1.0 THE FACILITY

This chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) serves as a general introduction and provides an overview of the topics covered in detail in other SER chapters, including areas of review, regulatory criteria and guidance, review procedures and findings, and conclusions.

1.1 Introduction

This SER documents the results of the safety review conducted by the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) on the NWMI application to obtain a construction permit for a production facility (NWMI production facility or facility) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," to be constructed in Columbia, Missouri.

By letter dated February 5, 2015 (Reference 1), NWMI submitted Part One of a two-part application for a construction permit, which, if granted, would allow NWMI to construct a medical isotope production facility in Columbia, Missouri. The staff acknowledged receipt of Part One of NWMI's two-part application for a construction permit under 10 CFR Part 50 in a notice published in the *Federal Register* (FR) on April 21, 2015 (80 FR 22227). An exemption from certain requirements of 10 CFR Part 2, Section 101 (10 CFR 2.101), "Filing of application," paragraph (a)(5) was granted by the Commission and published in the FR on October 24, 2013 (78 FR 63501), in response to a letter from NWMI dated August 9, 2013 (Reference 4). The exemption allowed NWMI to submit its construction permit application in two parts. Specifically, the exemption allowed NWMI to submit a portion of its application for a construction permit up to 6 months prior to the remainder of the application regardless of whether an environmental impact statement or a supplement to an environmental impact statement is prepared during the review of its application. In accordance with 10 CFR 2.101(a)(5), NWMI submitted the following in Part One of its construction permit application:

- Description and safety assessment of the site required by 10 CFR 50.34, "Contents of applications; technical information," paragraph (a)(1).

- Environmental report required by 10 CFR 50.30, "Filing of application; oath or affirmation," paragraph (f).

- Filing fee information required by 10 CFR 50.30(e) and 10 CFR 170.21, "Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses."

- General information required by 10 CFR 50.33, "Contents of applications; general information."

- Agreement limiting access to classified information required by 10 CFR 50.37, "Agreement limiting access to Classified Information."

The staff conducted a docketing acceptance review of NWMI's partial application and, by letter dated June 1, 2015 (Reference 6), determined that part one of NWMI's application for a construction permit was complete and acceptable for docketing. The application was assigned

Docket No. 50-609. A notice of docketing part one of NWMI's application was published in the FR on June 8, 2015 (80 FR 32418).

The staff performed an environmental review of the NWMI construction permit application and this review and its conclusions are documented in an environmental impact statement, published as NUREG-2209, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility," in May 2017 (Reference 22).

By letter dated July 20, 2015 (Reference 2), NWMI submitted the second and final part of its two-part application (Reference 3) for a 10 CFR Part 50 construction permit. Part Two of the application provided the remainder of the preliminary safety analysis report (PSAR) required by 10 CFR 50.34(a).

By letter dated December 24, 2015 (Reference 7), the staff informed NWMI that Part Two of its construction permit application for a production facility, as supplemented, contained the balance of the PSAR required by 10 CFR 50.34(a), was submitted in accordance with the requirements of 10 CFR 2.101(a)(5), and was placed, in its entirety, under Docket No. 50-609. This letter acknowledged NWMI's request for a construction permit for the proposed production facility. A notice of docketing was published in the FR on January 4, 2016 (81 FR 101). A notice of a 60-day opportunity to request a hearing and petition for leave to intervene was published in the FR on May 24, 2016 (81 FR 32793). No petitions were filed in response to the notice.

The safety review of the application for a construction permit for the 10 CFR Part 50 production facility is based on information in the application, as revised, and on the applicant's responses to requests for additional information (RAIs). Unless otherwise stated, this SER evaluates the information contained in Revision (Rev.) 3 of NWMI's PSAR, dated September 8, 2017 (Reference 60), as supplemented by responses to RAIs dated September 18, 2017 and September 28, 2017 (References 63 and 64, respectively).

1.1.1 Scope of Safety Review

The NWMI application discusses a proposed radioisotope production facility (RPF). The application describes performing various processes within the RPF. The following processes described in the application fall within the definition of "production facility," under 10 CFR 50.2, "Definitions": (a) irradiated low-enriched uranium (LEU) target receipt (from a network of U.S. research reactors); (b) irradiated LEU target disassembly and dissolution; (c) molybdenum-99 (Mo-99) recovery and purification; (d) uranium recovery and recycle; (e) waste management; and (f) associated laboratory and support area activities. Therefore, these processes are subject to the licensing requirements of 10 CFR Part 50. The staff refers to these processes as the production facility processes and the RPF area within which they are described to occur as "the production facility."

The NWMI application also describes performing a process that does not fall within the 10 CFR Part 50 definition of production facility. Specifically, NWMI PSAR Section 4.1.3.1.1, "Target Fabrication Process Overview," describes a target fabrication process consisting generally of receiving fresh LEU in metal form from a U.S. Department of Energy (DOE) supplier; fabricating LEU target material using uranyl nitrate, which consists of a combination of fresh LEU, recovered recycled LEU (referred to as "recovered scrap LEU" in NWMI PSAR Section 4.1.3.1.1, Rev. 0), and LEU recovered from the processing of irradiated targets; assembling, loading, and fabricating targets; and packaging the targets for shipment to a network of U.S. research reactors. NWMI PSAR Sections 4.1.3.1.2, "Target Fabrication

Physical Location," and 4.1.4.4, "Target Fabrication Area," explain that the target fabrication process will be performed in a separate area within the RPF called the target fabrication area.

NWMI PSAR Section 1.1, "Introduction," states that target fabrication will be licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," which will be "applied for under a separate license application submittal." As if October 25, 2017, the NRC has not yet received a 10 CFR Part 70 application from NWMI regarding the target fabrication process described in NWMI's 10 CFR Part 50 construction permit application.

Although the staff reviewed the entire application, including NWMI's descriptions related to 10 CFR Part 70 activities associated with target fabrication (e.g., possession and processing of enriched uranium and scrap recovery), the staff's review was limited to understanding the interface between the production facility processes and the target fabrication process in order to determine whether NWMI satisfies the requirements for the potential issuance of a construction permit for a 10 CFR Part 50 production facility. To the extent that the production facility and the target fabrication area share structures and systems (e.g., vessel cooling, ventilation, radioactive waste control, and instrumentation and control), these shared items were only evaluated to support the staff's conclusions regarding the issuance of a construction permit for NWMI's 10 CFR Part 50 production facility.

Consequently, the staff findings in this SER are limited to those required for licensing a production facility under 10 CFR Part 50.

1.1.2 Areas of Review

The review of the NWMI construction permit application consisted of two concurrent reviews: a safety review and an environmental review. The safety review was based on information in the application, as supplemented or revised by NWMI's responses to RAIs. The staff reviewed the NWMI application against applicable regulatory requirements in 10 CFR Part 50, using appropriate regulatory guidance and standards, as discussed below, to assess the sufficiency of the preliminary design of the NWMI production facility. As part of this review, the staff evaluated descriptions and discussions of the facility's structures, systems, and components (SSCs), with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI production facility was evaluated to ensure the sufficiency of principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions, to provide reasonable assurance that the final design will conform to the design bases. The preliminary items relied on for safety (IROFS) for the NWMI production facility were also evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents. The staff reviewed NWMI's analysis of the performance of the SSCs of the preliminary design of the production facility, with the objective of assessing the risk to public health and safety resulting from operation of the NWMI production facility.

In accordance with Section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. [United States Code] § 4332(2)(C)) and implementing NRC regulations in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," the staff prepared a final environmental impact statement (EIS) based on its independent assessment of the information provided by NWMI and information developed independently by the staff. The staff conducted an independent evaluation of the application and conducted a systematic, interdisciplinary review of the potential impacts of the proposed

action on the quality of the human environment and reasonable alternatives to NWMI's proposal. Before development of the Draft EIS, the staff published a notice of intent to prepare an EIS and invited the public to provide information relevant to the environmental review at a scoping meeting held on December 8, 2015, in Columbia, Missouri. The staff also provided opportunities for governmental and general public participation during the public comment period and meeting on December 6, 2016, in Columbia, Missouri, on the Draft EIS, and used publicly available guidance in the development of its Final EIS. The Final EIS, published as NUREG-2209, addressed comments received and meets the requirements of 10 CFR Part 51.

1.1.3 Regulatory Basis and Acceptance Criteria

The staff reviewed the NWMI application against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design of the NWMI production facility in support of the issuance of a construction permit. The staff evaluated the sufficiency of the facility's preliminary design, as described in the Rev. 3 of the PSAR, based on NWMI's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases and allow adequate margin for safety.

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 if the NRC makes the following findings:

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

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

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

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

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 are specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued

February 1996 (Reference 9). The staff's review in Chapter 2.0 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.

Although a construction permit, if issued, would authorize NWMI to proceed with construction of the NWMI production facility, the staff's evaluation of the preliminary design and analysis of the NWMI production facility does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur only after the staff completes an evaluation of the final design of the NWMI production facility, as described in the FSAR submitted as part of an NWMI operating license (OL) application.

In addition to the findings listed in 10 CFR 50.35, a construction permit application must also provide sufficient information to allow the Commission to make the following determinations in accordance with 10 CFR 50.40, "Common standards," and 50.50, "Issuance of licenses and construction permits":

(1) There is reasonable assurance: (i) that the construction of the 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.

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

(3) The applicant is financially qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

(4) 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.

(5) After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of the construction permit, subject to the conditions for protection of the environment set forth therein, is in accordance with Subpart A of 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

(6) The application meets the standards and requirements of the Atomic Energy Act (AEA) and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made.

While the NWMI construction permit application for a production facility is evaluated against all applicable regulatory requirements, the staff's evaluation of NWMI's preliminary design and analysis was based primarily on the following regulatory requirements:

- 10 CFR 50.2, "Definitions."
- 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities."
- 10 CFR 50.33, "Contents of applications; general information," paragraph (f).

- 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 50.42, “Additional standard for class 103 licenses.”
- 10 CFR 50.50, “Issuance of licenses and construction permits.”
- 10 CFR 50.55, “Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.”
- 10 CFR 50.58, “Hearings and report of the Advisory Committee on Reactor Safeguards.”
- 10 CFR Part 50, Appendix C, “A Guide for the Financial Data and Related Information Required to Establish Financial Qualifications for Construction Permits and Combined Licenses.”
- 10 CFR Part 50, Appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities.”
- 10 CFR 20.1201, “Occupational dose limits for adults.”
- 10 CFR 20.1301, “Dose limits for individual members of the public.”
- 10 CFR 70.61, “Performance requirements” and 10 CFR 70.62, “Safety program and integrated safety analysis” (referenced in the “Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors” (Reference 11), as an acceptable way to demonstrate compliance with 10 CFR Part 50 for radioisotope production facilities).

As required by 10 CFR 50.34(a)(3)(i), NWMI must describe the principal design criteria for its proposed production facility in the PSAR. NWMI has addressed the following principal design criteria for its proposed production facility consistent with 10 CFR 70.64, “Requirements for new facilities or new processes at existing facilities” (referenced in the ISG Augmenting NUREG-1537 as an acceptable way to demonstrate compliance with 10 CFR Part 50 for radioisotope production facilities), which were reviewed by the staff:

- Quality standards and records – Design is being developed and implemented in accordance with management measures to provide adequate assurance that IROFS will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

- Natural phenomena hazards – Design will provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

- Fire protection – Design will provide for adequate protection against fires and explosions.

- Environmental and dynamic effects – Design will provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

- Chemical protection – Design will provide for adequate protection against chemical risks produced from licensed material, facility conditions that affect the safety of licensed material, and hazardous chemicals produced from licensed material.

- Emergency capability – Design will provide for emergency capability to maintain control of: (i) licensed material and hazardous chemicals produced from licensed material, (ii) evacuation of on-site personnel, and (iii) on-site emergency facilities and services that facilitate the use of available off-site services.

- Utility services – Design will provide for continued operation of essential utility services.

- Inspection, testing, and maintenance – Design of IROFS will provide for adequate inspection, testing, and maintenance to ensure their availability and reliability to perform their function when needed.

- Criticality control – Design will provide for criticality control, including adherence to the double-contingency principle.

- Instrumentation and controls – Design will provide for inclusion of instrumentation and control (I&C) systems to monitor and control the behavior of IROFS.

- Facility and system design and facility layout will be based on defense-in-depth practices – Design will incorporate, to the extent practicable: (i) preference for the selection of engineered controls over administrative controls to increase overall system reliability, and (ii) features that enhance safety by reducing challenges to IROFS.

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 and fuel cycle facilities. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with 10 CFR 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 Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 10).

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 11).

- NUREG-1520, Rev. 1, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," dated May 2010 (Reference 24).

- NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," dated October 1983 (Reference 79).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, subpart H, does not mean that the performance requirements in subpart H are required for a radioisotope production facility license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, the staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers [IEEE] standards, American National Standards Institute/American Nuclear Society [ANSI/ANS] standards, and NRC office instructions) in the review of NWMI's application. The additional guidance was used 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 application.

1.1.4 Review Procedures

The staff's review of NWMI's application was informed by the staff's ISG Augmenting NUREG-1537, NUREG-1537, as well as other relevant guidance cited therein, cited in the

application, or used based on the staff's technical judgment. In particular, NWMI's 10 CFR Part 50 construction permit application only seeks authorization to construct the proposed NWMI production facility. Therefore, the level of detail needed in the application and the staff's corresponding SER is different than that needed for an OL application and corresponding SER. For the purposes of issuing a construction permit, the NWMI production facility may be adequately described at a functional or conceptual level in the PSAR. As such, NWMI has deferred providing some design and analysis details until the submission of its FSAR with its OL application.

The objective of the staff's evaluation was to assess the sufficiency of information contained in the NWMI application for the issuance of a 10 CFR Part 50 construction permit, in accordance with the requirements of 10 CFR Part 50. An in-depth evaluation of the NWMI design will be performed following the docketing of an NWMI application for an OL and its accompanying FSAR.

1.1.5 Resolving Technical Issues

For those technical areas that require additional information supported by research and development (e.g., a maturation of facility design), the staff has several options:

(1) The staff may determine that such technical issues must be resolved prior to the issuance of a construction permit.

(2) The staff may determine that such information may be left until the submission of the FSAR.

(3) The staff may require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit.

Technical issues that fall within the scope of the first option require additional information be provided in order to establish principal design criteria and/or design bases so that the staff may have confidence that the final facility design will conform to the design basis. The staff resolves such technical issues through RAIs.

In the second and third options, the staff may also issue RAIs to resolve identified technical issues. These types of technical issues include those that require a design maturity beyond what is required by 10 CFR 50.34(a) to issue a construction permit. Although determining what constitutes a preliminary versus a final design may be somewhat subjective, according to 10 CFR 50.34, a preliminary design must only include principal design criteria, the design bases, and general facility arrangement and approximate dimensions. This information should be sufficient to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. The staff may issue RAIs if it determines that doing so is necessary for the applicant to acknowledge certain technical deficiencies that could impact final design. Appropriate responses to these RAIs include commitments to resolving these deficiencies either in the FSAR or before the completion of construction.

During its review of the NWMI construction permit application, the NRC staff determined that additional information was required for it to complete its review and prepare this SER. Therefore, the staff prepared and issued RAIs dated March 28, 2016, September 29, 2016, January 25, 2017, March 29, 2017, and September 21, 2017 (References 12, 13, 14, 15, and 61, respectively). NWMI provided RAI responses in letters dated April 25, 2016,

November 28, 2016, March 6, 2017, April 28, 2017 (2), September 18, 2017, and September 28, 2017 (References 16, 17, 18, 19, 20, 63, and 64, respectively).

Additionally, SER Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," contains a listing of those elements of design, analysis, and administration identified as requiring additional research and development or correction by the applicant. The staff determined that resolution of these items is not necessary for the issuance of a construction permit, but that the applicant should ensure that these items are fully addressed in the FSAR supporting an NWMI OL application. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of an NWMI OL application.

1.1.6 Ongoing Research and Development

The provisions of 10 CFR 50.34(a)(8) allow for ongoing research and development to confirm the adequacy of the design of SSCs to resolve safety questions prior to the completion of construction. In accordance with 10 CFR 50.34(a)(8), and as described in NWMI PSAR Section 1.3.4, "Experimental Facilities and Capabilities," NWMI states the following:

> The RPF does not include experimental SSCs that require research and development (R&D) to:
>
> - Confirm adequacy of the facility design
> - Identify and describe the R&D program that will [be] completed to resolve any safety questions associated with such SSCs
> - Schedule the R&D program to show that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility.
>
> NWMI has and will continue to perform testing to validate the acceptable operating conditions for material and target solution compatibility at MURR [the University of Missouri – Columbia Research Reactor] and the DOE national laboratories prior to completion of RPF construction. Selected materials will be examined following irradiation testing at fluence levels expected in the operation of the target solution vessel for a 30-year lifetime. The testing will include specific work involving irradiation in a corrosive environment to examine the effects on the properties of selected raw materials and welded samples in an as-received and as-fabricated state. This work will be completed no later than December 31, 2017.

In accordance with 10 CFR 50.34(a)(8), and as described in NWMI's response to RAI 13.1-2 (Reference 31), there are ongoing research and development activities related to the safety of the uranium purification technology proposed to be used at the NWMI production facility. These include the following activities:

(1) Laboratory resin tests are being completed to determine the interactions between the solutions and resin as a function of temperature. The results from these tests will help define the hazard and accident controls if needed.

(2) Confirm the feasibility of a pressure relief system for a uranium ion exchange system or the need for a design change or separation technology change.

(3) Tests are being performed to evaluate the release of diamylamylphosphonate from the ion exchange column media during operation.

As described in Appendix A to this SER, the staff is tracking these activities and will verify their resolution prior to the completion of construction.

1.1.7 Advisory Committee on Reactor Safeguards Review

To support the Advisory Committee on Reactor Safeguards (ACRS) in providing an independent review and report to the Commission regarding the NWMI construction permit application, the staff presented the results of its safety evaluation to the ACRS Northwest Medical Isotopes Subcommittee at five meetings on June 19, July 11, August 22, August 23, and September 21, 2017. The staff presented the results of its NWMI construction permit application review to the ACRS Full Committee on November 2, 2017. The ACRS issued a letter on November x, 2017, which has been included as Appendix D, "Report by the Advisory Committee on Reactor Safeguards," of this SER, fulfilling the requirement of 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards," that the ACRS review and report on construction permit applications for a facility of a type described in 10 CFR 50.22.

The ACRS letter to the Commission recommended that the NWMI construction permit should be/not be approved. During the ACRS Northwest Medical Isotopes Subcommittee meetings, NWMI identified elements of design, analysis, and administration that require additional information to address the comments of the ACRS Northwest Medical Isotopes Subcommittee members. NWMI listed these items in its letters dated September 18, 2017 (Reference 63) and September 28, 2107 (Reference 65). The staff determined that the resolution of these items is not necessary for the issuance of a construction permit, but that the applicant expects that these items are addressed in the FSAR supporting an NWMI OL application. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of an NWMI OL application. These items are listed in Appendix A.4 of this SER.

1.1.8 Application Availability

Publicly-available documents related to the NWMI construction permit application may be obtained online in the Agencywide Documents Access and Management System (ADAMS) Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents," and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. For the convenience of the reader, the ADAMS accession numbers for publicly-available documents are provided in a table in Appendix B, "References," of this SER.

The current version (Rev. 3) of the NWMI PSAR submitted September 8, 2017, is publicly available in ADAMS under Accession No. ML17257A019 (Reference 60). Other public documents and correspondence related to this application may be found by searching for NWMI Docket Number, 50-609, or project number, PROJ803, in ADAMS. Portions of the application or correspondence containing sensitive information (e.g., proprietary information) are withheld from public disclosure pursuant to 10 CFR 2.390, "Public inspections, exemptions, requests for withholding."

1.1.9 NRC Staff Contact Information

The project manager for this SER was Michael Balazik, Project Manager, Division of Licensing Projects, U.S. Nuclear Regulatory Commission. Mr. Balazik may be contacted regarding this SER at 301-415-2856 or by e-mail at Michael.Balazik@nrc.gov. Appendix C, "Principal Contributors," to this SER provides a listing of principal contributors, including their areas of technical expertise and chapters of authorship.

1.2 Summary and Conclusions on Principal Safety Considerations

The staff evaluated the descriptions and discussions of the proposed NWMI production facility, as described in the NWMI application, as supplemented by the applicant. Based on its review, the staff makes the following findings:

(1) Applicable standards and requirements of the AEA and Commission regulations have been met.

(2) The acceptance criteria in or referenced in NUREG-1537 or the ISG Augmenting NUREG-1537, have been satisfied for a preliminary design supporting a construction permit application.

(3) Required notifications to other agencies or bodies related to this licensing action have been duly made.

(4) The design of the facility includes adequate margins of safety and there is reasonable assurance that the final design will conform to the design basis.

(5) There is reasonable assurance that the production facility can be constructed in conformity with the permit, the provisions of the AEA, and the Commission's regulations.

(6) NWMI identified credible accidents based on the preliminary design and designed IROFS to provide for the prevention of accidents or the mitigation of consequences of accidents. The staff has evaluated the accident analyses presented by NWMI in the PSAR and determined that NWMI identified appropriate preliminary controls to demonstrate, with reasonable assurance, that the performance objectives contained in 10 CFR 70.61 for the production facility can be met.

(7) Releases of radioactive materials and wastes from the facility are not expected to result in concentrations outside the limits specified by 10 CFR Part 20, Subpart D, "Radiation Dose Limits for Individual Members of the Public," and are as low as is reasonably achievable.

(8) The financial information, technical analyses and programs, and organization as described in the application demonstrate that NWMI is financially and technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations.

(9) The preliminary emergency plan provides reasonable assurance that NWMI will be prepared to assess and respond to emergency events.

(10) The application presents information at a level of detail that is appropriate for general familiarization and understanding of the proposed facility.

(11) The application describes the relationship of specific facility design features to the major processes that will be ongoing at the facility. This description includes the building locations of major process components and drawings illustrating the layout of the buildings and structures within the controlled area boundary that are used for the description.

(12) The application describes the major chemical or mechanical processes involving licensable quantities of radioactive material based, in part, on integrated safety analysis methodology. This description includes the building locations of major process components and brief accounts of the process steps.

(13) Issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public.

Therefore, the staff finds that, subject to certain conditions, the preliminary design and analysis of the NWMI production facility, as described in the NWMI PSAR, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Appendix A to this SER identifies certain permit conditions that the staff recommends the Commission include, if the construction permit is issued.

Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR

Based on these findings as documented in this SER, and subject to the conditions identified in Appendix A of this SER, the staff recommends that the Commission make the following conclusions for the issuance of a construction permit for the production facility in accordance with 10 CFR Part 50:

(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 that require R&D have been described by NWMI and an R&D 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, the proposed facility can

be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(5) There is reasonable assurance: (i) that the construction of the NWMI 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.

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

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

(8) 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.

(9) After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of the construction permit, subject to the conditions for protection of the environment set forth therein, is in accordance with Subpart A, "National Environmental Policy Act—Regulations Implementing Section 102(2)," of 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

(10) The application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications to other agencies or bodies have been duly made.

1.3 General Description

The staff evaluated the sufficiency of the general description of the NWMI production facility, as presented in NWMI PSAR Section 1.3, "General Description of the Facility," in part, by reviewing the geographical location of the facility; principal characteristics of the site; principal design criteria, operating characteristics, and safety systems; engineered safety features; instrumentation, control and electrical systems; coolant and other auxiliary systems; radioactive waste management provisions; radiation protection; the general arrangement of major structures and equipment; safety features of special interest; and novel facility design considerations using the guidance and acceptance criteria from Section 1.3, "General Description," of NUREG-1537, Parts 1 and 2.

NWMI is a limited liability company that was established in 2010 to ensure a domestic, secure, and reliable supply of Mo-99 for medical application. NWMI was formed under the laws of the state of Oregon and NWMI's corporate headquarters is located in Corvallis, Oregon. NWMI intends to construct and operate a production facility to recover and purify Mo-99 in Columbia, Missouri, at Discovery Ridge Research Park (Discovery Ridge), an emerging research park development owned and managed by the University of Missouri (MU) System. The proposed 3 hectare (ha) (7.4 acre) site is situated within Discovery Ridge, north of Discovery Ridge Drive. Discovery Ridge is located in the City of Columbia, Boone County, Missouri.

The NWMI application describes an RPF within which will be performing the following 10 CFR Part 50 production facility processes:

- Irradiated LEU target receipt (from a network of U.S. research reactors);
- irradiated LEU target disassembly and dissolution;
- Mo-99 recovery and purification;
- uranium recovery and recycle;
- waste management; and
- associated laboratory and support area activities.

The NWMI application also describes a target fabrication process consisting generally of receiving fresh LEU in metal form from a DOE supplier; fabricating LEU target material using uranyl nitrate, which consists of a combination of fresh LEU, recovered recycled LEU (referred to as "recovered scrap LEU" in NWMI PSAR Section 4.1.3.1.1, Rev. 0), and LEU recovered from the processing of irradiated targets; assembling, loading, and fabricating targets; and packaging the targets for shipment to a network of U.S. research reactors. PSAR Sections 4.1.3.1.2 and 4.1.4.4 explain that the target fabrication process will be performed in a separate area within the RPF called the target fabrication area and NWMI PSAR Section 1.1, Rev. 3, states that this process will be licensed under 10 CFR Part 70, which will be "applied for under a separate license application submittal."

As described in subsequent SER chapters, the design of the NWMI production facility includes engineered safety features to mitigate design-basis events or accidents, control and protection systems, equipment and processes related to handling and storage of byproduct material and special nuclear material, and fire protection systems. NWMI has a radioactive waste management program and a radiation protection program. Therefore, the staff concludes that the general description of the NWMI production facility, as described in NWMI PSAR Section 1.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit under 10 CFR Part 50.

1.4 Shared Facilities and Equipment

The staff evaluated the sufficiency of the evaluation of shared facilities and equipment, as presented in NWMI PSAR Section 1.4, "Shared Facilities and Equipment," using the guidance and acceptance criteria from Section 1.4, "Shared Facilities and Equipment," of NUREG-1537, Parts 1 and 2. The acceptance criteria state that the production facility should be designed to accommodate all uses or malfunctions of the shared facilities without degradation of the production facility.

Consistent with the review procedures of NUREG-1537, Part 2, Section 1.4, the staff confirmed that all facilities or equipment shared by the NWMI production facility are discussed in the PSAR. As stated in NWMI PSAR Section 1.4, "The NWMI RPF does not share any systems or equipment with facilities not covered by this Construction Permit Application." However, the NWMI RPF building does include both a production facility and a target fabrication area, which, while functionally separate, share common systems such as ventilation, cooling water, and waste processing systems. These shared facilities and equipment are described in the PSAR and are solely dedicated for use by the RPF.

The staff finds that there are no existing facilities or equipment that will be shared by the NWMI RPF and that the NWMI production facility represents new construction on previously

undeveloped property. The interface between the NWMI production facility and the target fabrication area, including common systems shared between them, is analyzed in other chapters in the PSAR. Therefore, the staff concludes that the shared facilities and equipment, as described in NWMI PSAR Section 1.4, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit under 10 CFR Part 50.

1.5 Comparison with Similar Facilities

The staff evaluated the sufficiency of the comparison of the NWMI production facility with other similar facilities, as presented in NWMI PSAR Section 1.5, "Comparison with Similar Facilities," using the guidance and acceptance criteria from Section 1.5, "Comparison with Similar Facilities," of NUREG-1537, Parts 1 and 2.

Section 1.5 of the NWMI PSAR states that the production facility is a conventional design, similar to the design used in other nuclear processing facilities that utilize hot cells. NWMI stated that it has developed extraction and purification chemistries, is designing and plans to construct a facility to extract and purify Mo-99, and intends to sell Mo-99 assuring a reliable, securable, and domestic supply of this medical isotope. In addition, NWMI will recover and recycle the LEU. The process equipment is typical of that used in a DOE nuclear facility, with geometrically favorable tanks, ion exchange columns, centrifugal contactors, evaporators, and batch solidification systems.

The dissolution of irradiated target material will use a standard hot nitric acid process. The offgas treatment unit operations are well known and commercially available. The molybdenum recovery and purification system selectively adsorbs molybdenum from the irradiated target solution. The molybdenum purification process is very similar to the Cintichem process developed in the 1950s and 1960s by Union Carbide. Cintichem, Inc. used the process until 1990 when the facility ceased operation as a means of purifying Mo-99 for use as a medical isotope.

The proposed uranium recovery process is a modification of a widely-used uranium separation and purification process known as plutonium-uranium extraction (PUREX). The PUREX process was developed in the late 1940s and uses tributyl phosphate to selectively remove uranium from a nitric acid solution typically containing a host of fission products and other actinide contaminants. The NWMI process uses similar chemistry but, instead of a solvent process, the active agent is attached to a solid substrate.

Consistent with the review procedures of NUREG-1537, Part 2, Section 1.5, the staff confirmed that the characteristics of any facilities compared with the proposed facility were similar and relevant. The staff also verified that the operating history of licensed facilities cited by the applicant demonstrated consistently safe operation, use, and protection of the public.

Based on its review, the staff finds that the level of detail provided on comparisons with similar facilities satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 1.5, allowing the staff to make the following findings:

(1) NWMI has compared the design bases and safety considerations of the NWMI production facility with similar facilities, as practicable. The history of these facilities demonstrates consistently safe operation that is acceptable to the staff.

(2) Aspects of NWMI's design that are similar to features in other facilities that have been found acceptable to the staff, should be expected to perform in a similar manner when constructed to that design.

(3) NWMI is using test data and operational experience from facilities with similar components in designing the production facility components, as practicable.

Therefore, the staff concludes that the comparisons with similar facilities, as described in NWMI PSAR Section 1.5, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit under 10 CFR Part 50.

1.6 Summary of Operations

The staff evaluated the sufficiency of the NWMI summary of operations, as presented in NWMI PSAR Section 1.6, "Summary of Operations," using the guidance and acceptance criteria from Section 1.6, "Summary of Operations," of NUREG-1537, Parts 1 and 2. Consistent with the review procedures of NUREG-1537, Part 2, Section 1.6, the staff verified that proposed operations of the NWMI production facility had been summarized.

NWMI listed the operations to be performed in the NWMI RPF, as follows:

- Receiving LEU from the DOE.
- Producing LEU target materials and fabrication of targets under 10 CFR Part 70.
- Packaging and shipping LEU targets to the U.S. research or test reactor network for irradiation.
- Receiving irradiated LEU targets for dissolution, recovery, and purification of Mo-99.
- Recovering and recycling LEU to minimize radioactive, mixed, and hazardous waste generation.
- Treating/packaging wastes generated by RPF process steps to enable transport to a disposal site.

Based on its review, the staff finds that the level of detail provided on the summary of operations satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 1.6. The proposed operations of the NWMI production facility are consistent with the relevant assumptions in later chapters of the PSAR, in which any safety implications of the proposed operations are evaluated.

Therefore, the staff concludes that the summary of operations, as described in NWMI PSAR Section 1.6, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit under 10 CFR Part 50.

1.7 Compliance with the Nuclear Waste Policy Act of 1982

The Nuclear Waste Policy Act of 1982 (42 U.S.C. § 10101) (Reference 23) provides that the U.S. government is responsible for the permanent disposal of high-level radioactive waste and

spent nuclear fuel, but the cost of disposal should be the responsibility of the generators and owners of such waste and spent fuel. The staff evaluated the sufficiency of NWMI's compliance with the Nuclear Waste Policy Act, as presented in NWMI PSAR Section 1.7, "Compliance with the Nuclear Waste Policy Act of 1982," using the guidance and acceptance criteria from Section 1.7, "Compliance with the Nuclear Waste Policy Act of 1982," of NUREG-1537, Parts 1 and 2.

As stated in NWMI PSAR Section 1.7, "The RPF does not produce either high-level nuclear wastes or spent nuclear fuel. Therefore, the Nuclear Waste Policy Act of 1982 is not applicable to the RPF." As described in NWMI PSAR Chapter 11.0, "Radiation Protection and Waste Management," NWMI has identified commercial disposition pathways for all of its radioactive waste.

As described in the American Medical Isotopes Production Act (42 U.S.C. § 2065(f)), radioactive material resulting from the production of medical radioisotopes that has been permanently removed from a reactor or subcritical assembly, and for which there is no further use, is considered to be low-level radioactive waste if it is acceptable under federal requirements for disposal as low-level radioactive waste. Since NWMI will be removing radioactive material resulting from the production of medical radioisotopes, the staff has determined that the NWMI facility will produce low-level radioactive waste and will not produce high-level nuclear wastes. As discussed in Chapter 11.0, "Radiation Protection Program and Waste Management," of this SER, NWMI plans to follow applicable NRC, DOE, and U.S. Department of Transportation regulations for disposal of its radioactive waste. Additionally, NWMI has identified licensed commercial disposal sites that can take receipt and dispose of the facility's solid radioactive waste. The staff finds that NWMI's plans for handling radioactive waste demonstrate appropriate consideration of regulatory requirements for the types of waste at the facility. Further evaluation of NWMI's plans for handling radioactive waste may reasonably be left for consideration during the review of NWMI's FSAR.

As defined in 10 CFR 72.3, "Definitions," spent nuclear fuel or spent fuel means "fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing." Since the NWMI process does not involve a power reactor or reprocessing of spent fuel, the staff has determined that the NWMI production facility will not produce spent nuclear fuel.

Therefore, since NWMI will not be producing spent nuclear fuel or high-level nuclear wastes, the staff confirms that the Nuclear Waste Policy Act is not applicable to this facility.

The staff notes that a provision of the American Medical Isotopes Production Act of 2012 (42 U.S.C. § 2065(c)(3)(A)(ii)) states that DOE would take title to, and be responsible for, the final disposition of radioactive waste created by the irradiation, processing, or purification of uranium leased from DOE for medical radioisotope production, if it determines that the producer (e.g., NWMI) does not have access to a disposal path. For example, if a disposal pathway for NWMI's Greater-Than-Class C Low-Level Radioactive Waste did not exist, DOE would be responsible for its disposal.

Chapter 11.0 of the NWMI PSAR describes NWMI's proposed radioactive waste management program, radioactive waste controls, and release of radioactive waste.

Therefore, the staff concludes that NWMI's description of the applicability of the Nuclear Waste Policy Act in Section 1.7 of the NWMI PSAR is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit for a production facility under 10 CFR Part 50.

1.8 Facility Modifications and History

The staff evaluated the sufficiency of NWMI's descriptions of facility modifications and history, as presented in NWMI PSAR Section 1.8, "Facility Modifications and History," using the guidance and acceptance criteria from Section 1.8, "Facility Modifications and History," of NUREG-1537, Parts 1 and 2.

As stated in NWMI PSAR Section 1.8, "There are no existing facilities at the proposed NWMI Discovery Ridge site, thus, no facilities modifications have occurred. This section is not applicable to the NWMI RPF."

The staff has determined that there are no existing facilities, there have been no modifications, and there is no history to report on the NWMI production facility. Therefore, this section is not applicable to this facility.

Therefore, the staff concludes that NWMI's description of facility modifications and history in NWMI PSAR Section 1.8 is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit for a production facility under 10 CFR Part 50.