Licensing Manager,” states the role of the NWMI Safety, Health, and Licensing (SH&L) Manager, who has overall responsibility for development and implementation of programs addressing worker safety and health. The SH&L Manager is responsible for NRC licensing, any State and local permitting, and compliance monitoring for license and permits. Safety and health is independent of operations and the SH&L Manager has the authority to shut down NWMI facility operations that are judged to be unsafe. The SH&L Manager also has responsibility for nuclear criticality safety, environmental protection, chemical safety, fire protection, security, emergency preparedness, and the integrated safety analysis.

NWMI PSAR Section 11.1.2.1.3, “Radiation Protection Manager,” states that the NWMI RPM reports directly to the SH&L Manager, who reports directly to the COO. While the SH&L Manager is tasked with overall responsibility for NRC licensing, the RPM is primarily responsible for the radiation protection program and, organizationally, has direct access to the COO in matters of radiological protection.

The RPM has primary responsibility for the development and implementation of programs affecting personnel radiation exposures and environmental impacts due to operations of the NWMI facility. The RPM is responsible for the following, described in Section 11.1.2.1.3 of the NWMI PSAR:

- Establishing and implementing the radiation protection program for the NWMI facility.
- Serving as the facility Radiation Safety Officer.
- Generating and maintaining procedures associated with the radiation protection program.
- Reviewing and auditing the radiation protection program to ensure compliance with regulations and associated regulatory guides.
- Adequate staffing of the radiation protection program for implementation.
- Establishing and maintaining the ALARA program.
- Establishing and maintaining the respiratory protection program.
- Monitoring internal and external worker doses.

- Complying with radioactive materials possession limits.
- Responsible for the calibration and quality assurance of radiological instrumentation.
- Establishing and maintaining the radiation safety training program.
- Performing annual audits of the radiation protection program.
- Establishing and maintaining the radiological environmental monitoring program.
- Posting restricted areas and developing occupancy guidelines.

NWMI PSAR Section 11.1.2.4, "Radiation Safety Committee," states that NWMI plans to use a Radiation Safety Committee to review the status of projects, performance, trends, and aspects of facility operations. The RPM chairs the Radiation Safety Committee and the committee is made up of staff from quality assurance (QA), operations, maintenance, and technical support, as deemed appropriate by the Plant Manager. The committee meets at least semi-annually. Minutes of the meetings are forwarded to all managers.

NWMI monitors performance through a graded approach to items and activities that affect the quality-related SSCs. The QA program is described in NWMI PSAR Chapter 12.0, Appendix C, "Quality Assurance Program Plan for the Design, Construction, and Operation of the Radioisotope Production Facility," and outlines responsibilities from the COO to facility staff for engagement in quality performance. Requirements for the QA organization include not only the review and implementation of procedures, but also the administration of corrective action and nonconformance, and the monitoring and implementation of the QA program plan through assessment, audit, and surveillance.

NWMI PSAR Chapter 12.0, Appendix C, Section C2.1.2.4.1, "Operations Manager," states that the Operations Manager reports directly to the Plant Manager and has responsibility for day-to-day NWMI facility operations activities. Inherent in this responsibility is assuring that operations are conducted safely and in compliance with license conditions.

NWMI PSAR Chapter 12.0, Appendix C, Section C2.1.2.5.1, "Shift Supervisors," states that the shift supervisors report to the Operations Manager and are first-line supervision for the safe operation of the NWMI facility. Shift supervisors will authorize day-to-day activities, including control of access to the facility, deliveries and shipments, work activities, equipment startup and shutdown, and directing abnormal and emergency actions.

NWMI PSAR Chapter 12.0, Appendix C, Section C2.1.3, "Staffing," states that NWMI will provide sufficient resources in personnel and materials to safely conduct operations. Staffing levels, staffing considerations, overtime restrictions, detailed procedures, and routine operations will be defined in the FSAR as part of NWMI's OL application. On-site personnel are required to work safely and to follow the rules, regulations, and procedures that have been established for their protection and the protection of the public. Personnel whose duties require (1) working with radioactive material, (2) entering restricted areas, (3) controlling facility operations that could affect effluent releases, or (4) directing the activities of others, are trained so that they understand and effectively carry out their responsibilities.

NWMI PSAR Section 12.1.4, “Selection and Training of Personnel,” states that the Procedures and Training Manager will be responsible to the Plant Manager for the development and implementation of training that ensures satisfactory operational performance in the areas of nuclear, industrial, and radiological safety. NWMI commits to ANSI/ANS 15.4-2007, “Selection and Training of Personnel for Research Reactors” (Reference 44), for the selection and training of personnel, including record maintenance and retention.

In NWMI PSAR Section 11.1.2.2, “Staffing of the Radiation Protection Program,” NWMI commits to providing sufficient resources in staffing and equipment for implementing an effective radiation protection program. The RPM will have a bachelor’s degree (or equivalent), as a minimum, in an engineering or scientific field and 4 years of applicable nuclear experience. NWMI commits that other members of the radiation protection staff will be trained and qualified consistent with ANSI/ANS 15.11-2009, “Radiation Protection at Research Reactor Facilities” (Reference 59).

NWMI PSAR Section 11.1.2.8, “Radiation Work Control Procedures,” states that all work performed in restricted areas of the NWMI facility will be performed under a RWP and consistent with the guidance RG 8.10, “Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable” (Reference 81). Procedures will be used to control radiation protection activities to ensure that the activities are carried out in a safe, effective, and consistent manner. Routine and non-routine activities will be performed under an RWP. Radiation protection procedures are to be prepared, reviewed, and approved to carry out activities related to the radiation protection program. Radiation protection procedures will be reviewed and revised, as necessary, by the radiation protection supervisor to incorporate any facility or operational changes.

NWMI PSAR Section 12.3, “Procedures,” states that operating procedures will provide appropriate direction to ensure that the NWMI facility is operated within its design basis and in compliance with TSs. Operating procedures will be written, reviewed, approved by appropriate management, controlled, and monitored to ensure that content is technically correct and that the wording and format are clear and concise. Procedure changes, including substantive and minor changes and temporary deviations, will comply with guidance in ANSI/ANS-15.1-2007, “The Development of Technical Specification for Research Reactors” (Reference 43).

NWMI PSAR Section 11.1.2.8 states that the RWPs will be developed with a limited duration and validity, except for standing RWPs, such as tours of the NWMI facility by shift personnel. The RPM, or designee, will approve an RWP. A designee must meet specific training requirements. The general idea is that an RWP will consider all necessary precautions, such as personal protective equipment, applicable stay times, recordkeeping, and required technician oversight. The issue and closure of an RWP will be the responsibility of the RPM. Shift supervisors are responsible for authorization of work activities in accordance with the RWP. RWPs will require the following:

- Review of planned activities and changes to activities inside restricted areas, or work with licensed material for potential to cause radiation exposures exceeding action levels or produce contamination.

- Specifying requirements for safety controls, personnel protective equipment, personnel monitoring, respiratory equipment, air sampling requirements, and technician oversight.

- Posting of RWPs at access points to restricted areas.

- Clear definition of work scope allowed.
- RWP closure.
- Record retention.

NWMI PSAR Section 11.1.2.5, “Training Programs,” states that all staff and visitors entering restricted areas will receive training commensurate with the radiological hazard to which they may be exposed. Visitors will be provided with trained escorts who have received radiation protection training. The design and implementation of the radiation protection training program will comply with the requirements of 10 CFR 19.12, “Instruction to workers.” Records of training will be maintained in accordance with 10 CFR Part 20.2110, “Form of records.”

Radiation protection training for NWMI facility staff will take into consideration a worker’s normally assigned work activities. The extent of these instructions will be commensurate with the radiological health protection considerations appropriate for the workplace. The development and implementation of the radiation protection training program will be consistent with the guidance provided in the following regulatory guidance documents:

- ASTM E1168-95, “Standard Guide for Radiological Protection Training for Nuclear Facility Workers” (Reference 91)
- ANSI/ANS-15.11, “Radiation Protection at Research Reactor Facilities” (Reference 59)
- RG 8.10, “Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable” (Reference 81)
- RG 8.13, “Instruction Concerning Prenatal Radiation Exposure” (Reference 69)
- RG 8.29, “Instruction Concerning Risks from Occupational Radiation Exposure” (Reference 74)

NWMI states that the level of radiation protection training is based on the potential radiological health risks associated with an employee's work responsibilities and incorporates the provisions of 10 CFR 19.12. In accordance with 10 CFR 19.12, any individual working at the facility who is likely to receive, in a year, a dose in excess of 1 mSv (100 mrem) shall be:

- Kept informed of the storage, transfer, or use of radioactive material.
- Instructed in the health protection problems associated with exposure to radiation and radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed.
- Required to observe, to the extent within the worker's control, the applicable provisions of the NRC regulations and licenses for the protection of personnel from exposure to radiation and radioactive material.

- Instructed of their responsibility to report promptly to the facility management, any condition which may cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and radioactive material.

- Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and radioactive material.

- Advised of the various notifications and reports to individuals that a worker may request in accordance with 10 CFR 19.13, “Notifications and reports to individuals.”

Retraining of previously trained personnel will be performed for radiological, chemical, industrial, and criticality safety at least annually. The retraining program will also include procedure changes and updating and changes in required skills. Changes to training will be implemented, when required, due to incidents potentially compromising safety or if changes are made to the facility or processes. Records of training will be maintained in accordance with the NWMI records management system. Training programs will be established in accordance with NWMI PSAR Section 12.10, “Radioisotope Production Facility Operator Training and Requalification.” The radiation protection sections of the training program will be evaluated at least annually by the SH&L Manager. The program content will be reviewed to ensure that it remains current and adequate to ensure worker safety.

NWMI PSAR Section 12.2.4 states that all aspects of facility operations, including radiation protection and laboratory programs, emergency preparedness, physical security, and operator training and requalification, will be audited every 2 years. NWMI PSAR Section 12.2.3, “Review Function,” states that the radiation protection program will be audited annually, at a minimum, by the Review and Audit Committee, to review all functional elements of the program, and meet the requirements of 10 CFR 20.1101(c). Deficiencies identified during an audit will be entered into the NWMI corrective action program.

NWMI PSAR Section 12.6, “Records,” states that the records management program will define the process for managing NWMI facility records and will be consistent with the requirements of applicable regulations. NWMI PSAR Section 11.1.2.9, “Recordkeeping,” states that, for additional radiation protection program commitments applicable to records and reports, NWMI will meet the following:

- 10 CFR Part 20, Subpart L, “Records,” and Subpart M, “Reports”

- 10 CFR 70.51, “Records requirements”

- 10 CFR 50.71, “Maintenance of records, making of reports”

- ANSI/ANS-15.8, “Quality Assurance Program Requirements for Research Reactors” (Reference 45)

- ANSI/ANS-15.11, “Radiation Protection at Research Reactor Facilities” (Reference 59)

Included in the NWMI record-keeping commitments are program provisions such as content; audits; reviews; survey results, including air sampling; area monitoring and personnel monitoring, both internal and external; and corrective action program referrals.

Based on its review, the staff finds that the description of the radiation protection program presented in the NWMI PSAR complies with the applicable requirements and that the level of detail provided on the radiation protection program is adequate and satisfies the regulations in 10 CFR 20.1101 and the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.2. Commitments related to key program personnel, radiation protection program staffing, independence of the radiation protection program from facility operations, establishment and functioning of a RSC, development of radiation protection procedures, providing radiation protection training, conducting radiation safety audits, and record-keeping activities are included in the application.

The staff review also finds, consistent with the guidance in NUREG-1537, Part 2, Section 11.1.2, that the applicant describes: (1) the roles, responsibilities, authorities, organization, and staffing of the radiation protection organization; (2) the roles, responsibilities, authorities, staffing, and operation of committees responsible for the review and audit of the radiation protection program; (3) the effectiveness and comprehensiveness of the radiation protection training program; (4) radiation protection plans and information that form the bases of procedures and the management systems employed to establish and maintain them; (5) the effectiveness and comprehensiveness of the program for independent oversight reviews and audits of the radiation protection program; (6) the effectiveness and comprehensiveness of the process to evaluate the radiation protection program to improve the program and the process to examine problems and incidents at the facility; and (7) the management of records relating to the radiation protection program.

The staff finds that NWMI's description of the radiation protection program provides reasonable assurance of NWMI management's commitment to radiation protection in order to protect the facility staff, the environment, and the public from exposure to radiation.

The staff finds that further information on the radiation protection program can be reasonably left for later consideration in the FSAR since it is not expected to impact construction of the facility, and because the facility's design bases support the control of radioactive material throughout the facility so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that NWMI's description of its radiation protection program is sufficient, and therefore NWMI meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.3 ALARA Program

The staff evaluated the sufficiency of the information provided on the NWMI program for maintaining worker and public doses and radiological releases ALARA, as described in NWMI PSAR Section 11.1.3 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.3 of NUREG-1537, Part 2. Consistent with the review procedures of NUREG-1537, Part 2, Section 11.1.3, the staff review included an assessment of the applicant's ALARA program to ensure that: (1) radiation doses received by facility staff and members of the public are maintained ALARA; (2) the highest levels of facility management are committed to the ALARA program; (3) exposure records are periodically reviewed, analyzed for trends and factors, and methods evaluated for reducing exposures; and

(4) sufficient emphasis and resources are given to ALARA considerations during design, construction, operation, maintenance, and disposal activities.

NWMI PSAR Section 11.1.3.1, “ALARA Policy,” states that NWMI’s policy is to conduct radiological operations in a manner to ensure the health and safety of its employees, contractors, visitors, and the public. NWMI is committed to ensuring that radiation exposures to workers and the public, and that releases of radioactivity to the environment, are maintained below regulatory limits. Deliberate actions will be taken to further reduce exposures and releases in accordance with a process focused on keeping exposures or releases ALARA. NWMI is fully committed to implementing an ALARA program that consistently reflects this policy.

NWMI PSAR Section 11.1.3.2, “Approach to ALARA Program,” states that NWMI is committed to the implementation of an ALARA program. The objective of the program is to make every reasonable effort to maintain facility exposures as far below the dose limits of 10 CFR 20.1201 as practical, and to maintain the radiation exposures to the public below the dose constraints of 10 CFR 20.1301, “Dose limits for individual members of the public.” The goals of the NWMI ALARA program are to ensure that occupational exposures and environmental releases are as far below regulatory limits as reasonably achievable.

NWMI PSAR Section 11.1.3.2 states that the NWMI facility design incorporates ALARA principles into processes, systems, and components. As the design matures, NWMI staff continues to evaluate suggested approaches to reduce radiation dose to workers and the public. Areas where facility personnel are expected to spend significant time are designed so that dose rates are maintained ALARA. The areas with higher doses rates will be minimized. Radiation areas will be established to minimize the spread of contamination and reduce unnecessary exposure of personnel to radiation. NWMI states that the controls and procedures for limiting access and personnel exposure (including allowable doses, effluent releases, ALARA goals, and criteria used for the action levels in radiation alarms systems) meet the applicable radiation protection program requirements and provide reasonable assurance that radiation doses to the environment, the public, and facility personnel will be ALARA. The NWMI ALARA program is supported at the highest levels of management for the facility.

NWMI PSAR Section 11.1.3.2 states that the RPM is responsible for implementing the NWMI ALARA program and ensuring that adequate resources are committed to support an effective program. An annual ALARA program evaluation report will be prepared that summarizes (1) radiological exposure and effluent release data for trends; (2) audits and inspections; (3) use, maintenance, and surveillance of equipment used for exposure and effluent control; and (4) other issues, as appropriate, that may influence the effectiveness of the radiation protection and ALARA programs. Copies of the report will be submitted to the COO, Radiation Safety Committee, and Plant Manager.

NWMI PSAR Section 11.1.3.2 states that the Radiation Safety Committee will review the effectiveness of the ALARA program at least every quarter and determine if exposures, releases, and contamination levels are in accordance with ALARA principles. The committee will also evaluate the results of assessments made by the Radiation Protection organization and reports of facility radiation levels, contamination levels, and employee exposures for identified categories of workers and types of operations. The Radiation Safety Committee report will be forwarded to all facility managers for their review.

NWMI PSAR Section 11.1.3.2 states that the design and implementation of the ALARA program will be consistent with the guidance provided in RGs 8.2, "Administrative Practices in Radiation Surveys and Monitoring," 8.13, "Instruction Concerning Prenatal Radiation Exposure," 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," and 8.37, "ALARA Levels for Effluents from Materials Facilities" (References 71, 69, 74, and 76, respectively). The overall operation of the facility will be consistent with the guidance provided in RG 8.10. NWMI commits to following the guidance of RG 4.21, "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning" (Reference 47), to minimize, to the extent possible, contamination of the facility and the environment, the generation of radioactive waste, and facilitate decommissioning.

NWMI PSAR Section 11.1.5.1, "Process Design for ALARA," and Section 11.1.5.2, "Facility Design for ALARA," provide examples of ALARA considerations which were incorporated into the NWMI facility and process designs in order to reduce personnel radiation exposures. A few examples are listed below:

- Modularization of components.
- HVAC system designed to maintain airflow patterns from lowest to highest potential for contamination.
- Conduct of maintenance and repair in lower radiation areas.
- Remote operation of equipment.
- Processing of irradiated targets under sub-atmospheric pressure.
- Equipment and component design to reduce the need for repair or maintenance.
- Equipment and piping design to minimize accumulation of radioactive materials.
- Remote cleaning and decontamination.

Based on its review, the staff finds that the level of detail provided on the ALARA program satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.3, and is consistent with the applicable guidance contained in RG 8.10. Specifically, the staff finds that the applicant's ALARA program helps to ensure that: (1) radiation doses received by facility staff and members of the public are maintained ALARA; (2) the highest levels of facility management are committed to the ALARA program; (3) exposure records are periodically reviewed, analyzed for trends and factors, and methods evaluated for reducing exposures; and (4) sufficient emphasis and resources are given to ALARA considerations during design, construction, operation, maintenance, and disposal activities.

Additionally, the staff finds that the applicant has clearly defined an ALARA program that has guided the design of plant features to ensure that occupational and public exposures will be maintained at the lowest practicable level; the applicant has designated a responsible individual for developing the ALARA program and formally evaluating its effectiveness annually; and a number of ALARA features have been included in plant design, such as attention to shielding to avoid radiation streaming situations, inclusion of maintenance features that provide for remote handling and flushing of components, features that minimize build-up of radioactive material in pipes, tanks, and other components, and separation of components and use of shielding whenever practical. The staff will review NWMI's ALARA program again during its review of the OL application.

Based on the information provided above, the staff concludes that the ALARA program is adequate and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.4 Radiation Monitoring and Surveying

The staff evaluated the sufficiency of the information provided on the NWMI radiation monitoring equipment and surveying program, as described in NWMI PSAR Section 11.1.4 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.4, "Radiation Monitoring and Surveying," of NUREG-1537, Part 2. The staff also considered the design of the instrumentation systems used for both routine and special radiation monitoring and sampling consistent with the applicable acceptance criteria in NUREG-1537, Part 2. The staff also evaluated the locations of air sampling or monitoring equipment to measure airborne concentrations of radioactive material to which people are exposed. The staff coordinated this review with the Chapter 7.0, "Instrumentation and Control Systems," review, and evaluated the design of the radiation instrumentation systems used for radiation monitoring and dosimetry, consistent with the acceptance criteria. The staff also considered whether these radiation monitors and alarm systems will be maintained, operated, calibrated, and subjected to surveillance in compliance with the appropriate standards and are addressed in the TSs. The staff reviewed the facility warning and annunciator systems to ensure they are designed to alert personnel to a radiological hazard or abnormal condition in sufficient time to enable them to respond in a planned appropriate manner. Finally, the staff also confirmed that the interface between the radiation monitoring system and the ESFs and the discussion of the radiation monitoring system in the emergency plan are appropriate.

NWMI PSAR Section 11.1.4 states that radiation surveys will be conducted for two purposes: (1) to ascertain radiation levels, concentrations of radioactive materials, and potential radiological hazards that could be present in the facility; and (2) to detect releases of radioactive material from facility equipment and operations. Radiation surveys will focus on those areas of the facility where the occupational radiation dose limits could potentially be exceeded.

Measurements of airborne radioactive material and/or bioassays will be used to determine that internal occupational exposures to radiation do not exceed the dose limits specified in 10 CFR Part 20, Subpart C, "Occupational Dose Limits."

NWMI PSAR Section 11.1.4 states that NWMI has established written procedures to ensure compliance with the requirements of 10 CFR Part 20, Subpart F, "Surveys and Monitoring." The procedures include program objectives, sampling procedures, and data analysis methods. Equipment selection is to be based on the type of radiation being monitored. The procedures will be developed for each instrument used, including the frequency and method of calibration, and the maintenance and calibration requirements. The survey program procedures will also specify the frequency of measurements and the recordkeeping and reporting requirements. The radiation survey and monitoring programs will be consistent with the guidance provided in the following references:

- RG 8.2, "Administrative Practices in Radiation Surveys and Monitoring" (Reference 71)
- RG 8.4, "Personnel Monitoring Device – Direct-Reading Pocket Dosimeters" (Reference 77)
- RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data" (Reference 78)

- RG 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program” (Reference 80)
- RG 8.25, “Air Sampling in the Workplace” (Reference 73)
- RG 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses” (Reference 75)
- ANSI N13.1, “Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities” (Reference 82)
- ANSI N13.6, “Practice for Occupational Radiation Exposure Records Systems” (Reference 83)
- ANSI N13.11, “Dosimetry-Personnel Dosimetry Performance Criteria for Testing” (Reference 84)
- ANSI N13.27, “Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters (Reference 85)”
- ANSI N323, “Radiation Protection Instrumentation Testing and Calibration – Air Monitoring Instruments” (Reference 86)
- ANSI/ANS 15.11, “Radiation Protection at Research Reactors” (Reference 59)
- ANSI/HPS N13.22, “Bioassay Programs for Uranium” (Reference 87)
- ANSI/HPS N13.30, “Performance Criteria for Radiobioassay” (Reference 88)
- NUREG-1400, “Air Sampling in the Workplace” (Reference 93)

NWMI PSAR Section 11.1.5.5.1, “Restricted Areas,” states that within the NWMI facility, access to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Personnel who have not been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

NWMI PSAR Section 11.1.4.1.1, “Personnel Monitoring,” states that three basic types of personnel monitoring equipment will be used at the facility: count rate meters (friskers), hand and foot monitors, and portal monitors. Friskers typically consist of handheld probes connected to a count rate meter and are used to ensure effective control of the spread of contamination. Handheld friskers will typically be placed in locations where conditions restrict the use of other monitors or for short-term use, as necessary, to ensure effective control of the spread of contamination. Instructions for the use of these instruments will be posted in a prominent location near the instrument. Hand and foot monitors typically consist of multiple detectors arranged to monitor only hands and feet. Hand and foot monitors will be used in applications where personnel need frequent egress. Portal monitors can quickly scan large surface areas of the body. Portal monitors will typically use large area beta and/or gamma sensitive detectors to monitor personnel.

NWMI PSAR Section 11.1.4 states that calibrations will be performed in accordance with established written procedures and documented prior to the initial use of, and a pre-determined frequency for, each airflow measurement instrument (used to measure flow rates for air or effluent sampling) and each radioactivity measurement instrument. Periodic operability checks will also be performed in accordance with established written procedures. Calibrations will be performed and documented on each airflow measurement and radioactivity measurement instrument, as follows:

- At least annually (or according to manufacturers' recommendations, whichever is more frequent)
- After failing an operability check
- After modifications or repairs to the instrument that could affect its proper response
- When the instrument is believed to have been damaged

Unreliable instruments will be removed from service until repairs are completed. Portal monitors, hand and foot monitors, and friskers will have the required sensitivity to detect alpha contamination on personnel to ensure that radioactive materials do not spread to the areas outside of the restricted areas. Instruments will be calibrated with sources that are within ±5 percent of the reference value and are traceable to the National Institute of Standards and Technology or equivalent.

NWMI PSAR Section 11.1.4 states that all personnel who enter restricted areas will be required to wear National Voluntary Laboratory Accreditation-compliant personnel dosimeters. Personnel will also be required to survey themselves prior to exiting restricted areas that may have the potential for contamination. All personnel whose duties require entry into restricted areas will wear individual external dosimetry devices (e.g., passive dosimeters such as thermoluminescent dosimeters (TLDs) that are sensitive to beta, gamma, and neutron radiation). External dosimetry devices will be evaluated at least quarterly to ascertain external exposures.

NWMI PSAR Section 11.1.6.1, “Routine Monitoring to Detect Contamination,” states that contamination survey monitoring will be performed for all process areas and areas in which radioactive materials are handled or stored. Surveys will include routine checks of non-process areas, including areas normally not contaminated. Monitoring will include direct radiation and removable contamination measurements. Survey procedures will be based on the potential for contamination of an area and operational experience. All restricted areas will be surveyed at least weekly. The change rooms will be surveyed at least daily. Various instruments, such as proportional counters and thin window Geiger-Mueller tubes, will be used at the NWMI facility to evaluate contamination levels.

NWMI PSAR Chapter 11.1.2.9, states that NWMI will maintain records of the radiation protection program (including program provisions, audits, and reviews of the program content and implementation), radiation survey results (air sampling, bioassays, external-exposure data from monitoring of individuals, internal intakes of radioactive material), and results of corrective action program referrals, RWPs, and planned special exposures. For additional program

commitments applicable to records and reports, activities in the NWMI facility will meet the following:

- 10 CFR Part 20 Subpart L, “Records,” and Subpart M, “Reports”
- 10 CFR 50.71, “Maintenance of records, making of reports”
- 10 CFR 70.51, “Records requirements”
- ANSI/ANS 15.8, “Quality Assurance Program Requirements for Research Reactors” (Reference 45)
- ANSI/ANS 15.11, “Radiation Protection at Research Reactor Facilities” (Reference 59)

Based on its review, the staff finds that the level of detail provided on radiation monitoring and surveying satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.4, allowing the staff to make the following findings: (1) the fixed and portable equipment used for radiation monitoring and sampling inside the production facility are appropriate for the tasks needed to be performed; (2) the general types of monitoring and surveillance equipment appear appropriate to the production facility; and (3) the commitments to implement a program consistent with NUREG-1537 and the ISG augmenting NUREG-1537 give reasonable assurance that radioactive material and associated radiation exposures will be detected, monitored, and sampled consistent with the 10 CFR Part 20 requirements and the facility ALARA program.

The staff also finds that the design of the instrumentation systems used for both routine and special radiation monitoring and sampling is effective to adequately monitor the production facility for radioactivity, and that the locations of air sampling or monitoring equipment are effective to measure airborne concentrations of radioactive material. The staff review also finds that radiation monitors and alarm systems will be maintained, operated, calibrated, and subjected to surveillance in compliance with the appropriate standards and will be addressed in the TSs. The staff finds that the production facility warning and annunciator systems are designed to alert personnel to a radiological hazard or abnormal condition in sufficient time to enable them to respond in a planned appropriate manner. Finally, the staff also confirmed that the interface between the radiation monitoring system and the ESFs and the discussion of the radiation monitoring system in the emergency plan are appropriate. Further information on radiation monitoring and surveying can be reasonably left for later consideration in the FSAR because the facility’s design bases support the control of radioactive material and monitoring for radiation throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR. Based on the information provided above, the staff concludes that the radiation monitoring and surveying program is adequate and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.5 Radiation Exposure Control and Dosimetry

The staff evaluated the sufficiency of the information provided on the NWMI radiation exposure control and dosimetry provisions, as described in NWMI PSAR Section 11.1.5, for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from

Section 11.1.5, “Radiation Exposure Control and Dosimetry,” of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria of NUREG-1537, Part 2, Section 11.1.5, the staff examined the facility exposure control and dosimetry programs for both external exposures and internal exposures to facility personnel and the public, and exposures to the environment, to confirm that plans and the bases of procedures for the control of external dose to workers and the public consider equipment and equipment design, shielding, radiation monitors and alarms, personnel protective equipment, and external radiation monitoring dosimetry. The staff also considered whether procedures for the control of internal exposure consider equipment and equipment design, engineered controls, personnel protective equipment, radiation monitors, alarms and samplers, bioassay methods, frequency, and action levels, and the models and methods used for internal dose evaluation.

The staff reviewed the engineered controls used to ensure radiation protection safety for each of the sources of radiation and radioactive material described in NWMI PSAR Section 11.1.1. The staff considered whether radiation protection measures have been implemented for sources of radiation and radioactive material. The staff reviewed that the radiation dose limits and bases were identified and the plans and programs to control doses were documented. The staff reviewed the descriptions of facility exposure conditions and methods used to derive administrative radiation dose limits. The staff evaluated the radiation protection engineered controls (e.g., the provisions of shielding, ventilation systems, and remote handling systems) to evaluate whether the design to reduce the potential for uncontrolled exposure or release was incorporated in the facility. The staff also reviewed the record keeping used to establish the conditions under which individuals were exposed to radiation.

The staff reviewed the engineered radiation exposure controls employed at the NWMI facility to determine whether the applicant provided sufficient information about the design of the confinement, radiological shielding, ventilation, remote handling, decontamination equipment, and entry control devices to allow for an assessment of the design of these radiological protection features. The staff reviewed whether the entry control devices employed were adequate to alert workers to, or prevent entry into, radiological areas, including high-radiation or very-high radiation areas, and whether the confinement system design provided reasonable assurance that uncontrolled radiological releases to the unrestricted environment, controlled area, or the restricted work area should not occur during any anticipated normal operations.

NWMI PSAR Section 11.1.5, states that NWMI management is committed to protecting NWMI facility workers, the public, and the environment from unacceptable exposure to radiation sources. NWMI’s policy is to conduct radiological operations in a manner that ensures the health and safety of employees, contractors, and the public. In achieving this objective, NWMI ensures that radiation exposure to workers and the public, and releases of radioactivity to the environment, are maintained below regulatory limits. Deliberate actions will be taken to further reduce exposures and releases in accordance with a process focused on keeping exposures and releases ALARA.

In 10 CFR Part 20, a “controlled area” is defined as an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. Due to the presence of administrative and physical barriers, members of the public do not have direct access to the controlled area of the facility and must be processed by security and authorized to enter the facility. NWMI PSAR Section 11.1.5.5.1 states that training for access to a controlled area is provided commensurate with the radiological hazard. Within the NWMI facility, access

to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Personnel who have not been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

NWMI PSAR Section 11.1.5.3, "Control of Entry," describes that the NWMI facility will include areas locked to limit access and alarms and signals that alert workers to or prevent unauthorized entry into radiation areas, high radiation areas, and very high radiation areas. Radiological zones with varied definitions and span of control have been designated for the facility site. The purpose of these zones is to: (1) control the spread of contamination; (2) control personnel access to avoid unnecessary exposure of personnel to radiation; and (3) control access to radioactive sources present in the facility. Public access to radiological zones is restricted as detailed in this section and as directed by facility management. Areas where personnel spend substantial amounts of time are designed to minimize the exposure received when routine tasks are performed, in accordance with the ALARA principles.

The following paragraphs describe the application of radiological area definitions in 10 CFR Part 20 to the NWMI facility and how the radiation protection program is implemented to protect workers and the general public on the NWMI site:

- **Unrestricted area**

  NWMI PSAR Section 11.1.5.5.3, "Unrestricted Areas," states that for the NWMI facility, the areas not specifically included within the definitions of restricted and controlled areas will be considered unrestricted areas. These areas can be accessed by facility personnel and by the public. The unrestricted area is governed by the limits in 10 CFR 20.1301," with the TEDE to individuals from the licensed operation not to exceed 1 mSv (100 mrem) in a year (exclusive of background radiation) or exceed 0.02 mSv (2 mrem) in any 1 hour.

- **Controlled area**

  NWMI PSAR Section 11.1.5.5.2, "Controlled Area," states that for the NWMI facility, the controlled area is the area within the perimeter fence but outside the restricted area and the Administrative Building, as shown in NWMI PSAR Figure 11-5, "Controlled and Unrestricted Areas." The area fence will limit public access to the controlled area of the site. Training for access to a controlled area will be provided commensurate with the radiological hazard. Area monitoring will demonstrate compliance with public exposure limits for such visitors. All NWMI personnel or contractor employees who work only in the controlled area will be subject to the exposure limits for the public, as stated in 10 CFR 20.1301.

- **Restricted area**

  NWMI PSAR Section 11.1.5.5.1 states that within the NWMI facility, access to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Personnel who have not been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

NWMI PSAR Section 11.1.5.5.1 also provides that additional areas defined below may exist within the restricted area. These areas may be temporary or permanent. The areas are posted to inform workers of the potential hazard in the area and to help prevent the spread of contamination. These areas are conspicuously posted in accordance with the requirements of 10 CFR Part 20 and are defined in the application as follows:

- A “radiation area” is defined as an area where radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (5 mrem) in 1 hour (hr) at 30 centimeters (cm) from the radiation source or from any surface that the radiation penetrates.

- A “high radiation area” is defined as an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (100 mrem) in 1 hr at 30 cm from the radiation source or 30 cm from any surface that the radiation penetrates.

- A “very high radiation area” is defined as an area, accessible to individuals, in which radiation levels exceed 5 Sievert (Sv) (500 rem) in 1 hr at 1 meter (m) from the source or from any surface that the radiation penetrates. The hot cells within the NWMI facility are an example of a very high radiation area. The hot cells will be radiologically shielded and isolated from access to individuals by the use of engineered physical barriers, including structural shield blocks and locked shield doors.

- An “airborne radioactivity area” is defined as an area, room, or enclosure where airborne radioactive materials either exist in concentrations that exceed the derived air concentrations (DAC) specified in 10 CFR Part 20, Appendix B, “Annual Limits on Intake [ALIs] and Derived Air Concentrations of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” or where an individual present in the area without respiratory protection equipment could exceed, during the hours the individual is present in a week, an intake of 0.6 percent of the ALI or 12 DAC-hr. There are no identified permanent airborne radioactive areas with the NWMI facility.

NWMI PSAR Section 11.1.5.5.1 states that areas that are designated as high radiation or very high radiation areas will not be accessible to individuals during routine operation of the NWMI facility. These areas will be radiologically shielded and isolated from access to individuals by the use of engineered physical barriers that include structural shield blocks and/or locked shield doors.

In its response to staff RAI 11.1-3a (Reference 17), which requested the requirements (e.g., dosimetry, personal protective equipment, etc.) and access controls for entering the NWMI

facility, NWMI indicated that the entire NWMI facility is a controlled area and that each door will have a two-credential access (e.g., fob/PIN, fob/biometric, or biometric/PIN) to access the Restricted Area within the NWMI facility. Furthermore, the RPP will require personnel to access dosimetry and portable survey instrumentation, as needed per the Radiation Work Permit, before entering the Restricted Area. Specific information on survey monitoring for individuals exiting the Restricted Area will be described in the FSAR. The staff is tracking this issue in Appendix A of this SER, and finds NWMI's response acceptable because it provides sufficient assurance that NWMI has incorporated ALARA into its preliminary design.

NWMI PSAR Section 11.1.5.2 describes the engineered features built into the NWMI facility design, which are active or passive features designed to mitigate the consequences of accidents and to keep radiological exposures to workers, the public, and the environment within acceptable values. Some of these features, as well as other ways in which radiation exposures are controlled, are listed below:

- Controlling HVAC system contamination by maintaining ventilation flow patterns from areas of lower radioactivity to higher radioactivity.

- Remote operation of processes, as well as the ability to conduct maintenance on equipment remotely.

- Facility Layout, to ensure access to a given area does not require passing through a higher radiation zone area.

- Processing irradiated targets and purification of Mo-99 under sub-atmospheric pressure.

- Providing redundancy of equipment or components to reduce the need for immediate repair to allow for reduction in radiation levels via decay.

- Training facility personnel in emergency evacuation procedures.

- Modularization of components.

NWMI PSAR Section 11.1.5.4, "Protective Equipment and Materials," states that personnel working within the restricted area will be required to wear appropriate personal protective clothing. Protective clothing, as prescribed by the RWP, will be selected based on the contamination level in the work area, anticipated work activity, worker health considerations, and consideration for non-radiological hazards present. Areas requiring protective clothing will be posted at each of the associated entry points. Radiation protection management and technical staff will be responsible for determining the need for protective clothing in each work area and for documenting the requirements in the RWP.

NWMI PSAR Section 11.1.6, "Contamination Control," states that when establishing radiological controls for work involving potential airborne radioactivity, the first consideration will be to use techniques that help prevent or reduce the potential for airborne radioactivity and maintain loose surface contamination in controlled areas within ALARA levels. Based on air sampling results and work evolutions, the RPM will select the appropriate respiratory protection required. Airborne radioactivity concentrations will be minimized to the extent practical by the use of engineered controls (e.g., confinement, ventilation, etc.). Respiratory protection equipment requirements will be specified on the area RWP.

NWMI PSAR Section 11.1.5.6.2, “External Dose,” states that external dose will primarily be received from the fission products produced from irradiated targets and associated processing. All personnel whose duties require entry into restricted areas will wear individual external dosimetry devices (e.g., passive dosimeters such as TLDs that are sensitive to beta, gamma, and neutron radiation). External dosimetry devices will be evaluated at least quarterly to ascertain external exposures. The ALARA goal on radiation exposure is set at 5 mSv/yr (500 mrem/yr) based on an administrative limit of 10 percent of the NRC limit of 0.05 Sv/yr (5 rem/yr) given in 10 CFR 20.1201. NWMI PSAR Section 11.1.5.6.2 states that if 25 percent of the ALARA goal (1.25 mSv [125 mrem]) is exceeded in any quarter, an investigation will be performed to determine what types of activities may have contributed to the worker’s external exposure. This investigation may include procedural reviews, efficiency studies of the air-handling system, cylinder storage protocol, and work practices, and the results will be documented. The RPM will be informed whenever an administrative limit is exceeded. The RPM will be responsible for determining the need for, and recommending, investigations or corrective actions to the responsible manager(s).

NWMI PSAR Section 11.1.5.6.1, “Internal Dose,” states that internal exposures for selected personnel are evaluated via direct bioassay (e.g., in vivo body counting), indirect bioassay (e.g., urinalysis), or an equivalent technique. For soluble (Class D) uranium, 10 CFR 20.1201(e) limits worker intake to no more than 10 milligrams of soluble uranium in a week. This limit is to protect workers from the toxic chemical effects of inhaling Class D uranium. If the facility annual administrative limit is exceeded, as determined from bioassay results, an investigation will be performed to determine what types of activities may have contributed to the worker’s internal exposure. Continuous air monitoring in airborne radioactivity areas may be performed to complement the bioassay program. Alarm setpoints on the CAMs in the airborne radioactivity areas may be used to provide an indication that internal exposures may be approaching the action limit. The NWMI facility annual administrative limit for the TEDE will be 0.02 Sv (2 rem). Internal doses will be evaluated at least annually.

NWMI PSAR Section 11.1.2.9 states that NWMI will report to the NRC any event that results in an occupational exposure to radiation exceeding the dose limits in 10 CFR Part 20 within the time specified in 10 CFR 20.2202, “Notification of incidents.” NWMI will prepare and submit an annual report of the results of individual monitoring to the NRC, as required by 10 CFR 20.2206, “Reports of individual monitoring.”

NWMI PSAR Section 7.6.3.1, “Air Monitoring,” states that radiation area monitor (RAMs) detector units will be housed in an environmentally suitable container that is mounted in a duct, on a wall, or other suitable surface. The sensitivity of each detector will be sufficient to have the alarm setpoint an order of magnitude higher than the detector threshold. Detectors are designed to be operational over a wide range of temperatures. Sensors will be mounted as close as practical to the most probable radiation sources with no objects, persons, pillars, and piping that could serve as shielding. The sensors will also be mounted so as to minimize inaccuracies due to any directionality of the detector. The RAMs are to be located in areas where personnel may be present and where radiation levels could become significant based on the following considerations:

- Occupancy status of the area, including time requirements of personnel in the area, the proximity to primary and secondary radioactive sources.

- Potential for increase in the background radiation level.

- Desirability of surveillance of infrequently visited areas.

NWMI PSAR Section 7.6.3.1 states that when the radiation (dose or dose rate) exceeds pre-determined levels, alarms will actuate in the control room and at selected detector locations. Visual alarms are to be accompanied by a simultaneous alarm annunciator at the selected detector locations and in the control room. The annunciator windows for the monitors will be located in the control room. The alarm can be manually reset when the alarm conditions are corrected. The local alarm horns and warning lights will remain on until the radiation level is below the preset level.

In its response to staff RAI 11.1-7 (Reference 17), which requested a description of the area monitoring plan and equipment NWMI intends to use to demonstrate compliance with public exposure limits, NWMI provided a general description of equipment and frequency of evaluation. Area monitoring is anticipated to be comprised of a combination of passive monitoring (TLDs changed out monthly or quarterly) and active monitoring systems (energy compensated Geiger-Mueller detector systems with local and remote monitoring capability). NWMI indicated that further details on the area monitoring program will be provided in the FSAR. The staff is tracking this issue in Appendix A of this SER, and finds that NWMI's response provides sufficient information for a preliminary design.

Based on its review, the staff finds that the level of detail provided on radiation exposure control and dosimetry provisions satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.5. The staff finds that NWMI's Restricted Area, Controlled Area, and Unrestricted Area definitions, proposed access controls, and area radiological posting methodology is consistent with the applicable requirements of 10 CFR Part 20 because they include required elements important to radiation exposure control. The staff finds that NWMI's use of exposure control and dosimetry programs for both external exposures and internal exposures of production facility personnel and the public, and exposures to the environment, is consistent with applicable regulations and guidance because it helps provide reasonable assurance that doses will be maintained ALARA and within applicable regulations. The staff finds that the plans and bases of procedures for the control of external dose to workers and the public consider equipment and equipment design, shielding, radiation monitors and alarms, personnel protective equipment, and external radiation monitoring dosimetry, which is also consistent with applicable regulations and guidance because these considerations help ensure adequate radiation exposure control. The staff additionally finds that the procedures for the control of internal exposure consider equipment and equipment design, engineered controls, personnel protective equipment, radiation monitors, alarms and samplers, bioassay methods, frequency, and action levels, and the models and methods used for internal dose evaluation, consistent with applicable regulations and guidance because these considerations are important for adequate control and assessment of internal radiation exposures.

The staff finds that the engineered controls used to ensure radiation protection safety for each of the sources of radiation and radioactive material are adequately described in NWMI PSAR Section 11.1.1. The staff finds that radiation protection measures have been implemented for sources of radiation and radioactive material. The staff finds that the applicant's proposed radiation dose limits and bases were identified and the plans and programs to control doses were adequately documented. The staff finds that the descriptions of facility exposure conditions and methods used to derive administrative radiation dose limits were adequately documented. The staff finds that radiation protection engineered controls (e.g., the provisions of

shielding, ventilation systems, and remote handling systems) effective to reduce the potential for uncontrolled exposure or release were incorporated in the facility. The staff finds that the record keeping used to establish the conditions under which individuals were exposed to radiation was adequately described.

The staff finds that the applicant discusses the procedures for use of personal dosimetry at the facility. The staff finds that provisions have been made for external and internal radiation monitoring of all individuals required to be monitored. The staff finds that the proposed dosimetry program is consistent with the requirements of 10 CFR Part 20 because it will help ensure adequate dose monitoring. The staff finds that the provisions incorporated for personal dosimetry, shielding, ventilation, remote handling, and decontamination equipment provide reasonable assurance that radiation doses are maintained ALARA and within applicable regulations.

The staff finds that further information on radiation exposure control and dosimetry can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive material and dose rates throughout the facility so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR. The staff also finds that certain information related to radiation exposure control and dosimetry (e.g., requirements for personnel dosimetry use) is not expected to impact construction of the facility.

Based on the information provided above, the staff concludes that the facility design features for radiation exposure control and dosimetry provisions meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.6 Contamination Control

The staff evaluated the sufficiency of the information provided on the NWMI contamination control program, as described in NWMI PSAR Section 11.1.6 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.1.6, "Contamination Control," of NUREG-1537, Part 2.

Consistent with the review criteria of NUREG-1537, Part 2, Section 11.1.6, the staff considered the elements of the NWMI contamination control program to ensure that:

- The program scope demonstrates understanding of problems caused by radioactive contamination;
- Procedures will be established to prevent radioactive contamination to the extent possible;
- The bases of procedures show that routine monitoring of locations, equipment, and personnel for contamination will be established and maintained;
- The bases of procedures show that no materials, equipment, or personnel will be permitted to leave an area known to be or suspected of being contaminated without being appropriately monitored;

- The contamination control program includes provisions to avoid, prevent, and remedy the occurrence and the spread of contamination;

- Contamination control training is established as part of comprehensive radiation protection and radioactive waste management training, as needed; and

- The contamination control program includes provisions for recordkeeping in accordance with 10 CFR Part 20 regarding occurrence and spread of contamination, sufficient in content and retention for cleanup of contamination, maintenance, and planning for eventual decommissioning of the facility.

The staff reviewed the plan in the construction permit application for ensuring control of radioactive contamination for NWMI. This included review and evaluation of the following:

- The depth and breadth of the plan and bases of procedures for anticipating, identifying, controlling further spread of, remedying, and recording information about occurrences of radioactive contaminating materials.

- Provisions for routine monitoring and access control to identify radioactive contamination and to assess and limit personnel exposures.

- The bases for TSs that control activities that have the potential to cause or spread contamination.

NWMI PSAR Section 11.1.6 describes the NWMI contamination control including the general equipment and facility layout design considerations to prevent the spread of contamination to the facility and the environment. When establishing radiological controls for work involving potential loose or airborne contamination, NWMI first considered techniques that help prevent or reduce the potential for airborne radioactivity and to maintain loose surface contamination in controlled areas within ALARA levels. NWMI defines two types of contamination as follows:

- Loose (removable) contamination, which can be removed from surfaces by smears and may contribute to airborne radioactivity and/or personnel contamination from routine activities. Loose contamination poses both an internal and external radiation hazard.

- Fixed contamination, which is not smearable and may only be reduced by using approved decontamination techniques, procedures, and equipment. Fixed contamination does not readily contribute to airborne radioactivity and/or personnel contamination from routine activities. Fixed contamination poses an external radiation hazard.

When establishing radiological controls for work involving potential airborne radioactivity, the first consideration was to use techniques that help prevent or reduce the potential for airborne radioactivity and maintain loose surface contamination in controlled areas within ALARA levels. Access to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Contaminated material and equipment that are removed from a restricted area will be appropriately packaged in preapproved containers, inventoried, and monitored prior to release. Personnel who have not

been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

NWMI PSAR Section 11.1.6.2, “Access Control to Contaminated Areas,” states that access to and egress from a restricted area will be through one of the monitor stations at the particular restricted area boundary. Access to and egress from each radiation area, contaminated area, or airborne radioactivity area within the restricted area may also be individually controlled. A contamination monitor (e.g., frisker, hand and foot monitor, or portal monitor), step-off pad, and container for any discarded protective clothing may be provided at the egress point from certain areas to prevent the spread of contamination.

The access control program will be established to ensure that:

- Signs, labels, and other access controls are properly posted and operative.
- Restricted areas prevent spread of contamination and have appropriate signage.
- Step-off pads, change facilities, protective clothing facilities, and personnel monitoring instruments are provided in sufficient quantities and locations.

NWMI PSAR Section 11.1.6.2 also states that action levels for skin and personal clothing contamination at the point of egress from restricted areas and any additional designated areas within the restricted area (e.g., a contaminated area that is provided with a step-off pad and contamination monitor) will not exceed 2.5 becquerel (Bq)/100 square centimeters (cm^2) (150 disintegrations per minute [dpm]/100 cm^2) alpha or beta/gamma contamination (corrected for background).

NWMI PSAR Section 11.1.2.5 states that all personnel and visitors entering restricted areas will receive training that is commensurate with the radiological hazard to which they may be exposed. The level of radiation protection training will be based on the potential radiological health risks associated with the employee’s work responsibilities and incorporate the provisions of 10 CFR 19.12. The radiation protection training program will take into consideration a worker’s normally assigned work activities. Abnormal situations involving exposure to radiation and radioactive material, which can reasonably be expected to occur during the life of the facility, will also be evaluated and factored into the training.

NWMI PSAR Section 9.1.2, “System Description,” provides a description of the NWMI facility ventilation system which includes air supply, process ventilation, and exhaust air systems and associated filters, fans, dampers, ducts, and control instrumentation. The building management system (BMS) is an instrumentation and control subset of the NWMI facility process control system. The BMS functions primarily to monitor the facility ventilation systems and monitor and control the mechanical utility systems.

NWMI PSAR Section 9.1.2 states that the NWMI facility will be ventilated such that airflows travel from areas of lower potential for contamination to areas of higher potential. To this end, the ventilation system will have four confinement zone designations, from lowest to highest potential for contamination. Zone IV is a non-confinement zone. NWMI PSAR Figures 9-1 through 9-3 identify the different confinement zones of each level, and include administration support areas, truck bays, and maintenance utility areas. Zones progress to Zone I, with the potential for highest contamination, which includes glove boxes, vessels, tanks, piping, and hot cells. NWMI PSAR Table 9-1, “Facility Areas and Respective Confinement Zones,” provides the

confinement description for each specific area. The final design of the ventilation system will be provided in the FSAR as part of NWMI's OL application; the staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 9.1.2 states that each ventilation zone will have four exhaust subsystems. Each exhaust filter train will consist of prefilters, two stages of high-efficiency particulate air (HEPA) filters, carbon adsorbers, and isolation dampers. An exhaust stack monitoring and sampling system will be provided on each stack. Stack monitoring and interlocks will monitor discharge and signal changing of filter trains during normal and abnormal operations. The exhaust stacks will be provided with continuous monitors for noble gases, particulates, and iodine. The stack monitoring system design basis is to continuously monitor the radioactive stack releases.

NWMI PSAR Section 11.1.4.1.2, "Air Monitoring," describes the air monitoring, using CAMs, which will be provided within the NWMI facility to provide indication of airborne activity. The CAMs will be operated to collect continuous samples. Portable CAMs may also be deployed when deemed necessary (e.g., non-standard maintenance activities). Continuous airborne radioactivity monitors will provide indication of the airborne activity levels in the restricted areas of the facility. When deemed necessary, portable air samplers may be used to collect a sample on filter paper for subsequent analysis in the laboratory. Monitor data will be collected for regular analysis and documentation. Monitors will be equipped with alarms. The alarms activate when airborne radioactivity levels exceed predetermined limits. The limits will be set with consideration given to both toxicity and radioactivity. The objective of the radiation monitoring system is to provide control room personnel with a continuous record and indication of radiation levels at selected locations where radioactive materials may be present, stored, handled, or inadvertently introduced.

NWMI PSAR Section 11.1.2.8 states that all work performed in a restricted area will be performed under an RWP. Routine and non-routine activities will be performed under an RWP that provides a description of the work to be performed (i.e., defines the authorized activities). The RWP will summarize the results of recent dose rate surveys, contamination surveys, airborne radioactivity results, and other relevant information. RWP procedures will require review of planned activities, changes to activities inside restricted areas, or work with licensed materials for the potential to cause radiation exposures that exceed action levels or produce radioactive contamination. Specific requirements for any necessary safety controls, personnel monitoring devices, protective clothing, respiratory protective equipment, and air sampling equipment are included.

NWMI PSAR Section 11.1.2.5 states that personnel who have previously been trained for radiological, chemical, industrial, and criticality safety will receive (retraining) refresher training at least annually. The retraining program will review procedure changes and any updates and changes in required skills. Changes to the training resulting from incidents potentially compromising safety or changes to the facility or processes will be incorporated as required.

Based on its review, the staff finds that the NWMI contamination control program helps ensure the control of radioactive contamination so that there is reasonable assurance that the health and safety of the facility staff, the public, and the environment will be protected. The staff finds that the level of detail provided on contamination control satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.6, allowing the staff to make the following finding: the description and level of detail on the contamination control program will meet the requirements of 10 CFR 20.1406, "Minimization of contamination." The staff finds that the

contamination control program scope is consistent with the potential problems which could be caused by contamination; procedures will be established to prevent contamination; routine monitoring will help identify and control contamination; personnel will be properly monitored and assessed for potential contamination; contamination control will be part of the overall radiation protection training provided to the workers; and recordkeeping will be maintained in accordance with the requirements of 10 CFR Part 20.

The staff finds that further information on contamination control can reasonably be left for later consideration in the FSAR because the facility's design bases support the control of radioactive material throughout the facility so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR. The staff also finds that certain information related to contamination control (e.g., requirements for personnel contamination monitoring) is not expected to impact construction of the facility.

Based on the information provided above, the staff concludes that the contamination control program meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.7 Environmental Monitoring

The staff evaluated the sufficiency of the information provided on the proposed NWMI environmental monitoring program, as described in NWMI PSAR Section 11.1.7 for the issuance of a 10 CFR Part 50 construction permit using the requirements in 10 CFR 20.1302, "Compliance with dose limits for individual members of the public," and the guidance in Section 11.1.7, "Environmental Monitoring," of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2.

10 CFR 20.1302 requires that the licensee make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301. The staff review focused on the adequacy of the proposed NWMI environmental monitoring program to provide confidence that a significant radiological impact on the environment from the facility would be detected, and the type and magnitude of the radiological impact would be determined. Additionally, the staff review of the proposed NWMI environmental monitoring program was used to verify the effectiveness of plant measures which are used to control the release of radioactive material and to verify that measurable concentrations of radioactive materials and levels of radiation are not higher than expected based on effluent measurements and modeling of the environmental exposure pathways.

Consistent with the review criteria of NUREG-1537, Part 2, Section 11.1.7, the staff evaluated whether the NWMI PSAR discusses the environmental quality commitments that the program should address and the standards that were used in the development of the program. The staff reviewed the methods used to establish the preoperational baseline conditions. The staff performed a qualitative review to evaluate the sufficiency of the methods and techniques to sample and analyze the radiological effect of facility operation. The staff considered whether the environmental monitoring program would be capable of detecting and assessing a significant radiological impact on the environment from the facility.

NWMI PSAR Section 11.1.7 states that the NWMI facility REMP will meet the requirements of 10 CFR 20.1302, and will be used to verify:

- Effectiveness of plant measures used to control the release of radioactive material, and
- Measurable concentrations of radioactive materials and levels of radiation are not higher than expected based on effluent measurements and modeling of environmental exposure pathways.

Methods for establishing and conducting environmental monitoring are provided in RG 4.1, "Radiological Environmental Monitoring for Nuclear Power Plants" (Reference 66) and NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors," (Reference 92) which provides detailed guidance on conducting effluent and environmental monitoring. Although the guidance provided in RG 4.1 and NUREG-1301 was originally written for nuclear power plants, due to the similarities between the airborne releases of radioactivity from nuclear power plants and the NWMI facility, NWMI states that it is appropriate to use the guidance of RG 4.1 and NUREG-1301 in the development of the NWMI environmental monitoring program.

NWMI PSAR Section 11.1.7.1, "Verification of Compliance," states that environmental monitoring data will be compared against permits and environmental reports to ensure compliance, in accordance with the guidance in RG 4.1, and NUREG-1301.

NWMI PSAR Section 11.1.7.3, "Establishment of Baseline Environmental Quality," states that background radiation values will be obtained during the baseline environmental survey by monitoring TLDs at multiple locations and that the survey will be conducted prior to construction and NWMI facility operation.

NWMI PSAR Section 11.1.7.4, "Environmental Surveillance Program," states that the following radiation exposure pathways will be considered for monitoring under the NWMI REMP:

- Waterborne exposure pathway;
- Direct radiation exposure pathway monitoring using TLDs;
- Airborne exposure pathway monitored using continuous air samples; and
- Ingestion exposure pathway.

NWMI PSAR Section 11.1.7.4.1, "Waterborne Exposure Pathway Monitoring," states that NWMI plans for no liquid discharge from the radiologically controlled area and no release of water from the facility to the adjacent environment that would affect surface water. There is no plan to sample adjacent surface water or aquatic life. The groundwater aquifer beneath the proposed NWMI facility site is the Mississippian aquifer. NWMI states that there are no defined liquid effluent release pathways, and that the groundwater is not expected to be contaminated due to operation of the NWMI facility. Groundwater sampling will not be included in the radiological environmental monitoring plan.

NWMI PSAR Section 11.1.7.4.2, "Direct Exposure Pathway Monitoring," states that TLDs will be used to provide measurements of direct radiation from radioactive materials located at the NWMI facility, radioactivity in airborne effluent, and the deposition of airborne radioactivity onto the ground. NUREG-1301 recommends 40 TLD locations and that at least one TLD be located a significant distance from the facility as a control to measure background radiation dose.

NWMI states that sixteen TLDs will be placed on the lot line, with a TLD placed at all four corners of Lot 15, and the remaining TLDs placed at approximately equal distances from each other. TLDs will also be located at the site boundary to evaluate the direct radiation dose. Seven TLDs will be located outside at entry points to the building where personnel may congregate or spend time outside of the NWMI facility building.

NWMI PSAR Section 11.1.7.4.3, "Airborne Exposure Pathway Monitoring," states airborne effluent releases from the NWMI facility will contribute to off-site doses. The airborne effluent exhaust from the vent stacks is expected to contain measurable quantities of noble gas radioactivity (e.g., Xenon and Krypton). Radioactive iodine, radioactive particulates, and tritium could also be present in the airborne effluent exhaust. However, most of the off-site exposure due to airborne effluent releases will be associated with noble gas and radioactive iodine releases. NWMI states that the tritium release rate would be a small fraction of the noble gas rates provided in Table 11-2 (several orders of magnitude less). NWMI also states that the dose contribution from tritium would be a small fraction of the dose contributions, and that the total public dose from all routine gaseous releases including tritium would remain well below 10 CFR Part 20 limits.

NWMI PSAR Section 11.1.7.4.3 states that Regulatory Position C.3.b of RG 4.1 indicates that airborne sampling should be included in the environmental monitoring programs for nuclear power plants. Since the NWMI facility includes airborne effluent releases and radioactivity in the airborne effluent can result in measurable off-site doses, the REMP will include airborne sampling. The airborne effluent exhaust from the vent stacks is expected to contain measurable quantities of noble gas radioactivity (e.g., Xenon and Krypton). Radioactive iodine, radioactive particulates, and tritium could also be present in the airborne effluent exhaust. Four CAMs will be located near the facility fence line, with one CAM being located in the direction of the prevailing wind (i.e., north-northwest) and the other three CAMs being located in the remaining cardinal directions (i.e., 90 degrees) from the first CAM location (i.e., west-southwest, south-southeast, and east-northeast). The CAM locations are shown in Figure 11-6 of the NWMI PSAR. An additional CAM will be located a sufficient distance from the NWMI facility, in the least prevalent wind direction, to provide background information for airborne activity.

NWMI PSAR Section 11.1.7.4.4, "Ingestion Exposure Pathway Monitoring," states that the extent of sampling to be done to consider doses from the ingestion pathway will be evaluated. NWMI states that particulates and iodine radionuclides are not expected to be present in measurable quantities in NWMI facility airborne effluent releases and biota monitoring will not be performed. If stack monitoring should indicate the presence of iodine or particulates in measurable quantities, or if the effluent monitor sample results indicate the presence of iodine or particulates in quantities large enough to result in a calculated dose at the property line that exceeds 10 percent of the dose constraint (i.e., 1 mrem/yr), a sampling plan will be developed. Milk samples are considered a better indicator of radioactive iodine in the environment than vegetation. Should effluent monitoring indicate measurable iodine release, a gamma isotopic analysis and Iodine-131 analysis will be performed on the samples following the guidance provided in Table 3.12-1, "Radiological Environmental Monitoring Program," of NUREG-1301.

Based on its review, the staff finds that the level of detail provided on the NWMI environmental monitoring program satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.7. The REMP described is appropriate for the facility and its projected impact, and the proposed REMP is consistent with the applicable portions of the NUREG-1537 and the ISG Augmenting NUREG-1537.

The staff finds that there is reasonable assurance that provisions of the environmental monitoring program will be effective to help ensure the safety of the public and the protection of the environment. The staff also finds that plans are identified to provide reasonable assurance that an environmental monitoring program can be effectively implemented and sustained during the day-to-day operation of the facility, and that any radiological impact on the environment will be accurately assessed. The staff finds that the proposed NWMI facility may release small quantities of radionuclides to the environment, but that the effluent activity releases would be managed to ensure compliance with applicable Federal, State, and local requirements. The staff did not find any identified abnormal sources of radiation onsite or within the vicinity of the site that would cause radiation levels to be any higher than the expected natural background radiation level. Finally, the staff finds that the background radiation values will be obtained during the baseline environmental survey by monitoring TLDs at multiple locations, and that this survey is to be conducted prior to construction and prior to NWMI facility operation. The staff will review NWMI's environmental monitoring program again during its review of the OL application.

Based on the information provided above, the staff concludes that the design of the REMP meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.8 Radioactive Waste Management Program

The staff evaluated the sufficiency of the information provided on the NWMI radioactive waste management program, as described in NWMI PSAR Section 11.2.1 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.2.1, "Radioactive Waste Management Program," of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria of NUREG-1537, Part 2, Section 11.2.1, the staff evaluated how the radioactive waste management program fits into the facility's overall management structure, how such wastes are identified and segregated effectively, how the waste management organization, with support from the radiation protection organization, will ensure that radioactive wastes are continuously controlled from formation to ultimate safe disposal, and what organizational entities are assigned responsibilities in the radioactive waste management program.

NWMI PSAR Section 11.2.1 states that the waste management program will be coordinated with the radiation protection program, and program management will report to the Plant Manager. NWMI PSAR Section 11.1, "Radiation Protection," describes the program and procedures for controlling and assessing radioactive exposures associated with radioactive sources, including radioactive waste streams. The goal of the waste management program is to minimize waste generation, minimize exposure of personnel, and to protect the public and environment. In response to RAI 11.2 1b (Reference 17), NWMI committed to provide an official charter describing the authority, duties, and responsibilities of personnel in the Waste Management organization. This information will be described in the FSAR as part of NWMI's OL application. The staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 11.2.1.1, "Waste Management Policy," states that NWMI management is committed to the ALARA philosophy for radioactive waste management. NWMI's policy is to conduct waste management operations in a manner that ensures the health and safety of employees, contractors, and the public, and to comply with all Federal, State, and local laws

and regulations for generation, storage, packaging, transportation, and disposal of wastes generated at the NWMI facility. NWMI PSAR Section 11.2.1.2, "Waste Management Procedures," states that procedures will be developed to provide for efficient and safe conduct of waste management operations.

NWMI PSAR Section 11.2.1.3, "Organizational Responsibilities," states that the Plant Manager will have direct responsibility for operation of the NWMI facility, and NWMI PSAR Section 11.2.1.3.2, "Waste Management Lead," states that the Waste Management Lead will have responsibility for implementing the waste management policy, including the development of procedures, shipping radioactive waste from the facility, providing technical input into the design of equipment, processes, and training program for waste management, and conducting self-assessments of the waste management operations.

NWMI PSAR Section 11.2.1.4, "Training," states that the radioactive waste management training program will be closely coordinated with the radiation protection training program to emphasize the importance placed on radiological safety of NWMI facility personnel and the public.

Based on its review, the staff finds that the applicant has described the design of the program to manage radioactive wastes in sufficient detail for the staff to conclude that NWMI has developed the bases for a complete and effective program; the program includes review, audit, and assessment provisions; and the program complies with all applicable regulations.

The staff finds that the description of the NWMI waste management program gives reasonable assurance that radioactive wastes will not escape the control of the facility and will not pose a risk of undue radiation exposure to the facility staff, the environment, and the public.

The staff finds that the level of detail provided on the radioactive waste management program satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.2.1. Personnel will be appropriately instructed to perform functions under the program in accordance with the requirements and facility systems are designed in a manner that will provide the capability to obtain the data needed to comply with the requirements. The staff finds that further information on the radioactive waste management program can reasonably be left for later consideration in the FSAR because the facility's design bases support the control of radioactive waste and other radioactive material throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR. The staff also finds that certain information related to radioactive waste management (e.g., descriptions of the Waste Management Organization) is not expected to impact construction of the facility.

Based on the information provided above, the staff concludes that the radioactive waste management program meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.9 Radioactive Waste Management Controls

The staff evaluated the sufficiency of the information provided on the radiation waste management controls, as described in NWMI PSAR Section 11.2.2 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.2.2, "Radioactive Waste Control," of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria in NUREG-1537, Part 2, Section 11.2.2, the staff reviewed the applicant's processes and procedures used to evaluate the production and handling of radioactive waste material. The staff considered whether appropriate monitoring and sampling will be performed and sufficient analyses will be completed to assess the extent of the radiation exposure from waste products. The staff reviewed whether the applicant sufficiently described methods to: (1) avoid inadvertent exposure of personnel or uncontrolled escape of the radioactive materials; (2) define and maintain continuous control of radioactive materials that require treatment and management as waste; and (3) reduce the quantities of radioactive waste.

NWMI PSAR Section 11.2.2 states that the NWMI facility processes that will produce radioactive waste are described in NWMI PSAR Chapter 4.0. NWMI will implement pollution prevention and waste minimization activities that review associated processes and procedures to ensure that the kinds and amounts of waste generated are minimized. Waste management control will include methods to avoid inadvertent exposure of personnel or uncontrolled escape of the radioactive materials, and maintain continuous control of radioactive materials that require treatment and management as waste.

NWMI PSAR Section 11.2.3.3, "Gaseous Radioactive Waste," states that production facility process waste gases will be processed by the offgas system which is design to filter and/or retain radioactive isotopes in the facility until the resulting release is at levels less than those defined in Table 2 of 10 CFR Part 20, Appendix B. NWMI PSAR Chapter 9.0, "Radioisotope Production Facility Auxiliary Systems," Section 9.1, "Heating Ventilation and Air Conditioning Systems," provides a detailed description of the process vessel vent system and the Zone I and Zone II HVAC treatment systems. Liquid waste resulting from these processes will be directed to the high-dose waste collection tank and processed through the high-dose waste treatment system, where the waste will be solidified.

Based on its review, the staff finds that the radiation waste management controls describes the methods by which the waste products from all procedures and processes will be monitored or otherwise assessed for radioactive material contents. The staff finds that, as needed, controls will be established on the waste streams and products designed to prevent uncontrolled exposures or escape of radioactive waste. The staff finds that the descriptions of the plans and procedures provide reasonable assurance that radioactive wastes will be controlled at all times in a manner that protects the environment and the health and safety of the facility staff and the public. Additionally, the staff finds that the applicant describes efforts to evaluate the generation of radioactive wastes at the facility to determine if there are ways to reduce the amount of waste produced.

The staff noted that descriptions of the Waste Staging and Storage Building (NWMI PSAR Section 9.7.2.2.8, "Waste Staging and Shipping Building (Class A Storage)") as well as plans and procedures to provide reasonable assurance that radioactive wastes will be controlled at all times in a manner that protects the environment and the health and safety of the facility staff and the public will be presented in the FSAR as part of the NWMI OL application.

The staff finds that the level of detail provided on the radiation waste management controls supports the preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.2.2, allowing the staff to make the following findings: (1) appropriate controls are described for radioactive waste management on the waste streams and products designed to prevent uncontrolled exposures or escape of radioactive waste; and (2)

the applicant has described programmatic measures to evaluate the generation of radioactive wastes at the facility to define actions to maintain and control waste generation.

The staff finds that further information on the radioactive waste management controls can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive waste and other radioactive material throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that the design of the radioactive waste management controls meets the applicable regulatory requirements and guidance for issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.10 Release of Radioactive Waste

The staff evaluated the sufficiency of the information provided on the release of radioactive waste, as described in NWMI PSAR Section 11.2.3 for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.2.3, "Release of Radioactive Waste," of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2. Consistent with the review criteria of NUREG-1537, Part 2, Section 11.2.3, the staff evaluated the discussions on release of radioactive waste for compliance with the regulations in Subpart K, "Waste Disposal," of 10 CFR Part 20.

NWMI PSAR Section 11.2.3 describes radioactive waste effluents expected to be released from the restricted to the unrestricted area. The discussion includes the type and quantities of radionuclides, methods and locations of release, methods of assessing the potential doses to people in the unrestricted area, and methods of comparing the consequences of releases with limits in applicable regulations.

NWMI PSAR Section 11.2.3.1, "Solid Radioactive Waste," describes the release of solid waste from the facility for disposal. The PSAR states that the majority of solid waste produced in the NWMI facility will be the high- and low-dose waste discussed in NWMI PSAR Chapter 9.0. Samples of this waste will be analyzed in the NWMI facility laboratory to ensure that the waste meets the disposal facility waste acceptance criteria. This waste will be stored for radioactive decay to meet shipping and disposal requirements, and then packaged in approved transportation casks for transport to the disposal facility. Additional information on the basis for waste volume projections provided in the PSAR for laboratory facilities and facility support waste will be further defined in the FSAR as part of NWMI's OL application. The staff is tracking this issue in Appendix A of this SER.

NWMI PSAR Section 11.2.3.2, "Liquid Radioactive Waste," states that the NWMI facility will not release any radioactive liquid waste. NWMI PSAR Section 11.2.3.3, "Gaseous Radioactive Waste," states that gases from the NWMI facility process and HVAC system will be processed as described in NWMI PSAR Chapters 4.0 and 9.0, respectively. The offgas system is designed to filter and/or retain these isotopes in the facility until the resulting release is at levels less than those defined in Table 2 of 10 CFR Part 20, Appendix B. Additional information on the offgas and ventilation systems will be provided in the FSAR as part of the OL application; the staff is tracking this issue in Appendix A of this SER. The gaseous radioactive emissions will be released through the NWMI facility's three exhaust stacks. Monitoring of the effluent is described in NWMI PSAR Section 11.1.4.1.2.

Based on its review, the staff finds that the discussions provide reasonable assurances that releases of airborne effluents from the facility and releases of solid waste from the facility for disposal will not exceed applicable regulations and will not pose unacceptable radiation risks to the environment.

The staff finds that the level of detail provided on the release of radioactive waste satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.2.3. The staff finds that radionuclides have been sufficiently identified by quantities, other relevant characteristics, release points, and relevant environmental parameters; and releases of radioactive effluents will likely be sufficiently managed, controlled, and monitored so that limits in applicable regulations would not be exceeded. The staff finds that further information on the release of radioactive waste can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive waste and other radioactive material throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that NWMI's description of its plan for release of radioactive waste is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.4.11 Respiratory Protection Program

The staff evaluated the sufficiency of the information provided on the respiratory protection program, as described in NWMI PSAR Section 11.3, "Respiratory Protection Program," for the issuance of a 10 CFR Part 50 construction permit using the guidance and acceptance criteria from Section 11.3, "Respiratory Protection Program," of the ISG Augmenting NUREG-1537, Part 2.

Consistent with the review criteria in the ISG Augmenting NUREG-1537, Part 2, Section 11.3, the staff examined whether the NWMI respiratory protection program provides adequate protection of personnel from airborne concentrations exceeding the limits of Appendix B to 10 CFR Part 20. The staff reviewed the proposed radiation protection equipment for providing the appropriate degree of personal protection. The staff evaluated the description of respirator selection, training, fit testing, storage, maintenance, repair, and QA.

NWMI PSAR Section 11.3 describes the NWMI respiratory protection program. The program documentation states that the use of engineering controls is preferred over the use of respirators to minimize radioactive materials in the air. However, there may be a need for confinement to control the concentrations of radioactive material in the air to maintain the TEDE ALARA.

NWMI PSAR Section 11.3 states that the radiological respiratory protection program is designed to comply with the requirements of ANSI Z-88.2, "American National Standard Practices for Respiratory Protection" (Reference 89); 10 CFR Part 20, Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," and 29 CFR 1910.134, "Respiratory Protection." Respirators will only be issued if the RPM determines that engineering controls may be ineffective, the total effective dose will be reduced by wearing respirators, and/or the physical stress of wearing a respirator will not interfere with workers' health and safety. Engineering controls include the following:

- Control of access
- Limitation of exposure times
- Use of respiratory protection equipment
- Other controls

NWMI PSAR Section 11.3 states that the NWMI facility design and analysis of the NWMI facility ventilation system ensures that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur during normal operational states and to mitigate the consequences of design basis accidents (e.g., maintaining a series of cascading pressure zones to draw air from the cleanest area to the most contaminated area of the RPF. In addition, the distribution and concentrations of any airborne radionuclides are limited by operation of the ventilation system so that during the full range of facility operations, no potential occupational exposures would exceed the design bases (e.g., 10 CFR Part 20). The NWMI HVAC system, also referred to as the ventilation system, is designed to ensure that temperature, relative humidity, and air exchange rates are within the design-basis limits for personnel and equipment and to ensure that all normal sources of airborne radioactive material are controlled so that occupational doses do not exceed the requirements of 10 CFR Part 20. The PSAR states that the system design is consistent with NWMI's ALARA program and includes ESFs built in.

NWMI PSAR Section 11.3 states that the facility ventilation system will maintain a series of cascading pressure zones to draw air from the cleanest areas of the facility to the most contaminated areas. Zone IV will be a clean zone that is independent of the other ventilation zones. Zone IV will be slightly positively pressurized with respect to the atmosphere. Zone III will be the cleanest of the potentially contaminated areas, with each subsequent zone being more contaminated and having lower pressures.

NWMI PSAR Section 9.1.2.2, "Supply Air System," states that the NWMI facility supply air system will provide conditioned air for facility workers and equipment and supply makeup air for NWMI facility exhaust air systems. A common supply air system will provide filtered and conditioned 100 percent outdoor air to all Zone III areas and some Zone II areas that require makeup air in addition to that cascaded from Zone III. Three separate exhaust systems will maintain zone pressure differentials and containment: (1) the Zone I exhaust system will service the hot cell, waste loading areas, target fabrication enclosures, and process offgas subsystems in Zone I; (2) the Zone II/III exhaust system will service exhaust flow needs from Zone II and Zone III in excess of flow cascaded to interior zones; and (3) a laboratory exhaust system will service fume hoods in the laboratory area. In response to RAI 11.3-1a (Reference 17), NWMI has committed to provide additional information on the facility ventilation system, including details of how the irradiated target receipt area will transition between ventilation Zones II and III during operating/maintenance activities, will be provided in the FSAR as part of the OL application; the staff is tracking this issue in Appendix A of this SER.

In NWMI PSAR Chapter 6.0 and Section 9.1.2.1, "Confinement," state that confinement is an ESF that is credited as being in place as part of the preliminary hazards analysis. Confinement is defined as an enclosure of the facility (e.g., the hot cell area in the NWMI facility) that is designed to limit the exchange of effluents between the enclosure and its external environment to controlled or defined pathways. The primary safety objective of the confinement system is to protect on-site workers, the public, and the environment. Personnel protection control features (e.g., adequate shielding and ventilation control) will minimize hazards normally associated with radioactive or chemical materials. The secondary design objective of the confinement system is to minimize the reliance on administrative or complex active engineering controls and provide a

confinement system that is as simple and fail-safe as reasonably possible. Confinement includes the capability to maintain sufficient internal negative pressure to ensure in-leakage (i.e., prevent uncontrolled leakage outside the confined area), but need not be capable of supporting positive internal pressure or significantly shielding the external environment from internal sources of direct radiation.

NWMI PSAR Section 6.2.1, "Confinement System," states that confinement will be provided by a combination of the enclosure boundaries (e.g., walls, floor, and ceiling), enclosure ventilation, and ventilation control system. The enclosure boundaries will restrict bulk quantities of process materials, potentially present in solid or liquid forms, to the confinement and limit leakage of gaseous components from the enclosure boundary by the control of the ventilation system. The ventilation and ventilation control systems will control the release of the gaseous components (including gas phase components and solid/liquid dispersions) to the confinement.

NWMI PSAR Section 11.1.2.8 states that all work performed in restricted areas will be performed under an RWP. Precautions to be taken by those performing the task, including personal protective equipment to be worn while working (e.g., gloves, respirators, personnel monitoring devices), stay-times or dose limits for work in the area, recordkeeping requirements (e.g., time or dose spent on job), and the attendance of a radiation protection technician during the work, will be defined in the RWP. The RPM or designee will approve the RWP.

NWMI PSAR Section 11.1.5.4 states that based on air sampling results and work evolutions, the RPM will select the appropriate respiratory protection required. Airborne radioactivity concentrations will be minimized to the extent practical by the use of engineered controls (e.g., containment, ventilation). When establishing radiological controls for work involving potential airborne radioactivity, the first consideration will be to use techniques that help prevent or reduce the potential for airborne radioactivity and maintain loose surface contamination in controlled areas within ALARA levels. Respiratory protection equipment requirements will be specified on the area RWP.

NWMI PSAR Section 11.3 states that if the decision is made to permit the use of respiratory protection equipment to limit the intake of radioactive material, only National Institute of Occupational Safety and Health (NIOSH)-certified equipment will be used. The respiratory protection program will meet the requirements of 10 CFR Part 20, Subpart H. The respiratory protection program will include the following elements:

- Air sampling to identify the potential hazard, select proper equipment, and estimate doses.
- Surveys and when necessary, bioassays, to evaluate actual intakes.
- Performance testing of respirators for operability (user seal-check for face-sealing devices and functional check for others) immediately prior to each use.
- Limitations on periods of respirator use and relief from respirator use.
- Determination by a physician that the individual user is medically fit to use respiratory protection equipment. This evaluation will be done prior to initial fitting of a face-sealing respirator, before the first field use of non-face sealing respirators, and either every 12 months thereafter, or periodically at a frequency determined by a physician.

- A respirator fit test will require a minimum fit factor of at least 10 times the assigned protection factor for negative pressure devices, and an overall fit factor of at least 500 for any positive pressure, continuous flow, and pressure-demand devices. The fit testing will be performed before the first field use of tight-fitting, face-sealing respirators. Subsequent testing will be performed at least annually thereafter. Fit testing must be performed with the face-piece operating in the negative pressure mode.

NWMI PSAR Section 11.3 also states that personnel using respirators will be informed that they may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief. Respirator use within the NWMI facility will provide for vision correction and adequate communication and allow for concurrent use of other safety or radiological protection equipment. Radiological protection equipment will be used in such a way as to not interfere with the proper operation of the respirator.

NWMI PSAR Section 11.3 states that atmosphere-supplying respirators will be supplied with respirable air of a quality that meets or exceeds the specifications of Compressed Gas Association (CGA) G-7, “Compressed Air for Human Respiration” (Reference 90), and CGA G-7.1, “Commodity Specification for Air” (Reference 94) and the requirements included in the regulations of the Occupational Safety and Health Administration, 29 CFR 1910.134(i)(1)(ii)(A) through (E).

NWMI PSAR Section 11.3 states that the NWMI radiological respiratory protection program will include written procedures for each of the following:

- Monitoring, including air sampling and bioassays
- Supervision and training of respirator users
- Fit testing
- Respirator selection
- Breathing air quality
- Inventory and control
- Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment
- Recordkeeping

NWMI PSAR Section 11.3 states that records of the respiratory protection program (including training for respirator use and maintenance) will be maintained in accordance with the NWMI records management program.

Based on its review, the staff finds that the respiratory protection program provides adequate protection of personnel because it will include use of ventilation systems and respirator equipment to help prevent airborne concentrations from exceeding the limits of Appendix B to 10 CFR Part 20. The staff finds that the proposed radiation protection equipment for providing the appropriate degree of personal protection and the description of respirator selection, training, fit testing, storage, maintenance, repair, and QA are adequate to ensure effective protection to the workers.

The staff finds that NWMI committed to provide an acceptable radiation protection program that includes a program to control airborne concentration of radioactive material with engineering controls and respiratory protection. In response to RAI 11.1-2a, NWMI stated it will provide its radiation protection program as part of its OL application; the staff is tracking this issue in Appendix A of this SER. The staff finds that the level of detail provided on the respiratory protection program satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 11.3, allowing the staff to make the following finding: the program is generally consistent (given the level of detail available at the facility design stage) with RG 8.15, and Subpart H and Appendix A of 10 CFR Part 20.

The staff finds that further information on the respiratory protection program can be reasonably left for later consideration in the FSAR because the facility's design bases support the control of radioactive material throughout the facility, so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to these design bases during the evaluation of the NWMI FSAR.

Based on the information provided above, the staff concludes that the design of the respiratory protection program meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

11.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility radiation protection and waste management programs, as described in NWMI PSAR Chapter 11.0, and finds that the preliminary design criteria of the radiation protection and waste management programs, including the principal design criteria, design bases, and information relating to materials of construction, general arrangement, and approximate dimensions: (1) provide reasonable assurance that the final design will conform to the design basis, and (2) meet all applicable regulatory requirements and acceptance criteria discussed in NUREG-1537 and the ISG augmenting NUREG-1537. Based on these findings, the staff has made the following conclusions regarding issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed production facility design criteria for radiation protection and waste management, 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 of the radiation protection and waste management programs, and which can reasonably be left for later consideration, will be provided in the FSAR.

(3) There is reasonable assurance that: (i) safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed production facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed production facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(4) 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.

(5) NWMI is technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

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