POLICY ISSUE
(Information)

November 16, 2017 SECY-17-0116

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: STAFF STATEMENT IN SUPPORT OF THE UNCONTESTED HEARING FOR ISSUANCE OF A CONSTRUCTION PERMIT FOR THE NORTHWEST MEDICAL ISOTOPES, LLC PRODUCTION FACILITY

PURPOSE:

This paper serves as the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) primary pre-filed testimony for the uncontested (mandatory) hearing for issuance of a construction permit for a production facility to Northwest Medical Isotopes, LLC (NWMI), under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."[1] This paper, with its references, provides the information requested to support the Commission's determination that the staff's review has been adequate to support the findings for issuance of a 10 CFR Part 50 construction permit. These findings are set forth in 10 CFR 50.35, "Issuance of construction permits," 10 CFR 50.40, "Common standards," 10 CFR 50.50, "Issuance of licenses and construction permits," and 10 CFR 51.105, "Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations."

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[1] In "Staff Requirements – SECY-15-0088 – Selection of Presiding Officer for Mandatory Hearings Associated with Early Site Permit Applications and Construction Permit Applications for Medical Isotope Production and Utilization Facilities" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15238B093), the Commission agreed to conduct the mandatory hearings associated with construction permit applications for medical radioisotope production and utilization facilities and directed the staff to follow Chapter IV of the Internal Commission Procedures, "Conduct of Mandatory Hearings on Applications for Combined Licenses," to the extent practical.

In accordance with the Internal Commission Procedures, this paper focuses on nonroutine matters supporting the findings related to 10 CFR Part 50 and 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Nonroutine matters with regard to areas of particular importance are matters that relate to any unique features of the production facility or novel issues that arose as part of the review process.

This paper does not address any new commitments or resource implications.

SUMMARY:

The staff's review of the NWMI 10 CFR Part 50 construction permit application is complete. The results of the staff's review are documented in the staff's safety evaluation report (SER), completed in November 2017 (ADAMS Accession No. ML17310A368), and the staff's final environmental impact statement (FEIS), completed in May 2017 as NUREG-2209, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility" (ADAMS Accession No. ML17130A862). Drafts of the construction permit and record of decision are available (ADAMS Accession Nos. ML17313A100 and ML17313A338, respectively).

This paper focuses on nonroutine matters that arose as part of the review process, such as unique features of the production facility or novel issues, as summarized below.

- The staff granted an exemption that enabled NWMI to submit its 10 CFR Part 50 construction permit application in two parts.

- NWMI's 10 CFR Part 50 application to construct a production facility also included descriptions of a target fabrication process that NWMI intends to apply for separately under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." Although the staff's safety review did not evaluate the safety of the described target fabrication process, the staff did consider the interface between the 10 CFR Part 50 production facility processes and the target fabrication process, in order to determine whether NWMI satisfies the safety requirements for the potential issuance of a construction permit for a 10 CFR Part 50 production facility, which includes the finding that the proposed facility can be constructed and operated safely at the proposed site.

- The staff evaluated the sufficiency of the NWMI quality assurance program plan (QAPP) using applicable regulations and guidance, including endorsed industry standards. To provide for adequate implementation of licensee commitments in the design, procurement, and construction of the NWMI production facility, the staff recommends that the construction permit include a condition similar to the requirements of 10 CFR 50.55(f), which requires that nuclear power plant and fuel reprocessing plant construction permit holders implement the quality assurance program (QAP) described in the safety analysis report.

- Consistent with applicable guidance, NWMI applied the 10 CFR Part 70 approach in conducting its accident and hazards analyses. The staff found that NWMI's use of integrated safety analysis (ISA) methodologies, its application of radiological and chemical consequence and likelihood criteria, and its establishment of management measures provide reasonable assurance that NWMI's ISA process contains the elements that support the adequate identification of capabilities and features to prevent

or mitigate potential accidents and protect the health and safety of the public and workers.

- As a matter of discretion, the staff determined that an environmental impact statement (EIS) should be prepared rather than an environmental assessment (EA). The staff made this determination on the grounds that (1) the EA might not support a finding of no significant impact, and (2) operation of the NWMI facility (a connected action) as described in the application would include target fabrication and scrap recovery, processes similar to those used by fuel fabrication facilities. As required by 10 CFR 51.20(b)(7), an EIS is to be prepared for the issuance of a license that authorizes possession and use of special nuclear material for processing and fuel fabrication and for scrap recovery.

- The staff conducted a broad-scope environmental review with respect to NWMI's 10 CFR Part 50 construction permit application. This environmental review included reviewing not only the potential environmental impacts from the construction of the 10 CFR Part 50 production facility, but also, as actions connected to the issuance of a construction permit, the potential environmental impacts from the operations and decommissioning of the 10 CFR Part 50 production facility and the construction, operations, and decommissioning related to the 10 CFR Part 70 target fabrication process, to the extent that information on this process was available in the 10 CFR Part 50 construction permit application. The staff determined that the potential impacts would be SMALL for all resource areas.

- In conducting its environmental review, the staff analyzed two alternative approaches to the proposed action (i.e., the uranium fission technology alternative and the linear-accelerator-based alternative) in depth. The staff determined that the potential impacts from these two alternatives for construction, operations, and decommissioning would be SMALL for all resource areas. When compared with the proposed action, these alternative technologies would not reduce or avoid adverse environmental effects.

Finally, this paper addresses the findings in 10 CFR 50.35, 10 CFR 50.40, 10 CFR 50.50, and 10 CFR 51.105 and provides, with its references, an adequate basis for the Commission to conclude that each of these findings can be made for the NWMI construction permit application.

BACKGROUND:

I. Application History

Guidance Developed by the Staff for Medical Radioisotope Facility Reviews

In anticipation of receiving a construction permit and operating license applications for utilization and production facilities dedicated to the production of molybdenum-99 (Mo-99), the staff developed a technology-specific Interim Staff Guidance (ISG) for radioisotope production facilities (RPFs).[2] The ISG augmented the guidelines for preparing and reviewing non-power

[2] Final 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 (ADAMS Accession No. ML12156A069), and Final Interim Staff Guidance Augmenting NUREG-1537, Part 2,

reactor applications contained in NUREG-1537,[3] and is referred to as the ISG Augmenting NUREG-1537 in this paper. NWMI used the ISG Augmenting NUREG-1537, as applicable, in preparing its application for a production facility used to process low-enriched uranium (LEU) targets, including its preliminary safety analysis report (PSAR).

Application, Ownership, and Location

As allowed by an exemption granted by the Commission and published in the *Federal Register* on October 24, 2013 (78 FR 63501), NWMI submitted the first part of its two-part construction permit application to construct a production facility on November 7, 2014. Part one of NWMI's application consisted primarily of an environmental report, but also included a description and safety assessment of the site and general information (ADAMS Accession No. ML14318A298). As part of its acceptance review, the staff determined that NWMI did not provide sufficient information in the environmental report for the staff to begin its review (ADAMS Accession No. ML14349A501). Specifically, NWMI did not include information on the affected environment at all anticipated LEU target irradiation sites or the environmental impacts associated with LEU target irradiation at those sites. In order to resolve these deficiencies, NWMI withdrew and resubmitted part one of its construction permit application on February 5, 2015 (ADAMS Accession No. ML15086A261).

On July 20, 2015, NWMI submitted the second part of its construction permit application, which contained the balance of the information required for its PSAR (ADAMS Accession No. ML15210A182). On September 8, 2017, NWMI submitted Revision 3 to its PSAR, which updated Chapters 1.0 through 18.0 (ADAMS Accession No. ML17257A019), as supplemented by letters dated September 18, 2017 (ADAMS Accession No. ML17265A048), and September 28, 2017 (ADAMS Accession No. ML17283A109).

The publicly available portions of the application are available in ADAMS and on the U.S. Nuclear Regulatory Commission (NRC) NRC Web site at http://www.nrc.gov/reading-rm/adams.html. There are portions of the application that contain nonpublic information and have been withheld in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." The nonpublic version of the application is also available in ADAMS, but is restricted to authorized users.

NWMI is a limited liability company organized under the laws of the state of Oregon. Its headquarters are in Corvallis, Oregon. NWMI is a private organization that was created primarily for the purpose of designing, constructing, and operating a medical RPF. The RPF will be located on previously undeveloped property within the Discovery Ridge research park in the City of Columbia, Boone County, Missouri. The property is owned by, and would be leased from, the University of Missouri. NWMI would construct, own, and operate the proposed RPF.

"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 (ADAMS Accession No. ML042430048).

[3] NUREG-1537, Part 1, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content, dated February 1996 (ADAMS Accession No. ML042430055) and NUREG-1537, Part 2, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria, dated February 1996 (ADAMS Accession No. ML042430048).

Additional information about NWMI and its ownership is available in part one of NWMI's construction permit application, as provided by letter dated February 5, 2015, and in Chapter 15.0 of the NWMI PSAR and the staff's NWMI SER. Additional information about the site location and characteristics appears in Chapters 1.0, 2.0, and 19.0 of the NWMI PSAR, as supplemented by NWMI's responses to the staff's requests for additional information (RAIs),[4] and in Chapters 1.0 and 2.0 of the staff's NWMI SER and in the NWMI FEIS.

Overview of the Staff's Safety Review Approach to the NWMI Construction Permit Application

The staff's safety review was tailored to the nature of NWMI's construction permit application and was informed by the staff's ISG Augmenting NUREG-1537, as well as other relevant guidance cited in the ISG, cited in the application, or used based on the staff's technical judgment. In particular, NWMI's construction permit application only seeks authorization to construct the proposed NWMI production facility. Therefore, the level of detail needed in the construction permit application and the staff's corresponding SER is less than that needed for an operating license application because of the lower potential for impact to public health and safety. 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 many design and analysis details until the submission of its final safety analysis report (FSAR) with its operating license application.

The objective of the staff's evaluation was to assess the sufficiency of the information contained in the PSAR for the issuance of a construction permit in accordance with 10 CFR 50.35(a), 10 CFR 50.40, and 10 CFR 50.50. An in-depth evaluation of the NWMI design will be performed following the staff's receipt of NWMI's FSAR submitted as part of its operating license application.

The staff's safety review was also tailored to the unique and novel technology described in NWMI's construction permit application. As explained in the staff's NWMI SER Section 1.1.1, "Scope of Safety Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical radioisotope production as its RPF. The RPF building is divided into two separate areas. One area will house the 10 CFR Part 50 production facility that is the subject of NWMI's construction permit application. The other area, where target fabrication will be performed, will be the subject of a separate application under 10 CFR Part 70. In the staff's NWMI SER and this paper, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a 10 CFR Part 50 production facility as "the NWMI production facility" or "the facility." In the staff's NWMI SER and this paper, 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 license as "the target fabrication area." As part of its safety review, the staff considered the anticipated interface between and effect on the NWMI production facility from the target fabrication area, to the extent that information on the target fabrication

[4] The staff prepared and issued RAIs dated March 28, 2016, September 29, 2016, January 25, 2017, March 29, 2017, and September 21, 2017 (ADAMS Accession Nos. ML16056A122, ML16236A013, ML17013A584, ML17069A408, and ML17262A111, 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 (ADAMS Accession Nos. ML16123A119, ML16344A049, ML17093A661, ML17128A065, ML17128A053, ML17265A048, and ML17283A109, respectively).

process was available in the 10 CFR Part 50 construction permit application. However, the staff's safety findings and conclusions in the staff's NWMI SER and this paper are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.[5]

The staff used its judgment to determine the extent to which established guidance and acceptable 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 the following documents:

- NUREG-1537, Parts 1 and 2;
- ISG Augmenting NUREG-1537, Parts 1 and 2;
- NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," dated June 2015 (ADAMS Accession No. ML15176A258); and
- NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," dated October 1983 (ADAMS Accession No. ML062190191).

Because the acceptance criteria in NUREG-1537 and the ISG Augmenting NUREG-1537 do not distinguish between criteria applicable to a construction permit review versus the review of a final design in support of an operating license application, the staff used its judgment, informed by regulatory requirements, and the detail provided in the NWMI application, in deciding which acceptance criteria should be used for the review of a construction permit. For example, per 10 CFR 50.34(a)(5), a construction permit applicant needs only identify probable subjects of technical specifications (TSs). Thus, acceptance criteria related to establishing TSs were not used for the staff's review of the NWMI construction permit application.

Additionally, the ISG Augmenting NUREG-1537, which updated and expanded the guidance originally developed for non-power reactors, indicates that whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility," as applicable. In addition, the ISG states that the use of ISA methodologies as described in 10 CFR Part 70 and NUREG-1520, the application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," the designation of items relied on for safety (IROFS), and the establishment of management measures are acceptable ways of demonstrating adequate safety for an RPF. 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

[5] Unlike the regulations for a 10 CFR Part 50 construction permit, the regulations in 10 CFR Part 70 do not require pre-construction approval based on a review of matters related to the proposed design bases and quality assurance program for a facility licensed to conduct the target fabrication processes described in the NWMI construction permit application. See 10 CFR 70.23 and 10 CFR 70.23a.

an RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of relevant reactor-based guidance in its evaluation of the PSAR is consistent with the ISG Augmenting NUREG-1537.

The staff evaluated the sufficiency of the NWMI preliminary design, as described in 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. Neither the staff's evaluation of NWMI's preliminary design nor the Commission's issuance of a construction permit constitute approval of any design feature or specification of the production facility. 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 application.

Advisory Committee on Reactor Safeguards

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 NWMI Subcommittee at four meetings on June 19, 2017; July 11, 2017; August 22-23, 2017; 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 6, 2017 (ADAMS Accession No. ML17310B511), 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 permits for a facility of the type described in 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities." The ACRS conclusions and recommendations, as well as the staff's response, are discussed later in this paper.

II. Outreach

Public Meetings

At NWMI's request, the staff hosted public meetings at NRC Headquarters prior to docketing the NWMI construction permit application in 2015. These meetings were used to discuss technical and environmental information related to the development of the application, clarify the applicability of relevant guidance, and provide the public with opportunities to ask questions on the NRC's review process. Public meetings were also held following the receipt of NWMI's application to discuss various topics, including RAIs, design updates, and ongoing research and development.

On December 8, 2015, the staff held a meeting in Columbia, Missouri, to discuss the environmental scoping process and to give members of the public an opportunity to provide comments on environmental issues that the staff should consider during its review of the application. After issuing the draft EIS on October 31, 2016 (ADAMS Accession No. ML16305A029), the staff held another public meeting in Columbia, Missouri, on December 6, 2016, to provide an overview of the draft EIS and to accept public comments on the document.

In total, the staff conducted 11 public meetings prior to and during the review of the application.

Federal Register Notices

The NRC published the following *Federal Register* notices, as required, for key milestones in the licensing process:

- On October 24, 2013, the NRC published a notice of exemption from 10 CFR 2.101(a)(5), allowing NWMI to submit its application in two parts (78 FR 63501).

- After the NRC received part one of NWMI's two-part application on February 5, 2015, the agency published a notice of receipt and availability on April 21, 2015 (80 FR 22227).

- The NRC docketed part one of the NWMI construction permit application on June 1, 2015, and published a notice of acceptance for docketing on June 8, 2015 (80 FR 32418).

- After the NRC received the second and final part of NWMI's two-part application on July 20, 2015, the agency published a notice of receipt and availability on November 6, 2015 (80 FR 68880).

- On November 18, 2015, the NRC published a notice of intent to prepare an EIS and to conduct scoping (80 FR 72115).

- The NRC docketed the second and final part of the NWMI construction permit application on December 24, 2015, and published a notice of docketing on January 4, 2016 (81 FR 101).

- On May 24, 2016, the NRC published a notice of opportunity to request a hearing and petition for leave to intervene, and order imposing procedures for access to Sensitive Unclassified Non-Safeguards Information (81 FR 32793).

- On November 9, 2016, the NRC published a notice of availability of the draft EIS for public comment and notice of a public meeting to present an overview of the draft EIS and to accept public comments on the document (81 FR 78865).

- On May 18, 2017, the NRC published a notice of availability of the FEIS (82 FR 22858).

Consultations

As part of its environmental review, in accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and other applicable statutes, including the Endangered Species Act, and the National Historic Preservation Act, the staff consulted with and obtained input from appropriate Federal, State, and local agencies, as well as Tribal organizations.

Adjudicatory Actions

On May 24, 2016, the NRC published in the *Federal Register* (81 FR 32793) a notice of opportunity to request a hearing and petition for leave to intervene, and order imposing procedures for access to Sensitive Unclassified Non-Safeguards Information. No petitions for leave to intervene were filed following publication of this notice.

III. Review Process and Methodology

The staff used the processes and methodologies, as applicable, described in the following documents to ensure quality, consistency, and completeness in preparation of the staff's NWMI SER and FEIS:

(1) **NUREG-1537, Part 1.** The principal purpose of the format and content guide is to suggest a uniform format for presenting information in non-power reactor applications, help ensure completeness of information provided, assist the staff and others in locating information, and aid in increasing the efficiency of the review process. While this guide presents a format for applications that is acceptable to the staff, conformance is not required.

(2) **NUREG-1537, Part 2.** The principal purpose of the standard review plan (SRP) is to ensure the quality and uniformity of staff safety reviews. It is also a vehicle for disseminating information on regulatory matters concerning non-power reactors and clarifying the staff review process for applicants, licensees, and the public. Each section of the SRP outlines areas of review, acceptance criteria, review procedures, and evaluation findings to guide the staff's review. The SRP is the most definitive basis available for evaluating whether an application meets applicable regulations established by the Commission.

(3) **Interim Staff Guidance.** For areas in which the existing SRP does not contain review guidance, the staff prepared and used the ISG Augmenting NUREG-1537, Parts 1 and 2, as referenced above. The ISGs clarify technical review approaches and address questions related to regulatory processes and licensing activities.

(4) **NUREG-1520, Revision 2.** This SRP assures that complete and uniform reviews are made of license applications for fuel cycle facilities. As applicable and referenced in NWMI's application, NUREG-1520 was used to evaluate NWMI's use of ISA methodologies, including the selection of design-basis events, as described in NUREG-1520 and in 10 CFR Part 70, for its 10 CFR Part 50 production facility safety analysis.

(5) **NUREG-0849.** This SRP assures that complete and uniform reviews are made of research and test reactor radiological emergency plans. As applicable and described in the ISG Augmenting NUREG-1537, NUREG-0849 was used to evaluate the NWMI preliminary emergency plan submitted in accordance with Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," to 10 CFR Part 50.

(6) **Regulatory Guides.** Regulatory guides (RGs) provide guidance to licensees and applicants on implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems and scenarios, and information needed by the staff in its review of applications for permits or licenses. Consistent with the ISG Augmenting NUREG-1537, RGs from Division 2, "Research and Test Reactors," were generally found to be applicable to NWMI. NWMI's PSAR identifies RGs from Division 2 and other divisions, including Division 1, "Power Reactors," Division 3, "Fuels and Materials Facilities," Division 4, "Environmental and Siting," and Division 5, "Materials and Plant Protection," as relevant to the construction permit application and discusses whether NWMI conformed to or departed from each RG. As appropriate, RGs endorse professional standards for use in the staff's reviews.

(7) Office Instructions. In its review, the staff followed administrative guidance contained in a number of office instructions. These internal documents address a range of procedural matters, including the staff's process for issuing RAIs, handling audits, ensuring the qualification and training of technical staff and managers, ensuring consistency between staff offices, and overseeing interactions with applicants, intervenors, and the public.

IV. Advisory Committee on Reactor Safeguards Review

The ACRS review of the NWMI construction permit application culminated with a letter to the Commission dated November 6, 2017, recommending that a construction permit can be issued to NWMI (ADAMS Accession No. ML17310B511).

The ACRS letter stated that the proposed facility can be constructed to withstand expected seismic loads, but that some additional attention will need to be given to high-frequency (i.e., greater than 10 Hertz) seismic motions that do not threaten the structural integrity of the facility, but may affect internal systems. The ACRS letter also stated that aircraft impact probabilities will be reassessed as a part of the final design to show that either these probabilities are sufficiently low or that the facility is sufficiently protected from aircraft impact and that threats to the facility posed by other man-made, external hazards such as highway traffic and nearby pipelines will be reassessed during the final design of the facility.

NWMI has committed to evaluating the potential seismic high-frequency impact, reassessing aircraft impact probabilities, and reassessing man-made external hazards such as highway traffic and nearby pipelines in its FSAR. The staff is tracking these commitments in its SER.

DISCUSSION:

I. Excluded Matters

This paper does not discuss matters that will be addressed and resolved as part of a 10 CFR Part 50 operating license application review or as part of a 10 CFR Part 70 application review, including any related licensing actions. The distinction between the staff's construction permit application review and any 10 CFR Part 50 operating license application review or 10 CFR Part 70 application review is discussed further below.

II. Exemption from NRC Regulations

Prior to the submission of NWMI's construction permit application, NWMI sought and was granted an exemption that enabled NWMI to submit its application in two parts. This exemption addressed the 10 CFR 2.101(a)(5) requirement that applications for a construction permit under 10 CFR Part 50 must be of the type requiring an EIS or a supplement to an EIS as described in 10 CFR 51.20(b) (ADAMS Accession No. ML13238A331) in order to submit such an application in two parts. Since NWMI's application is not of the type requiring an EIS or supplement to an EIS in 10 CFR 51.20(b), the application could not be submitted in two parts. Therefore, the exemption allowed NWMI to submit part one of its construction permit up to 6 months prior to the submittal of the remainder of the application, regardless of whether an EIS or a supplement to an EIS would be prepared for its construction permit application. NWMI submitted the following in part one of its construction permit application:

- the environmental report required by 10 CFR 50.30(f);

- the description and safety assessment of the site required by 10 CFR 50.34(a)(1);
- the filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21;
- the general information required by 10 CFR 50.33; and
- the agreement limiting access to classified information required by 10 CFR 50.37.

Part two of NWMI's construction permit application contained the remainder of the PSAR required by 10 CFR 50.34(a).

In its exemption request, NWMI noted that the regulation enabling two-part applications for construction permits sought to remove unnecessary obstacles to the timely and efficient licensing and construction of nuclear facilities that are of public interest. NWMI's exemption request contended that the Nation's demand for medical radioisotopes is a significant public health and safety concern similar to the concerns over energy sources and supply that the initial rule was created to address. NWMI stated that an exemption enabling it to submit a two-part application would facilitate the completion of the environmental review and ultimate issuance of the construction permit.

The staff evaluated the exemption request and determined that such an exemption was authorized by law, would not present an undue risk to public health or safety, and was consistent with the common defense and security, and that special circumstances were present as described in 10 CFR 50.12(a)(2)(ii). The staff determined that the underlying purpose of 10 CFR 2.101(a)(5) is to facilitate the application submittal process for construction permit applicants when it is in the interest of the public to remove unnecessary obstacles to meet the needs of the Nation. Recognizing that NWMI's proposed production facility would contribute towards meeting the nation's domestic demands for Mo-99 and its decay product (technetium-99m) in nuclear medicine procedures, the staff determined that the underlying purpose of the rule was achieved and that special circumstances were present. The staff's evaluation and approval of the exemption request appeared in the *Federal Register* on October 24, 2013 (78 FR 63501). A summary of this evaluation appears in Section 1.1, "Introduction," of the staff's NWMI SER.

III. Nonroutine Unique Facility Features and Novel Issues

Safety Matters

a. Licensing Considerations

Colocation of 10 CFR Part 50 Production Facility and 10 CFR Part 70 Target Fabrication Area

A unique aspect of the NWMI construction permit application is that it describes a single proposed RPF building divided into two separate areas where processes subject to different regulatory requirements will take place. Specifically, the application describes the following processes that will be performed within one area of the RPF: (1) irradiated LEU target receipt from a network of U.S. research reactors; (2) irradiated LEU target disassembly and dissolution; (3) Mo-99 recovery and purification; (4) uranium recovery and recycle; (5) waste management; and (6) associated laboratory and support area activities. These processes satisfy the definition

of "production facility" in 10 CFR 50.2.[6] Therefore, this area of the RPF is subject to the licensing requirements of 10 CFR Part 50 and construction of only this portion of the RPF would be authorized by the issuance of a construction permit in response to NWMI's application. In the staff's NWMI SER and in this paper, the staff refers to these processes as the production facility processes, and the area of the RPF within which they will be performed as "the production facility."

The NWMI construction permit application also describes another process, target fabrication, that will be performed within a separate area of the RPF. Specifically, the target fabrication process, as described in the application, consists 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 scrap LEU recycled from off-specification unirradiated targets, 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. In the staff's NWMI SER and in this paper, the staff refers to this process as target fabrication, and the area of the RPF within which it will be performed as "the target fabrication area." Although the NWMI construction permit application discusses this process, it states in NWMI PSAR Section 1.1 that the activities supporting its target fabrication process will be licensed under 10 CFR Part 70, which will be applied for under a separate license application submittal. At the ACRS Full Committee meeting of November 2, 2017, NWMI stated that it will submit the 10 CFR Part 70 application when it files its 10 CFR Part 50 operating license application in the future.

The staff reviewed the entire application, including NWMI's descriptions related to 10 CFR Part 70 activities associated with target fabrication, however, the staff's safety review was to determine whether NWMI satisfies the requirements for the potential issuance of a construction permit for a 10 CFR Part 50 production facility. As part of that review, the staff focused on the interface between the production facility processes and the target fabrication process. 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 NWMI SER conclusions regarding the issuance of a construction permit for NWMI's 10 CFR Part 50 production facility. The staff did not make any findings regarding the safety of any 10 CFR Part 50 design feature or specification. Such approval, if granted, will be made following the evaluation of the final design of the NWMI facility, as described in the FSAR submitted as part of an NWMI 10 CFR Part 50 operating license application. Likewise, any 10 CFR Part 70 licensing findings will be made based on the staff's evaluation of a 10 CFR Part 70 application. Therefore, granting the 10 CFR Part 50 construction permit will only authorize NWMI to construct the production facility portion of the RPF.[7]

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[6] These processes fall within the third definition of "production facility" in 10 CFR 50.2 because they are related to the processing of irradiated materials containing special nuclear material and do not fall under any of the exceptions to this definition (i.e., the NWMI facility would not be a laboratory scale facility designed or used for experimental or analytical purposes, the NWMI facility would exceed the specified amounts of plutonium and fission product activity, and the NWMI facility would process irradiated LEU in batches greater than 100 grams of enriched U-235).

[7] Inasmuch as NWMI recognizes that the construction of the target fabrication portion of the RPF is governed by 10 CFR Part 70, the staff informed NWMI of the requirements of 10 CFR 70.21(f) and 10 CFR 70.23(a)(7) regarding commencement of construction in emails dated March 1, 2017, and September 15, 2017 (ADAMS Accession Nos. ML17312A989 and ML17313A978, respectively).

Quality Assurance Program Plan Implementation and Design Change Management

The staff reviewed the NWMI application against applicable regulatory requirements in 10 CFR Part 50, using appropriate regulatory guidance and standards 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 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 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, including IROFS, in 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.

As part of this review, the staff evaluated the sufficiency of the NWMI QAPP, as described in Appendix C of NWMI PSAR Chapter 12.0, "Conduct of Operations," in part, by determining whether the applicant satisfied the relevant requirements of 10 CFR 50.34(a)(7) and by using the guidance from Section 12.9, "Quality Assurance," of NUREG-1537, Parts 1 and 2. The quality assurance (QA) requirements of 10 CFR 50.34(a)(7) specify that an applicant for a construction permit shall provide a description of the QAP to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. NUREG-1537 refers to American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," as endorsed by RG 2.5, "Quality Assurance Program Requirements for Research and Test Reactors," for the review of an applicant's QAP.[8]

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

Based on its review, the staff found that the information in NWMI PSAR Section 12.9, "Quality Assurance," in conjunction with Appendix C1, is sufficient and meets the guidance in ANSI/ANS-5.8-1995 and the QA requirements in 10 CFR 50.34(a)(7).

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[8] ANSI/ANS 15.8 was developed to address quality assurance standards for research and test reactors. The standards in ANSI/ANS 15.8 are similar to the quality assurance requirements contained in Appendix B to 10 CFR Part 50, which apply to nuclear power plants and fuel reprocessing plants. However, ANSI/ANS 15.8 includes additional guidance on quality assurance standards for experimental equipment and facility operations. As described in the ISG Augmenting NUREG-1537, the staff finds the use of this standard acceptable for the development of a radioisotope production facility quality assurance program.

If a construction permit is issued to NWMI, the staff will implement a construction inspection program, as described in NRC Inspection Manual Chapter (IMC) 2550, "Non-Power Production and Utilization Facilities (NPUFs) Licensed Under 10 CFR Part 50: Construction Inspection Program (CIP)." As part of its construction inspection program, the staff will review NWMI's design changes and design control process to verify the effective implementation of NRC requirements during construction, including implementation of the NWMI QAPP. The objectives of IMC 2550 include: (1) verification of the development of QA procedures, instructions, and other documents that are consistent with the NWMI QAPP; and (2) verification of the effective implementation of the NWMI QAPP, including timely implementation of organizational staffing, procedures, instructions, QA activities, design controls, engineering controls, and administrative controls necessary to achieve quality objectives.

In order to provide reasonable assurance that regulatory requirements and licensee commitments for QA are adequately implemented in the design, procurement, and construction of the NWMI production facility, the staff recommends that the construction permit include a condition similar to the requirements of 10 CFR 50.55(f), which requires that nuclear power plant and fuel reprocessing plant construction permit holders implement the QAP described in the safety analysis report. Because the NWMI production facility is neither a nuclear power plant nor a fuel reprocessing plant, the requirements of 10 CFR 50.55(f) would not apply to NWMI. The proposed condition, described in Section 12.4.8, "Quality Assurance," of the staff's NWMI SER, establishes a threshold for submitting changes in the QAPP description to the NRC; provides for the consistency and maintenance of documentation; defines when prior NRC approval of QAPP changes is required; and identifies the circumstances under which changes to the QAPP are considered accepted by the Commission. The inclusion of such a condition in the NWMI construction permit would (1) ensure consistency in the NRC's expectations of licensees implementing QAPs developed pursuant to 10 CFR 50.34(a)(7); (2) establish a criteria for notifying the NRC of any necessary changes to NWMI's QAPP; and (3) facilitate the correction of any identified deficiencies in the implementation of the QAPP through the NRC's enforcement process during construction inspection. The draft construction permit includes this condition and the staff has also listed this construction permit condition in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of the staff's NWMI SER.

b. Accident Analysis Methodology and Preliminary Hazards Analysis

Accident analyses for 10 CFR Part 50 facilities need to show that the health and safety of both the public and workers are protected; that potential radiological and non-radiological consequences have been considered in the event of malfunctions; and that the 10 CFR Part 50 facility is capable of accommodating disturbances in the functioning of SSCs. Additionally, accident analyses need to demonstrate that design features, safety limits, limiting safety system settings, and limiting conditions for operation ensure that no credible accident could lead to unacceptable radiological or non-radiological consequences. As described in NUREG-1537, in order to ensure conservatism in facility design and protection from radiological hazards, a set of licensing-basis events is established to cover a wide spectrum of postulated accidents at non-power reactors. Additionally, in order to assess the potential dose impact of a facility to the public, a non-credible hypothetical radiological fission product release is analyzed. This event, referred to as the maximum hypothetical accident (MHA), should bound all of the credible hazards resulting from the postulated accidents. For currently licensed non-power reactors, the MHA assumes a failure of the fuel or a fueled experiment that results in radiological fission product consequences that exceed those of credible accidents. Since the MHA is not expected to occur, only the potential consequences of the event are analyzed and not the initiating event

or scenario details. For non-power reactors, the MHA is based on conservative assumptions and the radiological consequences from such an event should be bounded by the occupational and public dose limits in 10 CFR Part 20, “Standards for Protection Against Radiation.”

As described in the ISG Augmenting NUREG-1537, applicants for RPFs may use the MHA concept to inform the design of their facility and analyze potential accidents. Alternatively, applicants for RPFs may choose to use the ISA methodologies as described in 10 CFR Part 70 and NUREG-1520, including the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, the designation of IROFS, and the establishment of management measures.

Although previous applicants for non-power reactors and RPFs have chosen to use the MHA methodology, NWMI chose to evaluate the consequence of the radiological and chemical processes that would occur within the NWMI production facility through the performance of an ISA using the guidance in the ISG Augmenting NUREG-1537 and NUREG-1520. The results of this evaluation are presented in NWMI PSAR Chapter 13.0 and in an ISA Summary. NWMI PSAR Section 13.1.1, “Methodologies Applied to the Radioisotope Production Facility Integrated Safety Analysis Process,” describes the different types of accident analysis methodologies as they are applied to the NWMI ISA. More specifically, NWMI defined accident likelihood categories, consequence severity categories, and a risk matrix that combined various likelihood and consequence categories to determine credible and non-credible scenarios consistent with the guidance in NUREG-1520. In addition, NWMI described several accident analysis methodologies in its ISA process, including accident consequence analysis, what-if and structured what-if analyses, hazards and operability (HAZOP) studies, event and fault tree analyses, and failure modes and effects analyses. The HAZOP methods were used to analyze each process node and to identify certain accident sequences that require additional assessment via the quantitative risk analysis process. As part of its preliminary hazards analysis (PHA), NWMI identified several accident-initiating events. For the purposes of issuing a construction permit, the staff found that it was acceptable for NWMI to develop top-level accident sequence categories to demonstrate that the PHA considers a full range of accidents.

To support its accident analysis, NWMI also uniquely defined “safety-related SSCs” as those items relied on to remain functional during postulated design-basis events, as well as “safety-related IROFS” as those SSCs identified through the accident analyses as required to meet the performance requirements of 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d). While the 10 CFR 50.2 definition of “safety-related structures, systems, and components” only applies to nuclear power reactors, the NRC found that NWMI’s definitions appropriately categorize SSCs, as well as specific equipment, areas, and conditions, at the NWMI production facility such that there is reasonable assurance that the facility is designed and would be operated to prevent or mitigate the consequences of accidents.

The staff found that NWMI’s accident analysis review methodology was consistent with the ISG Augmenting NUREG-1537 for RPFs, which states on page *vi* that the use of ISA methodologies as described in 10 CFR Part 70 and NUREG-1520, the application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, the designation of IROFS, and the establishment of management measures are acceptable ways of demonstrating adequate safety for an RPF.

Specifically, the staff evaluated the steps of NWMI's ISA process and the following specific analyses of radiological and criticality accidents to assess NWMI's implementation of its ISA methodology:

- spills and spray accidents;
- dissolver offgas accidents;
- leaks into the auxiliary systems accidents;
- loss of electrical power;
- natural phenomena accidents; and
- an additional 75 accident sequences identified in NWMI PSAR Table 13-24, "Analyzed Accident Sequences".

Based on its review, the staff found that NWMI's use of ISA methodologies, its application of radiological and chemical consequence and likelihood criteria, and its establishment of management measures provide reasonable assurance that NWMI's ISA process contains the elements that support the adequate identification of capabilities and features to prevent or mitigate potential accidents and protect the health and safety of the public and workers. Further, the staff found that the preliminary ISA performed by the applicant provides the basis to establish that the design of the production facility, including the associated SSCs, can adequately assure that acceptable risk to the workers and public can be established and maintained.

Environmental Matters

a. Determination to Prepare an EIS and to Make Findings in 10 CFR 51.105

A novel consideration for the environmental review of the NWMI construction permit application was determining the appropriate level of detail for the staff's environmental review. The NRC's regulations implementing NEPA are codified in 10 CFR Part 51. Environmental reviews for licensing actions, such as construction permits, operating licenses, or license amendments, fall into one of three categories: those identified as categorical exclusions, those requiring the preparation of an EA, and those requiring the preparation of an EIS. The regulations in 10 CFR 51.20, "Criteria for and identification of licensing and regulatory actions requiring environmental impact statements," describe several types of actions that would require an EIS.

Construction permits and operating licenses for RPFs are not specifically included in 10 CFR 51.20. Such activities may require an EA or an EIS, depending on the action's potential for significant impacts that may affect the quality of the human environment.

In order to operate and produce Mo-99, NWMI proposes to fabricate LEU targets at the proposed RPF and to irradiate the targets at separate research reactors. The target fabrication process will entail fabricating LEU target material that would then be encapsulated in metal cladding. The target material production will consist of acid dissolution of uranium, solvent extraction, evaporation of uranium to desired concentration, chemical treatment to form a solid LEU material, and material filtration, washing, and inspection. The uranium used for the target material will be from a combination of (1) fresh LEU (special nuclear material), (2) recovered scrap LEU from identified off-specification unirradiated targets during inspections, and (3) LEU recovered and recycled from the processing of irradiated targets.

An EA is used to determine whether the impacts from the proposed action may be significant and whether a finding of no significant impact can be made. If, based on the EA, the NRC concludes that the proposed action could result in significant impacts to the human environment, the agency would prepare an EIS. In some cases, the NRC may decide to prepare an EIS without first preparing an EA if there is the potential for significant impacts to the human environment or the proposed action involves a matter that the Commission, in the exercise of its discretion, has determined should be covered by an EIS. For the NWMI environmental review, the staff determined that, pursuant to 10 CFR 51.20(a)(2), the proposed action should be covered by an EIS as a matter of discretion. The staff made this determination on the grounds that (1) the EA might not support a finding of no significant impact, and (2) operation of the NWMI facility (a connected action) as described in the application would include target fabrication and scrap recovery, processes similar to those used by fuel fabrication facilities. As required by 10 CFR 51.20(b)(7), an EIS is to be prepared for the issuance of a license that authorizes possession and use of special nuclear material for processing and fuel fabrication and for scrap recovery.

As described in the application, the processing of uranium for target fabrication is similar to the uranium scrap recovery processes that fuel fabrication facilities use, which consist of acid dissolution, filtration, solvent extraction, uranium concentration, and powder conversion. The staff analyzed whether the NWMI construction permit application describes a process similar to that used by 10 CFR Part 70 license applications that require an EIS under 10 CFR 51.20(b)(7). In accordance with 10 CFR 51.20(b)(7), an EIS or a supplement to an EIS is required for the issuance of a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, or conversion of uranium hexafluoride pursuant to 10 CFR Part 70. The staff also considered the criteria in 10 CFR 51.20(a)(2) and 10 CFR 51.20(b)(14). The staff concluded that based on the information in NWMI's construction permit application, the NWMI proposed target fabrication process includes scrap recovery. Therefore, the staff determined that it should prepare an EIS for the NWMI application.

b. Scope and Connected Actions

A novel consideration for the environmental review of the NWMI 10 CFR Part 50 construction permit application was determining the scope of the environmental review and analysis of connected actions given the unique nature of the NWMI RPF. In accordance with 10 CFR 51.29, "Scoping-environmental impact statement and supplement to environmental impact statement," the staff determined the scope of the EIS and identified significant issues to be analyzed in depth. Consistent with 10 CFR 51.14(b), the staff used the definitions in Council on Environmental Quality regulation, 40 CFR 1508.25, "Scope," which implements NEPA and states that connected actions should be discussed in the same EIS. Actions that are closely related are connected if they: automatically trigger other actions that may require EISs; cannot or will not proceed unless other actions are taken previously or simultaneously; or are interdependent parts of a larger action and depend on the larger action for their justification. In its FEIS, the staff evaluated as connected actions associated with the issuance of the 10 CFR Part 50 construction permit (1) the operations and decommissioning of the 10 CFR Part 50 production facility, (2) the construction, operations, and decommissioning related to the target fabrication process described in the NWMI application, and (3) the transporting and irradiating of LEU targets at the identified research reactors. Therefore, under NEPA, the scope of the FEIS

is broader than the SER to avoid improper segmentation[9] of the review of potential impacts related to the issuance of a construction permit.

As described above, the FEIS evaluated the potential environmental impacts of connected actions even though the federal action currently under review is limited to the issuance of a construction permit. Additional federal actions requiring NEPA review would be initiated if NWMI, consistent with its representations, files an application for a 10 CFR Part 50 operating license and files an application for a 10 CFR Part 70 license related to target fabrication activities. Because the potential environmental impacts related to these activities have been addressed in the FEIS, the staff expects that it could satisfy its NEPA obligations by supplementing the FEIS, as appropriate, based on the environmental reports required to accompany these applications.[10]

NWMI proposes to construct the NWMI facility within the University of Missouri Discovery Ridge Research Park in Columbia, Missouri. The proposed Discovery Ridge site encompasses 7.4 acres. The facility would be composed of four main buildings (RPF building [which would house the production facility and the target fabrication area], administration building, waste management building, and diesel generator building) and other support structures (storage tanks, fuel tanks, parking lots, and berms). Construction of the target fabrication area within the RPF building, as well as the administration building, waste management building, diesel generator building, and support structures, are interdependent parts of the proposed NWMI production facility. Therefore, the FEIS considered the environmental impacts associated with the NWMI facility in its entirety, not just the production facility within the RPF building.

The staff determined that it is appropriate to evaluate the potential impacts from operations and decommissioning of the 10 CFR Part 50 production facility as well as from construction, operations, and decommissioning related the target fabrication process, given that such activities are connected to the construction of the 10 CFR Part 50 production facility and cannot proceed unless other actions (e.g., issuance of a 10 CFR Part 50 construction permit) are taken previously. Notably, in order to operate and produce radioisotopes in the proposed NWMI RPF (i.e., 10 CFR Part 50 activities), NWMI proposes to fabricate and process LEU targets (i.e., 10 CFR Part 70 activities). Additionally, operation of NWMI's proposed facility will depend on LEU targets being transferred to and from, and irradiated in, one or more research reactors that would apply to the NRC to be authorized, by an operating license amendment, to irradiate the NWMI LEU targets. Because Mo-99 production cannot occur until research reactors are licensed to irradiate NWMI's LEU targets and the environmental impacts from LEU target irradiation at research reactors have not been previously assessed, the staff concluded that LEU irradiation at research reactors is an interdependent part of the proposed NWMI facility operation. The staff also determined that transportation of LEU targets and irradiation of LEU targets at research reactors are actions connected to operation of the proposed NWMI facility. Therefore, the staff assessed the environmental impacts associated with transporting and irradiating LEU targets at the identified research reactors in the FEIS.

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[9] An agency impermissibly "segments" a NEPA review when it divides connected, cumulative, or similar federal actions into separate projects and thereby fails to address the true scope and impact of the activities that should be under consideration. *Delaware Riverkeeper Network, et al. v. Federal Energy Regulatory Commission, 753* F.3d 1304, 1313 (D.C. Cir. 2014).

[10] 10 CFR 51.95(b) provides that, in connection with the issuance of an operating license for a production facility, the staff will prepare a supplement to the FEIS on the construction permit which will update the prior environmental review. The staff expects that a similar approach could be adopted for the review of an NWMI 10 Part 70 application relating to target fabrication.

NWMI identified two research reactors to provide irradiation services in its construction permit application, the University of Missouri-Columbia Research Reactor (MURR) and the Oregon State University TRIGA Reactor (OSTR). NWMI is also considering the use of a third research reactor and stated in its environmental report that the research reactor design and operations would be similar to OSTR. The staff considered parameters for the potential third research reactor parameters (e.g., distance from the proposed NWMI RPF and modifications anticipated to support LEU target irradiation) based on OSTR to represent the potential environmental impacts. Therefore, the FEIS evaluated the environmental impacts associated with research reactor modifications and equipment refurbishment anticipated to support target irradiation, as well as the environmental impacts from target irradiation at MURR, OSTR, and a potential third research reactor to bound this connected action.

c. Range of Reasonable Alternatives

Chapter 5 of the FEIS describes alternatives to granting a construction permit for the proposed NWMI facility and the environmental impacts of those alternatives. The need to compare the proposed action with alternatives arises from the requirement in Section 102(2)(C)(iii) of NEPA. NEPA states that an EIS shall include an analysis of alternatives to the proposed action. The NRC implements this requirement through regulations in 10 CFR Part 51 and its ISG Augmenting NUREG-1537, which provide that the EIS will include an analysis that considers and weighs the environmental effects of the proposed action, the environmental impacts of alternatives to the proposed action, and alternatives available for reducing or avoiding adverse environmental effects.

As part of the FEIS, the staff considered alternative technologies to produce Mo-99. This analysis was novel for the NWMI review because several entities have proposed new technologies to produce Mo-99, and the proposed new technologies are at various stages of development. When a large number of potential alternatives exist, NEPA requires that an agency analyze a reasonable number of examples, covering the full spectrum of alternatives, in the EIS (46 FR 18026). For the alternative technologies analysis, the staff initially narrowed down the broad range of potential alternatives by considering five alternative technologies that had received cooperative agreements from the DOE National Nuclear Security Administration (DOE-NNSA). In awarding these cooperative agreements, DOE-NNSA based its decision, in part, on an evaluation of technical feasibility. These five alternative technologies were:

(1) neutron capture technology;
(2) aqueous homogenous reactor technology;
(3) selective gas extraction technology;
(4) uranium fission technology; and
(5) linear-accelerator-based technology.

The staff then considered whether sufficient environmental data existed to conduct a meaningful alternatives analysis for each of the five technologies. For the neutron capture, aqueous homogenous reactor technology, and selective gas extraction technology, the staff determined that, given the lack of environmental data regarding the potential impacts from construction, operations, and decommissioning, insufficient environmental information existed to meaningfully analyze the environmental impacts of these three alternatives. The staff determined that sufficient environmental data existed for the uranium fission technology alternative and the linear-accelerator-based alternative. The staff analyzed these alternatives in depth. The staff determined that the impacts from these two alternatives from construction, operations, and decommissioning would be SMALL for all resource areas. The staff also determined that the

impacts from the proposed action of target fabrication at the Discovery Ridge Research Park and off-site target irradiation would be SMALL for all resource areas. Therefore, the staff concluded that construction, operation, and decommissioning of an alternative technology would not reduce or avoid adverse environmental effects when compared with construction, operation, and decommissioning of the proposed NWMI facility.

IV. Findings

10 CFR 50.35(a):

(1) The applicant 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.

The principal architectural and engineering criteria incorporated into the proposed design of the NWMI production facility to protect the health and safety of the public are presented in the NWMI PSAR. Principal design criteria, design bases, administrative controls, passive safety features, and active safety features are found in the following PSAR chapters:

Chapter 1.0 The Facility
Chapter 2.0 Site Characteristics
Chapter 3.0 Design of Structures, Systems, and Components
Chapter 4.0 Radioisotope Production Facility Description
Chapter 5.0 Coolant Systems
Chapter 6.0 Engineered Safety Features
Chapter 7.0 Instrumentation and Control Systems
Chapter 8.0 Electrical Power Systems
Chapter 9.0 Auxiliary Systems
Chapter 11.0 Radiation Protection and Waste Management
Chapter 12.0 Conduct of Operations
Chapter 13.0 Accident Analysis
Chapter 14.0 Technical Specifications

The staff evaluated NWMI's preliminary design to ensure the sufficiency of principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions. As part of its review of the preliminary design, the staff evaluated descriptions and discussions of the production facility's SSCs, giving special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. Based on its evaluation, the staff concludes that NWMI's preliminary production facility design is sufficient to provide reasonable assurance that the final design will conform to the design bases. In addition, the staff reviewed NWMI's identification and justification for the selection of variables, conditions, or other items that are probable subjects of TSs for the NWMI production facility.

In areas for which the staff found that the information submitted initially was incomplete or insufficient to allow the staff to reach a conclusion, the staff issued RAIs to NWMI. The staff reviewed NWMI's RAI responses to ensure that the additional information provided was sufficient to support the staff's conclusion. Where necessary, NWMI provided supplemental RAI responses. As necessary, the staff also conducted audits of NWMI's records and calculations and performed its own confirmatory calculations.

The staff finds that the preliminary design and analysis of the NWMI production facility is sufficient because it: (1) provides reasonable assurance that the final design will conform to the design bases, (2) includes an adequate margin of safety, (3) demonstrates that SSCs adequately provide for the prevention of accidents and the mitigation of consequences of accidents, and (4) meets all applicable regulatory requirements and acceptance criteria included or referenced in NUREG-1537 and the ISG Augmenting NUREG-1537. Notably, releases of radioactive material and waste from operation of the facility are expected to remain below the limits in 10 CFR Part 20, Subpart D. Furthermore, the staff's review confirmed that radiological and non-radiological consequences of potential accidents will also be within acceptable limits with respect to the performance requirements of 10 CFR 70.61. This supports the staff's conclusion that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public. As discussed in Chapter 1.0 of the staff's NWMI SER, the staff made its inimicality finding after determining that NWMI met all applicable regulations and acceptance criteria.

Based on its review, the staff concludes that 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. NWMI meets the applicable standards and requirements of the Atomic Energy Act of 1954, as amended (AEA), and the Commission's regulations.

(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.

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility based on NWMI's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases. As such, the staff's evaluation of NWMI's preliminary design 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 application.

Throughout the PSAR, and in responses to RAIs, NWMI clearly indicated areas in which further technical or design information would be provided in the FSAR to complete the safety analysis for an operating license application. The staff is independently tracking those areas as regulatory commitments, and has provided a list of these commitments in Appendix A to the staff's NWMI SER. The staff will evaluate the status of these commitments as part of its review of an operating license application.

Based on its review of the application and responses to RAIs, the staff concludes that NWMI has provided reasonable assurance that further technical or design information, that can reasonably be left for later consideration, will be supplied in the FSAR. Thus, the staff concludes that NWMI has met the applicable standards and requirements of the AEA and the Commission's regulations.

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

As described in NWMI PSAR Chapter 1.0, and in response to RAI 13.1-2, NWMI identified four research and development activities:

- performing testing at the MURR and the DOE national laboratories to validate the acceptable operating conditions for material and target solution compatibility;

- completing laboratory resin tests to determine the interactions between solutions and resin as a function of temperature;

- performing tests to confirm whether a pressure relief system can be designed for an ion exchange column used in NWMI's uranium separation process approach; and

- performing tests to evaluate the release of diamylamylphosphonate from the ion exchange column media during operation.

In support of these activities, NWMI has provided descriptions of the affected SSCs and the remaining work to be performed. The staff listed these four research and development activities in Appendix A to the staff's NWMI SER and will verify that these activities are completed prior to the completion of construction.

The staff has also determined that, although the NWMI application addresses nuclear criticality safety, additional information is needed to confirm that, as the design is finalized, it continues to address nuclear criticality safety. Accordingly, the construction permit would be conditioned upon NWMI providing information related to (1) the incorporation of its revised upper subcritical limit into its final design and (2) the technical basis for the design of the criticality accident alarm system. These conditions must be satisfied prior to the completion of construction and terminate once NWMI submits its FSAR (i.e., when the NWMI final design is complete and submitted as part of an operating license application). The adequacy of the final design to address nuclear criticality safety will be evaluated during the staff review of an operating license application. The draft construction permit lists these two conditions, and the staff has also listed these two conditions in Appendix A to the staff's NWMI SER. These conditions are ministerial and confirmatory in nature since they do not require evaluation by the staff to make its findings with respect to the issuance of the construction permit. Additional details on the basis for each condition appear in the technical evaluations of the staff's NWMI SER, Chapter 6.0.

Based on its review of the NWMI construction permit application, the staff concludes that NWMI has described safety features and components that require research and development. Furthermore, NWMI will conduct a research and development program reasonably designed to resolve any safety questions associated with the compatibility of materials and system design and performance. Such further matters associated with nuclear criticality safety that require additional information would be addressed by conditions of the construction permit. Thus, the staff concludes that NWMI meets the applicable standards and requirements of the AEA and the Commission's regulations.

(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.

By letter dated September 28, 2017 (ADAMS Accession No. ML17283A108), NWMI stated that the latest date for completion of construction is expected to be December 31, 2022. NWMI's four research and development activities are required to be resolved in advance of the estimated completion of construction. Additionally, as described in Chapter 6.0 of the staff's NWMI SER, the two conditions of NWMI's construction permit that are related to nuclear criticality safety must also be satisfied prior to the completion of construction or will terminate once NWMI has finalized the design of its production facility and submits its FSAR.

Based on its review of the NWMI construction permit application, the staff concludes that there is reasonable assurance that NWMI's safety questions will be satisfactorily completed at or before the latest date for the completion of construction of the NWMI facility. Thus, the staff concludes that the applicable standards and requirements of the AEA and the Commission's regulations have been met.

(ii) taking into consideration the site criteria contained in Part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

The staff reviewed the application to ensure that issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public. The staff notes that the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," are applicable to nuclear power reactors and testing reactors, and not to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to those in 10 CFR Part 100 by using the guidance in NUREG-1537. The staff's review in Chapter 2.0 of the staff's NWMI 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. The staff also evaluated SSCs and equipment designed to ensure safe operation, performance, and shutdown when subjected to extreme weather, floods, seismic events, missiles (including aircraft impacts), chemical and radiological releases, and loss of offsite power.

As discussed in Chapters 11.0 and 13.0 of the staff's NWMI SER, the staff's review confirmed that radiological and non-radiological consequences of potential accidents will be within acceptable limits with respect to the performance requirements of 10 CFR 70.61. Thus, the staff concludes that the issuance of the construction permit will not be inimical to the health and safety of the public.

The staff's review of NWMI's preliminary emergency planning information concluded that the preliminary emergency plan contains the information required in Appendix E to 10 CFR Part 50. Therefore, as discussed in Chapter 12.0 of the staff's NWMI SER, the preliminary plan is acceptable and supports the staff's conclusion that issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public.

Based on its review of the application, as discussed in this paper and in the referenced documents, the staff concludes that there is reasonable assurance that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public. The staff also concludes that the provisions of the AEA and the Commission's regulations have been met. In some cases, the staff's finding required the inclusion of conditions in the construction permit. The draft construction permit lists these conditions.

10 CFR 51.105(a):

(i) Determine whether the requirements of Sections 102(2) (A), (C), and (E) of NEPA and the regulations in Subpart A of 10 CFR Part 51 have been met.

The NRC's environmental protection regulations for domestic licensing are in 10 CFR Part 51. The staff reviewed the application and the Commission's regulations in 10 CFR Part 51 and determined that 10 CFR 51.105(a) provided the applicable environmental findings. The staff performed this evaluation using applicable portions of the ISG Augmenting NUREG-1537.

In accordance with NEPA Section 102(2)(A) (42 U.S.C. § 4332(2)(A)), the staff prepared the FEIS based on its independent assessment of the information provided by NWMI and information developed independently by the staff, including through consultation with other agencies. The staff's technical analysis used a systematic, interdisciplinary approach to integrate information from many fields, including the natural and social sciences as well as the environmental design arts. Consequently, the staff concludes that its review comports with the requirements in Appendix A, "Format for Presentation of Material in Environmental Impact Statements," to 10 CFR Part 51. The staff concludes that the environmental findings in the FEIS constitute the "hard look" required by NEPA and have reasonable support in logic and fact.

In accordance with NEPA Sections 102(2)(C)(i–v) (42 USC § 4332(2)(C)(i–v)), the FEIS for the NWMI construction permit addresses: (1) the environmental impact of the proposed action, (2) any unavoidable adverse environmental effects, (3) alternatives to the proposed action, (4) the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity, and (5) any irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented.

As supported by correspondence presented in Appendices C and D to the FEIS, the staff concludes that it has fulfilled the requirement of NEPA Section 102(2)(C) by consulting with and obtaining comments from other Federal, State, and local agencies with jurisdiction by law or special expertise. The staff also filed the FEIS with the U.S. Environmental Protection Agency, furnished it to commenting agencies, and made it available to the public.

The staff concludes that the FEIS demonstrates that the staff adequately considered alternatives to the proposed action to the extent that it involves unresolved conflicts concerning alternative uses of available resources, consistent with the requirements of NEPA Section 102(2)(E) (42 USC § 4332(2)(E)). The alternatives considered in the FEIS include the no-action alternative, alternative sites, and alternative technologies.

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken.

Section 5.4 of the FEIS provides the staff's cost-benefit balancing. The staff concluded that in weighing the costs and benefits, the overall benefits of constructing, operating, and decommissioning the proposed NWMI facility in Columbia, Missouri, outweigh the disadvantages and costs based upon the following considerations:

- U.S. policy interest in ensuring a reliable supply of medical radioisotopes while minimizing the use of highly enriched uranium for civilian purposes;

- the small environmental impact, including radiological impacts and risk to human health, that would be caused by constructing, operating, and decommissioning the proposed NWMI facility in Columbia, Missouri;

- the economic benefit of constructing and operating the proposed NWMI facility to communities located near the proposed site; and

- the increased availability of medical radioisotopes for U.S. public health needs.

(iii) Determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values.

As noted above, in its FEIS, the staff considered the cost-benefit balancing as well as reasonable alternatives. Based on that analysis, the staff recommends that the construction permit be issued. The staff based its recommendation on: (1) the NWMI environmental report submitted as part of its construction permit application; (2) consultation with Federal, State, and local agencies and Tribes; (3) the staff's independent review; (4) the staff's consideration of public scoping comments related to the environmental review; (5) the staff's consideration of public comments on the draft EIS; and (6) the assessments summarized in the EIS, including the potential mitigation measures identified in the environmental report and in the EIS. In addition, in making its recommendation, the staff determined that the proposed location for the facility (Discovery Ridge Research Park site in Columbia, Missouri) was environmentally preferable to the alternative site considered (the MURR).

(iv) Determine, in an uncontested proceeding, whether the NEPA review conducted by the staff has been adequate.

The staff conducted an independent evaluation of the application; developed independent, reliable information; and conducted a systematic, interdisciplinary review of the potential impacts of the proposed action on the human environment and reasonable alternatives to NWMI's proposal. Before development of the draft EIS, the staff issued a notice of intent and invited the public to provide any information relevant to the environmental review. The staff also provided opportunities for governmental and general public participation during the public meeting on the draft EIS and used publicly available guidance in the development of its FEIS. The contents of the FEIS are in conformance with the requirements of Appendix A to 10 CFR Part 51.

The staff considered the purpose of and need for the proposed action, the environment that could be affected by the action, and the consequences of the proposed action, including mitigation that could reduce impacts. The FEIS considered the no-action alternative, alternative sites, and alternative technologies. The FEIS compared the alternatives to the proposed action. The staff considered any adverse environmental effects that could not be avoided should the proposed action be implemented, the relationship between short-term uses of the human environment and the maintenance and enhancement of long-term productivity, and any irreversible or irretrievable commitments of resources that would be involved in the proposed project.

The NRC filed the draft EIS with the U.S. Environmental Protection Agency for its review consistent with the requirements of Section 309 of the Clean Air Act (42 U.S.C. § 7609). The

staff considered all comments received on the draft EIS and, in Appendix A to the FEIS, described the manner in which each comment was dispositioned. The staff published a notice of opportunity to request a hearing and petition for leave to intervene, and no requests or petitions were filed.

On these bases, the staff concludes that, for the purpose of issuing the construction permit, it conducted a thorough and complete environmental review that was sufficient to meet the requirements of NEPA and the NRC's regulations and adequate to inform the Commission's action on the construction permit application.

CONCLUSION:

Based on the findings of its review in accordance with 10 CFR 50.35(a) and 10 CFR 51.105, the staff concludes that there is sufficient information for the Commission to issue the subject construction permit to NWMI, as guided by the following considerations described in 10 CFR 50.40 and 10 CFR 50.50, and as described in Chapter 1.0 of the staff's NWMI SER.

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

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

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

- 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.

- 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.

- The application meets the standards and requirements of the AEA and the Commission's regulations, and notifications, if any, to other agencies or bodies have been duly made.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

/RA/

Victor M. McCree
Executive Director
for Operations

SUBJECT: STAFF STATEMENT IN SUPPORT OF THE UNCONTESTED HEARING FOR ISSUANCE OF A CONSTRUCTION PERMIT FOR THE NORTHWEST MEDICAL ISOTOPES, LLC PRODUCTION FACILITY
DATED: November 16, 2017

ADAMS Accession No.: ML17313A037 ***via e-mail** **SECY-012**

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