

## Mandatory Hearing on Northwest Medical Isotopes Construction Permit Application

### Staff Scripts

*Overview Panel*

#### **Slide 1: Northwest Medical Isotopes Construction Permit Application Review**

**Speaker: Michele Evans**

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#### **Slide 2: Panelists**

Good Morning Chairman and Commissioners. My name is Michele Evans, Deputy Director of the Office of Nuclear Reactor Regulation. With me at the table this morning are MaryJane Ross-Lee, Joe Donoghue, and Brian Smith. This panel will provide context for the role of the U.S. Nuclear Regulatory Commission (or NRC) in domestic efforts to establish a reliable supply of molybdenum-99. We will introduce the methodology that the NRC staff used in its review of the Northwest Medical Isotopes construction permit application and introduce the unique aspects of the staff safety and environmental reviews that will be discussed further in the panels to follow.

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#### **Slide 3: <sup>99</sup>Mo Overview**

Moly

bdenum-99 decays into technetium-99 metastable – the most widely used medical radioisotope in the world. Technitium-99m is used in approximately 50,000 imaging procedures daily in the United States, accounting for about one half of the global demand. Technicium-99m is an effective diagnostic tool because of its chemical and nuclear properties. Specifically, pharmaceuticals readily tag to it, and its 6-hour half-life minimizes patient radiation exposure.

Currently, there is no domestically-produced molybdenum-99. While the United States continues to receive molybdenum-99 from overseas suppliers, significant amounts are lost in transit due to radioactive decay.

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#### **Slide 4: Establishing a Domestic Supply of <sup>99</sup>Mo**

Consistent with the United States policy to establish a domestic supply of molybdenum-99, the staff considers license applications for facilities that would produce molybdenum-99 without highly-enriched uranium.

In 2016, the NRC issued a 10 CFR Part 50 construction permit to SHINE Medical Technologies (or SHINE) for the production of molybdenum-99 using up to 8 accelerator-driven subcritical irradiation units and 1 production facility.

Since 2015, the staff has been actively reviewing a second medical radioisotope construction permit application submitted by Northwest Medical Isotopes, which, going forward, we will refer to as “Northwest” or “NWMI”. If granted, this construction permit would allow Northwest to build a 10 CFR Part 50 production facility in Columbia, Missouri. Once constructed, this facility would be used to produce molybdenum-99 from low enriched uranium targets that have been irradiated at existing research reactors.

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MaryJane Ross-Lee will now discuss the approach the staff used to review the Northwest construction permit application.

**Speaker: MaryJane Ross-Lee**

### **Slide 5: Conducting the NWMI Review**

Thank you, Michele.

The staff review of the Northwest construction permit application was supported by procedural efficiencies and lessons learned from previous reviews.

For example, the staff docketed the Northwest construction permit application in two parts. Part one of the application consisted primarily of the Northwest environmental report and general information required by 10 CFR 50.33 and was docketed in June 2015. Part two of the application contained the Northwest preliminary safety analysis report (or PSAR) and was docketed in December 2015. This two-part application submission enabled the staff to begin its environmental review months before the docketing of the full application and the commencement of the safety review.

Additionally, based on its experience with the SHINE review, the staff was able to use previously developed document templates to draft its safety evaluation report and environmental impact statement, and to issue clear, focused requests for additional information.

The staff also applied insights gained from the development of its non-power production and utilization facility construction oversight program to the review of the Northwest construction permit application. For example, in December 2015, the staff published Inspection Manual Chapter 2550, establishing a construction inspection program for non-power production and utilization facilities. One of the objectives of this construction inspection program is to verify whether a licensee adequately implements its quality assurance program during the construction of its facility. Therefore, to ensure the implementation of the program and to be consistent with Part 50 requirements for other Part 50 facilities, the staff recommends that the Northwest construction permit be conditioned to require the implementation of the quality assurance program described in the Northwest PSAR.

The staff completed its review within 23 months from the docketing of the application and spent approximately 10,000 hours reviewing the application. NRC contractors spent an additional 2,000 hours in support of the staff review.

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### **Slide 6: Authorizing Construction**

Northwest seeks authorization to construct a 10 CFR Part 50 production facility. NRC regulations require less detail for a Part 50 construction permit application than for a Part 50 operating license application or a Part 52 combined license application, particularly where the applicant does not seek approval of a final design. The required content of a construction permit application is specified in section 50.34, and includes:

- The preliminary design of the facility,
- A preliminary analysis of structures, systems, and components,
- Probable subjects of technical specifications,
- A preliminary emergency plan,
- A quality assurance program, and
- Ongoing research and development.

The Northwest application also describes activities to be conducted within a “target fabrication area” under a 10 CFR Part 70 license to be located in the same building as its proposed production facility. Northwest stated that it will submit this Part 70 application at a later date. As part of its construction permit safety review, the staff considered the anticipated interface between and impact on the Northwest production facility from the target fabrication area. However, the staff findings and conclusions in its safety evaluation report are limited to whether the Northwest production facility satisfies the Part 50 requirements for the issuance of a construction permit.

In its environmental review, the staff considered both the potential environmental impacts from the construction of the Part 50 production facility, and also the actions connected to the issuance of a construction permit. As documented in the staff final environmental impact statement (or EIS), connected actions, in part, include the construction, operations, and decommissioning related to the Part 70 “target fabrication area.”

Based on the information that Northwest has provided to date, Part 70, not Part 50, would govern the possession and use of special nuclear material in the portions of the site where target fabrication activities would occur. If Northwest were to commence construction on the portions of the site where target fabrication activities would occur, the ability of the staff to conduct future environmental and safety reviews of a Part 70 application for the “target fabrication area” would not be affected. However, the commencement of construction of the “target fabrication area” prior to the staff completing its environmental review of a Part 70 license application for the target fabrication activities may be grounds for the denial of the Part 70 license if Northwest does not obtain an exemption. In December 2017, Northwest submitted such an exemption request. The staff is currently performing a docketing acceptance review on this exemption request.

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### **Slide 7: Conducting the Review**

The staff evaluation of the Northwest construction permit application consisted of two concurrent technical reviews:

- one, a safety review based on the Northwest PSAR and
- the other, an environmental review based on the Northwest environmental report.

I will discuss the staff safety review and Joe Donoghue will discuss the staff environmental review.

The staff safety review assessed the sufficiency of the preliminary design, including the principal design criteria and design bases, of the proposed Northwest production facility.

The staff safety review was also subject to an independent review by the Advisory Committee on Reactor Safeguards. The Committee concluded that Northwest had demonstrated knowledge of potential hazards and accidents, and of safety requirements, and that the topics that the Committee had identified during its review were documented by the staff and Northwest. The staff will consider those technical areas undergoing final design during its review of a Northwest final safety analysis report (or FSAR) submitted as part of an operating license application.

Following the independent review of the Committee, the staff completed its safety evaluation report in November 2017.

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#### **Slide 8: Tailoring Review Methodology**

The staff safety review of the Northwest construction permit application considered the physical, radiological, chemical, and licensing processes of the proposed facility. Given the similarities between the proposed Northwest Part 50 production facility and existing Part 70 fuel cycle facilities, the staff adapted existing guidance documents to accommodate this unique combination of technical and licensing considerations. Specifically, the staff conducted its review by using guidance contained in NUREG-1537, which is the standard review plan for non-power reactors, the Interim Staff Guidance (or ISG) Augmenting NUREG-1537, which contains the standard review plan for medical radioisotope production facilities, and NUREG-1520, which is the standard review plan for fuel cycle facilities. In applying this guidance, the staff exercised its judgment to determine the applicability of acceptance criteria and evaluation findings. The staff also exercised its judgment in determining the level of detail needed for a preliminary versus a final design in the safety review of the Northwest construction permit application.

To support the issuance of a construction permit, the staff evaluated the descriptions and discussions of the Northwest structures, systems, and components, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the Northwest 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 as required by 10 CFR 50.34(a). The staff also evaluated the sufficiency of the preliminary design to provide reasonable assurance that the Northwest final design will conform to the design bases.

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#### **Slide 9: Additional Information**

An important part of the staff safety review was determining what additional technical and design information, not initially provided in the Northwest PSAR, was necessary to support the

issuance of the construction permit. To this end, the staff requested additional information and Northwest revised its application, as needed, in response to these requests.

The staff determined that, with the additional information, Northwest had provided the information necessary for the staff to complete its safety review.

The staff concluded that a construction permit should be issued, provided that it includes certain permit conditions to support the staff finding of reasonable assurance for the licensing action.

For example, one condition would require Northwest to provide, prior to the completion of construction, periodic updates on the design of its proposed criticality accident alarm system. This would require Northwest to establish the appropriate thickness of the shielding that would surround this system before construction is complete. If the shielding is too thick, the alarm system might not perform as required; if the shielding is too thin, radiation protection could become a concern.

Additionally, based on the Commission pre-hearing questions, the staff now recommends that the construction permit be conditioned to require that, prior to the beginning of construction, Northwest complete and submit to the NRC the results of a site-specific geotechnical investigation. This condition would require that the results of the geotechnical investigation be available to enable Northwest to identify sinkhole potential, soil characteristics, and liquefaction potential at the site that could impact the design of the facility before Northwest begins construction.

Consistent with 10 CFR 50.35, the recommended conditions would ensure that Northwest confirms that the final design of its facility will conform to the design bases as the design matures.

In instances where additional information may reasonably be left for later consideration in the FSAR, Northwest has made commitments to provide such information. These commitments are listed in Appendix A of the safety evaluation report and the staff will verify that they have been addressed during its review of a Northwest operating license application.

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Joe Donoghue will now discuss the staff environmental review of the Northwest construction permit application.

**Speaker: Joe Donoghue**

### **Slide 10: Environmental Requirements**

Thank you MaryJane.

The environmental review of the Northwest 10 CFR Part 50 construction permit application was performed in accordance with the National Environmental Policy Act of 1969, commonly referred to as NEPA. NEPA requires that agency decision making include the consideration of the environmental impacts of federal actions. NEPA also requires federal agencies to follow a systematic approach in evaluating potential impacts and to assess alternatives to those actions. The NEPA process involves public participation during prescribed periods and public disclosure.

The NRC regulations implementing NEPA are set forth in 10 CFR Part 51. These regulations describe when the staff should prepare an EIS, or an Environmental Assessment. NRC regulations do not require the preparation of an EIS for the issuance of a Part 50 construction permit for a medical radioisotope production facility. However, the staff determined that an EIS would be appropriate for the Northwest Part 50 construction permit application for two reasons:

One - An environmental assessment might not support a finding of no significant impact.

Two - Operation of the Northwest facility, which would be a connected action to the construction of the facility, would include the possession and use of special nuclear material for target fabrication and scrap recovery, processes similar to those used at fuel fabrication facilities. Notably, the issuance of a license to possess and use special nuclear material for scrap recovery requires an EIS to be prepared in accordance with 10 CFR 51.20(b)(7).

The purpose of the environmental review is to identify the environmental impacts of constructing the proposed facility, and the impacts of the connected actions of operating and decommissioning the facility, as well as alternatives to the facility. In combination with the safety review, the environmental review will inform the staff recommendation to the Commission of whether to issue the construction permit.

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#### **Slide 11: Environmental Review Process**

The environmental review process for preparing an EIS was conducted in accordance with 10 CFR Part 51. As depicted on the slide, there was a scoping period to gather input from the public, other governmental agencies, and Tribes regarding the scope of the EIS. The staff conducted an environmental site audit to view the environmental features at the proposed site and the alternative sites. In addition, the staff developed requests for additional information to clarify information in the Northwest Environmental Report, and to seek additional information not included in the Northwest Environmental Report.

Based on this information, the staff published the draft EIS for public comment in October 2016. The staff responded to all comments received in the Final EIS, which was published in May 2017. The staff also updated the final EIS in response to comments.

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#### **Slide 12: Proposed Discovery Ridge Site**

The proposed site is located approximately 3 miles southeast of the City of Columbia, Missouri and is owned by the University of Missouri. The proposed site consists of previously disturbed agricultural lands. The proposed site does not contain any surface water features, known threatened or endangered species, or known historical or cultural resources.

Based on its review, the staff determined that the impacts to all resource areas would be SMALL. An impact level of SMALL means that the environmental effects are not detectable or are so minor that they would neither destabilize nor noticeably alter any important attribute of the resource.

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Brian Smith will now discuss the statutory and regulatory basis for the issuance of a Part 50 construction permit and the staff's overall safety and environmental findings.

**Speaker: Brian Smith**

**Slide 13: Statutory and Regulatory Basis for Construction Permit Issuance**

Thank you, Joe.

Section 103 of the Atomic Energy Act authorizes the Commission to issue licenses for production facilities, subject to the Commission regulations. The principal safety requirements applicable to construction permits for production facilities are contained in 10 CFR Parts 20 and 50. The applicable environmental requirements are contained in 10 CFR Part 51.

After completing the required safety and environmental reviews, the staff determined that the Northwest application met the applicable requirements of 10 CFR Parts 20, 50, and 51.

This determination was reached, in part, by applying the guidance in the ISG Augmenting NUREG-1537, the standard review plan for medical radioisotope production facilities. This guidance allows applicants to use the performance requirements of 10 CFR 70.61 to demonstrate adequate safety for a medical radioisotope production facility, particularly with respect to postulated accidents. For example, the performance requirements of 10 CFR 70.61 can be used to establish criteria to protect against chemical hazards and ensure subcriticality under normal and credible abnormal conditions.

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**Slide 14: Construction Permit Findings**

The staff review supports the four findings required by 10 CFR 50.35 for the issuance of a construction permit.

The first finding is that the applicant has described the proposed design of the facility. The staff used 10 CFR 50.34(a), and its guidance to evaluate the sufficiency of the Northwest preliminary design, making sure that its proposed design bases and criteria are consistent with NRC regulations and guidance. Based on its review, the staff concludes that Northwest 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 second finding is that the applicant has identified technical or design information that can reasonably be left for later consideration in the FSAR. The PSAR identified such information. This includes, for example, the Security and Emergency Plans, facility operating procedures, and certain design information that Northwest committed to provide in the FSAR. As discussed, these commitments are listed in Appendix A of the safety evaluation report and the staff will confirm that Northwest addresses these items in its FSAR.

The third finding is that the applicant has identified safety features that required further research and development. While Northwest did not identify any structures, systems, or components that require research and development to confirm the adequacy of the facility design, Northwest did

describe on-going validation testing at the University of Missouri – Columbia Research Reactor and at the Department of Energy national laboratories; resin testing; and ion exchange column testing. As described in the safety evaluation report, the staff is tracking these items and will verify their resolution prior to the completion of construction as part of its review of an operating license application.

The fourth finding is that, for those safety questions and Northwest research programs, there is reasonable assurance that Northwest will be able to complete the research programs before the latest date of construction, and taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated without undue risk to the public.

Northwest has stated that the latest date of construction would be December 31, 2022. The staff expects that the Northwest testing programs will be completed in advance of this date. The additional permit conditions related to criticality safety must also be satisfied prior to the completion of construction.

The site criteria in Part 100 only apply to power reactors and testing facilities, and thus do not apply to the proposed Northwest facility. However, the staff considered similar site-specific conditions in its review, including meteorology, geology, and seismology. The staff also evaluated external events such as extreme weather, floods, and aircraft impacts.

Northwest intends to design its facility such that potential doses to workers and the public from postulated accidents are within the limits of 10 CFR Part 20. Chemical accident consequences would be mitigated consistent with the performance requirements of 10 CFR 70.61. Northwest intends to select items relied on for safety and appropriate management measures based on the results of its integrated safety analysis to mitigate potential radioactive and chemical consequences resulting from accident conditions. Thus the staff finds that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

Additionally, for the purpose of issuing the construction permit, the staff conducted an environmental review sufficient to meet the requirements of NEPA and to inform the Commission action on the construction permit request.

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### **Slide 15: Construction Permit Considerations**

Based on its findings, the staff concludes that there is sufficient information for the Commission to issue the subject construction permit to Northwest, as guided by the following considerations described in 10 CFR 50.40 and 10 CFR 50.50:

There is reasonable assurance: that the construction of the Northwest facility will not endanger the health and safety of the public, and that construction activities can be conducted in compliance with the Commission regulations;

Northwest is technically and financially qualified to engage in the construction of its proposed facility;

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



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 this 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 regulations; and

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

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### **Slide 16: Introducing the Review Panels**

In the panels that follow, the staff will discuss novel aspects of its review of the Northwest construction permit application. Safety Panel 1 will discuss the unique licensing considerations associated with the colocation of the proposed Northwest production facility and target fabrication area. This panel will also cover the implementation of the Northwest quality assurance program plan and design change management. The information presented in this panel is described in greater detail in chapters 1, 4, and 12 of the staff safety evaluation report. Additionally, Safety Panel 1 is prepared to discuss Chapters 2, 3, 5, and 6 of the Safety Evaluation Report.

Safety Panel 2 will follow this with details on the accident analysis methodology, as described in Chapter 13 of the safety evaluation report. Additionally, Safety Panel 2 is also prepared to discuss Chapters 7, 8, 9, 11, 14, and 15 of the safety evaluation report.

Finally, the Environmental Panel will provide a summary of the staff determination to prepare an EIS for this application, the scope of the EIS and connected actions, and the analysis of alternatives.

This concludes the staff overview panel. We are prepared to respond to any questions that you may have at this time.

## *Safety Panel 1*

### **Slide 1 Northwest Medical Isotopes Construction Permit Application Review**

**Speaker: Alexander Adams**

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### **Slide 2: Panelists**

Good morning Chairman and Commissioners. My name is Al Adams. This panel will discuss the unique licensing considerations of the proposed Northwest production facility. I will discuss the licensing process and summarize the staff interactions with the Advisory Committee on Reactor Safeguards, or the ACRS. Michael Balazik will discuss the licensing of the production facility, and David Tiktinsky and Steve Lynch will discuss the proposed permit conditions.

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### **Slide 3: Licensing Process**

The 10 CFR Part 50 regulations define three types of production facilities, one of which is a facility used for the processing of irradiated materials containing special nuclear material. Northwest seeks to construct a Part 50 production facility that would process irradiated low enriched uranium (or LEU) targets for the recovery and purification of molybdenum-99.

The construction permit licensing requirements for the proposed Northwest production facility are similar to those for other non-power facilities licensed under 10 CFR Part 50, such as research reactors. However, unlike research reactors licensed to perform research and development activities under Section 104 of the Atomic Energy Act, the Northwest production facility would be licensed to commercially produce medical radioisotopes under Section 103 of the Atomic Energy Act. As such, the Northwest construction permit application is also subject to an independent review by the ACRS and a mandatory hearing.

As we will describe throughout our panels today, the staff encountered unique licensing considerations based on the Northwest design maturity, site selection, and proposed technology.

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### **Slide 4: Advisory Committee on Reactor Safeguards Review**

The staff presented the results of its safety review at four ACRS subcommittee meetings last summer. As a result of ACRS subcommittee discussions, the staff performed additional independent analysis of the issues of aircraft impacts and seismic response to confirm the adequacy of the Northwest production facility design bases.

To confirm the seismic design of the proposed Northwest production facility, the staff developed a general seismic design response spectrum incorporating site amplification factors for the proposed site. The staff found that the seismic response was acceptable for the issuance of a construction permit because large facility structures, components, and equipment would not be impacted. However, the staff did identify a potential high-frequency seismic design response

that could impact smaller components such as electrical relays, piping, and instrumentation. The staff is tracking this issue as a regulatory commitment in Appendix A.4 of its safety evaluation report.

The staff also performed a confirmatory analysis of the Northwest aircraft impact frequencies. The total aircraft impact frequency calculated by the staff was  $10^{-7}$  per year. This is of the same order of magnitude as that calculated by Northwest. The staff finds that Northwest should evaluate the impact of a general aviation crash in its final design. Northwest stated in its PSAR that the general aviation crash will be evaluated in the operating license application.

The staff presented the results of its review of the Northwest construction permit application to the ACRS full committee on November 2, 2017. The ACRS recommended the issuance of a construction permit in its letter dated November 6, 2017, which is contained in Appendix D of the staff safety evaluation report.

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Michael Balazik will now discuss licensing considerations unique to the Northwest production facility.

**Speaker: Michael Balazik**

#### **Slide 5: Production Facility Licensing**

Thank you, Al.

Northwest proposes to irradiate LEU targets at existing U.S. research reactors. After irradiation, the targets would be transported back to the Northwest facility. Northwest would then process these irradiated targets and separate the molybdenum-99 from other fission products in a portion of the proposed facility. Because Northwest is proposing to process irradiated special nuclear material in batch sizes of greater than 100 grams of uranium-235, this portion of the facility meets the definition of a production facility in 10 CFR 50.2.

The proposed production facility would use several physical and chemical processes that are similar to those performed at fuel cycle facilities. These processes would include dissolvers, ion exchangers, and concentrators.

To support its review, the staff used the guidance in NUREG-1537, the Interim Staff Guidance (or ISG) Augmenting NUREG-1537, and NUREG-1520.

In applying this guidance, the staff used its judgment to determine the extent to which the guidance was relevant to the review of the Northwest construction permit application, because much of the guidance was originally developed for completed facility designs.

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#### **Slide 6: Unique Licensing Considerations**

A unique licensing aspect of this review is that the 10 CFR Part 50 construction permit application describes a single facility where processes subject to different regulatory regimes will occur. One process consists of disassembly and dissolution of irradiated targets,

molybdenum-99 recovery and purification, uranium recovery and recycle, and waste management. This process constitutes the production facility for which Northwest has requested a construction permit and which is subject to the licensing requirements of Part 50.

The construction permit application also describes a target fabrication process. This process consists of fabricating LEU targets containing unirradiated uranium, uranium from previously irradiated targets, and potentially uranium scrap from off-specification targets. Although the construction permit application discusses this process, the Northwest application states that Northwest plans to submit a 10 CFR Part 70 application for these activities. Northwest has also stated that it would submit its Part 70 application with its Part 50 operating license application and would request that the NRC issue a single license for the entire facility, which is permissible under NRC regulations [10 CFR 50.52]. The staff only considered target fabrication to understand the interface between the two processes and impact on the production facility process.

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David Tiktinsky will now discuss the interface between the production facility and target fabrication area in more detail. He will also identify the proposed permit conditions.

**Speaker: David Tiktinsky**

#### **Slide 7: Relationship between Production Facility and Target Fabrication**

Thank you, Michael.

While the Northwest application described both production facility and target fabrication activities, Northwest only requested a construction permit for a Part 50 production facility. The staff reviewed the entire application, including the Northwest descriptions related to Part 70 activities associated with target fabrication. However, the staff review was to determine whether Northwest satisfies the requirements for the potential issuance of a construction permit for a Part 50 production facility. As part of this review, the staff focused on the interface between the production facility and target fabrication processes as well as the impact of target fabrication processes on the production facility. Any systems or components that are shared between the two processes were evaluated to support the conclusions of the staff regarding the issuance of a construction permit for the Part 50 production facility only. A Part 50 construction permit, if issued, would only authorize Northwest to construct the production facility portion of its facility. The separate requirements of Part 70 would govern the target fabrication portion of the facility.

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#### **Slide 8: Proposed Permit Conditions**

Provided that the requirements for the issuance of a construction permit are satisfied, the regulations in 10 CFR Part 50 generally allow the design to mature from a preliminary to a final design without requiring specific NRC approval. Pursuant to 10 CFR 50.35, the construction permit does not constitute the NRC approval of the safety of any design feature, unless the applicant specifically makes this request. Instead, the approval of the safety of design features is made during the staff review of the final design submitted in the operating license application. The staff determined that permit conditions were necessary regarding criticality safety, quality

assurance, and site characteristics, in order to confirm adequate design bases and assure quality.

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### **Slide 9: Criticality Safety Conditions**

The staff recommends the inclusion of a construction permit condition associated with the criticality accident alarm system because of the concern that shielding could interfere with the ability of the criticality accident alarm system to detect an inadvertent criticality, and because the Northwest evaluation of criticality accident alarm system coverage has not been completed.

The staff also recommends a permit condition on the subcritical limit to confirm that Northwest will integrate the revised subcritical limit in the criticality calculations and design analysis of the facility for its final design because it is possible that some of the Northwest criticality calculations and design analysis will need to be redone to incorporate the revised subcritical limit. Based on the Northwest use of conservative modeling practices, and its conservative validation methodology, the staff has reasonable assurance that its margin of subcriticality is acceptable to ensure subcriticality of the proposed production facility under normal and credible abnormal conditions.

These proposed permit conditions are confirmatory and ministerial in nature because they are intended to confirm that Northwest considers certain information as it develops and implements its final design and because their satisfaction is accomplished by the submission of periodic reports. A safety review of the adequacy of the information will await the review of an operating license application.

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Steve Lynch will now discuss additional proposed permit conditions on quality assurance and site specific geotechnical investigations.

**Speaker: Steve Lynch**

### **Slide 10: Quality Assurance Condition**

Thank you, David.

In order to provide reasonable assurance that the regulatory requirements and licensee commitments for quality assurance are adequately implemented during construction, the staff recommends that the Northwest construction permit include a quality assurance condition similar to the requirements of 10 CFR 50.55(f), which apply to nuclear power plant and fuel reprocessing plant construction permit holders. The proposed condition would require Northwest to implement its quality assurance program plan (or QAPP) as described in its PSAR and would support the adequate implementation of licensee commitments in design, procurement, and construction.

Specifically, the inclusion of this permit condition would:

- (1) Ensure that Northwest implements its QAPP;
- (2) Provide for consistency and maintenance of documentation;
- (3) Establish criteria for notifying the NRC of changes to the QAPP, and;
- (4) Require correction of deficiencies in the implementation of the QAPP.

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### **Slide 11: Geotechnical Condition**

Based on the staff review of the Northwest description and safety assessment of the Discovery Ridge site, the staff determined that Northwest had satisfied the requirements of 10 CFR 50.34(a)(1)(i) and that the design basis of the facility described in Chapter 3 of the PSAR satisfied the requirements of 10 CFR 50.34(a)(3). However, in light of the potential for unidentified sinkholes, undesirable soil characteristics, and liquefaction, Northwest has committed to performing a site-specific geotechnical investigation. Based on issues raised by Commission pre-hearing questions, the staff has reconsidered its decision to track the results of the Northwest geotechnical investigation via regulatory commitments. Since the site-specific investigation could reveal geological features impacting the design bases of the facility, the staff recommends that the Northwest construction permit be conditioned to require that, prior to the beginning of construction, Northwest complete and submit the results of the geotechnical investigation.

The results of the geotechnical investigation would inform Northwest design activities, would inform the staff construction inspection program, and would confirm the adequacy of the Northwest production facility design basis, including any design changes made in accordance with the Northwest QAPP. The staff review of an operating license application will determine whether the final design is adequate for operation of the production facility.

This concludes the Safety Panel 1 presentation. We are prepared to respond to any questions that you may have at this time.

## *Safety Panel 2*

### **Slide 1: Northwest Medical Isotopes Construction Permit Application Review**

**Speaker: Michael Balazik**

*Next Slide, please.*

### **Slide 2: Panelists**

Good afternoon Chairman and Commissioners. My name is Michael Balazik. This panel will discuss the unique accident analysis considerations of the proposed Northwest production facility.

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### **Slide 3: Accident Analysis Methodology**

10 CFR 50.34(a)(4) requires that a PSAR assess the risk to the public health and safety from a proposed facility. The ISG Augmenting NUREG-1537 provides that an applicant for a medical radioisotope production facility may satisfy this requirement, in part, by performing an integrated safety analysis (or ISA).

An ISA involves identifying potential accident sequences in facility operations and designating items relied on for safety (or IROFS) to either prevent or mitigate their consequences to an acceptable level. An ISA is typically required for 10 CFR Part 70 licenses for fuel cycle facilities. However, the ISG Augmenting NUREG-1537 provides that an ISA may be used for medical radioisotope production facilities because (1) Part 50 does not contain specific requirements for accident analyses for medical radioisotope production facilities and (2) the anticipated radiological and chemical hazards associated with the processes at medical radioisotope production facilities are similar to those associated with fuel cycle facilities. Specifically, the ISG states that the use of ISA methodologies as described in Part 70, the application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, the designation of IROFS, and the establishment of management measures is an acceptable way of demonstrating adequate safety for a medical radioisotope production facility.

In its application, Northwest used a Part 70 ISA methodology for its accident analyses, including the designation of IROFS. Northwest also stated that it will provide a description of management measures in an operating license application to demonstrate the availability and reliability of the IROFS.

Using the criteria in 10 CFR 70.61, consistent with the ISG Augmenting NUREG-1537, the staff evaluated the radiological and chemical consequences that Northwest developed and found that the Northwest ISA methodology was sufficient for the issuance of a construction permit.

In Chapter 1 of its construction permit application, Northwest stated that, for both normal releases and postulated accident releases, it intends to meet the dose standards in 10 CFR 20.1201 and 20.1301. While these dose standards were not intended to be used to evaluate postulated accident conditions, the staff finds their use for this purpose to be conservative and consistent with applicable guidance.

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April Smith will now provide details on the staff evaluation of the Northwest ISA methodology.

**Speaker: April Smith**

**Slide 4: ISA Methodology**

Thank you, Michael

As Michael described, Northwest performed an ISA of the proposed production facility. To support the establishment of the design basis and to identify the major features or components for the protection of the health and safety of the public, the ISA methodology includes an accident analysis of the radiological and chemical hazards of the facility. Northwest submitted the results of the ISA with its application as an ISA Summary.

The ISA Summary describes the ISA methodology and the methods used by Northwest to perform hazard analyses. These methods included standard industry techniques such as hazard and operability analyses. The hazard analyses results facilitate identification of accident sequences that may require additional assessment via quantitative risk analysis.

The ISA Summary also defines accident sequence likelihood categories, consequence severity categories, and a risk matrix that combined various likelihood and consequence categories to determine acceptable and unacceptable scenarios. The staff determined that these categories and the risk matrix are consistent with staff guidance for fuel cycle facilities conducting similar activities as Northwest.

Furthermore, the staff determined that the Northwest use of these hazard and risk analysis methods is consistent with what has been used in fuel cycle facilities that have prepared ISAs.

The staff evaluated the sufficiency of the ISA methodology to identify, analyze and determine the consequences of accident sequences, in part, by reviewing the processes conducted inside the production facility. The staff determined that the Northwest use of its ISA methodology is consistent with NUREG-1520 and the ISG Augmenting NUREG-1537 for medical radioisotope production facilities.

The staff also reviewed accident sequences related to the loss of confinement, the mishandling or malfunction of equipment, inadvertent nuclear criticality, fires, and external events including natural phenomena and loss of electrical power. Additionally, the staff considered postulated accident sequences related to the activities within the target fabrication area to determine their potential impact on the Northwest production facility.

Next slide, please.

**Slide 5: ISA Methodology (continued)**

10 CFR 70.61 describes the requirements to render accident sequences with high consequences as highly unlikely and accident sequences with intermediate consequences as unlikely. In order to conform to the requirements in 70.61 and the guidance in NUREG-1520, Northwest identified IROFS to either prevent accidents or to mitigate the consequences of



accidents. Northwest also identified IROFS to prevent an inadvertent criticality and to adhere to the double contingency principle as defined in 10 CFR 70.4. Adhering to the double contingency principle means that process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

As part of the ISA process, after IROFS are identified, management measures are applied. Management measures, as Michael described, are quality assurance elements that assure that IROFS are reliable and available when needed. The staff found it reasonable to leave for later consideration the review of management measures as part of its review of a Northwest operating license application.

The staff concluded that the Northwest ISA methodology contains the elements that support the adequate identification of capabilities and features to prevent or mitigate potential accidents and to protect the health and safety of the public and workers. Therefore, it is sufficient for the issuance of a construction permit.

*Next slide, please.*

David Tiktinsky will now provide details on the staff evaluation of the Northwest radiological and criticality safety accident evaluation.

**Speaker: David Tiktinsky**

#### **Slide 6: Radiological and Criticality Safety**

Thank you, April.

The staff reviewed the Northwest analysis of accidents with radiological and criticality consequences. This analysis included event sequences involving liquid spills, sprays, and leaks. Consistent with the ISG augmenting NUREG-1537, Northwest considered the consequence levels as stated in the performance requirements of 10 CFR 70.61 for postulated accidents and the radiological release limits in 10 CFR Part 20. In its review, the staff looked at the engineered safety features and IROFS proposed by Northwest to prevent or mitigate the impacts of the identified accident sequences. The staff evaluation of the identified accidents is similar to that previously done in the staff review of fuel cycle facility applications except for the unique aspect of having to evaluate the radiological impacts of the separation of fission products.

The staff reviewed the accident sequences identified by Northwest in the PSAR and determined that Northwest had adequately identified credible accident sequences with potential radiological consequences or that could cause an inadvertent criticality. The staff also found that Northwest had described a nuclear criticality safety program that will, if properly implemented, ensure that all facility processes are subcritical under both normal and credible abnormal conditions, and will comply with the double contingency principle.

*Next slide, please.*

James Hammelman will now provide details on the staff evaluation of the Northwest chemical safety evaluation.

**Speaker: James Hammelman**

**Slide 7: Chemical Safety**

Thank you, David.

The staff reviewed the Northwest process and facility design as well as the Northwest analysis of chemical safety-related accidents and assessment of chemical safety controls. The review examined the engineered safety features that Northwest identified to protect against releases of licensed material or the hazardous chemicals produced from processing of licensed material.

In order to estimate the impact of energetic chemical reactions not analyzed in the construction permit application, the staff conducted an independent analysis of potential energetic chemical reactions that could damage equipment and possibly injure nearby personnel. Based on the staff evaluation, it is expected that the hot cell wall will be able to withstand a pressure pulse from potential reactions of the organic ion exchange media. Therefore, the staff concluded that it was acceptable to defer the review of the Northwest analysis of this hazard until the operating license application.

Northwest stated that it will perform additional testing to evaluate the feasibility of a pressure relief system for mitigating potential exothermic reactions of the ion-exchange material. Additionally, Northwest will also evaluate the potential for the release and thermal decomposition of the organic material used in the ion exchange media for uranium purification. The results of this additional testing will be integrated into the operating license application.

The staff determined that the Northwest preliminary facility design, proposed process operations, and engineered safety features can provide adequate protection of the public from chemical hazards at the proposed facility.

*Next slide, please.*

Michael Balazik will now provide a summary of the staff evaluation of the Northwest accident analysis.

**Speaker: Michael Balazik**

**Slide 8: Summary of Accident Analysis Findings**

Thank you, James

Based on its review the staff concludes that, for the purposes of issuing a Construction Permit, there is reasonable assurance that the ISA methodology proposed by Northwest is sufficient to identify accident sequences and IROFS. The ISA approach also supports the determination that the facility hazards have been adequately identified and that the preliminary design, including the engineered safety features, will protect the health and safety of workers and the public.

This concludes the Safety Panel 2 presentation. We are prepared to respond to any questions that you may have at this time.

*Environmental Panel*

**Slide 1: Northwest Medical Isotopes Construction Permit Application Review**

**Speaker: Benjamin Beasley**

*Next page, please*

**Slide 2: Panelists**

Good afternoon Chairman and Commissioners. My name is Benjamin Beasley and I am the Chief for the Environmental Review and National Environmental Policy Act Branch. With me today to discuss the environmental review of the Northwest 10 CFR Part 50 construction permit application are Nancy Martinez, a Physical Scientist; Michelle Moser, a Biologist; and David Drucker, a senior environmental project manager. We are all from the Division of Materials and License Renewal in NRR.

Next Slide, please.

**Slide 3: Environmental Review**

Part of the staff review of the Northwest construction permit application included an environmental review, which was conducted in parallel with the safety review that you heard about earlier. The staff performed the environmental review in accordance with the National Environmental Policy Act, commonly referred to as NEPA. In doing its NEPA review, the staff followed the environmental review process for preparing an environmental impact statement described in 10 CFR Part 51 and the Interim Staff Guidance Augmenting NUREG-1537. An environmental impact statement is commonly referred to as an E I S.

The following presentations provide an overview of the staff environmental review for the Northwest application, while highlighting the unique aspects of this review. The three novel issues that we will highlight today are: related actions that were included in the scope of the environmental review; the staff decision to prepare an EIS; and staff analyses to determine the range of reasonable alternatives analyzed in the EIS.

Next slide, please.

Nancy Martinez will now discuss the scope of the environmental review and the scoping process.

**Speaker: Nancy Martinez**

**Slide 4: Scope of the Review: Proposed Action and Connected Actions**

Thank you, Ben.

One of the first issues considered in the environmental review of the Northwest Part 50 construction permit application was determining the scope of the review based on the proposed action and connected actions given the unique nature of the proposed facility.

The Northwest application describes a single proposed radioisotope production facility building divided into two separate areas where processes subject to different regulatory regimes would take place if the facility is licensed to operate.

Consistent with 10 CFR 51.14(b), in performing its NEPA review, the staff used the Council on Environmental Quality definition of connected action contained in 40 CFR 1508.25. Actions that are closely related are connected if they:

- 1) automatically trigger other actions that may require environmental impact statements;
- 2) cannot or will not proceed unless other actions are taken previously or simultaneously; or
- 3) are interdependent parts of a larger action and depend on the larger action for their justification.

On the next slide, I am going to discuss how the staff used the definition of connected actions to determine the scope of the environmental review for the Northwest application.

Next Slide, please

### **Slide 5: Proposed Action and Connected Actions**

The staff determined that the scope of the environmental review for the issuance of a construction permit includes construction activities at the proposed site as well as post-construction activities on and offsite because they are connected actions.

Construction at the site will include building a target fabrication area, an administration building, a waste management building, a diesel generator building, and support structures. Because the construction of these buildings and support structures is an interdependent part of constructing the proposed Northwest production facility, the staff also considered these environmental impacts. In addition, operations and decommissioning of the proposed production facility are connected actions to production facility construction because they cannot proceed unless a 10 CFR Part 50 construction permit is issued. Therefore, the staff considered the environmental impacts from these actions as part of its environmental review of the Northwest application.

Construction of the target fabrication area, which would be collocated with the proposed production facility within one building, is a connected action to the construction of the production facility. Additionally, operations and decommissioning of the target fabrication area, which is to be licensed under Part 70, are connected actions because they would not occur unless a Part 50 construction permit is issued. Therefore, the staff considered the environmental impacts from these actions as part of its environmental review of the Northwest application.

Furthermore, operation of the proposed Northwest production facility will depend on low enriched uranium (or LEU) targets being transferred to and from, and irradiated in, one or more research reactors. Because moly-99 production cannot occur until research reactors are licensed to irradiate these targets and because the environmental impacts from LEU target irradiation at research reactors have not been previously assessed, the staff concluded that target irradiation at research reactors and transportation of targets to and from the research reactors are an interdependent part of the proposed Northwest production facility operation and, therefore, are also connected actions.

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## **Slide 6: Environmental Impact Statement (EIS)**

One of the steps in the environmental review process was determining whether to prepare an Environmental Assessment or an Environmental Impact Statement.

Licensing actions that require an EIS are described in 10 CFR 51.20. The proposed issuance of a construction permit for a medical radioisotope production facility is not specifically listed in 10 CFR 51.20. However, pursuant to 10 CFR 51.20(a)(2), the NRC may exercise its discretion to determine that a licensing action should be covered by an EIS.

After reviewing the Northwest application, the staff determined that the preparation of an EIS would be an appropriate means to assess the environmental impacts of the proposed action. The staff made this determination primarily for two reasons.

First, the staff determined that operation of the Northwest facility, a connected action to constructing the facility, would include a type of action that would require an EIS. Specifically, the application describes that, in support of operation, Northwest would fabricate target material that would then be encapsulated in metal cladding. The uranium used for the target material would be from a combination of (1) fresh LEU, (2) recovered LEU from material scrapped during the target fabrication process, and (3) LEU recovered and recycled from the processing of irradiated targets. Therefore, operation of the Northwest facility, as described in the application, would include the use of special nuclear material for processes which require an EIS under 10 CFR 51.20(b)(7).

Second, the staff determined that, in this instance an environmental assessment may not support a finding of no significant impact. An environmental assessment is used to determine whether the impacts from a proposed action may be significant and whether a finding of no significant impact can be made. If, based on the environmental assessment, the staff concludes that the proposed action could result in significant impacts to the human environment, then the staff would prepare an EIS. Because the staff was not certain that an environmental assessment would have supported a finding of no significant impact for the Northwest application, it determined that the direct preparation of an EIS would be the most efficient path forward.

*Next Slide, please.*

## **Slide 7: Scoping Process**

The staff published the Notice of Intent to prepare an EIS and commenced a 45-day scoping period to provide the public an opportunity to participate in the environmental scoping process in November 2015. Scoping is the process by which the staff identifies the specific impacts and significant issues to be considered in the preparation of an EIS. During this time, the staff held a public scoping meeting in the City of Columbia, Missouri, to gather input from the public; Federal, State, and local agencies; and Tribes regarding issues to consider in the EIS. Six attendees provided oral comments at the public scoping meeting. The oral comments expressed the benefits of constructing and operating the proposed facility, mostly focusing on economic development and job growth. In addition, the staff received eight written comment letters or emails from Federal and State agencies and Tribal nations. Written comments were related to a variety of environmental issues including the potential impacts to threatened and endangered species from construction of the facility, the potential contamination to groundwater, and the consideration of alternative sites.

The staff responded to comments received during the scoping period in a scoping summary report and included relevant information from in-scope comments in the draft EIS.

Next slide, please.

Michelle Moser will now discuss environmental impacts of the proposed action and alternatives.

**Speaker: Michelle Moser**

### **Slide 8: Environmental Review Areas**

Thank you, Nancy.

In developing the EIS, the staff reviewed the information included in the Northwest environmental report, visited the proposed site, considered scoping comments, and conducted an independent review to characterize the site. The environmental resources described in the EIS include both the human and natural environment, such as ecological resources, water resources, and the socioeconomic conditions surrounding the proposed site.

The proposed site is located within a “shovel ready” industrial park for future development. Past agricultural activities have previously disturbed the area. Common grass species currently cover the site, which provides low-quality habitat for wildlife and birds. The proposed site does not contain any surface water features, threatened or endangered species, or historical or cultural resources.

Next slide, please.

### **Slide 9: Environmental Impacts**

To evaluate the environmental impacts of the proposed action, the NRC established three levels of significance for potential impacts: SMALL, MODERATE, and LARGE. The staff determined that the environmental impacts of the proposed Northwest facility, including all connected actions, would be SMALL for all resource areas. SMALL is defined as environmental effects that are not detectable or are so minor that they would neither destabilize nor noticeably alter any important attribute of the resource. The project-specific activities and site-specific conditions are the basis for the SMALL findings, such as the condition of the previously disturbed site; the low-quality wildlife habitat on the site; the limited ground disturbance that would occur; the use of a public water system to obtain and discharge water; and adequate controls to ensure that radiological exposures would be within regulatory limits.

Next slide, please.

### **Slide 10: Consultations**

Under Section 7 of the Endangered Species Act, the staff must consult with the Fish and Wildlife Service to determine if the proposed action may affect threatened and endangered species. The staff determined that the proposed action would have “no effect” on threatened and endangered species because the proposed site does not provide suitable habitat. Although Fish and Wildlife Service concurrence on a “no effect” determination is not required, the staff submitted a copy of the draft EIS to the Fish and Wildlife Service for its review. In response, the

U.S. Department of the Interior, which includes the Fish and Wildlife Service, stated that it had no comments on the draft EIS. Accordingly, the NRC has fulfilled its consultation obligations under the Endangered Species Act.

Under Section 106 of the National Historic Preservation Act, the staff must consult with the Missouri State Historic Preservation Office to determine whether historic properties would be affected by the proposed action. In addition, the staff consulted with 31 Tribes and the Advisory Council on Historic Preservation. The staff determined that the proposed action would have no impact on known historic properties because the staff did not identify any resources on the proposed site that would be eligible for protection under the National Historic Preservation Act. In November 2016, the Missouri State Historic Preservation Office concurred with the staff determination that no historic properties would be affected. Accordingly, the NRC has fulfilled its consultation obligations under the National Historic Preservation Act.

Next slide, please.

### **Slide 11: Alternatives**

The staff also assessed potential alternatives to granting a construction permit. The need to compare the proposed action with alternatives arises from one of the requirements in Section 102 of NEPA, which states that the EIS will include an analysis that considers and weighs the environmental impacts of the proposed action, the environmental impacts of alternatives to the proposed action, and alternatives available for reducing or avoiding adverse environmental impacts.

Accordingly, the staff considered the environmental impacts of the no-action alternative, or if the NRC were to deny the construction permit application. In addition, the staff examined alternative sites by first reviewing the Northwest site selection process. In the first step of its site selection process, Northwest evaluated a variety of environmental and economic factors to narrow down the number of potential alternative sites to four. In the second step of its site selection process, Northwest scored each of these four sites based on 10 criteria to determine which sites would be eliminated from detailed study and which sites would be considered for in depth study. Northwest determined that the University of Missouri- Columbia Research Reactor site would be considered for in depth study. The staff considered the environmental impacts at that site, which varied from the proposed site because other buildings currently exist on the site, surface water resources and mature trees are adjacent to the site, and the population is greater surrounding the site. Finally, the staff examined alternative technologies to produce molybdenum-99, which was a unique aspect of the staff review of the Northwest application.

Next slide, please.

### **Slide 12: Alternative Technologies**

The alternative technologies analysis was novel because several entities have proposed new technologies to produce molybdenum-99 and the proposed new technologies are at various stages of development. The Council on Environmental Quality regulations implementing NEPA provide guidance when a large number of potential alternatives exist. In such situations, NEPA only requires that an agency analyze a reasonable number of examples, covering the full spectrum of alternatives.

The staff considered the range of possible alternatives, or various methods to fulfill the stated purpose and need of the proposed action, which is to produce molybdenum-99. The staff initially limited the analysis to the five technologies that the Department of Energy's National Nuclear Security Administration awarded cooperative agreements for financial support. The decision to award cooperative agreements was based, in part, on an evaluation of the technical feasibility. Thus, these five technologies appear to be reasonable. Additionally, the staff concluded that the five entities awarded cooperative agreements covered the spectrum of potential alternatives based on the general land use requirements, power levels, and other environmental factors. The five alternative technologies were:

- neutron capture,
- aqueous homogenous reactor,
- selective gas extraction,
- linear-accelerator-based, and
- subcritical fission.

The staff then considered whether sufficient environmental data existed to conduct a meaningful alternatives analysis for each of the five technologies. For example, the staff looked for publicly available documents that described the air emissions, estimated dose exposures, water use, building footprints, and other environmental parameters for each technology. The staff determined that sufficient environmental data existed to meaningfully assess the environmental impacts for the subcritical fission technology and the linear-accelerator-based technology. The staff did not identify sufficient environmental data for the other three technologies. Therefore, these three technologies were eliminated from further detailed analysis.

Next slide, please.

David Drucker will now discuss the cost benefit analysis.

**Speaker: David Drucker**

**Slide 13: Costs and Benefits**

Thank you, Michelle.

In accordance with 10 CFR 51.105(a), the staff weighed the environmental, economic, technical and other benefits against the environmental and other costs for the proposed action, the alternative site, the alternative technologies, and the no-action alternative.

The main costs included the environmental degradation directly associated with the proposed action, as well as the financial costs of construction, operations, and decommissioning of the proposed Northwest facility. The staff determined that the environmental impacts would be SMALL for all resource areas at the Northwest proposed site.

In terms of the benefits considered, the proposed action would result in several societal, medical, and economic benefits. For example, the proposed action is consistent with the U.S. policy of ensuring a reliable supply of medical radioisotopes while minimizing the use of highly enriched uranium. In addition, the production of moly-99 would increase the availability of medical radioisotopes for U.S. public health needs. Furthermore, constructing and operating the proposed Northwest facility would result in economic benefits, such as tax revenue and employment opportunities, to communities located near the Northwest site.



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#### **Slide 14: Draft Environmental Impact Statement**

In October 2016, the staff issued the draft EIS for public comment. During this comment period, the staff requested input from the public, other Federal, State, and local agencies, and Tribes, regarding the data, analyses, and conclusions in the Draft EIS. The NRC held a public meeting in Columbia, Missouri, at which seven commenters made oral statements. In addition, the staff received five letters or emails which included comments from the Sierra Club and from the U.S. Environmental Protection Agency addressing a variety of environmental issues.

The staff did not receive any comments that resulted in significant revisions to the EIS. However, the comments from the Sierra Club and the Environmental Protection Agency did cause the Staff to modify the EIS. These comments and the Staff responses to the comments are provided in the final EIS, which was published in May 2017.

Next slide please.

#### **Slide 15: Staff Conclusion and Recommendation**

In accordance with 10 CFR 51.105(a), the staff weighed the environmental, economic, technical and other benefits against the environmental and other costs, and considered reasonable alternatives to the proposed action. Based on small environmental impacts associated with the proposed Northwest facility, and the societal, medical, and economic benefits associated with the proposed Northwest facility, the staff determined that the benefits outweigh the small environmental costs. Therefore, in the EIS, the staff recommends the issuance of a construction permit to Northwest.

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#### **Slide 16: Future NEPA Analyses**

Future staff NEPA analyses with regard to Northwest are possible for the three items shown on the slide:

First, if Northwest were to submit an application for an operating license for a 10 CFR Part 50 production facility, the staff would prepare a supplement to the EIS developed for the construction permit in accordance with 10 CFR 51.95(b). The supplement to the final EIS would update the environmental review by discussing issues or topics not included in the final EIS, and any different and significant new information regarding matters discussed in the final EIS. As part of the operating license application, Northwest would be required to submit a supplemental environmental report. The staff would independently evaluate the information provided in the supplemental environmental report and would conduct its own independent review to determine if any different and significant new information has become available since publication of the final EIS. The staff would follow the environmental review process described in 10 CFR Part 51 in preparing the supplement to the EIS, including scoping, requesting comments on the EIS, and updating the supplement to the EIS based on public comments received.

Second, if Northwest were to submit a 10 CFR Part 70 application for a license to possess and use special nuclear material for target fabrication, including scrap recovery, Northwest is

required by regulation to submit an environmental report in support of this application. The staff would evaluate this information as appropriate.

Third, the Staff will conduct a separate environmental review for each license amendment request submitted by research reactor licensees to the NRC to irradiate Northwest targets.

This concludes the environmental panel presentation. We are prepared to respond to any questions that you may have at this time.

## *Closing Statement*

### **Speaker: Michele Evans**

The Staff review of the Northwest construction permit application supports the national policy objectives of establishing a domestic supply of molybdenum-99. The Northwest review presented a number of unique technical and licensing considerations for the staff. The timely completion of this review required the expertise, cooperation, and dedication of staff throughout the agency.

The Staff evaluated the Northwest preliminary design to ensure sufficiency of information to provide reasonable assurance that the final design will conform to the design bases. The Staff found that the Northwest use of integrated safety analysis methodologies, its application of radiological and chemical consequences and likelihood criteria provide reasonable assurance that the Northwest ISA process contains the elements to 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.

The objective of the Staff evaluation was to assess the sufficiency of information contained in the Northwest application for the issuance of a construction permit. As such, the Staff evaluation of the preliminary design and analysis of the proposed Northwest production facility does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the facility, as described in the final safety analysis report as part of the Northwest operating license application.

The Staff also considered the potential environmental impact of the proposed facility in accordance with the National Environmental Policy Act.

The staff will continue to engage Northwest on its exemption request that is currently under acceptance review, and any future applications it may submit to the NRC.

Based on the findings of the Staff review, as documented in the safety evaluation report and final environmental impact statement, and in accordance with 10 CFR Parts 50 and 51, the Staff concludes that there is sufficient information for the Commission to issue the subject Part 50 construction permit, with certain conditions, to Northwest Medical Isotopes.

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 **Mandatory Hearing on Northwest Medical Isotopes Construction Permit Application Staff Scripts** have been served upon the following persons by Electronic Information Exchange.

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[Original signed by Herald M. Speiser ]  
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Dated at Rockville, Maryland,  
this 23<sup>rd</sup> day of January, 2018