4.0 RADIOISOTOPE PRODUCTION FACILITY DESCRIPTION

The facility description addresses the principal features, operating characteristics, and parameters of the proposed Northwest Medical Isotopes, LLC (NWMI or the applicant) production facility. The primary functions of the facility are to disassemble and dissolve targets; recover and purify molybdenum-99 (Mo-99); and package Mo-99.

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility as presented in Chapter 4.0, "Radioisotope Production Facility Description," of the NWMI preliminary safety analysis report (PSAR), Revision 3. As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production And Utilization Facilities," production facility as "the NWMI production facility," or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

4.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 4.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of the NWMI facility systems 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 facility, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI facility was evaluated to ensure the principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions, are sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed NWMI's identification 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 TSs for the facility in Chapter 14.0, "Technical Specifications," of this SER.

Areas of review for this chapter included the facility and process description, the facility biological shield, the radioisotope extraction system, and special nuclear material (SNM) processing and storage.

4.2 Summary of Application

NWMI PSAR Chapter 4.0 contains a summary description of the production facility where NWMI plans to disassemble and dissolve irradiated low enriched uranium (LEU) targets, recover and purify Mo-99, and package Mo-99. Chapter 4.0 describes the design of the facility and the processes employed within it, and includes the principal safety considerations that were factored into the facility design, construction, and expected operation. It also describes the facility's biological shield, the radioisotope extraction system, and SNM processing and storage. The NWMI production facility includes the irradiated target receipt bay, hot cells, waste management facilities, a laboratory, and utilities.

4.3 Regulatory Basis and Acceptance Criteria

The staff reviewed the NWMI PSAR Chapter 4.0 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 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 final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described and identified by NWMI, and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

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

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI facility. However, the staff evaluated NWMI'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 this chapter of the SER evaluated the facility and process description, the facility biological shield,

the radioisotope extraction system, and processing and storage to issuance of the construction permit for the production facility will not be inimical to public health and safety.

4.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility are as follows:

- 10 CFR 50.23, “Construction permits.”
- 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.”
- 10 CFR 50.45, “Standards for construction permits, operating licenses, and combined licenses.”
- 10 CFR Part 20, “Standards for Protection against Radiation.”

4.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI’s construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC’s regulatory requirements in 10 CFR, the staff used:

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

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility," as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (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, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements," when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a radioisotope production facility license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, and American National Standards Institute/American Nuclear Society (ANSI/ANS) standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG Augmenting NUREG-1537, Parts 1 and 2; and the NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

4.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 4.0 to assess the sufficiency of the preliminary design and performance of NWMI's production facility for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance of NWMI's production facility is demonstrated by following applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 4.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of this technical evaluation is described in SER Section 4.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of NWMI's production facility 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 NWMI's production facility, as described in the FSAR, submitted as part of NWMI's operating license (OL) application.

4.4.1 Facility and Process Description

The staff evaluated the sufficiency of NWMI's facility and process description of its facility, as described in NWMI PSAR Section 4.1, "Facility and Process Description," for the issuance of a construction permit using the guidance and acceptance criteria from Section 4b.1, "Facility and Process Description," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of Section 4b.1 of the ISG Augmenting NUREG-1537, Part 2, the information submitted in NWMI PSAR Section 4.1 is descriptive in nature and requires no technical analysis. The information in this section provides background for the descriptions of the facility provided in later sections and chapters of the application. The staff reviewed the information in this section to ensure a general understanding of the facility and consistency with other sections of the application.

NWMI PSAR Section 4.1 contains a summary description of the facility. Consistent with Section 4b.1 of the ISG Augmenting NUREG-1537, Part 2, this section includes the principal safety considerations that were factored into the facility design, construction, and operation. The design bases and functions of the systems and components are presented in sufficient detail to allow a clear understanding and to ensure that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the staff and the public. Drawings and diagrams are provided to allow a clear and general understanding of the physical facility features and of the processes involved. The primary function of the facility is to extract, purify, package, and ship medical radioisotopes. The primary fission product barrier in the facility consists of vessels and associated piping, which contain the irradiated SNM and fission products (in solid, liquid, or gaseous form) during the separation process.

NWMI PSAR Section 4.1, provides a summary of the maximum amount of SNM and the physical and chemical forms of SNM used in the process.

NWMI PSAR Section 4.1 contains a summary description of the raw materials, byproducts, wastes, and finished products of the facility. This information includes data on expected levels of trace impurities or contaminants in the final product (particularly fission products or transuranic elements) characterized by identity and concentration.

NWMI PSAR Section 4.1 contains a general description of the design basis and implementation of any criticality safety features of the facility for establishing and maintaining a nuclear criticality safety program. The staff evaluation of the criticality safety program is discussed in Section 6.4.5, "Nuclear Criticality Safety," of this SER.

NWMI PSAR Section 4.1 contains a description of the radiological protection features designed to prevent the release of radioactive material and used to maintain radiation levels below applicable radiation exposure limits. The staff evaluation of the engineered safety features that will provide radiological protection to workers and the environment in accident scenarios is discussed in Chapter 13.0, "Accident Analysis," of this SER.

NWMI PSAR Section 4.1 contains a description of the design basis and implementation of any hazardous chemical safety features of the facility for establishing and maintaining a hazardous chemical safety program. The staff evaluation of the chemical safety program is discussed in Section 13.4.9, "Analyses of Accidents with Chemical Hazards," of this SER.

Based on its review of NWMI PSAR Section 4.1, the staff finds that the level of detail is sufficient to provide a general understanding of the production facility and the isotope production process.

Therefore, the staff concludes that the summary description of the NWMI production facility and processes, as described in NWMI PSAR Section 4.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

4.4.2 Radioisotope Production Facility Biological Shield

The staff evaluated the sufficiency of NWMI's facility biological shield, as described in NWMI PSAR Section 4.2, "Radioisotope Production Facility Biological Shield," for the issuance of a construction permit using the guidance and acceptance criteria from Section 4b.2, "Processing Facility Biological Shield,'' of the ISG Augmenting NUREG-1537, Parts 1 and 2, which refers to Section 4.4, "Biological Shield," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of Section 4.4 of NUREG-1537, Part 2, the staff considered whether the objectives of the shield design bases are sufficient to protect the health and safety of the public and the facility staff, and that the preliminary design achieves the design bases.

NWMI PSAR Section 4.2 states that the facility biological shield will provide an integrated system of features that protect workers from the high-dose radiation generated during the radioisotope processing to recover Mo-99. The primary function of the biological shield will be to reduce the radiation dose rates and accumulated doses in occupied areas to not exceed the limits of 10 CFR Part 20 and the guidelines of the facility ALARA (as low as is reasonably achievable) program. The shielding and its components will withstand seismic and other concurrent loads, while maintaining containment and shielding during a design basis event.

NWMI PSAR Section 4.2.2, "Shielding Design," describes the shield design, which includes a description of the shielding materials of construction, nuclear properties of shielding materials, the structural integrity of shielding design, and construction of the facility biological shield. The shield design also describes the functional design of the biological shield, showing entry and exit facilities for products, wastes, process equipment, and operating staff.

NWMI PSAR Section 4.2.2.3, "Design of Penetrations," states that the penetrations provided for ventilation, piping, shield plugs, personnel entryways, and viewports in biological shield structures will reduce the shielding effectiveness. The magnitude of the reduced effectiveness will depend on geometry, material composition, and source characteristics. NWMI PSAR Section 4.2.2.3 also states that each penetration in a shield will be evaluated in the final design for its impact on the effectiveness of the shield in which it is located. Penetrations are designed with offsets and steps to prevent direct streaming of radiation through the penetration.

NWMI PSAR Section 4.2.5, "Ventilation System for the Biological Shield Structure," states that the ventilation around the biological shield structure will be Zone II/III supply and the Zone I exhaust. The biological shielding will be subjected to ambient temperature conditions. The Zone I exhaust will provide ventilation of the hot cell and confinement of the hot cell atmosphere, and maintain the hot cell at negative pressure. The supply air will maintain the temperature for personnel comfort. The process off-gas treatment system will provide confinement of the chemical vapors from the process equipment within the hot cell and treat the radioactive

off-gases through retention, adsorption, and filtration. NWMI PSAR Section 9.1.2, "System Description," states that supply air will be conditioned.

Based on its review of NWMI PSAR Section 4.2, the staff finds that the level of detail provided on the biological shield demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 4.4 allowing the staff to make the following findings: (1) there is reasonable assurance that the shield designs will limit exposures from the facility sources of radiation so as not to exceed the limits of 10 CFR Part 20 and the guidelines of the facility ALARA program; (2) there is reasonable assurance that the shield can be successfully installed with no radiation streaming or other leakage that would exceed the limits of 10 CFR Part 20 and the guidelines of the facility ALARA program; and (3) facility components are sufficiently shielded to avoid significant radiation-related degradation or malfunction.

Therefore, the staff concludes that the preliminary design of the NWMI facility biological shield, as described in NWMI PSAR Section 4.2, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis (e.g., evaluation of penetrations in the shield) can reasonably be left for later consideration in the FSAR since the biological shield's design bases reduce radiation dose rates and accumulated doses to within regulatory requirements following ALARA guidelines.

4.4.3 Radioisotope Extraction System

The staff evaluated the sufficiency of NWMI's facility radioisotope extraction system, as described in NWMI PSAR Section 4.3, "Radioisotope Extraction System," for the issuance of a construction permit using the guidance and acceptance criteria from Section 4b.3, "Radioisotope Extraction System," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of Section 4b.3 of the ISG Augmenting NUREG-1537, Part 2, the staff considered whether the information provided a clear understanding of the processes and verified that the information presented in this section is consistent with the information in other sections and chapters of the PSAR (e.g., accident analyses presented in Chapter 13.0, engineered safety features presented in Chapter 6.0, and probable subjects of technical specifications presented in Chapter 14.0).

NWMI PSAR Section 4.3 describes the radioisotope extraction process from the time irradiated targets enter the facility through the Mo-99 product shipment. The radioisotope extraction process includes the following major systems: (a) irradiated target receipt and disassembly (irradiated target receipt subsystem), (b) irradiated target receipt and disassembly (target disassembly subsystem), (c) target dissolution, and (d) molybdenum recovery and purification.

The staff notes that NWMI PSAR Section 4.3 provides a complete description, including diagrams and drawings, in sufficient detail to give a clear understanding of the extraction and purification process and how the process can be performed within regulatory limits.

Based on its review, the staff finds that the level of detail provided on the NWMI production facility's radioisotope extraction process, as described in NWMI PSAR Section 4.3, demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 4b.3, allowing the staff to make the following findings: (1) NWMI PSAR Section 4.3 provides a detailed account of

the SNM in process in the NWMI production facility, along with any included fission-product radioactivity, and gives a clear understanding that these operations can be conducted safely in this facility; (2) the processing of irradiated targets is described in sufficient detail to provide confidence that the SNM and byproduct material can be controlled throughout the production facility processes so that the health and safety of the public and workers will be protected; (3) the criticality control measures provided throughout the radioisotope extraction process are consistent with a double-contingency principle[1] and provide suitable defense-in-depth for the production facility processes; and (4) engineered safety features have been developed to provide safe margins for all safety-related process variables.

Therefore, the staff concludes that the preliminary design of the NWMI facility radioisotope extraction system, as described in NWMI PSAR Section 4.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis (e.g., additional criticality control analysis) can reasonably be left for later consideration in the FSAR since the design bases provide for the control of all radioisotope extraction processes and protection of workers and the public. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

4.4.4 Special Nuclear Material Processing and Storage

NWMI PSAR Section 4.4, "Special Nuclear Material Processing and Storage," describes the processing components and procedures involved in handling, processing, and storing SNM beyond the radioisotope extraction process. NWMI PSAR Section 4.4.1, "Processing of Irradiated Special Nuclear Material," describes the processing of irradiated LEU, which comprises the uranium recovery and recycle system. The product of the uranium recovery and recycle system will be recycled LEU with doses low enough to be directly handled without shielding. NWMI PSAR Section 4.4.2, "Processing of Unirradiated Special Nuclear Material," describes the processing of the fresh and recycled LEU, which comprises the target fabrication system. As noted above in Section 4.0, the staff only reviewed the NWMI target fabrication area to understand the interface between and impact on the NWMI production facility from the target fabrication area. The staff's findings and conclusions in the SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

Processing of Irradiated Special Nuclear Material

The staff evaluated the sufficiency of the NWMI facility irradiated SNM processing and storage, as described in NWMI PSAR Section 4.4.1, for the issuance of a construction permit using the guidance and acceptance criteria from Section 4b.4.1, "Processing of Irradiated Special Nuclear Material," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of Section 4b.4.1 of the ISG Augmenting NUREG-1537, Part 2, the staff considered whether the information provided a clear understanding of the

[1] The double-contingency principle is defined in 10 CFR 70.4, "Definitions," to mean "that process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible." ANSI/ANS-8.1-1983, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors" (Reference 30), further provides that "[p]roper application of the double contingency principle provides assurance that no single error or loss of a control will lead to the possibility of a criticality accident."

processes and verified that the information presented in this section is consistent with the information in other sections and chapters of the PSAR (e.g., accident analyses presented in Chapter 13.0, engineered safety features presented in Chapter 6.0, and probable subjects of technical specifications presented in Chapter 14.0).

NWMI PSAR Section 4.4.1 provides a clear description of the process systems and components to allow a good understanding that the facility can be operated within regulatory limits. The processing components are compatible with the process material so as to withstand the effects of corrosion and radiation. The processing system is designed to manage fission-product and radiolysis gases that evolve in the process.

The uranium recovery and recycle system description in NWMI PSAR Section 4.4 provides information regarding the SNM processing time cycle, process, process equipment, SNM and radioactive inventories, and the hazardous chemicals used in the system of the NWMI production facility. NWMI PSAR Figure 4-72, "Uranium Recovery and Recycle Process Functions," provides an overview of the uranium recovery and recycle process. Uranium-bearing raffinate from the Mo-99 recovery and purification system is processed by the uranium recovery and recycle system.

The SNM processing time cycle identifies the functions for lag storage for feed storage and product solutions described in NWMI PSAR Section 4.3.1, "Extraction Time Cycle." The process description (NWMI PSAR Section 4.4.1.1, "Process Description") provides a detailed account of the SNM in process during normal operations and provides the basis for equipment design.

The arrangement and design of the processing equipment, including normal operating conditions, are described in NWMI PSAR Section 4.4.1.2, "Process Equipment Arrangement," and NWMI PSAR Section 4.4.1.3, "Process Equipment Design." These sections describe the equipment in sufficient detail to provide reasonable assurance that the SNM and byproduct material can be controlled throughout the process in the NWMI production facility.

The description of SNM in terms of physical and chemical form, volume in process, required criticality control features, and radioactive inventory in process is provided in NWMI PSAR Section 4.4.1.4, "Special Nuclear Material Description," and NWMI PSAR Section 4.4.1.5, "Radiological Hazards." The hazardous chemicals that are used or may evolve during the process, along with the provisions to protect workers and the public from exposure, are described in NWMI PSAR Section 4.4.1.6, "Chemical Hazards." NWMI PSAR Table 4-46, "Molybdenum Recovery and Purification System In-Process Special Nuclear Material Inventory,"[2] specifies the stream, chemical form, concentration, and SNM mass.

A discussion of criticality control features is also contained in NWMI PSAR Section 4.4.1.4, including passive design and active engineered features supporting the adherence to the double-contingency principle. This section applies the criticality control features that are discussed in NWMI PSAR Chapter 6.0, "Engineered Safety Features," Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility." NWMI states that the criticality control features for this subsystem will include passive design and active engineered features.

[2] This table contains security-related information and has been withheld from public disclosure in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding."

Additionally, NWMI states that the passive design features will include geometric constraints of the floor, process equipment, workstations, and ventilation system. The active engineered features will include a requirement for continuous ventilation. The staff will review these passive and engineered design features in greater detail in NWMI's OL application.

NWMI PSAR Section 4.4.1.6 provides a summary of the maximum amounts of chemicals used in the process and the associated chemical hazards. This section also identifies any required chemical protection provisions that are designed into the process systems and components. The chemical reagents for uranium recovery and recycle are listed in NWMI PSAR Table 4-54, "Uranium Recovery and Recycle Chemical Inventory." In addition to the chemical reagents, off-gases will include nitric oxide, nitrogen dioxide, and nitric acid fumes.

NWMI states that it will have chemical inventory controls, including separation of chemicals based on the potential for exothermic reactions. These controls, in addition to procedures controlling the processing of irradiated SNM, will include measures to prevent accidents. The staff will review these controls when they are made available in NWMI's OL application.

Based on its review, the staff finds that the level of detail provided on NWMI's processing of irradiated SNM in its production facility, as described in NWMI PSAR Section 4.4.1 and the included tables and figures, demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 4b.4.1 allowing the staff to make the following findings for the NWMI production facility: (1) the process descriptions in Section 4.4.1 of the PSAR provide a detailed account of the SNM in process in the NWMI production facility, along with fission-product radioactivity, and gives a clear understanding that these operations can be conducted safely in the facility; (2) the production facility processing facilities and apparatus have been described in sufficient detail to provide reasonable assurance that the SNM and byproduct material can be controlled throughout the process so that the health and safety of the public and workers will be protected; and (3) the criticality control measures provided are consistent with the double-contingency principal, and provide suitable defense-in-depth for the contained processes.

Therefore, the staff concludes that the preliminary description of the processing of irradiated SNM, as described in NWMI PSAR Section 4.4.1, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis (e.g., additional information on passive and engineered design features and chemical inventory controls) can reasonably be left for later consideration in the FSAR since the facility's design bases support the control of SNM and byproduct material throughout the production facility processes so that the health and safety of the public and workers will be protected. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

Processing of Unirradiated Special Nuclear Material

Section 4.4.2 of the NWMI PSAR describes the target fabrication system and process. Targets are fabricated from fresh LEU metal and recycled uranyl nitrate. As described in Section 4.4.2 of the NWMI PSAR, "The system begins with the receipt of LEU from the DOE [U.S. Department of Energy] supplier, and ends with packaging new targets for shipment to the irradiation facilities." The fabrication of targets is similar to processes at fuel-cycle facilities that manufacture fuel, which are licensed under 10 CFR Part 70. Although the staff reviewed the entire application, including NWMI's descriptions related to the target fabrication process, the

staff review was only to determine whether the NWMI production facility satisfied the requirements for the issuance of a 10 CFR Part 50 construction permit. Since the information provided in Section 4.4.2 of the NWMI PSAR does not impact the construction of the NWMI production facility, the staff has made no findings or conclusions on this section of the NWMI PSAR.

4.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of NWMI's facility, as described in NWMI PSAR Chapter 4.0, and finds that the preliminary design of NWMI's facility, including the principal design criteria, design bases, and information relative to materials of construction and general arrangements, provides reasonable assurance that the final design will conform to the design basis and meets all applicable regulatory requirements and acceptance criteria in or referenced in the applicable guidance, including the ISG Augmenting NUREG-1537.

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

(1) NWMI has described the proposed design of the production facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis and which can reasonable be left for later consideration, will be supplied in the FSAR.

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

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