

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

COMMISSIONERS:

Kristine L. Svinicki, Chairman
Jeff Baran
Stephen G. Burns

In the Matter of

NORTHWEST MEDICAL ISOTOPE, LLC

(Medical Radioisotope Production Facility)

Docket No. 50-609-CP

CLI-18-06

MEMORANDUM AND ORDER

On January 23, 2018, we held a hearing on the application of Northwest Medical Isotopes, LLC (NWMI) for a permit to construct a medical radioisotope production facility in Columbia, Missouri.¹ The purpose of the evidentiary hearing was to consider the sufficiency of the NRC Staff's review of NWMI's application. As discussed below, we conclude that the Staff's review was adequate to support the findings set forth in our regulations. We authorize issuance of the construction permit.

¹ See Northwest Medical Isotopes, LLC; Notice of Hearing, 82 Fed. Reg. 56,276 (Nov. 28, 2017) (Notice of Hearing); Tr. at 1-220 (attached to Order of the Secretary (Setting Deadline for Proposed Transcript Corrections) (Jan. 29, 2018) (unpublished) (as amended by Order of the Secretary (Adopting Proposed Transcript Corrections, Admitting Post-Hearing Exhibits, and Closing the Record of the Proceeding) (Feb. 22, 2018) (unpublished) (Transcript Correction Order))).

I. BACKGROUND

A. Proposed Action

NWMI seeks to build a medical radioisotope production facility at the Discovery Ridge Research Park in Columbia, Missouri, to produce molybdenum-99. Molybdenum-99 decays to technetium-99m, a radioisotope used in tens of thousands of medical procedures daily in the United States.² NWMI requested and received an exemption to submit its construction permit application in two parts.³ It submitted Part 1 on February 5, 2015, and Part 2 on July 20, 2015.⁴

The Staff spent approximately 10,000 hours, with an additional 2,000 hours from outside technical experts, reviewing NWMI's application to determine whether it complies with the Atomic Energy Act of 1954, as amended (AEA), and the NRC's regulations.⁵ The Staff's review included an analysis of the environmental impacts of constructing, operating, and decommissioning the NWMI facility, in accordance with the National Environmental Policy Act of 1969 (NEPA).⁶ The Advisory Committee on Reactor Safeguards (ACRS), a committee of

² Tr. at 17 (Mr. Fowler).

³ See Request to Submit a Two-Part Application—Northwest Medical Isotopes, LLC, 78 Fed. Reg. 63,501, 63,504 (Oct. 24, 2013).

⁴ See Northwest Medical Isotopes, LLC; Construction Permit Application, 80 Fed. Reg. 32,418, 32,418 (June 8, 2015) (docketing Part 1 of the application); Northwest Medical Isotopes, LLC, 81 Fed. Reg. 101, 102 (Jan. 4, 2016) (docketing Part 2 of the application). See generally Ex. NRC-006A to NRC-006I, Northwest Medical Isotopes, LLC, Construction Permit Application (Construction Permit Application). Staff exhibits NRC-007A to NRC-007J contain the non-public portions of the application, and, as such, they were filed on the non-public docket for this proceeding.

⁵ Tr. at 59-60 (Ms. Ross-Lee).

⁶ *Id.* at 61, 68-69.

technical experts charged with reviewing and reporting on safety studies and applications for construction permits and facility operating licenses, provided an independent assessment of the safety aspects of the application.⁷ The ACRS recommended that the construction permit be issued.⁸

B. Review Standards

Section 189a. of the AEA requires that we hold a hearing on an application to construct a commercial production or utilization facility.⁹ The Staff published a notice of hearing in the *Federal Register* and provided an opportunity for interested members of the public to petition for leave to intervene.¹⁰ No petitions to intervene were filed. Therefore, there was no separate contested hearing.

⁷ Letter from Dennis C. Bley, Chairman, ACRS, to Kristine L. Svinicki, Chairman, NRC (Nov. 6, 2017), at 3 (ADAMS accession no. ML17310B511) (ACRS Letter); see AEA § 182b., 42 U.S.C. § 2232(b); 10 C.F.R. §§ 1.13, 50.58.

⁸ ACRS Letter at 1; see Letter from Victor M. McCree, Executive Director for Operations, to Dennis C. Bley, Chairman, ACRS (Dec. 8, 2017) (ML17324A412) (responding to the ACRS Letter).

⁹ AEA § 189a., 42 U.S.C. § 2239(a) (“The Commission shall hold a hearing after thirty days’ notice and publication once in the Federal Register, on each application under section 103 or 104b. for a construction permit for a facility, and on any application under section 104c. for a construction permit for a testing facility.”). The Staff determined that the proposed NWMI facility qualifies as a section 103 facility. See Tr. at 100 (Mr. Adams); Ex. NRC-001, “Staff Statement in Support of the Uncontested Hearing for Issuance of a Construction Permit for the Northwest Medical Isotopes, LLC Production Facility,” Commission Paper SECY-17-0116 (Nov. 16, 2017), at 7 (Staff Information Paper); Ex. NRC-008, Safety Evaluation Report Related to the Northwest Medical Isotopes, LLC Construction Permit Application for a Production Facility (Nov. 2017; revised Jan. 2018), at 1-5 to 1-6 (SER).

¹⁰ Medical Radioisotope Production Facility; Northwest Medical Isotopes, LLC, 81 Fed. Reg. 32,793, 32,793 (May 24, 2016).

We issued a second notice that set the time and place for the uncontested hearing and outlined the standards for our review.¹¹ The standards track the two major areas of focus for the review of a license application: the Staff's safety and environmental reviews. On the safety side, we must determine whether:

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;
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;
3. safety features or components, if any, that 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; and
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 C.F.R 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.¹²

In making these findings, we are guided by the additional considerations in 10 C.F.R.

§ 50.40. We consider whether:

1. the processes to be performed, the operating procedures, facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with NRC regulations, including the regulations in 10 C.F.R. Part 20, and that the health and safety of the public will not be endangered;

¹¹ Notice of Hearing, 82 Fed. Reg. at 56,276-77.

¹² 10 C.F.R. § 50.35(a); Notice of Hearing, 82 Fed. Reg. at 56,276-77.

2. the applicant is technically and financially qualified to engage in the proposed activities;
3. the issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public; and
4. any applicable requirements of Subpart A of 10 C.F.R. Part 51 have been satisfied.¹³

Overlapping this last consideration are the environmental findings that we must make to support issuance of the construction permit.¹⁴ The findings reflect our agency's obligations under NEPA, a statute that requires us to consider the impacts of NRC actions on environmental values.¹⁵ To ensure that these obligations are fulfilled for this construction permit proceeding, we must:

1. determine whether the requirements of NEPA section 102(2)(A), (C), and (E), and the applicable regulations in 10 C.F.R. Part 51, have been met;
2. 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;
3. 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; and
4. determine whether the NEPA review conducted by the NRC Staff has been adequate.¹⁶

¹³ 10 C.F.R. § 50.40(a)-(d).

¹⁴ *See, e.g., id.* § 51.105(a).

¹⁵ NEPA § 102(2), 42 U.S.C. § 4332(2); 10 C.F.R. § 51.10.

¹⁶ Notice of Hearing, 82 Fed. Reg. at 56,276-77 (citing 10 C.F.R. § 51.105).

If we determine that the application meets the standards and requirements of the AEA and the NRC's regulations and that any notifications to other agencies or bodies have been duly made, we will issue a construction permit "in such form and containing such conditions and limitations" that we deem "appropriate and necessary."¹⁷ We do not review NWMI's application *de novo*; rather, we consider the sufficiency of the Staff's review—that is, we determine whether the Staff's review was sufficient to support the required findings.¹⁸

C. The Hearing Process

The Staff completed its environmental review of the NWMI application in May 2017, with the publication of the Final Environmental Impact Statement (FEIS).¹⁹ The timeline of activities for the uncontested hearing, however, was triggered by the Staff's publication of the Safety Evaluation Report (SER) in November 2017.²⁰ At that time we also received the Staff's information paper, which serves as the Staff's pre-filed testimony for the uncontested hearing.²¹

¹⁷ 10 C.F.R. § 50.50.

¹⁸ See *SHINE Medical Technologies, Inc.* (Medical Radioisotope Production Facility), CLI-16-4, 83 NRC 58, 64 (2016); *Exelon Generation Co.* (Early Site Permit for Clinton ESP Site), CLI-05-17, 62 NRC 5, 34-36 (2005).

¹⁹ Ex. NRC-009, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility" (Final Report), NUREG-2209 (May 2017) (FEIS).

²⁰ Ex. NRC-008, SER, at i; see Internal Commission Procedures, ch. IV, "Commission Meetings/Hearings" (Mar. 24, 2016), at IV-11 to IV-20 (ML17297B791).

²¹ Ex. NRC-001, Staff Information Paper, at 1.

1. Pre-hearing Activities

We issued forty-nine questions on environmental and safety-related topics for NWMI and the Staff to answer in writing in advance of the hearing.²² In addition, we invited interested states, local government bodies, and federally recognized Indian Tribes to provide statements for us to consider as part of the uncontested proceeding.²³ The Missouri Department of Economic Development, the City of Columbia, Missouri, and the Boone County Commission submitted letters in support of the proposed NWMI facility.²⁴ The Missouri Department of Natural Resources offered comments on NWMI's construction permit application.²⁵ In addition, Senators Ron Wyden and Claire McCaskill submitted a letter in support of the application, asking us to give it full and fair consideration.²⁶

2. The Hearing

The scheduling note, issued to the parties before the hearing, set the topics for and the order of presentations at the hearing.²⁷ In the first panel, witnesses for NWMI and the Staff

²² See Order of the Secretary (Transmitting Pre-Hearing Questions) (Dec. 13, 2017) (unpublished) (Pre-Hearing Questions). We also issued four questions that contain sensitive unclassified non-safeguards information and that therefore were filed on the non-public docket for the proceeding. The parties' responses to those questions, including a Staff response to a public question that contained non-public information, were also filed on the non-public docket.

²³ Notice of Hearing, 82 Fed. Reg. at 56,277.

²⁴ Ex. NWMI-008, Letters of Support (Dec. 29, 2017), at 2-4.

²⁵ Letter from Dru Buntin, Missouri Department of Natural Resources, to the Commission (Dec. 18, 2017) (ML17353A098).

²⁶ Ex. NWMI-008, Letters of Support, at 1.

²⁷ Memorandum from Annette L. Vietti-Cook, Secretary of the Commission, to NWMI and Counsel for the Staff (Jan. 16, 2018) (ML18016A763) (Scheduling Note).

provided an overview of the construction permit application and the Staff's review. The next two panels focused on safety-related issues, and the final panel focused on environmental issues. The Staff made available thirty-eight witnesses at the hearing.²⁸ Fourteen of these witnesses were scheduled panelists; the remainder stood by to answer questions on topics relating to their expertise.²⁹ A total of seven witnesses offered testimony on behalf of NWMI on panels at the hearing and in pre-filed written testimony.³⁰

a. Summary of the Overview Panels

Nicholas Fowler, NWMI Chief Executive Officer; Carolyn Haass, NWMI Chief Operating Officer; Steven Reese, NWMI Irradiation Services Manager; and Roy Brown, Vice President of Government Affairs and Strategic Alliances for Curium Pharma (Curium), provided testimony for the NWMI overview panel.³¹ Mr. Fowler provided background on the company, its mission, and the location and general business model of the proposed facility.³² Mr. Brown described the need for a reliable domestic supply of molybdenum-99 and Curium's support of NWMI's construction permit application.³³ Ms. Haass and Dr. Reese described the general design of the

²⁸ Tr. at 11.

²⁹ Scheduling Note at 1-5; Tr. at 11.

³⁰ See *List of Anticipated Witnesses (Revision 1)* (Jan. 16, 2018); Tr. at 14; Ex. NWMI-011-R, *Applicant's Pre-Filed Testimony of Carolyn C. Haass* (Jan. 16, 2018) (NWMI Pre-Filed Testimony).

³¹ Tr. at 17-55; Scheduling Note at 1.

³² Tr. at 17-22.

³³ *Id.* at 22-25.

facility, NWMI's production process, and considerations in preparing the construction permit application.³⁴

Michele Evans, Deputy Director for Reactor Safety Programs and Mission Support, Office of Nuclear Reactor Regulation (NRR); Mary Jane Ross-Lee, Deputy Director of the Division of Licensing Projects, NRR; Joseph Donoghue, Deputy Director of the Division of Materials and License Renewal, NRR; and Brian Smith, Deputy Director of the Division of Fuel Cycle Safety, Safeguards and Environmental Review, Office of Nuclear Material Safety and Safeguards (NMSS), provided background on the Staff's review of the construction permit application.³⁵ Ms. Evans provided background on the use of molybdenum-99 and the United States' policy to develop a domestic supply of the radioisotope.³⁶ Ms. Ross-Lee described the Staff's safety review and the regulatory standards by which the Staff conducted its review, and Mr. Donoghue discussed the Staff's environmental analysis.³⁷ Mr. Smith provided the Staff's findings in support of issuance of the construction permit.³⁸

b. Summary of the Safety Panels

The first safety panel focused on chapters 1 and 4 of the SER and the unique licensing considerations for the proposed NWMI facility.³⁹ Ms. Haass, Dr. Reese, and Gary Dunford,

³⁴ *Id.* at 26-37.

³⁵ Scheduling Note at 2; Tr. at 56-93.

³⁶ Tr. at 56-58.

³⁷ *Id.* at 58-70.

³⁸ *Id.* at 70-77.

³⁹ Scheduling Note at 2-3; Ex. NWMI-005-R, U.S. Nuclear Regulatory Commission, Commission Mandatory Hearing, Safety Panel 1 Presentation (Jan. 16, 2018) (NWMI Safety Panel 1

NWMI Process Engineering Manager, testified for NWMI, with Michael Corum, NWMI Senior Technical Advisor, joining them on the panel.⁴⁰ Alexander Adams, Chief of the Research and Test Reactors Licensing Branch, NRR; Michael Balazik, Project Manager, Research and Test Reactors Licensing Branch, NRR; David Tiktinsky, Senior Project Manager, Fuel Manufacturing Branch, NMSS; and Steven Lynch, Project Manager, Research and Test Reactors Licensing Branch, NRR, provided testimony for the Staff.⁴¹ In addition to chapters 1 and 4, SER chapters 2, 3, 5, 6, and 12 were subject to our examination during the first safety panel.⁴²

The second safety panel focused on chapter 13 of the SER, which addressed the applicant's analyses for radiological and chemical exposure accidents.⁴³ In particular, the discussion centered on the novel application of accident analysis methodologies from 10 C.F.R. Part 70.⁴⁴ Mr. Corum testified for NWMI, with Ms. Haass, Dr. Reese, and Mr. Dunford joining him on the panel.⁴⁵ Mr. Balazik; April Smith, Reliability and Risk Analyst, Programmatic Oversight and Regional Support Branch, NMSS; Mr. Tiktinsky; and James Hammelman, Senior

Presentation); Ex. NRC-011, Northwest Medical Isotopes Construction Permit Application Review, Mandatory Hearing (Safety Panel 1) (Jan. 16, 2018) (Staff Safety Panel 1 Presentation).

⁴⁰ Tr. at 95-99; Scheduling Note at 2.

⁴¹ Tr. at 99-110; Scheduling Note at 2.

⁴² Scheduling Note at 3.

⁴³ *Id.* at 3-4.

⁴⁴ *Id.*

⁴⁵ Tr. at 128-32; Scheduling Note at 3.

Chemical Engineer, Fuel Manufacturing Branch, NMSS, provided testimony for the Staff.⁴⁶ Chapters 7, 8, 9, 11, 14, and 15 also were subject to our examination during the second safety panel.⁴⁷

c. Summary of the Environmental Panel

The environmental panel discussed the Staff's decision to prepare an environmental impact statement (EIS) for the NWMI facility, the scoping process, connected actions, the Staff's consultation with other agencies and Indian Tribes, the Staff's consideration of environmental impacts, and the Staff's analysis of alternatives to the proposed action.⁴⁸ Ms. Haass and Dr. Reese testified for NWMI.⁴⁹ Benjamin Beasley, Chief of the Environmental Review and NEPA Branch, NRR; Nancy Martinez, Physical Scientist, NRR; Michelle Moser, Biologist, NRR; and David Drucker, Senior Project Manager, NRR, provided testimony for the Staff.⁵⁰

After the hearing, we issued five additional questions for written answers from NWMI and the Staff.⁵¹ We admitted NWMI's and the Staff's responses as exhibits, adopted corrections to the hearing transcript, and closed the hearing record.⁵²

⁴⁶ Tr. at 132-41; Scheduling Note at 3.

⁴⁷ Scheduling Note at 4.

⁴⁸ *Id.* at 4-5.

⁴⁹ Tr. at 161-67; Scheduling Note at 4.

⁵⁰ Tr. at 167-86; Scheduling Note at 4.

⁵¹ Order of the Secretary (Transmitting Post-Hearing Questions) (Jan. 30, 2018) (unpublished) (Post-Hearing Questions).

⁵² Transcript Correction Order at 1.

II. DISCUSSION

NWMI has represented that the final detailed design will be submitted as part of a future operating license application.⁵³ Although we authorize issuance of the construction permit, which, when issued, constitutes an authorization to NWMI to proceed with construction, our decision does not constitute approval of the design.⁵⁴

The discussion that follows provides a survey of the key facts that support our findings. We do not discuss every aspect of NWMI's construction permit application, the Staff's review, or our sufficiency review. Our decision to authorize issuance of the construction permit, however, is based on the record in its entirety.

A. The Proposed Design

Although the design described in the construction permit application is preliminary,⁵⁵ NWMI proposes to fabricate low-enriched uranium targets and ship them to one or more research reactors for irradiation.⁵⁶ NWMI would obtain low-enriched uranium from the U.S. Department of Energy for target fabrication.⁵⁷ After irradiation, these targets would be returned

⁵³ See, e.g., Ex. NWMI-011-R, NWMI Pre-Filed Testimony, at 42; Tr. at 44-45, 47-48 (Ms. Haass); 10 C.F.R. § 50.35(c).

⁵⁴ See 10 C.F.R. § 50.35(b); Ex. NRC-008, SER, at 1-5.

⁵⁵ NWMI represented that at the time it submitted its construction permit application, its design was about forty to forty-five percent complete. It expects the design to be about eighty to eighty-five percent complete at the start of construction. Tr. at 44-45 (Ms. Haass).

⁵⁶ See Ex. NRC-006B, Construction Permit Application, Preliminary Safety Analysis Report, at 1-1.

⁵⁷ *Id.*

to the NWMI facility for processing to extract molybdenum-99.⁵⁸ Low-enriched uranium also would be recovered from the processed targets to fabricate new targets.⁵⁹

Aside from target irradiation, which would take place at either the University of Missouri Research Reactor, the Oregon State University TRIGA Reactor, or a third (as yet unidentified) reactor, NWMI's proposed activities all would take place within a single Radioisotope Production Facility (RPF) located on a site in the Discovery Ridge Research Park in Columbia, Missouri.⁶⁰ This includes the activities that fall within the definition of a 10 C.F.R. Part 50 "production facility" that are the subject of this licensing proceeding: receiving and processing irradiated low-enriched uranium targets from the research reactors, recovering and purifying molybdenum-99, and recovering and recycling low-enriched uranium to create new targets.⁶¹ But it also includes activities that will be the subject of future licensing actions before NWMI may operate the proposed facility. In addition to applying for and obtaining an operating license under 10 C.F.R. Part 50, NWMI will need to apply for and obtain a license under 10 C.F.R. Part 70 to receive,

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 1-1, 1-16 to 1-18; Ex. NWMI-004-R, U.S. Nuclear Regulatory Commission, Commission Mandatory Hearing, Northwest Medical Isotopes, LLC Radioisotope Production Facility Overview (Jan. 16, 2018), at 3-4 (NWMI Overview Panel Presentation); see *also* Ex. NWMI-011-R, NWMI Pre-Filed Testimony, at 6, 22 (describing the proposed batch process, which would be based on whether targets are irradiated at the University of Missouri Research Reactor or the Oregon State University TRIGA Reactor).

⁶¹ Ex. NRC-008, SER, at 1-2; Ex. NRC-006B, Construction Permit Application, Preliminary Safety Analysis Report, at 1-1; Ex. NWMI-004-R, NWMI Overview Panel Presentation, at 3; see 10 C.F.R. § 50.2 ("production facility").

possess, and use special nuclear material in its operations, including the proposed target fabrication process.⁶²

In view of the fact that a future special nuclear material license application under 10 C.F.R. Part 70 will be required, NWMI's construction permit application includes a description of Part 50 activities and Part 70 activities in order to show the interfaces between the target fabrication area and the production facility.⁶³ Additionally, NWMI used 10 C.F.R. Part 70 to fulfill certain requirements for its construction permit application. For example, NWMI used the methodology described in 10 C.F.R. Part 70, Subpart H for its accident analysis.⁶⁴ NWMI prepared an Integrated Safety Analysis (ISA) Summary and identified accident sequences and their consequences, as well as preliminary items relied on for safety (IROFS).⁶⁵

NWMI stated that its proposed design incorporates safety-related and non-safety-related structures, systems, and components that NWMI further categorized based on whether they

⁶² Ex. NRC-006B, Construction Permit Application, Preliminary Safety Analysis Report, at 1-1, 1-17; Tr. at 27 (Ms. Haass); see 10 C.F.R. pt. 70. NWMI also will require a byproduct material license under 10 C.F.R. Part 30 to process and ship molybdenum-99. Ex. NRC-006B, Construction Permit Application, Preliminary Safety Analysis Report, at 1-1; see 10 C.F.R. pt. 30. Additionally, any research reactor that partners with NWMI will submit a license amendment application to irradiate targets for the NWMI facility. See Tr. at 27 (Ms. Haass). And the holder of the Certificate of Compliance for the cask that NWMI plans to use to ship irradiated targets will seek to amend that Certificate of Compliance. See *id.* at 27-28, 40-41 (Ms. Haass).

⁶³ Tr. at 28 (Ms. Haass).

⁶⁴ See Ex. NRC-006G, Construction Permit Application, Preliminary Safety Analysis Report, at 13-3, 13-6; Ex. NRC-008, SER, at 13-1; Tr. at 28 (Ms. Haass).

⁶⁵ Ex. NRC-006G, Construction Permit Application, Preliminary Safety Analysis Report, at 13-3; Ex. NRC-008, SER, at 13-1. IROFS are engineered or administrative controls or control systems that are applied to reduce the likelihood of an accident such that the event either becomes highly unlikely or its consequences are reduced to meet the performance requirements in 10 C.F.R. § 70.61. See 10 C.F.R. § 70.61(b)-(e).

would be designed to meet the performance requirements in either (1) 10 C.F.R. § 70.61 for accidents, or (2) 10 C.F.R. Part 20 for normal operations.⁶⁶ As NWMI explained, “safety-related IROFS” are structures, systems, and components that would be required to meet the performance requirements in section 70.61.⁶⁷ “Safety-related non-IROFS” are structures, systems, and components “that provide reasonable assurance that the RPF can be operated without undue risk to the health and safety of workers, the public, and [the] environment,” and include structures, systems, and components to meet the criteria in 10 C.F.R. Part 20 for normal operations.⁶⁸ “Non-safety-related” structures, systems, and components are those “related to production and delivery of products or services” that are not classified as “safety-related.”⁶⁹

NWMI’s Quality Assurance Program Plan is structured in accordance with these categories, with varying degrees of oversight depending on the purpose of the structure, system, or component. For example, the “full measure” of the plan, “Quality Level 1,” will be applied to safety-related IROFS, “including items in which [their] failure or malfunction could directly or indirectly result in a condition that adversely affects workers, the public, [or the] environment, as described in [section] 70.61.”⁷⁰ The plan covers the Part 50 production facility and the Part 70 target fabrication area, including shared systems between the two.⁷¹ NWMI’s

⁶⁶ Ex. NWMI-005-R, NWMI Safety Panel 1 Presentation, at 3-4; Tr. at 95-97 (Dr. Reese).

⁶⁷ Ex. NWMI-005-R, NWMI Safety Panel 1 Presentation, at 4.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.* at 5.

⁷¹ See Ex. NRC-006F, Construction Permit Application, Preliminary Safety Analysis Report, at C-1 (“NWMI’s [Quality Assurance Program Plan] has been developed to provide safety and

seismic classification categories, which define the design standards for the integrity of facility structures, systems, and components, also take into account their intended function. “Seismic Category I” applies to IROFS and structures, systems, and components required to support shutdown of the RPF and to maintain the facility in a safe shutdown condition.⁷² “Seismic Category II” applies to structures, systems, and components designed to prevent structural failure during a safe-shutdown earthquake or whose interaction with Seismic Category I items could degrade the function of a safety-related structure, system, or component or “result in an incapacitating injury to occupants of the main control room.”⁷³ The “Non-seismic” Category applies to structures, systems, and components that are neither Category I nor Category II.⁷⁴ As part of its hearing materials, NWMI provided a list of major structures, systems, and components, together with their safety classification, quality assurance level, and seismic classification, to illustrate its design methodology.⁷⁵ For example, NWMI classifies the RPF structure as an IROFS with Quality Level 1 and Seismic Category I designations.⁷⁶

reliability during design, construction, and operation . . . of the RPF.”); Ex. NRC-004, *NRC Staff Revised Responses to Commission Pre-Hearing Questions* (Jan. 16, 2018), at 5 (Staff Pre-Hearing Responses). The Staff’s responses to our pre-hearing questions are numbered separately from the cover pleading in Ex. NRC-004. Citations to this document refer to the page numbers of the responses.

⁷² Ex. NWMI-005-R, NWMI Safety Panel 1 Presentation, at 6.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 7.

⁷⁶ *Id.* When NWMI develops the technical specifications for the RPF, “[e]ach IROFS will need to be examined and will likely become the subject of a limiting condition of operation . . . [technical specification].” Ex. NRC-008, SER, at 14-2. The Staff stated that it “will review NWMI’s proposed technical specifications, including the translation of IROFS into technical

At the hearing, the Staff discussed the interface between Parts 50 and 70 and the scope of the Staff's review of NWMI's construction permit application.⁷⁷ The Staff explained that although NWMI's application described proposed activities within the target fabrication area, its safety review focused on the proposed activities that would be licensed under Part 50.⁷⁸ As part of this review, however, the Staff considered activities within the target fabrication area to the extent that the area shares structures, systems, and components with the production facility (for example, "vessel cooling, ventilation, radioactive waste control, and instrumentation and control").⁷⁹ The Staff's findings in the SER "are limited to those required for licensing a production facility under 10 [C.F.R.] Part 50."⁸⁰

The Staff stated that it evaluated NWMI's descriptions of its structures, systems, and components, paying "special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations."⁸¹ The Staff evaluated the sufficiency of NWMI's preliminary design in accordance with NRC regulations and used regulatory guidance,

specifications," during its review of NWMI's operating license application." Ex. NRC-004, Staff Pre-Hearing Responses, at 29.

⁷⁷ Scheduling Note at 3; Ex. NRC-011, Staff Safety Panel 1 Presentation, at 6-7. We asked several questions both before and during the hearing to get a better understanding of this issue. See, e.g., Pre-Hearing Questions at 2-3, 17-19; Tr. at 193-94 (Commissioner Burns), 218-19 (Chairman Svinicki).

⁷⁸ Ex. NRC-008, SER, at 1-3; Tr. at 105 (Mr. Tiktinsky).

⁷⁹ Ex. NRC-008, SER, at 1-3; Tr. at 105-06 (Mr. Tiktinsky).

⁸⁰ Ex. NRC-008, SER, at 1-3.

⁸¹ *Id.*

as applicable, to support its review.⁸² Because most of this guidance originally had been developed for completed facility designs, the Staff exercised “its technical judgment to determine the extent to which the guidance was relevant to the review of the . . . construction permit application.”⁸³ In particular, the Staff’s review was informed by the Final Interim Staff Guidance (ISG) Augmenting NUREG-1537, which it developed to aid the Staff in reviewing applications for radioisotope production facilities.⁸⁴ The Staff also determined that certain methodologies described in NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” “are an acceptable way of demonstrating adequate safety” given the similarities in the design and operation of a radioisotope production facility and a fuel cycle facility licensed under 10 C.F.R. Part 70.⁸⁵

Consistent with this guidance, the Staff found that NWMI’s use of the methodology in 10 C.F.R. Part 70, Appendix H to develop its accident analysis—particularly NWMI’s “application of

⁸² *Id.*; Tr. at 103 (Mr. Balazik).

⁸³ Tr. at 103 (Mr. Balazik); see also Ex. NRC-004, Staff Pre-Hearing Responses, at 1-5 (providing examples of areas where the Staff applied its technical judgment).

⁸⁴ Ex. NRC-001, Staff Information Paper, at 3-4 (citing Final Interim Staff Guidance Augmenting NUREG-1537, “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 Homogenous Reactors, Parts 1 and 2 (ML12156A069 and ML12156A075) (Oct. 2012) (Final ISG Augmenting NUREG-1537)). See generally “Guidelines for Preparing and Reviewing Applications for Licensing Non-Power Reactors: Standard Review Plan and Acceptance Criteria,” NUREG-1537, Parts 1 and 2 (Feb. 1996) (ML12251A353 (package)).

⁸⁵ Ex. NRC-004, Staff Pre-Hearing Responses, at 2. See generally “Standard Review Plan for Fuel Cycle Facilities License Applications” (Final Report), NUREG-1520, rev. 2 (June 2015) (ML15176A258) (NUREG-1520). The Final ISG Augmenting NUREG-1537 borrows extensively from NUREG-1520 for guidance on the sufficiency of an applicant’s facility description and accident analyses. Final ISG Augmenting NUREG-1537, Part 1, at v.

the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 C.F.R. § 70.61; designation of IROFS; and establishment of management measures”—is “an acceptable way of demonstrating adequate safety at radioisotope production facilities.”⁸⁶ The Staff evaluated “[t]he preliminary . . . [IROFS] for the NWMI production facility . . . to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents.”⁸⁷ The Staff focused its review of NWMI’s accident analyses on the production facility, but the Staff also examined “[t]he target fabrication process . . . to determine whether operations in this area could introduce radiological and chemical hazards that significantly increased the accident consequences for the NWMI production facility licensed under the regulations of 10 [C.F.R.] Part 50.”⁸⁸ Similarly, because NWMI’s Quality Assurance Program Plan applies to the entire RPF, including the target fabrication area, the Staff reviewed the plan under 10 C.F.R. Part 50 and the guidance in NUREG-1537 and also considered “how the [plan] could be applied to [structures, systems, and components] shared between the 10 C.F.R. Part 50 production facility and the target fabrication area.”⁸⁹

B. The Proposed Site

NWMI plans to construct the RPF on a 7.4 acre (3 hectare) site in the Discovery Ridge Research Park in Columbia, Missouri.⁹⁰ The Research Park is owned by the University of

⁸⁶ Ex. NRC-004, Staff Pre-Hearing Responses, at 26.

⁸⁷ Ex. NRC-008, SER, at 1-3.

⁸⁸ *Id.* at 13-6.

⁸⁹ Ex. NRC-004, Staff Pre-Hearing Responses, at 6.

⁹⁰ Ex. NRC-008, SER, at 2-2.

Missouri.⁹¹ The site “is primarily characterized by relatively flat surfaces” and was previously used for agriculture.⁹² It sits approximately 3.5 miles (5.6 kilometers) from the University of Missouri main campus.⁹³

The population within 5 miles (8 kilometers) of the NWMI facility site, based on 2010 estimates, is approximately 68,766.⁹⁴ The two permanent residences that are nearest to the NWMI facility site—one to the south and the other to the northeast— are both about one third of a mile (one half of a kilometer) from the center of the site.⁹⁵ Several industrial and transportation facilities are located within 5 miles (8 kilometers) of the site, including other facilities located within the Discovery Ridge Research Park.⁹⁶ The Columbia Regional Airport is located approximately 6.5 miles (10.4 kilometers) from the site.⁹⁷

The findings for the issuance of a construction permit require that we take into consideration the site criteria in 10 C.F.R. Part 100 to ensure that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.⁹⁸ The Part 100 criteria apply to nuclear reactors and therefore do not expressly

⁹¹ See *id.*; Ex. NRC-009, FEIS, at 2-1.

⁹² Ex. NRC-008, SER, at 2-2; Ex. NRC-009, FEIS, at 3-40.

⁹³ Ex. NRC-006B, Construction Permit Application, Preliminary Safety Analysis Report, at 2-1.

⁹⁴ Ex. NRC-008, SER, at 2-2.

⁹⁵ Ex. NRC-006B, Construction Permit Application, Preliminary Safety Analysis Report, at 2-10.

⁹⁶ See Ex. NRC-008, SER, at 2-2; Ex. NRC-006B, Construction Permit Application, Preliminary Safety Analysis Report, at 2-41 to 2-42.

⁹⁷ Ex. NRC-008, SER, at A-20.

⁹⁸ 10 C.F.R. § 50.35(a)(4)(ii).

apply to the NWMI facility, but the Staff considered principles similar to those in Part 100 in its review of the suitability of the proposed site.⁹⁹ The Staff reviewed NWMI's analyses of the geography and demography of the site; the proposed facility's interaction with nearby industrial, transportation, and military facilities; and site-specific issues relating to meteorology, hydrology, geology, seismology, and geotechnical engineering.¹⁰⁰ In addition, the Staff evaluated structures, systems, and components 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."¹⁰¹

In our pre-hearing questions, we asked the parties to address issues related to the proposed site in more detail, particularly regarding NWMI's commitment to conduct a site-specific geotechnical investigation for the operating license stage of the proceeding.¹⁰² In view of the application's description of a recent sinkhole occurring less than a mile from the site, as well as the presence of limestone solution features (such as caves and sinkholes) in Boone County, we asked NWMI to further discuss how these geotechnical features might manifest at the proposed site.¹⁰³ We also asked NWMI to describe the methods of geotechnical

⁹⁹ Ex. NRC-001, Staff Information Paper, at 23.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² See, e.g., Pre-Hearing Questions at 4-6.

¹⁰³ Pre-Hearing Questions at 4-5 (citing Ex. NRC-006B, Construction Permit Application, Preliminary Safety Analysis Report, at 2-92).

investigation that NWMI plans to use to detect caves and sinkholes and to describe the measures it would take to mitigate the effects of a cave roof collapse on the ground surface of the site.¹⁰⁴ We asked the Staff to explain its rationale for tracking NWMI's planned site-specific geotechnical investigation as a series of commitments to be fulfilled as part of NWMI's operating license application.¹⁰⁵

In response, NWMI stated that there are 418 documented sinkholes with a depth of 20 feet (6.1 meters) or greater within Boone County, 290 of which are located in the county's southwestern corner.¹⁰⁶ The documented sinkholes are considered to be relatively stable. The largest known sinkhole in the state (encompassing 700 acres (283 hectares)) is located in the western part of the county.¹⁰⁷ NWMI further explained that a preliminary geotechnical investigation was conducted at the Discovery Ridge site in 2011, which included one borehole sample on the proposed NWMI facility site.¹⁰⁸ This preliminary investigation "provided information on subsurface conditions, groundwater, and soil types, profiles, and stability" and informed NWMI's preparation of its construction permit application.¹⁰⁹ NWMI stated that its site-specific geotechnical investigation "will be conducted to ensure that the area does not have the

¹⁰⁴ *Id.* at 5.

¹⁰⁵ *Id.*

¹⁰⁶ Ex. NWMI-001-R, *Response to [] Commission's Public Pre-Hearing Questions* (Jan. 16, 2018), at 8 (NWMI Pre-Hearing Responses). NWMI stated that the 2015 Boone County Hazards Mitigation Plan "shows that the project site is northeast of the nearest areas considered to have the potential for sinkholes." *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 9.

¹⁰⁹ *Id.*

potential for sinkholes.”¹¹⁰ If the potential for sinkholes is identified, NWMI proposes to incorporate one of two alternatives in the final design of the RPF as part of its operating license application: “(1) excavate [the] site both vertically and horizontally to remove that potential and backfill with structural fill, or (2) install piers to bedrock to support the substructure if a sinkhole does occur.”¹¹¹

The Staff stated that, based on its review of NWMI’s application, it determined that “NWMI had given appropriate attention to site features affecting the design” and had satisfied the requirements in 10 C.F.R. § 50.34(a)(1)(i) and (a)(3).¹¹² The Staff explained that any changes to NWMI’s design, be it to excavate and backfill the site or to install piers in the bedrock, would be implemented in accordance with NWMI’s Quality Assurance Program Plan, which the Staff found to be satisfactory.¹¹³ Additionally, the Staff stated that it “would verify the adequacy of the management and implementation of such design changes through its construction inspection program and its review of the results of the site-specific geotechnical investigation.”¹¹⁴ The Staff also noted its determination to replace the regulatory commitments associated with the site-specific geotechnical investigation with a proposed permit condition that would require NWMI to submit the results of its investigation in a report to the NRC prior to the

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² Ex. NRC-004, Staff Pre-Hearing Responses, at 9.

¹¹³ *Id.* at 10.

¹¹⁴ *Id.*

beginning of construction.¹¹⁵ The Staff revised the SER and the draft permit to include the proposed condition.¹¹⁶

Following the hearing, we asked the parties for comments on proposed revisions to the condition “intended to broaden the condition to ensure the detection of ‘any site features that could impact the final design bases of the facility.’”¹¹⁷ As revised, the condition would state:

Prior to the beginning of construction, NWMI shall (a) complete a geotechnical investigation to identify any potential voids that may adversely impact the stability of subsurface materials and foundation, soil and rock characteristics, and liquefaction potential at the site and (b) submit the results of this investigation, including any design changes made to the facility based on the findings of the investigation, in a report to the NRC. This condition terminates once NWMI submits the results of the geotechnical investigation in either this report or as part of its final safety analysis report, whichever occurs first.¹¹⁸

Neither NWMI nor the Staff has objected to the revision.¹¹⁹

As part of its geotechnical investigation, NWMI stated that borehole and soil compaction tests will be performed to characterize soil and rock and investigate soil liquefaction potential.¹²⁰

¹¹⁵ *Id.* at 11.

¹¹⁶ *Id.* (citing Ex. NRC-008, SER, at 2-17, A-1 to A-2, and A-4; Ex. NRC-002, Northwest Medical Isotopes, LLC, Docket No. 50-609, Medical Isotope Production Facility Construction Permit (Jan. 16, 2018), at 3 (Draft Construction Permit)).

¹¹⁷ Post-Hearing Questions at 2 (quoting Ex. NRC-004, Staff Pre-Hearing Responses, at 11).

¹¹⁸ *Id.*

¹¹⁹ Ex. NWMI-012, *Response to [] Commission’s Public Post-Hearing Questions* (Feb. 6, 2018), at 3 (NWMI Post-Hearing Responses) (also noting NWMI’s preference for tracking the investigation via commitments); Ex. NWMI-001-R, NWMI Pre-Hearing Responses, at 10; Ex. NRC-014, *NRC Staff Responses to Commission Post-Hearing Questions* (Feb. 6, 2018) (Staff Post-Hearing Responses) (response to post-hearing question 1); see *infra* section E (revising the Staff’s proposed permit condition).

¹²⁰ Tr. at 124 (Mr. Corum).

To identify subsurface anomalies such as caves or sinkholes, either electromagnetic mapping, electrical conductivity and resistivity imaging, or microgravity and surface wave spectral analysis will be used.¹²¹ NWMI also plans to have conducted “a complete mapping of the bedrock below the site . . . in case the NWMI final design warrants facility support using pylons that rest on the bedrock surface.”¹²²

C. Technical and Design Information for Later Consideration

In addition to the permit condition pertaining to the site-specific geotechnical survey, the Staff proposed two permit conditions pertaining to criticality safety and one permit condition pertaining to the Quality Assurance Program Plan.¹²³ The Quality Assurance Program Plan condition would require NWMI to implement the quality assurance program described in its Preliminary Safety Analysis Report and sets forth procedures for permissible changes to the program—that is, changes that do “not reduce the commitments in the program description.”¹²⁴ Part of the NRC’s construction inspection program would require the Staff to determine whether NWMI has implemented its quality assurance program.¹²⁵ The Staff stated that it recommended the permit condition to ensure implementation of the program, consistent with the requirements for other Part 50 facilities.¹²⁶

¹²¹ Ex. NWMI-012, NWMI Post-Hearing Responses, at 3.

¹²² *Id.*

¹²³ Ex. NRC-008, SER, at A-1 to A-2; Ex. NRC-002, Draft Construction Permit, at 2-3.

¹²⁴ Ex. NRC-008, SER, at A-2; Ex. NRC-002, Draft Construction Permit, at 3.

¹²⁵ Tr. at 59 (Ms. Ross-Lee).

¹²⁶ *Id.*

With regard to the criticality safety permit conditions, both must be completed prior to the completion of construction and both terminate when NWMI submits its final safety analysis report. One condition would require NWMI to submit periodic reports regarding the design of the Criticality Accident Alarm System (CAAS).¹²⁷ These reports also must demonstrate sufficient detector coverage to meet the requirements in 10 C.F.R. § 70.24(a).¹²⁸ Although the Staff was satisfied with NWMI's criticality safety analysis for the purposes of the construction permit, the Staff sought to ensure that the final design will comply with NRC requirements.¹²⁹ Explaining the basis for this permit condition, the Staff stated that "the presence of permanently-installed shielding for the facility could interfere with the ability of detectors to detect the minimum accident of concern" and that if an evaluation of CAAS coverage "is not completed prior to installation of permanent shielding or other structural materials, there is a potential that the final design may not satisfy the detector coverage requirements . . . [in 10 C.F.R. §] 70.24(a)."¹³⁰ In light of this potential, the Staff sought "assurance that the CAAS design will have the capability to detect the minimum accident of concern" and thus recommended including the CAAS permit condition.¹³¹

¹²⁷ Ex. NRC-002, Draft Construction Permit, at 3.

¹²⁸ *Id.*

¹²⁹ See Ex. NRC-008, SER, at 6-19 to 6-20.

¹³⁰ *Id.* at 6-19.

¹³¹ *Id.* A CAAS condition with similar requirements was included in the construction permit for the SHINE Medical Radioisotope Production Facility. See SHINE Medical Technologies, Inc., Construction Permit No. CPMIF-001 (Feb. 29, 2016), at 2-3 (ML16041A471).

The second criticality safety permit condition would require NWMI to ensure, consistent with the revised upper subcritical limit “established in Revision 2 of NWMI’s Validation Report,” “that all nuclear processes are evaluated to be subcritical under all normal and credible abnormal conditions” for each area described in NWMI’s preliminary criticality safety evaluations and prior to each area being completed.¹³² In addition, NWMI would be required to submit periodic reports notifying the NRC whether NWMI’s revised upper subcritical limit required any change to NWMI’s criticality safety evaluations.¹³³ For this proposed permit condition, the Staff explained that the incorporation of additional benchmarks in NWMI’s Validation Report resulted in a new upper subcritical limit and noted that some of NWMI’s criticality calculations and design analysis may need to be redone at the operating license stage.¹³⁴ The Staff recommended the condition “in order to confirm that the applicant will integrate the revised [upper subcritical limit] in the criticality calculations and design analysis of the facility.”¹³⁵

¹³² Ex. NRC-002, Draft Construction Permit, at 2 (citing Ex. NRC-006E, Construction Permit Application, Preliminary Safety Analysis Report, § 6.3.1.1). Nuclear criticality safety limits are established to “ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety.” Ex. NRC-006E, Construction Permit Application, Preliminary Safety Analysis Report, at 6-30. “A common approach to ensuring subcriticality is to determine a maximum k_{eff} limit below which the licensee’s calculations must fall . . . referred to . . . as the [upper subcritical limit].” NUREG-1520, at 5-B-1. A k_{eff} of 1.0 is critical. The upper subcritical limit is defined as follows: “ $k_{\text{subcritical}} = 1.0 - \text{bias} - \text{bias uncertainty} - \text{margin of subcriticality for safety}$.” Final ISG Augmenting NUREG-1537, Part 1, at 39. And “[i]n general, a margin of subcriticality for safety of 0.05 has been found acceptable for typical nuclear processes involving [low-enriched uranium], without a detailed justification.” Final ISG Augmenting NUREG-1537, Part 1, at 39.

¹³³ Ex. NRC-002, Draft Construction Permit, at 2-3.

¹³⁴ Ex. NRC-008, SER, at 6-18.

¹³⁵ *Id.*

As it finalizes the design of its facility, NWMI will need to undertake additional research and development. NWMI identified four areas for additional research and development: (1) testing to validate the acceptable operating conditions for material and target solution compatibility at the University of Missouri Research Reactor and U.S. Department of Energy National Laboratories; (2) laboratory resin testing to determine the interactions between solutions and resin as a function of temperature; (3) testing to confirm whether a pressure relief system is a feasible design for NWMI's proposed ion exchange column; and (4) testing to evaluate the release of diamylamylphosphonate (DAAP), which would be used in the uranium purification system, from the ion exchange column media during operation.¹³⁶ The Staff is tracking these items as regulatory commitments and will verify that they have been resolved prior to the completion of construction.¹³⁷

The Staff also will be tracking several other items listed as regulatory commitments in Appendix A of the SER that NWMI must include in the Final Safety Analysis Report with its operating license application.¹³⁸ For example, in response to deficiencies in NWMI's aircraft impact analysis identified in meetings with the ACRS and in the Staff's independent review,¹³⁹ NWMI committed to "reexamine and ensure the accuracy of its estimates for aircraft take-offs

¹³⁶ *Id.* at 13-24, A-37. The Staff explained in the SER that, among other things, the "[r]elease of DAAP . . . represents a potential criticality issue if [it] were to collect as a separate phase in a non-geometrically favorable vessel." *Id.* at A-37.

¹³⁷ *Id.* at A-37.

¹³⁸ *Id.*, App. A. Some of these commitments were identified in NWMI's responses to Staff requests for additional information; some were identified as a result of meetings with the ACRS. *See id.* at A-3, A-35; Tr. at 93.

¹³⁹ *See* Ex. NRC-008, SER, at 2-9 to 2-10.

and landings at the Columbia Regional Airport and for the surrounding heliports.”¹⁴⁰ NWMI also committed to ensure that the accident analyses contained in its Final Safety Analysis Report conform to the requirements in 10 C.F.R. § 70.61.¹⁴¹

Additionally, NWMI committed to use NRC Regulatory Guide 1.60, “Design Response Spectra for Seismic Design of Nuclear Power Plants,” for the final seismic design with a ground acceleration response of 0.2 g—the same seismic design for the University of Missouri

¹⁴⁰ Ex. NRC-008, SER, at A-36. In recommending issuance of the construction permit, the ACRS noted that NWMI will reassess “[a]ircraft impact probabilities . . . 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.” ACRS Letter at 3.

We also asked NWMI to discuss its response to these deficiencies. See Pre-Hearing Questions at 4; Tr. at 126 (Commissioner Baran). NWMI attributed the deficiencies to the use of outdated information and inadequate peer review. Ex. NWMI-001-R, NWMI Pre-Hearing Responses, at 6. It stated that it “used a systematic process to evaluate the root cause in accordance with [its quality assurance program] and identified corrective actions to fix the deficiencies in the aircraft analysis in the [operating license application].” Ex. NWMI-001-R, NWMI Pre-Hearing Responses, at 6; see also Tr. at 126-27 (Mr. Corum). The Staff evaluated the corrective actions and found them to be adequate. Tr. at 127 (Mr. Adams).

¹⁴¹ Ex. NRC-008, SER, at A-4. We asked the parties a number of questions regarding NWMI’s accident dose assessment methodology and the Staff’s independent review. See Pre-Hearing Questions at 11-15. We also asked the parties to address the fact that NWMI had taken credit for an elevated release even though the proposed exhaust stack would sit only 10 feet above the top of the 65 foot RPF, rather than its being 2.5 times the height of the adjacent RPF, as advised in Regulatory Guide 1.145, “Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants.” Tr. at 146-47 (Commissioner Baran); Post-Hearing Questions at 3. Among other things, the Staff stated that it found NWMI’s dose calculations sufficient for the purposes of the construction permit application, noting in particular that NWMI has not requested approval of the stack height, NWMI has designated the stack as an IROFS, and NWMI has committed to meeting the dose requirements in 10 C.F.R. Part 20. Tr. at 208 (Mr. Balazik). The Staff stated that “NWMI will develop appropriate models to estimate dose consequences as the design of the facility matures” and that the Staff “will perform additional analysis of NWMI’s dose calculations” during the operating license stage. Ex. NRC-014, Staff Post-Hearing Responses, at 3.

Research Reactor and for the Callaway Nuclear Power Plant.¹⁴² As part of its review, the Staff prepared “a general seismic design response spectrum incorporating site amplification factors for the proposed NWMI facility site.”¹⁴³ The Staff found the response acceptable for frequencies in the 1 to 10 hertz range of the design response spectrum, which tend to impact large structures, components, and equipment. The Staff identified, however, “a potential high-frequency (e.g., greater than 10 [hertz]) impact to electrical relays, piping, and instrumentation.”¹⁴⁴ Thus, NWMI committed to “provide an evaluation of the effects of high frequency spectral accelerations (i.e., [greater than] 10 hertz) on high-frequency sensitive structures, systems, and components” as part of its final design.¹⁴⁵

NWMI also provided a preliminary Emergency Response Plan that discusses provisions for coping with radiological emergencies and minimizing accident consequences.¹⁴⁶ Among other things, the plan describes “the activation process, assessment actions, corrective actions, and protective actions to be taken for each class of emergencies.”¹⁴⁷ Appendix A of the SER

¹⁴² Ex. NRC-008, SER, at 2-16.

¹⁴³ *Id.*

¹⁴⁴ *Id.* The Staff noted that “[a] major factor affecting the high frequency response will be excavation depth of the site.” *Id.* NWMI will provide “additional information on the seismic requirements and evaluations of the NWMI facility and associated IROFS” in the operating license application. *Id.*

¹⁴⁵ *Id.* at A-35.

¹⁴⁶ *Id.* at 12-11; Ex. NRC-006F, Construction Permit Application, Preliminary Safety Analysis Report, at A-1.

¹⁴⁷ Ex. NRC-008, SER, at 12-16.

contains several commitments for NWMI to provide detailed emergency planning information when it submits its Final Safety Analysis Report.¹⁴⁸

D. The Staff's Environmental Review

The Staff prepared an EIS to fulfill its obligations under NEPA because it determined that the preparation of an Environmental Assessment might not support a finding of no significant impact and because some of NWMI's proposed activities, namely the processing of uranium for target fabrication, are similar to activities that require an EIS under NRC regulations.¹⁴⁹

Although the Staff's safety review was limited to the findings necessary for issuance of the construction permit, the Staff's environmental review was broader in scope. The Staff evaluated the environmental impacts of facility construction, operations, and decommissioning, as well as the environmental impacts of transporting and irradiating the low-enriched uranium targets at offsite research reactors—an "interdependent part" of operating the proposed NWMI facility.¹⁵⁰

The Staff considered the impacts of irradiation services at the University of Missouri Research Reactor and the Oregon State University TRIGA Reactor and based its review of the impacts from a potential third research reactor using parameters from the Oregon State University TRIGA Reactor (for example, distance from the proposed NWMI facility and potential reactor modifications).¹⁵¹

¹⁴⁸ *Id.* at A-16.

¹⁴⁹ Ex. NRC-001, Staff Information Paper, at 17.

¹⁵⁰ Ex. NRC-009, FEIS, at 1-6.

¹⁵¹ Ex. NRC-001, Staff Information Paper, at 19.

The Staff issued the draft EIS (DEIS) in October 2016 and the FEIS in May 2017.¹⁵² The Staff held two public meetings near the site—a public scoping meeting in December 2015 and a meeting on the DEIS in December 2016.¹⁵³ The Staff also performed a site audit, during which the Staff, among other things, toured the proposed site and the University of Missouri Research Reactor.¹⁵⁴

The proposed site is located in a “shovel ready industrial park”¹⁵⁵ and has been disturbed, having previously been used for agriculture, mainly livestock grazing.¹⁵⁶ There are no surface water features on site.¹⁵⁷ “Common grass species currently cover the site, which provide low-quality habitat for wildlife and birds.”¹⁵⁸ The Staff considered the environmental impacts of the proposed action in the following resource areas: land use and visual resources, air quality and noise, geologic environment, ecological and water resources, historic and cultural

¹⁵² “Environmental Impact Statement for Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility” (Draft Report for Comment), NUREG-2209 (Oct. 2016) (ML16305A029); Ex. NRC-009, FEIS.

¹⁵³ Ex. NRC-009, FEIS, at xxi; see Northwest Medical Isotopes, LLC, 80 Fed. Reg. 72,115 (Nov. 18, 2015); Construction Permit Application for the Northwest Medical Isotopes, LLC, Medical Radioisotope Production Facility, 81 Fed. Reg. 78,865 (Nov. 9, 2016).

¹⁵⁴ Ex. NRC-009, Final EIS, at 1-4. In addition to its being a potential facility for the irradiation of NWMI targets, the University of Missouri Research Reactor was selected for analysis as an alternative site for constructing the NWMI facility. *Id.* at 5-1; see *infra* note 179 and accompanying text.

¹⁵⁵ Tr. at 176 (Ms. Moser).

¹⁵⁶ *Id.* at 175-76, 189.

¹⁵⁷ *Id.* at 176 (Ms. Moser).

¹⁵⁸ *Id.*

resources, socioeconomics, human health, waste management, and transportation.¹⁵⁹ It found that the direct and indirect impacts of the proposed action in each of these areas would be small.¹⁶⁰ Impacts are considered “small” if they “are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource.”¹⁶¹ The Staff also determined that “it is not likely” that the construction, operations, and decommissioning of the proposed facility “would have disproportionately high and adverse human health and environmental effects on minority and low-income populations living near Discovery Ridge.”¹⁶²

To fulfill its obligations under section 7 of the Endangered Species Act of 1973, the Staff compiled a table of federally listed endangered species using, among other things, the U.S. Fish and Wildlife Service’s online database and the information in NWMI’s Environmental Report.¹⁶³ The Staff defined the action area for the purposes of this review to include the 7.4 acre (3 hectare) NWMI facility site, the temporary staging area that would be used for construction

¹⁵⁹ Ex. NRC-013, Northwest Medical Isotopes, Construction Permit Review, Mandatory Hearing (Environmental Panel) (Jan. 16, 2018), at 8 (Staff Environmental Panel Presentation). Additionally, the Staff considered potential cumulative impacts of the construction, operations, and decommissioning of the proposed NWMI facility. Ex. NRC-009, FEIS, at 4-65.

¹⁶⁰ Tr. at 176 (Ms. Moser).

¹⁶¹ Ex. NRC-009, FEIS, at 1-3.

¹⁶² *Id.* at 4-54 to 4-55.

¹⁶³ *Id.* at 3-43. Section 7 of the Endangered Species Act requires an agency, in consultation with and with the assistance of the Secretary of the Interior or the Secretary of Commerce (as appropriate), to ensure that “any action authorized, funded, or carried out by such an agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat of such species.” Endangered Species Act § 7(a)(2), 16 U.S.C. § 1536(a)(2). The Fish and Wildlife Service (under the Department of the Interior) and the National Marine Fisheries Service (under the Department of Commerce) jointly administer the act.

equipment, and “the surrounding area where runoff drains and activities would be audible to wildlife.”¹⁶⁴ The Staff found that the site provides unsuitable habitat for these species.¹⁶⁵ The Staff “did not identify any candidate species or proposed or designated critical habitats within the action area.”¹⁶⁶ The Staff therefore concluded “that [f]ederally listed, proposed, or candidate species are unlikely to occur within the action area.”¹⁶⁷ The Staff similarly found that state listed or endangered species are unlikely to occur within the proposed NWMI facility site.¹⁶⁸

In accordance with the National Historic Preservation Act of 1966, the Staff reviewed whether the proposed action would have any effect on historic and cultural resources. The Staff contacted thirty-one tribes, the Missouri State Historic Preservation Office, and the Advisory Council on Historic Preservation to initiate consultation under the act.¹⁶⁹ Six tribes provided input on the Staff’s environmental review; one of these tribes requested consulting party status.¹⁷⁰ In response to this tribe’s request, NWMI provided the results of a cultural resource survey that it had performed for its construction permit application, in which NWMI found no

¹⁶⁴ Ex. NRC-009, FEIS, at 3-43.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 3-43 to 3-44. The Staff stated that although it was not required to do so given its “no effect” finding, it provided the DEIS to the Fish and Wildlife Service; the Department of the Interior responded that it had no comment. Tr. at 177 (Ms. Moser).

¹⁶⁹ Tr. at 177-78 (Ms. Moser); *see also* Ex. NRC-009, FEIS, at 4-25 to 4-26.

¹⁷⁰ Ex. NRC-004, Staff Pre-Hearing Responses, at 32.

evidence of historic or cultural resources.¹⁷¹ After it had the opportunity to review the DEIS, the tribe indicated that it “did not anticipate that the proposed project would adversely impact any cultural resources or human remains protected under the [National Historic Preservation Act], NEPA, or other [f]ederal or Tribal laws.”¹⁷² Based on its review of available historic information, tribal consultation, and NWMI’s cultural resource survey, the Staff concluded that no known historic or cultural resources would be affected by the proposed project.¹⁷³ The Missouri State Historic Preservation Office concurred with the Staff’s conclusion.¹⁷⁴

The Staff also analyzed alternatives to the proposed action.¹⁷⁵ This review included consideration of the no-action alternative, one alternative site, and two alternative technologies.¹⁷⁶ The Staff “evaluated each alternative using the same resource areas that were used in evaluating impacts from the proposed action.”¹⁷⁷

For the no-action alternative, i.e., if the construction permit were to be denied, the Staff found that no changes would occur on the site, but the alternative also would not meet the purpose of the proposed action—to provide a domestic supply of molybdenum-99.¹⁷⁸ The Staff

¹⁷¹ *Id.*; Ex. NRC-009, FEIS, at 3-51.

¹⁷² Ex. NRC-004, Staff Pre-Hearing Responses, at 33.

¹⁷³ Ex. NRC-009, FEIS, at 3-51, 4-26 to 4-27.

¹⁷⁴ *Id.* at 3-51; Tr. at 178 (Ms. Moser).

¹⁷⁵ Ex. NRC-009, FEIS, ch. 5.

¹⁷⁶ *Id.* at 5-1.

¹⁷⁷ *Id.* at xxiv.

¹⁷⁸ *Id.* at 5-2.

reviewed NWMI's site-selection process and examined one alternative site—the University of Missouri Research Reactor site.¹⁷⁹ The University of Missouri Research Reactor is eligible for inclusion on the National Register of Historic Places.¹⁸⁰ It is located 4 miles (6.4 kilometers) from the Discovery Ridge Research Park site.¹⁸¹

The Staff compared the environmental costs and benefits of the proposed action at the alternative site with the costs and benefits of the proposed action at the Discovery Ridge Research Park site. The Staff found that the impacts at the University of Missouri Research Reactor site would be small for all resource areas except for noise, which would be small to moderate.¹⁸² Additionally, there would be a potential adverse impact to historic properties at the University of Missouri Research Reactor site if the proposed NWMI facility (as located on that site) were to impact the University of Missouri Research Reactor's inclusion on the National Register of Historic Places.¹⁸³ Because the impacts in some resource areas potentially would be greater at the University of Missouri Research Reactor site, the Staff concluded that the Discovery Ridge site was the environmentally preferable alternative site.¹⁸⁴

Given the University of Missouri Research Reactor site's proximity to the Discovery Ridge site, we asked the Staff to elaborate on its conclusion that the two sites "likely cover the

¹⁷⁹ *Id.* at 5-1.

¹⁸⁰ *Id.* at 3-67.

¹⁸¹ *Id.*

¹⁸² *Id.* at 5-85.

¹⁸³ *Id.*

¹⁸⁴ *Id.* at 5-88.

full spectrum of alternatives and provide sufficient information for sound decisionmaking.”¹⁸⁵ The Staff explained that there were two main reasons for this determination. First, the Staff stated that “the spectrum of likely environmental impacts from the proposed action was relatively limited due to the small size of the proposed facility, the limited footprint and excavation required, and the use of county water rather than surface water or [groundwater] resources.”¹⁸⁶ And second, the Staff stated that the two sites had different baseline environmental conditions—the University of Missouri Research Reactor site has existing buildings, a higher population, surface water features, and mature trees; while the Discovery Ridge site has been cleared and is devoid of existing buildings, surface water features, and mature trees.¹⁸⁷

The Staff selected two technologies for its alternatives analysis: uranium fission technology and linear accelerator-based technology.¹⁸⁸ The Staff initially considered the five technologies that had been awarded cooperative agreements by the Department of Energy’s National Nuclear Security Administration: (1) neutron capture technology; (2) aqueous homogenous reactor technology; (3) selective gas extraction technology; (4) uranium fission technology; and (5) linear accelerator-based technology.¹⁸⁹ The Staff determined, however, that sufficient data to describe the environmental impacts of these technologies existed only for the

¹⁸⁵ Pre-Hearing Questions at 20 (quoting Ex. NRC-009, FEIS, at 5-7).

¹⁸⁶ Ex. NRC-004, Staff Pre-Hearing Responses, at 39.

¹⁸⁷ *Id.*

¹⁸⁸ Ex. NRC-009, FEIS, at 5-1.

¹⁸⁹ *Id.* at 5-53 to 5-54.

uranium fission and linear accelerator-based alternatives, and thus the Staff selected these technologies for in-depth evaluation.¹⁹⁰ The Staff concluded that each of these technologies, if constructed, operated, and decommissioned at the Discovery Ridge site, would have similar environmental costs and benefits to NWMI's proposed production process.¹⁹¹

Considering the results of its environmental review, the Staff recommended the issuance of the construction permit to NWMI.¹⁹² At the operating license stage, the Staff will prepare a supplement to the FEIS to address any new and significant information that was not available during its review of the construction permit application.¹⁹³ Because the Staff also considered the impacts of target fabrication as well as transporting and irradiating targets at research reactors, the Staff stated that it likely will use a similar process to identify new and significant information for its environmental review of other licensing actions associated with operating the NWMI facility, including the Part 70 license application and any research reactor license amendment requests.¹⁹⁴

¹⁹⁰ *Id.* at 5-55.

¹⁹¹ *Id.* at 5-87 to 5-88.

¹⁹² *Id.* at 6-11.

¹⁹³ Ex. NRC-004, Staff Pre-Hearing Responses, at 33.

¹⁹⁴ *Id.* at 33-34. NWMI seeks to begin construction of the RPF, including the Part 70 target fabrication area, upon issuance of the construction permit. Ex. NWMI-010, Letter from Carolyn C. Haass, NWMI, to NRC Document Control Desk (Dec. 18, 2017), at 3 (Exemption Request). On December 18, 2017, NWMI applied for an exemption from 10 C.F.R. § 70.21(f), which requires “[a]n application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery or conversion of uranium hexafluoride, or for the conduct of any other activity which the Commission has determined pursuant to [10 C.F.R. Part 51, Subpart A] will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted, and shall be accompanied by an Environmental Report.” 10 C.F.R. § 70.21(f).

E. Findings

We have conducted an independent review of the sufficiency of the Staff's safety findings, with particular attention to the topics discussed above. Our findings, however, are based on the record as a whole. Based on the evidence presented in the uncontested hearing, including the Staff's review documents and the testimony provided, we find 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 it has identified major features or components incorporated therein for the protection of the health and safety of the public. Further technical or design information as may be required to complete the safety analysis has reasonably been left for later consideration and will be supplied in the Final Safety Analysis Report. NWMI has described the safety features or components that require research and development and has identified and will establish a research and development program reasonably designed to resolve any safety questions associated with these features or components. On the basis of the foregoing, we find that there is reasonable assurance that open safety questions will be resolved satisfactorily at or before the latest date stated in the application for completion of construction of the proposed facility. Taking into consideration the

According to NWMI, its exemption request is supported by the FEIS because it determined that RPF activities, including target fabrication, will not "affect the quality of the environment after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives." Ex. NWMI-010, Exemption Request, at 3 (quoting 10 C.F.R. § 70.23(a)(7)). NWMI's exemption request is a separate licensing action and not necessary to the decision we make today authorizing issuance of the construction permit. The Staff will review and make a determination on the request in due course. Tr. at 211 (Mr. Lynch). The Staff stated, however, that construction of the target fabrication portion of the RPF "before submitting a 10 C.F.R. Part 70 application and without obtaining exemptions from 10 C.F.R. §§ 70.21(f) or 70.23(a)(7)" would be at NWMI's own risk. Ex. NRC-014, Staff Post-Hearing Responses, at 6; see also Tr. at 211 (Mr. Lynch).

site criteria in 10 C.F.R. 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.

In making these findings, we also conclude that: (1) there is reasonable assurance that construction of the facility will not endanger the health and safety of the public, and the authorized activities can be conducted in compliance with the NRC's regulations, including the requirements in 10 C.F.R. Part 20; (2) NWMI is technically and financially qualified to engage in the activities authorized;¹⁹⁵ (3) issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public;¹⁹⁶ and (4) NWMI's application meets the standards and requirements of the AEA and the NRC's regulations. Required notifications to other agencies or bodies have been duly made.¹⁹⁷ Additionally, the Staff should revise the permit condition regarding the site-specific geotechnical investigation as stated in section II.B, above. With that revision, we find that the Staff's proposed permit conditions are appropriately drawn and sufficient to provide reasonable assurance of adequate protection of public health and safety.¹⁹⁸

We also conducted an independent review of the Staff's environmental analysis in the FEIS, taking into account the particular requirements of NEPA. NEPA section 102(2)(A) requires agencies to use "a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts" in

¹⁹⁵ See, e.g., Ex. NRC-008, SER, ch. 15.

¹⁹⁶ See, e.g., *id.*

¹⁹⁷ See, e.g., 10 C.F.R. § 2.104(a); Ex. NRC-009, FEIS, at 1-7 to 1-8.

¹⁹⁸ See 10 C.F.R. §§ 50.35(b), 50.50; Ex. NRC-002, Draft Construction Permit, at 3-4.

decisionmaking that may impact the environment.¹⁹⁹ We find that the environmental review team used the systematic, interdisciplinary approach that NEPA requires.²⁰⁰

NEPA section 102(2)(C) requires us to assess the relationship between local short-term uses and long-term productivity of the environment, to consider alternatives, and to describe the unavoidable adverse environmental impacts and the irreversible and irretrievable commitments of resources associated with the proposed action.²⁰¹ The discussion of alternatives is in chapter 5 of the FEIS; the other items are discussed in chapter 6.²⁰² The environmental review team found that the short-term uses of the environment—construction, operations, and decommissioning of the NWMI facility—would commit land and energy indefinitely or permanently.²⁰³ In addition, the project would bring increased employment, expenditures, and tax revenues that would directly benefit local, regional, and state economies in the short term.²⁰⁴ After the facility is decommissioned, wildlife may return to the site if it is restored to suitable habitat, but the use of land to meet waste disposal needs would reduce its long-term

¹⁹⁹ NEPA § 102(2)(A), 42 U.S.C. § 4332(2)(A).

²⁰⁰ See, e.g., Tr. at 168-84 (providing an overview of the Staff's environmental review methodology and findings); Ex. NRC-013, Staff Environmental Panel Presentation, at 5-15. The environmental review team consisted of twelve individuals with expertise in disciplines including biology, geology, hydrology, human health, socioeconomics, and cultural resources. Ex. NRC-009, FEIS, at 8-1 to 8-2 (listing contributors from the NRC and Idoneous Consulting).

²⁰¹ NEPA § 102(2)(C)(ii)-(v), 42 U.S.C. § 4332(2)(C)(ii)-(v).

²⁰² Ex. NRC-009, FEIS, chs. 5-6.

²⁰³ *Id.* at 6-10.

²⁰⁴ *Id.*

productivity.²⁰⁵ The installation of service lines (electric power and water, for example) during construction of the proposed facility “would be available and beneficial for future use” after decommissioning.²⁰⁶

Chapter 6 of the FEIS includes a chart of the unavoidable adverse environmental impacts during construction, operations, and decommissioning, along with actions to mitigate those impacts.²⁰⁷ The environmental review team found that the unavoidable adverse impacts of the project would be small for all resource areas.²⁰⁸ Examples of measures to mitigate these impacts include restoring agricultural land temporarily affected during construction with native species of vegetation and preventing fugitive dust by watering unpaved and disturbed areas.²⁰⁹

Finally, with regard to irreversible and irretrievable commitments of resources, the environmental review team concluded that construction of the NWMI facility would irretrievably consume construction materials (for example, concrete, granular material, steel, and asphalt), unless NWMI recycles them after decommissioning.²¹⁰ During operations, uranium would be irreversibly and irretrievably committed.²¹¹ Additionally, birds would be lost to collisions with

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.* tbl.6-2.

²⁰⁸ *Id.* at 6-5.

²⁰⁹ *Id.*

²¹⁰ *Id.* at 6-11.

²¹¹ *Id.*

facility structures.²¹² The Staff also found that electricity, fuel, and water would be expended, but that the amounts used for constructing, operating, and decommissioning the NWMI facility would not be “expected to deplete available supplies or exceed available system capacities.”²¹³

We must weigh these unavoidable adverse environmental impacts and resource commitments—the environmental “costs” of the project—against the project’s benefits.²¹⁴ Considering the need for a reliable supply of medical isotopes in the United States and the expected increase in jobs and tax revenue, we find that the benefits of the project outweigh the costs described above. Moreover, we have considered each of the requirements of NEPA section 102(2)(C) and find nothing in the record that would lead us to disturb the Staff’s conclusions on those requirements.

NEPA section 102(2)(E) calls for agencies to study, develop, and describe appropriate alternatives.²¹⁵ The alternatives analysis is the “heart of the environmental impact statement.”²¹⁶ Based on the Staff’s testimony at the hearing, as well as the discussion in the FEIS, we find that the environmental review identified an appropriate range of alternatives with respect to the no-action alternative, alternative technologies, and alternative sites and adequately described the environmental impacts of each alternative.²¹⁷ We find reasonable the Staff’s conclusion that

²¹² *Id.*

²¹³ *Id.*

²¹⁴ *Cf.* 10 C.F.R. § 51.105(a).

²¹⁵ NEPA § 102(2)(E), 42 U.S.C. § 4332(2)(E).

²¹⁶ 10 C.F.R. pt. 51, subpt. A, app. A, § 5.

²¹⁷ *See, e.g.*, Tr. at 178-81; Ex. NRC-009, FEIS, ch. 5.

“the environmentally preferred alternatives are the construction, operations, and decommissioning of the NWMI facility at the Discovery Ridge site . . . , the linear accelerator-based facility at the Discovery Ridge site. . . , [and] the subcritical fission-based facility at the Discovery Ridge site.”²¹⁸

In sum, for each of the topics discussed at the hearing and in today’s decision, we find that the Staff’s review was reasonably supported in logic and fact and sufficient to support the Staff’s conclusions. Based on our review of the FEIS, we also find that the remainder of the FEIS was reasonably supported and sufficient to support the Staff’s conclusions. Therefore, as a result of our review of the FEIS, and in accordance with the Notice of Hearing for this uncontested proceeding, we find that the requirements of NEPA section 102(2)(A), (C), and (E), and the applicable regulations in 10 C.F.R. Part 51, have been satisfied with respect to the construction permit application. We independently considered the final balance among conflicting factors contained in the record of this proceeding. We find, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, that the construction permit should be issued.

²¹⁸ See Ex. NRC-009, FEIS, at 6-4 to 6-5.

III. CONCLUSION

We find that, with respect to the safety and environmental issues before us, the Staff's review of NWMI's construction permit application was sufficient to support issuance of the construction permit. We *authorize* the Director of the Office of Nuclear Reactor Regulation to issue the permit for the construction of the NWMI Medical Radioisotope Production Facility, contingent upon inclusion of the revised permit condition described in Section II.B. Additionally, we *authorize* the Staff to issue the record of decision, subject to its revision as necessary to reflect the findings in this decision.

IT IS SO ORDERED.

For the Commission

NRC SEAL

/RA/

Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 3rd day of May, 2018.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)
)
NORTHWEST MEDICAL ISOTOPES, LLC)
) Docket No. 50-609-CP
)
(Medical Radioisotope Production Facility))
)
(Mandatory Hearing))

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **COMMISSION MEMORANDUM AND ORDER CLI-18-06** have been served upon the following persons by Electronic Information Exchange.

U.S. Nuclear Regulatory Commission
Office of Commission Appellate Adjudication
Mail Stop: O-16B33
Washington, DC 20555-0001
ocaamail@nrc.gov

U.S. Nuclear Regulatory Commission
Office of the Secretary of the Commission
Mail Stop: O-16B33
Washington, DC 20555-0001
hearing.docket@nrc.gov

U.S. Nuclear Regulatory Commission
Office of the General Counsel
Mail Stop: O-14A44
Washington, DC 20555-0001
Mitzi Young, Esq.
Jeremy Wachutka, Esq.
Catherine Scott, Esq.
Catherine Kanatas, Esq.
John Tibbetts, Paralegal
mitzi.young@nrc.gov
jeremy.wachutka@nrc.gov
catherine.scott@nrc.gov
catherine.kanatas@nrc.gov
john.tibbets@nrc.gov

Carolyn Haass
Chief Operating Officer
Northwest Medical Isotopes, LLC
22500 Hope Dale Avenue
Parker, CO 80138
carolyn.haass@nwmedicalisotopes.com

[Original signed by Herald M. Speiser]
Office of the Secretary of the Commission

Dated at Rockville, Maryland,
this 3rd day of May, 2018