UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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

ORDER
(Setting Deadline for Proposed Transcript Corrections)

The Commission held an evidentiary hearing on January 23, 2018, at its Rockville, Maryland headquarters to receive testimony and exhibits in the captioned proceeding. The hearing transcript is appended to this Order. Pursuant to my authority under 10 C.F.R. § 2.346(a) and (j), the parties may file any proposed transcript corrections no later than February 5, 2018. Transcript corrections should be limited to the identification of transcription errors that are material to the substance of the testimony or statements involved. The parties may coordinate their responses and file a joint set of corrections.

IT IS SO ORDERED.

For the Commission

NRC SEAL

/RA/

Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 29th day of January, 2018.

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Hearing on Construction Permit for Northwest Medical Isotopes Production Facility: Section 189(a) of the Atomic Energy Act Proceeding

Docket Number: N/A

Location: Rockville, Maryland

Date: January 23, 2018

Work Order No.: NRC-3474 Pages 1-220

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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HEARING ON CONSTRUCTION PERMIT FOR NORTHWEST MEDICAL ISOTOPES PRODUCTION FACILITY: SECTION 189(A) OF THE ATOMIC ENERGY ACT PROCEEDING

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TUESDAY,

JANUARY 23, 2018

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ROCKVILLE, MARYLAND

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The Commission met in the Commissioners' Hearing Room at the Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, at 9:02 a.m., Kristine L. Svinicki, Chairman, presiding.

COMMISSION MEMBERS:

KRISTINE L. SVINICKI, Chairman

JEFF BARAN, Commissioner

STEPHEN G. BURNS, Commissioner

ALSO PRESENT:

ANNETTE VIETTI-COOK, Secretary of the Commission

MARGARET DOANE, General Counsel

NRC STAFF:

ALEXANDER ADAMS, JR., Chief, Research and Test Reactors Licensing Branch, NRR

MICHAEL BALAZIK, Project Manager, Research and Test Reactors Licensing Branch, NRR

BENJAMIN BEASLEY, Chief, Environmental Review and NEPA Branch, NRR

JOSEPH DONOGHUE, Deputy Director, Division of Materials and License Renewal, NRR

DAVID DRUCKER, Senior Project Manager, NRR

MICHELE EVANS, Deputy Director for Reactor Safety Programs and Mission Support, NRR

JAMES HAMMELMAN, Senior Chemical Engineer, Fuel Manufacturing Branch, NMSS

STEVEN LYNCH, Project Manager, Research and Test Reactors Licensing Branch, NRR

NANCY MARTINEZ, Physical Scientist, NRR

MICHELLE MOSER, Biologist, NRR

MARY JANE ROSS-LEE, Deputy Director, Division of Materials and License Renewal, NRR

APRIL SMITH, Reliability and Risk Analyst, Programmatic Oversight and Regional Support Branch, NMSS

BRIAN SMITH, Deputy Director, Division of Fuel Cycle Safety, Safeguards and Environmental Review, NMSS

DAVID TIKTINSKY, Senior Project Manager, Fuel Manufacturing Branch, NMSS

JEREMY L. WACHUTKA, Counsel for NRC Staff

NWMI REPRESENTATIVES:

ROY BROWN, Curium Pharma

MICHAEL CORUM, Senior Technical Advisor, NWMI

GARY DUNFORD, Process Engineering Manager, NWMI

NICHOLAS FOWLER, CEO, NWMI

CAROLYN HAASS, COO, NWMI

STEVEN REESE, Irradiation Services Manager, NWMI

CONTENTS

P R O C E E D I N G S

9:02 a.m.

CHAIRMAN SVINICKI: Well good morning, everyone. I call this hearing to order. I want to welcome the applicant, Northwest Medical Isotopes, LLC, the NRC staff, members of the public in the room with us, and those who are observing this proceeding remotely.

The Commission convenes today to conduct an evidentiary hearing on Northwest Medical Isotopes' construction permit application for a medical radioisotope production facility in Columbia, Missouri. This hearing is required under Section 189(a) of the Atomic Energy Act of 1954, as amended.

The Commission also will be reviewing the adequacy of the NRC staff's environmental impact analysis under the National Environmental Policy Act of 1969 or NEPA.

The general order of the hearing is as follows: First, I will address procedural matters associated with the swearing in of witnesses and the admission into the record of the parties' exhibits. Northwest Medical Isotopes and the NRC staff will then provide testimony in witness panels that provide an overview of the application, as well as address safety

and environmental issues associated with its review with Commission questions following each panel.

The Commission expects to issue a decision after the hearing promptly, with due regard to the complexity of the issues, after it makes the following necessary findings.

On the safety side, the Commission will determine whether, in accordance with 10 CFR Section 50.35(a), (1) the applicant has described the proposed design of the facility, including the principal architectural and engineering criteria for the design and has identified the major features or components incorporated there 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 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, taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public; (5) in making these findings, the Commission also will be guided by the considerations in 10 CFR Section 50.40, which include the Commission's determination as to whether issuance of the construction permit will not be inimical to the common defense and security or the health and safety of the public.

On the environmental side, the Commission will: (1) determine whether the requirements of the National Environmental Policy Act Section 102(2)(a),(c), and (e) and the applicable regulations in 10 CFR 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 need for review conducted by the NRC staff has been adequate.

This meeting is open to the public and we do not anticipate the need to close the meeting to discuss nonpublic information. If a party believes that a response to a question may require reference to nonpublic information, then that party should answer the question to the extent practicable with information from the publicly available record and file any nonpublic response promptly after the hearing on the nonpublic docket.

I would ask my fellow commissioners whether they have any opening remarks.

Hearing none, we will begin by addressing a few procedural matters, the swearing in of witnesses, and the official admission of hearing exhibits.

We will begin by swearing in the NRC staff witness and we will address the NRC staff exhibits. And then I will shift to the representative of Northwest Medical Isotopes for the exact same process, but we will conduct this for the NRC staff first.

So counsel for the NRC staff, please introduce yourself.

MR. WACHUTKA: Good morning. My name is Jeremy Wachutka and I, along with Mitzi Young, are counsel for the NRC staff.

CHAIRMAN SVINICKI: Thank you. Would you please read the names of the staff witness? As you read those names, each witness should stand as her or his name is read and please remain standing.

MR. WACHUTKA: Yes, the NRC staff witnesses are Alexander Adams, Stephen Alexander, John Atchison, Michael Balazik, Daniel Barrs, Stewart Bland, Anthony Bowers, Michael Dusaniwsky, Michele Evans, Mary Gitnick, James Hammelman, Gregory Hofer, Robert Johnson, Louise Lund, Steven Lynch, Stephen Marschke, Clifford Munson, Enver Odar, Annie Ramirez, Mary Jane Ross-Lee, Mollie Semmes, Edward Tomlinson, April Smith, Brian Smith, Charles Teal, David Tiktinsky, Christopher Tripp, Richard Turtil, Benjamin Beasley, Joseph Donoghue, David Drucker, Kevin Folk, Edward Helvenston, Robert Hoffman, Nancy Martinez, Michelle Moser, Jeffrey Rickhoff, George Wilson.

CHAIRMAN SVINICKI: Thank you and it's very helpful that all of you are generally on this side of the room. So I'm going to look that way as I

know administer the oath. Please raise your right hand while I read the oath.

Do you swear or affirm that the testimony you will provide in this proceeding is the truth, the whole truth, and nothing but the truth?

Thank you, you may put your hands down.

Are there any witnesses who did not take the oath?

If there are -- are there any objections to including the witness list as part of the record?

MS. HAASS: No.

CHAIRMAN SVINICKI: Thank you. In the absence of objections, the witness list is admitted into the record. I thank the witnesses for taking the oath and they may be seated.

Next, we will formally admit the staff exhibits into the record. NRC staff counsel, are there any changes to your exhibit list previously submitted?

MR. WACHUTKA: There are no changes.

CHAIRMAN SVINICKI: Please read the range of numbers of the exhibits to be admitted.

MR. WACHUTKA: The NRC staff has submitted exhibits NRC-001 through NRC-013.

CHAIRMAN SVINICKI: Is there a motion to

admit the exhibits into the record?

MR. WACHUTKA: Yes, the NRC staff moves to admit these exhibits into the record.

CHAIRMAN SVINICKI: Ms. Haass, are there any objections to the admission of the exhibits and the exhibit list as part of the record?

MS. HAASS: No, there is not.

CHAIRMAN SVINICKI: In the absence of objection, the exhibits and exhibit list are admitted into the record.

We will now turn to the exact same process with Northwest Medical Isotopes, starting with the presentation of Northwest Medical Isotope witnesses.

Would the representative for Northwest Medical Isotopes, Ms. Haass, please introduce yourself.

MS. HAASS: Yes, I am Carolyn Haass. I am the Chief Operating Officer of Northwest Medical Isotopes, LLC.

CHAIRMAN SVINICKI: Thank you. Would you please read the names of Northwest Medical Isotopes' witnesses? And each witness should stand as her or his name is read and please remain standing.

I see that you are identified as a witness yourself, Ms. Haass. Once all of the names have been

read, I would ask that you also stand.

MS. HAASS: Thank you. Yes, Roy Brown, Ralph Buler, Michael Croum, Gary Dunford, Nicholas Fowler, Steve Reese, and myself, Carolyn Haass.

CHAIRMAN SVINICKI: Thank you. Would all of the Northwest Medical Isotopes' witnesses please raise their right hands while I read the oath?

Do you swear or affirm that the testimony you will provide in this proceed is the truth, the whole truth, and nothing but the truth?

Thank you. You may put your hands down.

Are there any witnesses for Northwest Medical Isotopes who did not take the oath? It looks like it's a more manageable list. So I think I saw that you all did. Thank you.

Staff counsel, are there any objections to including the witness list as part of the record?

MR. WACHUTKA: There are no objections.

CHAIRMAN SVINICKI: In the absence of objections, the witness list is admitted into the record. The witnesses may be seated. Thank you.

We will now turn to the formal admission of Northwest Medical Isotopes' exhibits. Ms. Haass, are there any changes to your exhibit list?

MS. HAASS: No, there is not.

CHAIRMAN SVINICKI: Would you please read just the range of numbers of the exhibits to be admitted?

MS. HAASS: NWMI-001 through NWMI-011.

CHAIRMAN SVINICKI: Is there a motion to admit the exhibits into the record?

MS. HAASS: Yes.

CHAIRMAN SVINICKI: Staff counsel, are there any objections to the admission of the exhibits and the exhibit list into the record?

MR. WACHUTKA: There are no objections.

CHAIRMAN SVINICKI: In the absence of objections, the exhibits and exhibit list for Northwest Medical Isotopes are admitted into the record.

Counsel for the staff is excused.

Ms. Haass, I invite you now to join your co-witnesses for the first witness panel at the other witness table.

I'll give you a moment to get seated there.

For our first presentation, Northwest Medical Isotopes will provide an overview of its application. After each overview panel, we will have a round of questions from the Commissioners.

For the three subsequent presentations, the two safety panels and the environmental panel, first Northwest Medical Isotopes and then the staff witnesses will testify, followed by an opportunity for the Commission to pose questions to both parties in the same question and answer period.

The Commissioners will have an opportunity to bank their time, as they see fit, to focus on particular questions over the course of the hearing. And we will rotate the order of questioning throughout the day.

I remind the witnesses of this panel and other panels who will appear before us throughout the day, that they remain under oath and that the Commission is familiar with their pre-hearing filings.

And if an individual should need to come to the podium, which is to my left in front of the Commission's table here, to respond to a question or otherwise speak, please approach the podium and wait to be addressed and recognized and to be sworn in, if you have not previously been sworn in.

With those procedural matters dispositioned, I now turn to our first overview panel and I ask Northwest Medical Isotopes to please proceed. And prior to presenting, please be sure to

introduce yourself, if you have not already done so.

So, Ms. Haass, your panel may proceed.

MS. HAASS: Thank you. I will be turning it over to Nicholas Fowler, who is the Chief Executive Officer of Northwest Medical Isotopes.

CHAIRMAN SVINICKI: Thank you. Please proceed.

MR. FOWLER: Thank you, Madam Chair, Commissioners. It's a pleasure to be here for the first of what we imagine to be a great number of significant milestones with the Nuclear Regulatory Commission.

It bears repeating that the technetium isotope is the most commonly utilized nuclear isotope for imaging, over 85 percent of all diagnostics and nuclear imaging use technetium, the daughter isotope of moly or molybdenum-99. In the U.S. alone, 40,000 to 50,000 diagnostic procedures are done daily, yet there is no domestic supply. Northwest Medical Isotopes aspires to be that domestic supply and we aspire to deliver a domestic, secure, and reliable source of moly-99.

For some of us, 2008 to 2010, where we exhibited and experienced significant shortages of moly-99 may be a distant memory but, for those of us

close to the industry, it is not so much a memory but a current reality.

As we gather in this hearing, both South Africa and Australia reactor capabilities are currently offline and straining the existing supply chain for moly-99.

So this application that Northwest Medical Isotopes presents to the Nuclear Regulatory Commission is both timely and important to the country.

Northwest Medical Isotopes is a unique company. We were founded by healthcare services providers, who intimately understand the application of moly-99. A confluence of those healthcare services providers with world class research universities, Oregon State University and University of Missouri, and industry professionals who understand how to turn this into a business.

We are also unique amongst the thus far declared applicants for construction permits in that we have not applied for nor received any public financing. One hundred percent of our financing has been privately sourced and, therefore, our business absolutely has to pencil out and it does.

If I could direct your attention now to slide number 2, this is, again, a repeat of our

mission. We aspire to be the domestic, secure, and reliable source of moly-99.

The graphic depicts the current supply chain going from the irradiation of low-enriched uranium to a processing facility where the moly is extracted, delivery to the United States generator manufacturers, and onward into the medical supply chain.

We have circled the target processing facility as, to borrow a phrase from the personal computer industry, we intend to be plug-n-play. We don't intend to disrupt the supply chain. We intend to enhance the supply chain.

We use uranium fission as our base process and that is in quotes the gold standard for the industry. Now, our intent is to make our moly-99 indistinguishable to the generator manufacturers from their current supply. Very little change, if any, will be required to the distribution channels.

However, we have innovated and we've innovated through a network of irradiation services providers by using university research reactors, specifically those at the University of Missouri and that at the Oregon State University. So by doing so, we intend to create the most reliable supply that

network of the irradiation services reactors can provide that assurance of supply into our radioisotope production facility.

Our extraction processes are based all on low-enriched uranium. And so we have advanced to the safe and reliable sources of chemistry extraction for moly-99.

If I can then now ask that we move to slide 3 and focus on some of the assumptions that we have made about our business. First and foremost, we intend to build the production capacity for a minimum of half of the U.S. supply requirements with the ability of surge capacity to go to nearly 100 percent of the U.S. supply, as necessary.

Our radioisotope production facility incorporates the manufacture and production of targets, the dissolution of those targets and extraction of moly, and the recovery of low-enriched uranium. We produce moly through a fission-based process, the, quote, gold standard in the industry.

I've already highlighted the network of university reactors that provides us reliability in our supply, as well as the ability to have multiple shipments per week, given that the isotope is perishable, so we can have the freshest, capable

product.

Our analysis indicates that the fission product releases comply with the environmental release criteria and our waste production stream is Class A and Class B and C wastes no greater than Class C.

And then if I could ask that we move to slide 4 to give you the site characteristics and details of our intended facility.

The University of Missouri has a Discovery Ridge Research Park proximate to the university and geographically nearly center in the United States, making it a near-ideal location for the radioisotope production facility. It will be located, as the graphic indicates, at the entrance of the Discovery Ridge Research Park on an approximately 7.4 acre site. This site has been used for generations in agricultural production, so the land is disturbed. It has no surface water features. It has been determined to have no threatened nor endangered species and no historical or cultural resources have been identified to date.

The aspiration of the University of Missouri and Northwest Medical Isotopes is that this research park become an ecosystem, so to speak, of radioisotope production with Northwest Medical

Isotopes as being a significant and anchor tenant.

With that, I'd like to turn my time over to Mr. Roy Brown, Vice President of Curium Pharma.

MR. BROWN: Good morning. My name is Roy Brown and I am Vice President of Government Affairs and Strategic Alliances for Curium radiopharmaceuticals. My undergraduate degree is in radiation biophysics and I hold a master's in business administration.

One of my principal responsibilities is to develop and implement our strategy for long-term isotope supply for our nuclear medicine products.

Curium is a major radiopharmaceutical producer with manufacturing plants in Maryland Heights, Missouri, Petten in the Netherlands, and Saclay, France. Curium also operates a moly production facility in our plant in the Netherlands that is capable of producing more than half of the global demand for moly-99. We are the world's largest producer of technetium generators used in nuclear medicine.

Moly-99 and its daughter technetium-99m account for more than 85 percent of the 35 million nuclear medical procedures performed each year around the world.

These nuclear medicine diagnostic procedures can be used in more than 100 different applications for the early detection and staging of cancer, the detection of coronary artery disease, bone and lung imaging, and imaging of various functions of other organs in the body.

A steady and reliable supply of moly-99 with its three-day half-life is critically important to nuclear medicine. Currently, the majority of the world's supply of moly-99 comes from Europe. A domestic supply would ease concerns in getting that moly into the U.S. for technetium-99m generator production.

In recent years, we've experienced several difficulties getting moly into the U.S. One example is a volcano in Iceland in April of 2010 which prevented commercial aircraft from crossing the Atlantic, which left moly stuck in Europe, unable to get to the U.S.

Curium also had a shipment of bulk moly-99 sitting in the Brussels Airport ready for shipment, when terrorists detonated two bombs in March of 2016, delaying that shipment to our Maryland Heights facility in Missouri.

A domestic production capacity for moly-99

would ease these types of problems and potentially increase manufacturing efficiencies from the reduced decay lost during transit of the moly-99.

We have been closely following the development of Northwest Medical Isotopes' project. NWMI plans to use a fission-based approach to moly-99 production, which you have already heard is the gold standard by which all other production methods are measured.

NWMI-produced moly would likely be indistinguishable from moly we currently produce in our existing fleet of European reactors and, therefore, would not likely require redesign of our technetium-99 technology in our generators. Moly-99 from neutron activation has low specific activity and is not usable in our generators or any of the other current technetium-99 generators currently on the market.

NWMI's proposed network of university research reactors in the U.S. could enable the universities to balance their missions of research, education, and service and, equally important, provide a consistent, reliable, and less-interrupted supply of moly-99 for U.S. patients.

In addition, the novel chemistry of

Northwest recaptures the uranium oxide targets with the target material as part of the extraction and purification process, enabling the recycling and reuse of the LEU. This process could reduce the waste volume generated, which is one of the largest challenges of moly-99 production and is our highest single cost of production for our moly production in the Netherlands.

In summary, Curium believes Northwest Medical Isotopes' technology offers distinct advantages because it is based on well-proven fission method of moly production and uses existing reactors.

Their operations will, importantly, also be based on low-enriched uranium which meets the objectives of the U.S. Government Nonproliferation Policy as stated in the 2012 Nuclear Security Summit in Seoul, South Korea and the 2014 Nuclear Security Summit in The Hague in the Netherlands.

We are aware of the detailed review made by Northwest's application by the NRC staff and the recommendations of the ACRS. In view of this, Curium encourages the Commission to issue the Northwest construction permit.

Thank you for the opportunity to provide these comments this morning.

CHAIRMAN SVINICKI: Thank you. Does that conclude the overview presentation from Northwest Medical Isotopes?

MS. HAASS: No, it does not.

CHAIRMAN SVINICKI: Okay.

MS. HAASS: We have -- I plan on going through a summary of our licensing approach and give you a little bit more detail of our facility, both myself and Steve Reese.

CHAIRMAN SVINICKI: Okay, thank you. Please proceed.

MS. HAASS: Okay, can we please go to page 5?

So Northwest Medical Isotopes, what we are doing is we are seeking authorization for us to construction and eventually operate a production under 10 CFR Part 50. And in this production facility, there are five primary activities that will be completed under the Part 50. One is we will receive irradiated low-enriched uranium targets from the network of universities that Nick has indicated previously. We would then process those irradiated LEU targets and that means in processing we would dissolve them. We would recover and purify the moly. Then we would like to recover and recycle the low-

enriched uranium. And we would treat and package all waste that was generated, as well we would provide areas for associated laboratory activities and other support activities, such as chemical makeup, those types of things.

Page 6, please.

We also will have some other additional licensing activities that we need to do. One of the things that you will see in the graphic that is on this page is we have a Part 70 portion of our facility, where we will be manufacturing our target. And in that portion of the facility, we will produce our LEU target material, which will then be put in to the targets themselves, and those targets will be fabricated and QA'd and those targets are sent to the universities for irradiation.

So there is a Part 70 portion of this facility as well. Also, we will have -- we will be seeking a license for the Part 30 or the handling of byproduct material.

In addition, we recognize that the university reactors will also have to do license amendments for their facilities so they can irradiate their targets, as well as we do know that there is a cask that will be used for the shipment of the

irradiated targets that will have to have a license amendment done on the cask. We are aware of that and those items are in our schedule and we are working towards that.

One thing to note here is the document, the construction permit application that you have received is a complete document, where we evaluated -- we not only evaluated the Part 50 portion but we also evaluated the target fabrication area because we have to show the interfaces between the two. We understand that and we also have to show where our shared systems and activities are. So we have done that.

In developing this document, we used NUREG-1537 and the associated Interim Staff Guidance that was developed, as well as NUREG-1520. We completed an ISA for the entire facility. We didn't just focus on the 50. We did it for both the 50 and 70 portions of the facility.

We have identified IROFS and management matrix, so we could demonstrate that the facility is safe.

We also evaluated all the radiological and chemical hazards. We evaluated those against the performance criteria of 10 CFR 70.61.

Page 7 shows a very high-level schedule

that we want to start construction this year, preferably in the second quarter. We plan on ending construction in the later portions of 2019. And this is all calendar year, not fiscal year. So I apologize for not stating that up front.

We would like to start our facility -- do the startup and cold commissioning in the fourth quarter of 2019, with the hot commissioning and commercial operations to begin in early 2020. And then we are looking at decommissioning in 2050.

Page 8, please. So this gets a bit more detailed into what our facility does. And this is covering both the Part 50 and the Part 70. And so what you're seeing is we have four primary activities in this facility.

And if you go to your far left, you see you have target fabrication and there are three primary activities in target fabrication. One is you produce the LEU target material; then it is encapsulated; and then it is packaged so it can be sent to the universities for irradiation.

You notice that there's one picture in the middle and that is a picture of the University of Missouri. That is showing we do irradiation. That is the one thing we do not do in our facility but, as

Nick Fowler stated, we use a network of universities so we can have a securable, reliable supply of moly because irradiation -- the reactors had issues in the past of being online due to maintenance or other items like that.

The second activity is our facility is the irradiated target disassembly and dissolution. So we bring those targets into our facility. We disassemble them. And this is all done in a hot cell type area, where they are shielded, those types of items.

We take those targets out. We open them up. We put the material into a vessel and we dissolve it with nitric acid.

Once you dissolve that, then the primary thing that we do in this facility is we are trained to separate and purify the moly. And that is the critical path of this facility so you will always see us focused on that, not that the other materials in the facility aren't important in how you deal with the waste aspect, that's always the primary thing on a weekly basis.

Once that is done, then we will then focus on the low-enriched uranium recovery and recycle. The reason you want to recover and recycle this low-enriched uranium is you have very little burnup. So

it would be too expensive just to go throw that out. And so we are looking at recovering that and we can get into more detail, if you'd like to talk about that.

But that is the primary activities of our facility.

Page 9, please. Some other operating characteristics of our facility. We have a zoning ventilation system. It has been divided into four zones, where the airflow is directed form the lowest to the highest level of contamination with Zone I ventilation system being an initial confinement barrier. That is where our gloveboxes, our tank hot cell, or our processing hot cells are.

We also have designed a biological shield, which will provide an integrated system of features that protects the workers from high doses of radiation. And we've also identified engineered safety features and these engineered safety features are both active and passive. They're designed to mitigate the consequences of accidents and keep radiological exposures to worker at a minimum or at acceptable values.

And one note here, confinement is going to be considered in the ESF for us.

Page 10, please. Page 10 just is showing the inputs and outputs of our facility. You know you have to have your reagents. You have to have your low-enriched uranium that comes from DOE. They are inputs to our facility.

And we know that an output is we send the unirradiated targets to the university. They irradiate, the targets come back. We process it. And outputs are the moly itself; the LEU, whether we return it to DOE or we decide to dispose of it -- and that's a business question more than you know anything else; and then the waste handling.

And the types of waste we will have will be Class A, B, and C and we will not be generating anything greater than Class C.

Page 11. Page 11 shows a picture, a very high-level picture of our facility. Our facility, the first level is about 52,000 square feet and that includes the areas for target fabrication, the hot cell processing, and our waste management area.

There is a basement area within this 52,000 square feet and it's where our tank hot cell is. This is where all our critically-safe tanks are for uranium recycle and recovery, and some other things.

There is a second level of this facility, where the majority of the mechanical equipment will be.

And there are some outbuildings. And you can see the little gray buildings over to your right -- well, I guess to your left there. Sorry. And those outbuildings include you know where your diesel generator is, there is a waste management building.

And then you also see in the lower right, we have an administration building that will -- that is where we will manage the facility from.

Some basic stats on the facility. It's about a 65-foot in height facility. The stack will be 75 feet. There is loading docks and it's about 15 feet below grade. That's about how far we go under.

I'm going to pass it over to Steve Reese and he's going to do the last few slides.

MR. REESE: Good morning. If I could have slide 12, please.

So I'm going to three last topics, the first of which deals with radioactive inventory. So certainly when we talk about Chapter 13 and accident analysis, it's important to understand where our radioactive inventory exists.

So we can divide into basically three

categories. One is the fresh LEU and the processing of the fresh LEU to produce targets. That's ostensibly the Part 70 side. That was identified earlier.

The second part is the receipt of the freshly irradiated targets and the processing for the desire to produce a moly product in the end and also to clean and -- essentially clean and scrub the uranium for recycling purposes.

And then the final part is radioactive waste.

So we know that the inventory is largely going to be driven by from which reactor each of the targets comes from. And we have a pretty good understanding of the characteristics that each reactor will be providing these targets and what these targets look like coming out.

For MURR, we anticipate eight targets, nominally for normal operation, and for the OSTR the Oregon State TRIGA Reactor, we're anticipating 30 -- approximately 30 targets.

Too, you know the maximum inventory, because the inventory on each of these targets, depending on which reactor they come from, will be different and we can appreciate that.

And also we know that the movement of radioactive material in the facility is going to be dynamic because we're moving things but also because of radioactive decay.

So if you look to the right, there is a graphic that tends to -- that is trying to illustrate this. So in the upper portion, we are looking at things that are happening during the early stages of processing. So this is creating the moly product and the initial movement of the uranium for cleaning.

And then the bottom portion essentially is trying to demonstrate what it looks like after the batch is processed, such that we know where most of the radioactive inventory is residing as a function of time.

If I may have slide 13, please.

With respect to transportation, this is related to this effort in terms of the connected actions. In the environmental review, we are very aware of the needs of transporting radioactive material for this project. It involves the use of research reactors, so there is an inherent need to transport material.

We have identified the packages associated with each of the transportation evolutions for

radioactive material. I won't get into the details of each of those, just to say that we've identified them. So what we're looking at is we know we are going to be receiving fresh shipments from Y-12. We also will be shipping unirradiated fresh targets to the research reactors.

After they are irradiated, we will be receiving radioactive material in the form of the irradiated targets. We will also -- but the shipment of those will be the responsibility of each of the reactor facilities.

We will also be shipping from our facility the moly product itself and there will be radioactive waste that is generated and we have identified both the class of waste that goes into each container and how those containers will be utilized and processed over time.

Finally, moving to the last slide, slide 14, the last thing we wanted to go over in the overview was quality assurance program. We have a quality assurance program that follows 15.8, which is the Quality Assurance Program Requirements for Research Reactors because that is the group under which we are getting licensed. It follows Reg Guide 2.5 which is the associated reg guide for that quality

assurance program. And also we wanted to make sure that our quality assurance program meets the 70.64 requirement.

And with that, we'll move on to slide 15 and I'll turn it over to Carolyn for questions.

MS. HAASS: Yes. So that concludes our overview and we'd like to take any questions you may have.

CHAIRMAN SVINICKI: Okay, thank you for that overview presentation, which was very helpful because this is a very unique facility.

We will begin this question and answer period with my questions. So, let me begin. This is in no particular order but just some clarifying questions, I think.

So on slide 4, you showed an overhead view or depicted the Discovery Ridge Research Park. And I know that the lot that your facility would occupy was in agriculture uses. As you would move toward your desired operational date of 2020, do you envision that there is a likelihood that the other occupants in the Discovery Ridge Research Park, that that could change substantially from how it is now? Could it be more heavily occupied? What is your projection at the time at which the facility would go operational?

MR. FOWLER: I'll be happy to address that. First, I would note that our facility is near the entrance of the research park and is designed to have minimal impact on the remainder of the research park.

As to the population of currently vacant sites, I can only pass on hearsay from the University of Missouri. It would be best directed to them but they are actively developing this research park and aspire to have additional occupants within the research park. And as I previously mentioned in my remarks, their intent is and our intent is to establish an ecosystem of like-minded and similar radioisotope production facilities and handling facilities.

CHAIRMAN SVINICKI: That's helpful. And I realize that it is merely a forecast but it sounds like with active efforts to fill other spaces in the park, there is at least the potential that it could be a little bit busier and more occupied than it is today if those efforts are successful by the university.

I know that the overall contemplated business here is dependent on irradiation in university reactors. You have named two specifically. A third reactor has been referred to.

So I draw the conclusion that the two identified university reactors there is some very concrete certainty in that, perhaps even in the third although they are not yet named. Do you contemplate that over the period of operation there would be other potential university research reactors that would be participating in the irradiation process or do you view the set of two named and one unnamed as the basic kind of class or universe of research reactors that would be engaged in your operations over the course of time?

MR. FOWLER: Thank you for that question, Madam Chair.

The intention is a balance between the cost of sustaining multiple participants in an irradiation network and the sustenance of an assured and reliable supply. Our analysis indicates that the ideal number is between two and three, under the current operating tempos of the university reactors and hence, our application specifically and explicitly identifies two. And a third is in the background as being contemplated but not within the immediate horizon.

CHAIRMAN SVINICKI: Thank you. And Ms. Haass, I believe, stated during the course of her

presentation that the overall activities necessary to amend the licenses for the university reactors and also needed licensing work for certificates of compliance for over-the-road packaging, that those items are contemplated in your integrated schedules and time has been provided for that.

How would you characterize the level of certainty around that? In some cases, these actions need to be taken by other entities, other than Northwest Medical Isotopes. Would you characterize that there is a commitment on the part of those entities and that that area of the integrated schedule, you have confidence of that portion of your integrated schedule?

MS. HAASS: Yes, we have services agreement with the universities and they have committed to a schedule. We do work with them in a very detailed fashion. We support them in their license amendment, in preparing it so it can be done on a specific schedule and so that they understand our facility and what we are doing.

Like on the certificate of compliance for the cask, we're very aware of the cask that we need to use to ship the irradiated targets, we currently envision using the research reactor cask. And we know

who the owner of that COC is. We have been working with them. We've already done the modeling that we needed to do so they can start writing the license amendment for that.

And even with the reactors, we have already -- we've done a lot of modeling to go develop the information that is required in those license amendments. And there are certain things that are being done behind the scenes that are business sensitive to us but we are working directly with them.

And Steve Reese is also the director of the Oregon State University TRIGA Reactor. And so he can go a little bit into more detail if you would like to.

CHAIRMAN SVINICKI: Okay. Well, perhaps knowing that I would ask you, if you are able to provide this in a public setting. Are there physical modifications that are contemplated or necessary at university reactor locations in order to fulfill this irradiation service?

MR. REESE: Yes. So each reactor is unique. We know which modifications need to be done at University of Missouri and we know which modifications need to be done at Oregon State TRIGA Reactor. It doesn't change the footprint of the

facility at all. These will be modifications that essentially address the target handling.

CHAIRMAN SVINICKI: Okay. So is it accurate to state that they are of the nature that any user of the research reactor who had a research program might come in and need modest set of physical modifications to allow their research to be pursued? It is akin to that in complexity. Is that accurate?

MR. REESE: Yes. So I mean we couldn't do this and preclude research at the research reactor. So that it was done from the very beginning that was realized.

CHAIRMAN SVINICKI: Okay and my last question is somewhat general for anyone on the panel.

You do have a number of licensing actions. There is a bit more complexity here. Some are undertaken solely by Northwest Medical Isotopes, others are external parties, as Ms. Haass just responded.

When you look at your integrated schedule, what do you view as the critical path item in all of the licensing activities that lead up to permission to operate the facility? Is there any one thing?

MR. REESE: I can begin to address that and I would invite Ms. Haass to add to it.

Our overall schedule that was presented in the presentation, the critical path is clearly the licensing action not only for Northwest Medical Isotopes but the connected actions of parties. So we do focus a tremendous amount of our energy on the licensing approach and we stay under a close contact with the Nuclear Regulatory Commission team to telegraph the activities and strategize on the application process to ensure that we're meeting the requirements in an initial submission, as opposed to iterate through to process.

But clearly, the regulatory process is the critical path to our schedule.

CHAIRMAN SVINICKI: By that answer, is it accurate to characterize that you foresee no unique and unexpected complexities during the construction period?

MS. HAASS: You are correct, yes. We don't see any unique items. I mean this -- we understand what our facility needs to be. We understand -- we're already working through our final design.

Yes, there are always difficulties in finishing your design. You know we always worry about the structural aspect because if seismic, those types

of things, but those things can be worked through.

And you know we have the right team to go do that. They have already done this in the past, whether they've done it with Commercial Power or even for the Department of the Energy in some of their processing facilities.

CHAIRMAN SVINICKI: Okay, thank you all very much for those responses.

Next, we will turn to Commissioner Baran. Please proceed.

COMMISSIONER BARAN: Good morning. Thank you for your presentations. I'm actually interested in picking up right where you left off, which on the completeness of the design.

How complete do you consider the design of the facility to be right now and what level of completeness do you envision before construction begins?

MS. HAASS: So on the first question of where we are now, for the application itself, we're at a different design than when we submitted the application two years ago because we have continued on with that design. At the submission of this, we believe we are probably somewhere around the 40-45 percent complete in design but since that time, we

have gone in and we have worked through a lot of our process design and we are now working -- you know we are doing at the final design. We look at it both from the natural phenomena perspective because that is a very basic input from a structural and civil perspective. We're working through that.

So at the start of construction, we believe to be able to go to have construction drawings and to be able to do that, we believe we are going to have to be somewhere around 80 to 85 percent complete in design.

COMMISSIONER BARAN: Okay. Part 50 construction permit applicants typically analyze production facility accident scenarios using a concept of a maximum hypothetical accident. You took a different approach here and used the Part 70 integrated safety analysis analogy for all potential accident scenarios.

Can you talk a little bit about why you decided on the integrated safety analysis approach and do you think it provides more detailed or less detailed review of potential accident scenarios than the maximum hypothetical accident approach?

MR. REESE: That's a very interesting question and was the subject of a lot of discussion

very early on. Honestly, mostly it was driven by their recognition that this licensing action was going to be a shared exercise between the Part 50 and the Part 70 folks, simply because -- and the staff would in a much better position to provide you details on this, but it's pretty clear that the licensing falls under Part 50. But it's also very clear the way this facility will function, that Part 70 plays a very significant role.

So as a compromise, not wanting to do two separate efforts, we chose one effort that was allowed for the Part 50 under 1537 and also would meet the needs of the Part 70 folks. So, to do that, the maximum hypothetical accident doesn't help you on the Part 70 side.

COMMISSIONER BARAN: I see, okay. So it allows you a more streamlined, one approach --

MR. REESE: Yes, we wanted to do it once.

COMMISSIONER BARAN: -- for both aspects of it.

MR. REESE: Yes.

COMMISSIONER BARAN: Okay.

MS. HAASS: And just to reiterate, when we did this license action, you know we looked at the facility as a whole. We did not just do the Part 50.

When you read our application, it will have the complete facility, both the Part 50 and the 70 activities and how they are integrated.

COMMISSIONER BARAN: Okay. The NRC staff included a number of regulatory commitments for the applicant to address prior to or within the operating license application. Can you talk briefly about how you are tracking those commitments to ensure that they would be met?

MR. REESE: Could you repeat that?

COMMISSIONER BARAN: Sure. So for the regulatory commitments that have been identified by the staff in this process that would be kind of a background in terms of getting construction permits, a lot of those would be preconditions of a submittal of an operating license application. Some of them would be included in the operating license application.

Can you just talk briefly about how you are tracking those to make sure all those commitments would be met?

MS. HAASS: So we do have a commitment list. We understand from our initial application that we have submitted, based on all the RAIs we got, and where we said that we would -- said we will be

supplying that in the operating license application. We have documented that, obviously, in a commitment tracking list.

We also put it into our application where we have to go in and answer that question before we can take that out because we have a very interactive document.

COMMISSIONER BARAN: Okay, thank you very much.

CHAIRMAN SVINICKI: Thank you, Commissioner. We now recognize Commissioner Burns.

COMMISSIONER BURNS: Good morning and thank you for your testimony as we begin the proceedings today.

A few questions related to the overview of the facility and this overview panel. One thing I would be interested in, what level of public involvement did you have during the site selection process and what kind of feedback did you receive from the local community when selecting the location for the proposed facility?

MR. FOWLER: Thank you, Commissioner. I can begin the answer and ask Ms. Haass to complete the answer.

We initiated the selection of the sites

through a logistics analysis exercise that was largely internal. And that was to identify logistically-ideal sites around the country, depending upon our anticipated reactor network, balancing transportation time, and the operating tempos of each of the reactors.

Once we down-selected from a handful of sites to a smaller number of sites is when we initiated the more public process. And in each facility location potential, we contacted the local business organization, be it the Chamber of Commerce, or through the Economic Development arm, or through the university system to begin the outreach.

And had a series of dialogues that were proprietary between those organization and Northwest Medical Isotopes, until we got down to the final selection of Columbia, Missouri where, through the environmental action, we broadened the scope of conversations to be very public and visited publicly with business groups, with civic groups, with the Native American groups, as well as the university community prior to the formal environmental application.

Ms. Haass, would you like to add to that?

MS. HAASS: Actually, no, I think you

covered everything. I mean it was a very detailed process you know visiting the communities, visiting the university -- the potential universities.

And as Nick said, you know we looked throughout the country. We looked anywhere there was a university research reactor, whether it was in the Northeast, it was in Wisconsin, Texas, California, wherever.

And it really came down to -- the first thing we did, part of the internal processes, was there even the ability of these research reactors to support us. And I'll be honest, I'll give you a good example, and there is nothing against this university but Wisconsin has a phenomenal reactor. Unfortunately, they built their mechanical engineering building around the reactor and you can't get in and out. So we knew that that wasn't going to work for us.

So transportation and just the logistics of getting in and out, that's where we got our short list from.

COMMISSIONER BURNS: Thank you for that.

You referred to the Interim Staff Guidance implementing NUREG-1537, which is really a line to the licensing of non-power reactors. And I recognize this

as the second proceeding we've had in the last year or so where we're sort of banging a square peg in a round hole, if you will. But understanding that, because of the provisions in the Act and in the regulations, and I think Mr. Reese, I may follow-up a little bit on your answer with respect to this integration, particularly Part 50 and Part 70.

But the question I have for you, how do you think that guidance worked and have you reflected on any sort of lessons learned from it or communicated with the staff with respect to those kinds of lessons or how it worked in practice, as you were developing the application and going through the review?

MR. REESE: If I may, so 1537 is pretty good about laying out what you need to cover under each chapter. And the ISG was an attempt to cover some newer concepts that were coming down the pipe -- if you recall, aqueous homogeneous reactors was one of them, to try to address specifics of that.

So along comes Northwest Medical Isotopes that is yet different again because 1537 and even the ISG, I think it may be a little bit of a jump here, but I think it was envisioned that the irradiation facility would be co-located with the processing facility. Here we have a situation where we don't

have any irradiation going on and it's just purely processing.

So there wasn't specific guidance for our specific characteristics but 1537 did a pretty reasonable job allowing us to articulate what you want the safety issues associated with the facility.

COMMISSIONER BURNS: Okay, thanks.

MR. FOWLER: And if I could --

COMMISSIONER BURNS: Sure, Mr. Fowler.

MR. FOWLER: -- add very, very briefly. From a purely business standpoint, not from a technical guidance standpoint, in any business the schedule risk and unknown risks are the most challenging and most expensive to manage. And given the small number of companies that have gone through this process, there is significant risk inserted into our businesses because of the lack of precedent actions.

Specifics that I would request in the future, again from a purely business standpoint, is schedule and cost. It has been challenging for us, as a business who is completely privately funded, to manage schedule and cost through the regulatory process. And I'm sure this is not the first time that you have heard that input.

COMMISSIONER BURNS: Okay, I think not. I appreciate the answer because that does, I think, help -- it's something for us to reflect on as we go into licensing proceedings. Some what I will call more normalized but also where we are trying to adapt and integrate different parts of the regulations.

And finally, my last question on that is about integration, in a sense of the regulations. You talk about in terms of the operating license, having the Part 50 portion but also the Part 70, which in my impression from the record, as well as your presentation, that is the significant portion is the Part 70 type operations, if you will.

But is it also intention that you would have the Part 30 license as part of that as one integrated license? I wasn't clear from what I heard.

MS. HAASS: Yes, we would have one integrated license.

COMMISSIONER BURNS: Okay.

MS. HAASS: What we would do is we would have a very detailed crosswalk so it can identify where the Part 50 items are being met, where the 70, and where the 30 are met. And so we've spent significant time developing that.

COMMISSIONER BURNS: Thank you.

MR. REESE: All right, so it's true, if I could correct -- not correct but continue on with what Carolyn said, I think what we've worked out with the staff is that, and you saw this on a graphic earlier, that there is a Part 70 area and there is a Part 50 area. And it's a bit of a compromise and the reason why is it is pretty clear that the Part 50 area encompasses definitions found in Part 50 but it also contains Part 70 issues and Part 30 issues.

So what I think will likely happen is a Part 50 license will be issued with that, whereby we have to meet all the requirements of Part 70 and Part 30 underneath that Part 50 license.

But it also was identified that the Part 70 area that was shown in the graphic is essentially just doing Part 70 and nothing else.

So with that in mind and because there was an ability for one to reasonably and intellectually wall that off, such that there is no activities associated with basically anything other than Part 70, there was a decision made that that section alone would have a separate Part 70 license and only a Part 70 license. So we are in a situation where we have one building and we're going to have two licenses, one Part 70 and one Part 50, which is the reason why we've

been using that language back and forth this morning.

COMMISSIONER BURNS: Okay. All right, thank you. I'll leave it at that for now.

CHAIRMAN SVINICKI: Okay, thank you to the Northwest Medical Isotopes overview panel. I'm now going to ask the NRC staff witnesses to come and take the seats here at the table behind their name plates. And I'll give them a moment to come over here and do that.

While they are getting seated, I would note that in this panel, the NRC staff will provide an overview of its review of the application and a summary of its regulatory findings.

As the NRC staff witnesses take their seats, I would ask that they introduce themselves prior to presenting their portion of the presentation or if the NRC lead witness for the panel wants to introduce them, either of those are appropriate. Just make sure that you introduce yourself or you have been introduced before you present.

And with that, I am prepared to request that the staff proceed. They're still turning pages and opening binders but if we're ready to go, I turn it over to whoever is taking the lead here.

Michele, please proceed.

MS. EVANS: All right, good morning, Chairman, Commissioners. Can I have the first slide -- second slide. There we go.

So my name is Michele Evans and I'm a deputy director in the Office of Nuclear Reactor Regulation. And I also have a cold. Excuse me.

Okay, so with me at the table this morning are Mary Jane Ross-Lee, Joe Donoghue, and Brian Smith. This panel will provide context for the role of the U.S. Regulatory Commission or the NRC in domestic efforts to establish a reliable supply of molybdenum-99, also referred as moly-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's safety and environmental reviews that will be discussed further in the panels to follow.

Next slide, please.

Moly-99 decays into technetium-99 metastable, the most widely used medical radioisotope in the world. Technetium-99m is used in approximately 50,000 imaging procedures daily in the United States, accounting for about one-half of the global demand. Technetium-99m is an effective diagnostic tool because

of its chemical and nuclear properties, specifically, pharmaceuticals readily tag to it and its six-hour half-life minimizes patient radiation exposure.

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

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Consistent with the United States policy to establish a domestic supply of moly-99, the staff considers license applications for facilities that would produce moly-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 moly-99 using up to eight accelerator-driven subcritical irradiation units in one 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 moly-99 from low-enriched uranium targets that have been irradiated at existing research reactors.

Next slide.

So Mary Jane Ross-Lee will now discuss the approach the staff used to review the Northwest construction permit application. M.J.

MS. ROSS-LEE: Thank you, Michele, Chairman, Commissioners.

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 a Northwest construction permit application in two parts. Part 1 of the application consisted primarily of the Northwest environmental report and general information required by 10 CFR 50.33 and was docketed in June of 2015. Part 2 of the application contained the Northwest Preliminary Safety Analysis Report or PSAR and was docketed in December of 2015.

This two-part application process 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 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 a 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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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 when the applicant does not seek approval of the 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; 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 licensed 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 focused on the interface between the production facility and target fabrication processes, as well as the impact of the target fabrication processes on the production facility. However, the staff's 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 staff's 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 the 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 a Part 70 license, if Northwest does not obtain an exemption.

In December of 2017, Northwest submitted such an exemption request. The staff is currently performing a docketing acceptance review on this exemption request.

Next slide, please.

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 Northwest's environmental report.

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

The staff safety review assessed the sufficiency of the preliminary design, including the principle design criteria and design basis 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 the 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 a part of an operating license application.

Following the independent review of the committee, the staff completed its Safety Evaluation Report in November of 2017.

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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 exercises judgment to determine the applicability of acceptance criteria and evaluation findings. The staff also exercises judgment 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 the design and operating characteristics, unusual or novel design features, and principal safety considerations. The

preliminary design of the Northwest production facility was evaluated to assure the sufficiency of principal design criteria, design basis, 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 would conform to the design basis.

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An important part of the staff's safety review is determining what additional technical and design information not initially provided in the Northwest PSAR was necessary to support the issuance of a 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 has 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 include 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 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 prehearing 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 conforms to the final design of its -- confirms that the final design of its facility would conform to the design basis 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 the Northwest operating license application.

Next slide, please. Joe Donoghue will now discuss the staff environmental review of the Northwest construction permit application.

MR. DONOGHUE: Thank you, Mary Jane. Good morning, Chairman, Commissioners.

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 decisionmaking 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 their

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 environmental assessment. NRC regulations do not require the preparation of an EIS for the issuance of a Part 50 construction permit for a medical isotope production facility; however, the staff determined that an EIS would be appropriate for the Northwest Part 50 construction permit and application for two reasons: 1) an environmental assessment might not support a finding of no significant impact; and 2) 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) and (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 for the facilities.

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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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 of 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 of 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 the comments.

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The proposed site is located approximately three 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, no threatened or endangered species, or no 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 resources.

Next slide, please. Brian Smith will now discuss the statutory and regulatory basis for the issuance under Part 50 construction permit and the staff's overall safety and environmental findings.

MR. B. SMITH: Thank you, Joe. Good morning, Chairman, Commissioners.

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 in 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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The staff review supports the four findings required by 10 CRF 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 ongoing 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 this review of an operating license application.

The fourth finding is that for those safety questions and Northwest's 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 their 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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Based on these 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 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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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 co-location 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's Safety Evaluation Report.

Additionally, Safety Panel 1 is also

prepared to discussion 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 and we are prepared to respond to any questions you may have at this time.

CHAIRMAN SVINICKI: Thank you to the NRC staff Overview Panel for that presentation.

We begin the questions this go around with Commissioner Baran. Please proceed.

COMMISSIONER BARAN: Thanks. Thank you for your presentations.

We heard from both of the overview panels that the Northwest Medical Isotopes building is designed to have two portions, the production

facility, which would be regulated under Part 50, and the target fabrication area, which would be regulated under Part 70.

My understanding is that the construction permit would only authorize construction of the production facility portion of the building. Is that right?

MS. ROSS-LEE: That is correct.

COMMISSIONER BARAN: There appear to be two separate provisions in Part 70 that require the applicant to have a Part 70 license before commencing construction of the Part 70 portion of the facility. And as M.J. mentioned, Northwest applied for an exemption from one of those two provisions in December.

If Northwest receives a construction permit and the exemption is also granted, would Northwest then be authorized to construct the Part 70 portion of the facility?

MR. B. SMITH: Yes, sir.

COMMISSIONER BARAN: Okay and so there is no other affirmative authorization they would need to commence construction of the Part 70 portion?

MR. B. SMITH: Not that I'm aware of, sir.

COMMISSIONER BARAN: Okay. And has the

staff previously granted an exemption to those Part 70 requirements in other cases? Is this something that's happened before or is this something new?

MR. B. SMITH: I was told this morning that the staff checked and they cannot find that any similar exemption had been granted.

COMMISSIONER BARAN: Okay. And is that really just a result of this being the first time we had kind of one building with a Part 50 and a Part 70 portion?

MS. EVANS: I am going to look to staff for that. I believe that that is the unique characteristic of this particular facility but I would like them to confirm that.

CHAIRMAN SVINICKI: There is some discussion going on off to the side. So, again, please if you come to the podium, would you please introduce yourself, give your affiliation, and then respond? Thank you.

MR. LYNCH: Yes --

CHAIRMAN SVINICKI: Oh, and I'm sorry, have you been sworn?

MR. LYNCH: Yes, I have been sworn in.

CHAIRMAN SVINICKI: Okay, thank you.

MR. LYNCH: My name is Steven Lynch and I

work in the Office Nuclear Reactor Regulation here at the NRC.

To answer your question, it is correct to characterize that the reason we have not had a similar exemption request to the one that Northwest submitted is due to the uniqueness of the considerations and the interactions between Part 50 and Part 70 for this application and facility.

COMMISSIONER BARAN: Okay, great. Thank you.

During the review of the construction permit application, the staff identified commitments for the final facility design that would apply to both the Part 50 and Part 70 portions of the facility. Some examples are fire suppression systems, ventilation systems, and chemical hazard accident scenarios.

At what point in the process does the staff anticipate being able to determine that these commitments have been met?

MS. ROSS-LEE: The commitments would be verified during the review of the Final Safety Analysis Report.

We would, as part of their construction inspection program, we would be able to look at the

commitments that they have made and ensure that they are being taken. But the final verification would come with the operating license.

COMMISSIONER BARAN: Okay. And can you just talk for a minute, just so we kind of understand the sequencing here? So if a Part 70 application is submitted, that's going to be considered kind of at the same time as the operating license review or how does that fit together so that for the pieces that affect both the Part 50 and the Part 70 portions of the building, that's getting analyzed?

MR. B. SMITH: From what we have been told, is that they plan to submit a consolidated license application for both the Part 50 facility and the Part 70 facility and also address Part 30 requirements as well.

COMMISSIONER BARAN: Thank you. That's all I have. Thanks.

CHAIRMAN SVINICKI: Thank you very much.

Commissioner Burns.

COMMISSIONER BURNS: I'm going to follow-up on that. Does the staff anticipate, if we get to this stage, issuing a single license that covers Part 50, 70, 30 as it does with respect to power reactors?

MR. B. SMITH: Yes. The reason why I

hesitate there is my history is Part 70 licensing primarily, uranium-enrichment plant licensing, where we issue a single license that cover Parts 30, 40, and 70.

CHAIRMAN SVINICKI: Okay and I note that the NRC counsel might be helping you out here with a lifeline. So, would you please introduce yourself for the record and respond?

MR. BALAZIK: Hi, this is Mike Balazik. I have been sworn in and I'm a project manager at NRR.

The regulations allow you to combine applications and also combine licenses. So I think that would be a determination that Northwest would need to make but it is allowed by the regulations.

COMMISSIONER BURNS: Well, I would also think that the staff would make some judgment on that. But that's just an aside.

Let me go back. I just want to make sure I understand. What is this exemption for and why are we pursuing it as an exemption? Why is that not, in effect, a Part 70 licensing action itself?

Why put it in the guise of an exemption, other than maybe our regulations?

MR. B. SMITH: Well --

COMMISSIONER BURNS: Actually, let me go

through it. My first question is what is the purpose of the exemption that they've applied for.

MR. B. SMITH: The purpose of the exemption is to allow them to be able to start construction before receiving a license issued in accordance with Part 70.

COMMISSIONER BURNS: Which they would, otherwise, not need.

MR. B. SMITH: I'm not sure I follow.

COMMISSIONER BURNS: Well, they could disturb the land, they could start building, they could do any number of things until you got to the Part 70 licensing.

So, again, the exemption is focused on for what purpose?

CHAIRMAN SVINICKI: Okay, this is an interesting topic area. We have another presenter at the podium. Please introduce yourself and your affiliation and whether or not you've been sworn in.

MR. TIKTINSKY: Yes, my name is David Tiktinsky. I've been sworn in and I work for NMSS.

So the purpose of the exemption as it was issued was to request an exemption from 70.17. So that is the requirement to submit an application with environmental report and wait a period of nine months

for the staff to evaluate that environmental report prior to its ability to begin construction.

So that part of it. And then there is the other part of the finding of 70.23(a)(7) is where the Director of the Office of Nuclear Material Safety and Safeguard needs to make an evaluation of the environmental considerations and provide that evaluation to an applicant prior to the commencement of construction. And in that portion of the regulation, it says that if construction begins prior to that notification, then they would be subject to denial of the license.

COMMISSIONER BURNS: Okay. So in this circumstance, let me make sure I understand perhaps the fine points, we're not actually being asked to determine the Part 70 -- in fact the circumstances you described, that we're not being asked to decide that. Is that -- have I got that correct?

All we're deciding is, in effect, a narrow, if you will, Part 50 determination. And the piece of it that goes to this blue piece of the facility on Part 70, that's down the road. And thus, because that's down the road, by disturbing the land now, that that somehow would not conform to Part 70.

Have I got this correct?

MR. BALAZIK: So, the application that we have received is for a production facility under Part 50. We have not received an application for a target fabrication facility under Part 70 but Northwest has indicated that they want to begin construction of that Part 70 facility, which is co-located within the same building as the production facility.

So their request for an exemption -- and I mistakenly spoke -- it's 70.21(f) not 70.17 is the request for exemption. So 70.21(f) is what they've requested an exemption for, is purely to allow them to begin construction of both pieces of the facility at the same time.

COMMISSIONER BURNS: Okay. And when does the staff expect to -- maybe I misunderstood. The staff has not determined as yet its position or view on this exemption or has it?

MR. BALAZIK: The staff is performing an acceptance review of the exemption right now, as we speak.

COMMISSIONER BURNS: Are we expected to -- how does that staff decision affect what the Commission is being asked to decide here today, or does it?

MR. BALAZIK: It's a totally separate

point from the construction permit application.

MS. ROSS-LEE: I would -- yes, the action before the Commission is for the Part 50 construction permit. We are not asking, at this point, for Commission consideration of the exemption under Part 70.

COMMISSIONER BURNS: Okay and the environmental review that's been done, the scope of that environmental review is only with respect to the Part 50 part of the facility or haven't -- go ahead, Mr. Donoghue.

MR. DONOGHUE: Now the scope of the environmental review included the operation and decommissioning of the facility, including the Part 70 aspects.

COMMISSIONER BURNS: Okay. All right, I may have some follow-up questions after this why we are down this path but that will do it for now.

CHAIRMAN SVINICKI: Okay. And again, after I ask my questions, I will turn to you if you have formulated another. You're tossing it over to me and I do wish I had a moment myself to contemplate those responses to formulate my questions.

But I'm tempted to ask a follow-on question. I'm not sure if it's going to be helpful.

If the exemption were never approved, again, would it allow them to construct basically the shell of -- we're calling it the Part 70 facility but it is I think the area of the building within which they would conduct the Part 70 licensed activities if we subsequently licensed them.

So it's not waiving the need for a license. Again, the last witness who came to the podium clarified that this is a narrow -- a request for relief on a narrow set of Part 70 requirements, which is that you have to submit something nine months in advance of disturbing the land and allow the staff to contemplate that and the director of the NMSS to make some sort of determination. So it is fairly narrow what they're asking.

But if NRC never approved that exemption, would that mean that they could not disturb the land or construct the foundation or the shell, or that they could do so but they would do so at risk of two things -- at risk of those activities and at risk of denial of the Part 70 license?

MR. B. SMITH: You are correct, they are doing it at risk.

CHAIRMAN SVINICKI: Okay. All right, thank you.

Just on a more general topic of the proposed license or permit conditions and then the regulatory commitments that were developed along the way. It's a fairly broad set and to me it's akin to something -- I don't know if it is a real thing or just a concept -- but it's called muscle memory. And for athletes and performing artists it means that if you do something repetitively, you have a good instinct for how to navigate it.

Two-step licensing is something that NRC has been more focused on one-step licensing in the new reactor area under Part 50 -- 52. So I think for Part 50, in some ways our predecessors who had to navigate the level of detail and review for the construction permit versus the level of detail and review for the operating license, I think that organizations may be this is something that we don't do as routinely. So it is something that the staff had to navigate for this application for SHINE and maybe for Watts Bar, too, to a certain degree as well, which was also two-step licensing in the last ten-year history of the agency.

But I think the staff has, again, attempted to navigate that while also leaving for the operating license phase of the review those things

that are going to be associated with greater design detail, with greater process throughput sheets, and other things that the staff, at the time of the operating license review will have access to that they don't have access to now.

That being said, there is a long list, not so much of the conditions that are proposed, but maybe of the regulatory commitments. I think that both the applicant panel and you, by my colleagues, have been asked somewhat of how we're going to track and maintain cognizance of those commitments. Does the staff want to talk --

Well, also let me note that in the course of leading up to the mandatory hearing based on the Commission's prehearing questions, the staff has determined that one of the things that might have been a regulatory commitment would perhaps become a permit condition.

So could someone on the staff panel describe how it is that you navigated the difference between the proposed conditions to the permit versus what I'll term a kind of softer set of regulatory commitments that go over a longer span of time? And I think you responded to Commissioner Baran that those are things with the FSAR that would be addressed that

is kind of the furthest out point at which those should all be met.

But does anyone want to talk about navigating that process? And then of course, if the applicant had asked for specific approval of like systems, structures, and components, you would have had to kind of front load some of the safety determinations but they didn't, to my knowledge, request that that be done in any case.

It's looking like maybe Brian or Mary Jane want to respond to that.

MR. B. SMITH: You are correct on that last statement about asking for specific safety approvals of certain aspects of the facility. They did not do that with this construction permit application.

MS. ROSS-LEE: I'll answer the high level but then I may ask for staff to give some more detailed and specifics.

But when the staff was making the determinations, they were looking at the existing guidance that we had in place, the combination of the NUREGs and the ISGs, trying to figure out what exactly is information that we need to have for assurance for the construction permit stage. And then that

information which can reasonably be left for the operator license or the final safety analysis part review conditions, for instance like as I mentioned with the criticality, those things, for instance, that are critical to actual construction, for instance, the shielding thickness, if that isn't looked at prior to the actual operating license issuance, that would be something that we wouldn't or would be challenging to go back in, at that point in time, and actually make a change for it.

So, that was one of the considerations for why that should be a condition versus some of the commitments, which are things that can be looked at as it is being constructed, things that can be looked at perhaps through the construction inspection program, and then things that can be verified through the actual issuance of the operator license and review in the Final Safety Analysis Report.

But I will ask if the project manager or the staff has any additional information.

CHAIRMAN SVINICKI: It looks like they feel you have covered it. And again, I was just asking at a relatively high level. It does sound like the staff brought some discernment to this.

Again, there are any number of issues --

I am confident the staff identified any number of areas of technical inquiry in the review of the construction permit application that need favorable resolution in order for an operating license to be granted.

I think the more nuanced element that the staff is to address is some of those can -- the applicant can proceed at risk in certain areas. We don't want to have a burdensome or overwhelming set of conditions and regulatory commitments that are really meant to secure the success of the operating license. Some of that responsibility for submitting a successful operating license application has to reside with the applicant. And as the regulator, what we need to be careful to do is not to pre-involve ourselves into design judgments and other things that the applicant will be making, in order to secure their success for them.

So I'm not in any way assessing that the staff ventured into that territory here but the issues here need to have a nexus to the action in front of us, which is the issuance of the construction permit.

Does the staff ascertain that the permit conditions -- my understanding is they need to be no more than ministerial in nature. Is it the staff's

view that the conditions for the permit that have been proposed are ministerial in nature?

MS. ROSS-LEE: Yes.

CHAIRMAN SVINICKI: And then the set of regulatory commitments, by my review, some of them had their origins in the engagements in front of the Advisory Committee on Reactor Safeguards. Nonetheless, the staff is the regulatory expert here. Does the staff in all instances endorse that set of regulatory commitments, whether or not they were initially identified by the Advisory Committee on Reactor Safeguards, which is not a licensing entity?

MS. ROSS-LEE: Yes, the staff does.

CHAIRMAN SVINICKI: Okay, thank you very much.

Do either of my colleagues, based on their earlier questions for the Overview Panel have follow-up questions for the Overview Panel?

COMMISSIONER BURNS: Not now.

CHAIRMAN SVINICKI: Okay. Okay, with that, we will now treat ourselves to the opportunity to stretch our legs and take a short break, while we set up for the first of the Safety Panels.

I am going to state that we will reconvene at eleven o'clock because I think -- I'm of a personal

view the first break is always one where you really need it. So we will reconvene in ten minutes.

Thank you.

(Whereupon, the above-entitled matter went off the record at 10:51 a.m. and resumed at 11:06 a.m.)

CHAIRMAN SVINICKI: Okay, I call the hearing back to order. Thank you all for returning to your seats so promptly.

This is the first safety panel presentation. The parties will address relevant sections of the application and two chapters, in particular, from the Safety Evaluation Report, Chapters 1 and 4, including a discussion of the unique licensing considerations for the proposed radioisotope production facility which are, one, co-location of the production facility and the target fabrication area and, two, implementation of the quality assurance program.

And again, this is the first of the combined panels we have for the remainder of the hearing. And "by combined," I mean that we will hear from both the Applicant and the NRC staff and, then, we will follow that with the Commission's questions and answers.

So, for this Safety Panel 1, we begin with Northwest Medical Isotopes. Please proceed and, prior to presenting, please be sure to identify yourself. Thank you.

MS. HAASS: Hello. I'm Carolyn Haass with Northwest Medical Isotopes.

And can you please go to page 2?

On page 2, what you're seeing is an overview of our facility. I think you recognize the difference between the Part 50 and 70 portions of the facility. But, if you look at the Part 50 portion of the facility, the gray area, what we've done is we've outlined the areas that will be the waste management area for us, where we bring in the irradiated targets from the university reactors -- it's the unloading bay -- as well as the tank hot cell.

And if you go just below the tank hot cell and to the left, you will see where our processing hot cells will be for the disassembly, dissolution, and moly recovery and purification. And just below that you'll see our utility area and laboratory area.

Page 3, please.

MR. REESE: All right. So, at page 3, I want to begin a discussion on structures, systems, and components, our SSCs. So, design of the facilities

based upon applicable standards, guidance, code, and criteria, such that reasonable assurance can be provided that the structures, systems, and components, SSCs, will perform as intended. So, we have to inform our discussion of the SSCs as they relate to Chapter 13 as it relates to accidents and, also, normal operations for protection of public safety and the health environment and, also, occupational safety, too, as well.

And we recognize that certain components in this facility, certain SSCs, will be important to safety. What we have tried to do is design these things nor recognize them ahead of time, such that we can pay particular attention to them through the design phase and the construction phase.

As such, we need to define some terms. So, if I could ask you to go to slide 4? Slide 4, we talk about the definition of how we define safety-related. Essentially, it has to be integral. It's the classification of applied items relied on to maintain function during or following postulated design basis events. So, we basically want these components to work during an accident and to maintain a safe shutdown condition. As such, we have to be cognizant of both the design requirements for

accidents under 7061 space and, also, normal operating parameters under, ostensibly, 10 CFR 20.

So, moving on to below on slide 4, you'll that we've defined four safety systems and components. Those safety-related items relied on for safety are those that we want to defend against 7061. Safety-related non-IROFS are those that meet 10 CFR 20, and non-safety-related is basically anything else.

What we've done is we've crosswalked that, if we go to slide 5, with the Quality Level 1 associated with the IROFS, Quality Level 2 associated with 10 CFR 20, and Quality Level 3 associated with the balance.

With that, I'll turn it over to Gary.

MR. DUNFORD: Good morning. I'm Gary Dunford with Northwest Medical Isotopes, and I'm going to quickly run us through slides 6 and 7.

So, slide 6, please.

Consistent with what Steve just talked about in Chapter 3, following our quality level discussion is a discussion on seismic, and we have three classifications, Seismic Category I, II, and, then, non-category.

So, the facility right now, we've benchmarked the facility seismic evaluation to a .2g

ground motion and, then, we'll use Reg Guide 1.60 Spectra in the analysis.

Category I, Seismic Category I is a piece of equipment that is part of the analysis we say has to both have integrity and still perform its function. So, the IROFS that we'll talk about in the next slide will identify those systems that have that particularly unique integrity and function. Category II is it needs to maintain its integrity, so it doesn't fall, on a Category I, or from a personal injury type of perspective. And then, the non-seismic would be the NC or NS, the last category.

So, the next slide is really our table listing our major systems and structures in the facility. So, that's the first column, the system codes. It goes over to the main processing systems and the support systems and the various safety systems are, actually, in there, too.

The next column is the highest classification. So, if it says IROF, that means some portion of that system has been classified as an IROF. And then, if you go to the seismic classification, you're going to find that the IROFS are going to pretty much relate to Seismic Category I or in a non-IROF or -- I'm sorry -- a safety-related system, non-

IROF would be Category II. There's a couple of small exceptions to that, and they are just where some components will get used both in the normal power and in the standby power, as an example.

I guess my time is up.

CHAIRMAN SVINICKI: Thank you. Thank you to Northwest Medical Isotopes for that part of Safety Panel 1.

I would now ask the NRC staff, as they are doing, to please occupy the spaces behind their name cards, and when they are prepared, would they begin? And again, please identify yourself prior to giving your portion of the presentation.

Okay, if you're ready, please proceed. Thank you.

MR. ADAMS: 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, Dave Tiktinsky, and Steve Lynch are with me at the table today.

Can I have slide 3, please?

The 10 CFR Part 50 regulations define three types of production facilities, one of which is use for the processing of irradiate materials containing special nuclear materials. 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 facilities 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 isotopes 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.

Next slide, please.

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 basis.

To confirm the seismic design of the proposed Northwest production facility, the staff developed a general seismic design response spectrum incorporating site amplification factors of 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 A4 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 greater than an order of magnitude of 10 to the minus 7th 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 states 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 2nd, 2017. The ACRS recommended the issuance of a construction permit in its letter dated November 6th, 2017, which is contained in Appendix D of the staff's Safety Evaluation Report.

Next slide, please.

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

MR. BALAZIK: Thank you, Al.

My name is Michael Balazik.

Northwest proposes to irradiate low enriched uranium 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 236, this portion of the facility meets the definition of a production facility as defined 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 include dissolvers, ion exchangers, and concentrators.

To support its review, the staff used the guidance in NUREG-1537, also the Interim Staff Guidance augmenting NUREG-1537, and NUREG-1520. In applying this guidance, the staff used its technical 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.

Next slide, please.

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 10 CFR Part 50.

The construction permit application also describes the target fabrication process. This process consists of fabricating low enriched uranium targets containing unirradiated uranium, uranium from previously irradiated targets, and potentially uranium scrap from off-spec 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 will submit its Part 70 application with its Part 50 operating license application, and will request that the NRC issue a single license for the entire facility, which is permissible under NRC regulations.

The staff only considered target fabrication to understand the interface between the two processes and the impact on the production facility.

Next slide, please.

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

MR. TIKTINSKY: Thank you, Michael.

My name is David Tiktinsky. I'm with the Office of Nuclear Material Safety and Safeguards.

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.

Next slide, please.

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 design features is made during a 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 basis and ensure quality.

Next slide, please.

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 the criticality accident alarm system coverage has not been completed.

The staff also recommends a permit condition on the subcritical limit to confirm that the 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 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

it's 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 administerial 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.

Next slide, please.

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

MR. LYNCH: Thank you, David.

Good morning, Chairman and Commissioners.

Again, my name is Steven Lynch with the Office of Nuclear Reactor Regulation.

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, one, ensure that Northwest implements its QAPP; two, provide for consistency and maintenance of documentation; three, establish criteria for notifying the NRC of changes to the QAPP, and, four, require correction of deficiencies in the implementation of the QAPP.

Next slide, please.

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 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 the issues raised by the Commission in pre-hearing questions, the staff has reconsidered its decision to track the results of the investigation via regulatory commitments.

Since a site-specific investigation could reveal geological features impacting the design basis 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 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.

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

CHAIRMAN SVINICKI: Thank you very much to all the presenters.

We'll begin the question-and-answer period

this time with Commissioner Burns. Please proceed.

COMMISSIONER BURNS: Thank you, Chairman.

If we could, could we put up the diagram of the facility? I think in the Northwest presentation for this panel, put their slide No. 2 up. It's the radioisotope production facility.

Next. There. Keep it there. Thank you.

I will turn a couple of questions here. So, just to make sure I'm clear about this, in some of the discussion we've been having, you know, Part 50 versus Part 70, and also understanding the facility itself, this diagram shows sort of an architectural rendering from a bird's eye view of what the facility looks like. Now that, is that one building?

MS. HAASS: That is correct, that is one building.

COMMISSIONER BURNS: That is one building. Obviously, because some of the issues are what's being handled where or differently.

So, in terms of the evaluation, in terms of what the staff has done to date, the staff's evaluation focuses on the gray area? Is that --

MR. REESE: That is correct, sir.

COMMISSIONER BURNS: Okay. But how do you integrate the rest, the blue area, the Part 70 area

into your evaluation as to whether or not the building itself or the proposed construction was adequate, would be adequate?

MR. LYNCH: Sure. So, the staff, in its review of the construction permit application, did consider the interface between the target fabrication area and the 10 CFR Part 50 production facility. During the construction of the facility, the staff will inspect those structural elements -- for example, the point of concrete and shielding -- to ensure the integrity of those items as they're being constructed in that interface between the Part 50 and Part 70 areas.

COMMISSIONER BURNS: Okay. Are there particular things -- actually, I'll ask the Applicant first -- are there particular things in terms of the interface between the design of the building between the blue section and the gray section that affected either side? And I will say either side, the Part 50 side or the anticipated Part 70 side. Are there particular things that affect it and affect that wall, I'm going to say, that wall between the two sections or that integration between the two sections?

MR. REESE: So, if you pull up slide 2?

COMMISSIONER BURNS: Yes, yes.

MR. REESE: So, there's a couple of things that both sides will share. You obviously have criticality safety issues on both sides.

COMMISSIONER BURNS: Yes.

MR. REESE: That's pretty clear.

But we are going to transfer clean uranium material from the Part 50 to the Part 70 side.

COMMISSIONER BURNS: Okay.

MR. REESE: And so, that's a direct physical connection and an obvious safety connection between the two.

And other than that, it's mostly on the other end of the process where we're talking about waste handling, because those are commingled, the two, as well.

COMMISSIONER BURNS: Okay. All right. Thanks.

Staff, any comment with respect to that?

MR. TIKTINSKY: Yes, I guess --

COMMISSIONER BURNS: Or unique aspects in terms of the integration of these two sides, if you will, of the facility?

MR. TIKTINSKY: So, the Applicant provided a preliminary integrated safety analysis which covered both parts of the facility. The staff only evaluated

the Part 50 part, but what we did look at is the accidents that were identified in the Part 70 target fabrication area and any impact they may have on the 10 CFR production facility.

COMMISSIONER BURNS: And I take it, then, your conclusion was that the provisions or the design and anticipated construction of the Part 50 side was adequate, given the anticipated design and architectural features of the Part 70 side?

MR. TIKTINSKY: Yes.

COMMISSIONER BURNS: Okay. Thank you.

One of the questions I have on a different building relates to the diesel generator building. In response to pre-hearing Question 11, staff indicates that the diesel generator is part of the non-safety-related standby power. Yet, the Applicant committed to protecting the diesel generator building. And I guess I'm trying to understand the status of the staff's review and evaluation of the diesel generator building, the status of the staff's review of that, given that it is a non-safety-related structure and, arguably, does not require NRC approval. So, how is that integrated into our review?

MR. BALAZIK: I would say that the staff at this point did not look at the structure of the

diesel generator building, and that would be something that we would look at in the operating license review. But, at this point, we've indicated that it's not safety-related and we wouldn't necessarily look at the structure of that building. The only safety-related part of the standby electrical power is the UPSes which are not in that building yet.

COMMISSIONER BURNS: Okay. All right. Thank you.

We had a discussion -- I appreciated the discussion -- on the quality assurance program. Again, as I understand it, because if you look at Appendix B and 50.55, it applies to power reactors and other facilities primarily, but here we have a quality assurance program which is typical.

I would take it, then, am I right to conclude that the quality assurance type of program or the quality assurance program required for the Part 50 facility, to the extent that we would impose on the Part 70 portion of the facility, that they would be compatible?

MR. LYNCH: Yes. Our understanding is that the quality assurance program developed by the Applicant will be applied to both the Part 50 and Part 70 aspects of the facility.

COMMISSIONER BURNS: Okay, and that doesn't create kind of regulatory disharmonies?

MR. LYNCH: No, it does not.

COMMISSIONER BURNS: Thank you.

And the last question for the Applicant, could you please briefly describe the pertinent features of the facility design that will prevent and mitigate chemical leaks?

MR. DUNFORD: This is Gary Dunford.

So, put slide 2 back up again, please.

In the lower center of the gray area, next to the outside wall you'll see all the tanks. And that is our chemical makeup area. So, that's an area that will have separation of compatible chemicals, oxidizers, reducers, and it would have dyking and various aspects like that.

There are also parts of the chemical system that are criticality-based for backflows out of the vessels and stuff, and those would be inside the tank area itself, but they would be part of the system. So, if we went back, actually, to the earlier slide, it would have said the chemical system had IROFS, and that's why most of the chemical system is just safety-related.

COMMISSIONER BURNS: Okay.

MR. DUNFORD: And it doesn't have IROFS. But that piece is where we got to the IROFS.

COMMISSIONER BURNS: Okay. All right. Thank you.

Thank you, Chairman.

CHAIRMAN SVINICKI: Thank you, Commissioner Burns.

I'll proceed with a few questions myself right now.

So, as the NRC staff has presented, it recommends that the construction permit be conditioned to require that, prior to the beginning of construction, Northwest would complete and submit the results of a geotechnical investigation.

So, to Northwest Medical Isotopes, if the construction permit is granted, when would you contemplate undertaking that geotechnical survey or investigation? Or is that something that you have undertaken for your own purposes or begun to undertake already?

MS. HAASS: Yes. So, we know that we will be doing some additional geotechnical investigations, and we are in the process of selecting that contractor.

CHAIRMAN SVINICKI: Okay. So, it's just

the planning and preparation has begun, but the actual investigation itself has not begun yet?

MS. HAASS: Correct.

CHAIRMAN SVINICKI: Okay. Thank you very much for that.

And for the NRC staff, one of the areas to be evaluated to make the findings necessary for issuance of the construction permit are related, one of the findings is related to the articulation of a research and development program that will be adequate to resolve issues that we predict will be identified. In terms of the staff, the staff has evaluated that and made an affirmative conclusion about it.

Can the staff talk a little bit more, though, about predicting what will be necessary there, and not so much validating the areas identified by the Applicant as needing research and development, but gaining confidence that other technical areas don't require R&D? So, anything else that might be a gap area? How did the staff go about making an affirmative conclusion that the scope of the R&D would be adequate?

MR. LYNCH: The research and development program is required to be identified by the Applicant with 50.34(a)(8). The staff looked at the scope that

Northwest initially identified, including at the University of Missouri Research Reactor and the Department of Energy. In order to ensure that this was inclusive, the staff did ask, request for additional information to see if there were any additional items that Northwest needed to include in this program. And Northwest did respond to these requests for additional information, indicating that it had certain resin testing that it needed to conduct as well. So, we ascertained that they were complete in their identification based on their responses to requests for additional information.

CHAIRMAN SVINICKI: Are there any R&D areas associated with the subsequent Part 70 submittal or is that scoped in here? Or is this just a look at the application before the staff right now?

MR. LYNCH: For now, it is just looking at the application before the staff for Part 50.

CHAIRMAN SVINICKI: Okay. Thank you.

And can the staff conclude -- it's my understanding, based on the -- or could the staff confirm my understanding, based on reviewing the record, that the staff does not consider the 50.59 criteria to be applicable during construction? Is that accurate?

MR. ADAMS: Yes. Yes, ma'am, that is accurate.

CHAIRMAN SVINICKI: Okay. Thank you.

And my colleague, Commissioner Burns, asked a little bit about the quality assurance program and its application. But could the staff comment more generally on how it assured itself of the sufficiency of the graded approach -- or that's my term; I don't know if the staff would use that -- the graded approach to the QA program for this very unique facility and some of the philosophy that guided the staff's determination that's what is proposed by the Applicant will be sufficient?

MR. LYNCH: Sure. I can start with a high-level description, and if you need more details, we can refer to the technical staff.

For the review of this application, the staff primarily evaluated the Northwest quality assurance program based on ANSI Standard 15.8, which was developed for research and test reactors. The criteria for quality assurance in this ANSI standard is very similar to what's in Appendix B that would be applied to nuclear power reactors. However, it has been modified to be more technology-neutral to apply to various types of technologies and, also, to account

for the fact that smaller facilities, like research reactors and other non-power facilities, may not be large corporation and may have smaller staffs. So, the language has been adapted for these smaller types of facilities.

And the staff has previously applied this to the SHINE medical isotopes construction permit application review, and we applied it here and found that this guidance was sufficient to evaluate the quality assurance program.

CHAIRMAN SVINICKI: So, would the staff characterize, based on that answer, that the QA program as proposed here by Northwest is generally covering the same areas as a full Appendix B program? It may just be that it's a graded application of those subject matter areas under Appendix B?

MR. LYNCH: Yes, that is a correct characterization.

CHAIRMAN SVINICKI: Okay. Thank you.

And those are my questions. We'll turn now to Commissioner Baran.

COMMISSIONER BARAN: Thanks.

As we've discussed a little bit on this panel, the NRC staff proposed a construction permit conditioned to require the Applicant to complete a

characterization of the site's foundation and soil prior to beginning construction. This is to determine the potential for sinkholes at the site.

I know, Steven, you talked about this a little bit, but could you just briefly discuss the thinking behind this new permit condition, as opposed to it being a commitment?

MR. LYNCH: Yes. So, the staff had initially recommended that the geotechnical investigation be included as a series of regulatory commitments because the Applicant had accurately characterized the site, based on available information, to meet the requirements of 50.34(a). However, as part of the staff's reasonable assurance finding, we were making this finding based on the assumption that Northwest would complete the geotechnical investigation prior to the beginning of construction.

And this is consistent with statements that the Applicant had stated in their application and before the ACRS. Initially, the staff had anticipated that this work would be completed in 2017, well before the completion of the staff's review. Given that there is more uncertainty as to when this will be completed, and the Applicant's indication that it

would like to begin construction soon after the issuance of a construction permit, the staff believes it's appropriate to track this as a condition.

COMMISSIONER BARAN: Okay. And let me just ask the Applicant, what's your view about whether this permit condition is warranted?

MS. HAASS: I am sorry, can you repeat that?

COMMISSIONER BARAN: Just what's your view about whether this permit condition is warranted, as opposed to a series of regulatory commitments?

MS. HAASS: In our response to that question, we actually have said that we would like to see that as a regulatory commitment, not as a permit condition. We understand the importance of doing this additional geotechnical work because of the CARSS formation at the site that could potentially give you a sinkhole. But we know that -- I mean, we've already continued on with our design, understanding, you know, having certain assumptions in there. And we don't believe that there's that large a risk.

COMMISSIONER BARAN: Okay. I understand this is really kind of a judgment call about which approaches to use.

MS. HAASS: It is.

COMMISSIONER BARAN: Would there be any particular challenges that having a license condition there would pose for you?

MS. HAASS: No, there will not.

COMMISSIONER BARAN: Okay. So, it's really -- and this isn't to minimize it -- it's just kind of a basic preference for you would rather have more flexibility rather than less; you would rather have fewer license conditions than more?

MS. HAASS: Correct.

COMMISSIONER BARAN: Okay. According to the Applicant, the scope of the geotechnical investigation was expected to be finalized this month. Is the scoping still on track to be completed in January?

MS. HAASS: Yes.

COMMISSIONER BARAN: Okay. And at a high level, what is the geotechnical investigation going to involve?

MR. CORUM: Well, typically, it would involve -- I'm sorry, I'm Michael Corum with NWMI -- involve soil borings, compacting testing, and tests for soil liquefaction capability.

COMMISSIONER BARAN: Okay. And going back to the staff, is that description consistent with what

you all have in mind for the geotechnical investigation?

MR. LYNCH: Yes, it is.

COMMISSIONER BARAN: Okay. If the investigation were to reveal the potential for sinkholes at the site, the Applicant identified two ways to address the issue. One would be excavating, then backfilling with structural fill. And the other would be installing piers for support.

How confident is the staff that these two methods would be sufficient to address any sinkhole potential discovered by the investigation?

MR. LYNCH: Staff believes that the two alternatives provided by Northwest are reasonable to address potential, sinkhole potential at the facility. However, if another design alternative is necessary, the staff will consider that as it is proposed by Northwest.

COMMISSIONER BARAN: Okay. And does Northwest have anything to add on that point?

MS. HAASS: No.

COMMISSIONER BARAN: Okay. Just following up on this, on the applicability of 50.59, the staff confirmed it doesn't apply to the construction permit. Is there a change process, a similar change process,

incorporated into the Applicant's quality assurance program?

MR. BALAZIK: Yes, there is.

COMMISSIONER BARAN: Okay. But it's separate from 50.59 and --

MR. BALAZIK: It is separate from 50.59. And what Northwest has done is they have developed this change process program and have incorporated some of the criteria of 50.59 in there.

COMMISSIONER BARAN: Okay. And that's consistent with Northwest's understanding?

MS. HAASS: Correct. It will be a 50.59-like process.

COMMISSIONER BARAN: Okay, great.

The ACRS identified several deficiencies in the Applicant's aircraft impact analysis. In response to pre-hearing Question 6, the Applicant attributed these deficiencies to dated information and the lack of an adequate peer review. Can the Applicant just briefly walk us through your corrective actions on the aircraft analysis?

MS. HAASS: Go ahead.

MR. CORUM: Okay. We conducted a root-cause analysis to determine what the problem was. We feel like we have appropriately dealt with the issue

and, to our satisfaction, it will not occur in the future. And for all future applications of safety analysis, in particular, for the final design, that will be done under our QA program at NWMI rather than at a contractor's.

COMMISSIONER BARAN: And has the staff evaluated these corrective actions, and have you found them to be adequate?

MR. ADAMS: We've reviewed the answer to the Northwest question, and, yes, we believe the corrective actions are adequate.

COMMISSIONER BARAN: Okay, great. Thank you.

CHAIRMAN SVINICKI: All right. Thank you very much.

To Commissioner Burns, do you have anything else?

COMMISSIONER BURNS: No.

CHAIRMAN SVINICKI: Okay. So, I, again, thank the witnesses for Safety Panel 1.

And we will now enter our lunch break period. We're pretty much right on schedule, which is a good thing. So, we will reconvene this hearing at 1:15 p.m. and start again at that time.

I would ask all witnesses to please be in

the room promptly. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:46 p.m. and resumed at 1:17 p.m.)

CHAIRMAN SVINICKI: Well, thank you everyone and good afternoon. I call the hearing to order once again. We will now proceed with the second safety panel. And the parties will address sections of the application and Chapter 13 of the Safety Evaluation Report regarding the application of 10 CFR Part 70 methodologies for the analysis of radiological and chemical exposure accidents. I remind all of the witnesses that they remain under oath and that the commission is familiar with your pre-hearing filings. And as we did with Safety Panel 1, we will begin this combined panel with the presentation from the witnesses from Northwest Medical Isotopes. Please proceed. And once again, prior to presenting please be sure to introduce yourself or identify yourself. Thank you.

MR. CORUM: Good afternoon Chairman and commissioners. I am Michael Corum with NWMI and I will be providing the integrated safety analysis and criticality safety presentation for them. Slide two, please. Consistent with the ISG augmenting NUREG 1537, NWMI used the ISA methodology identified in 10

CFR 70, subpart H to conduct the safety analysis for its radioisotope production facility. Additional guidance from NUREGs 1520 and 1513 was used in the process to apply radiological and chemical consequences and likelihood criteria to meet the performance criteria -- or, requirements in 10 CFR 7961.

The ISA concludes with identification of items relied on for safety and the management measures to demonstrate adequate safety for the RPF. Slide three, please. The ISA process begins with a process hazards analysis that provides a systematic examination of processes, equipment, structures and personnel activities by a complete team of safety analysts and process designers to ensure all hazards that could result in unacceptable consequences were identified, adequately evaluated and appropriate protective measures applied. Slide four, please.

Quantitative assessments were developed to address events and hazards identified in the PHA that required additional evaluation. Event trees were used in certain circumstances for quantitative failure analysis. And in some of these cases the analysis demonstrated failure frequencies were highly unlikely and no other analysis was needed to meet the

performance criteria. For events with failure frequencies that were less than highly unlikely and had adverse consequence, the risk matrix in NUREG 1520 was used to identify unacceptable intermediate and high consequence events. IROFS were also then developed to prevent the event or mitigate the consequence. And management measures were identified to ensure that the IROFS were -- are reliable and available to perform the intended function on demand. Slide five, please.

Initiating events for the sequences identified in the PHA included operator error, loss of power, external events and critical equipment malfunctions or failures. And the last bullet on this slide acknowledges that the ISA is a living document and will be updated during final design. And the ISA summary will be submitted as part of the Operating License Application. Slide six, please.

This slide gives an overview of the documents that make up the NWMI ISA. There's eight documents that are associated with radiological events, one document that's completely related to chemical safety process events and then the ISA summary is part of the -- is part of the -- the documentation as well as the process hazards analysis.

If we could skip to slide eight, please.

Criticality analysis is a part of the ISA process and includes evaluations that are based on industry standards to satisfy the double-contingency principle in addition to meeting the performance criteria in 10 CFR 7061. And criticality is considered to be a high consequence event for the ISA purposes and for the purposes of meeting the performance criteria. The CSE describes the system to be evaluated, the process and equipment involved in normal evaluation, criticality acts and the scenarios documented in the PHA, evaluation of accident and off-normal scenarios with applications of the double-contingency principle, identification of controls and designation of IROFS.

For NWMI the facility was divided into 13 process areas that define the system for evaluation from a criticality safety perspective. CSEs were supported by calculations performed and documented in the six analysis reports that are shown at the bottom right. The calculations were performed using the Monte Carlo code, MCMP version 6.1 with the ENDF/B - VII cross-section library. If we could go back to slide seven, please.

Because of the uncertainty involved with

the computer code based on stochastic methods like MCNP a code validation was necessary. To prepare for the code validation the NWMI process was investigated to determine the suitable parameters to include in that validation. Critical experiments were selected from the International Handbook of Evaluated Criticality Safety Benchmark Experiments that adequately represent the uranium enrichment, geometry moderator reflector and neutron energy for the NWMI process. The experiments were then modeled using MCNP. Calculations were completed and the results analyzed to determine an upper subcritical limit of 0.924 for NWMI. Slide nine, please.

This -- the information contained here for the accident analysis from the ISA is documented in the NWMI PSAR Chapter 13 and these are some of the initiating events that are associated with those. I believe that's the balance of my time.

CHAIRMAN SVINICKI: Thank you. I will now as the NRC staff to occupy the spaces behind their name cards and proceed with the NRC staff's portion of Safety Panel 2. Please proceed whenever you're ready.

MR. BALAZIK: Slide two, please. Good morning Chairman, commissioners. My name is Michael Balazik. This panel will discuss the unique accident

analysis considerations of the proposed Northwest production facility. Next slide, please.

10 CFR 50.34 alpha 4 requires that a PSER assess the risk to the public health and safety from the 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 otherwise known as an ISA. An ISA involves identifying potential accident sequences and facility operations and designing 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 cycles facilities. However, the ISG augmenting NUREG 1537 provides that an ISA may be used for a medical isotope -- radioisotope production facilities because one, part 50 does not contain specific requirements for accident analysis for medical radioisotope production facilities, and two, an anticipated radiological and chemical hazards associated with the processes at medical and radioisotope 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 radiological and chemical consequences and likelihood criteria are contained in the performance requirements of 10 CFR 70.61, the designation of items relied on for safety and the establishment of management measures in an acceptable way of demonstrating adequate for a medical radioisotope production facility.

In its application Northwest used a Part 70 ISA methodology for its accident analysis -- including the designation of IROFS. Northwest also stated that it will provide a description of management measures and 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 one of its Construction Permit Application, Northwest stated 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. Next slide, please.

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

MS. A. SMITH: Thank you, Michael. My name is April Smith. 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 combine 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 use of these hazard and risk analyses methods by Northwest 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 analyses in part by reviewing the processes conducted inside the production facility. The staff determined that the use of an ISA methodology by Northwest is consistent with NUREG 1520 and the ISG augmenting NUREG 1537 for medical isotope 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 the 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. 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 guidances NUREG 1520, Northwest identified IROFS to either prevent accidents or to mitigate the consequence of accidents. Northwest also identified IROFS to prevent 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 design should incorporate sufficient factors of safety to require at least two unlikely, independent and concurrent changes in process conditions before 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 the 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.

MR. TIKTINSKY: Thank you, April. My name is David Tiktinsky in the Office of Nuclear Materials Safety and Safeguards. The staff reviewed the Northwest analysis of accidents with radiological and criticality consequences. This analysis included events 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 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.

MR. HAMMELMAN: 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 engineer safety features that Northwest identified to protect against the release of licensed material or hazardous chemicals produced from the processing of licensed material.

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

Northwest stated it will perform additional testing to evaluate the feasibility of a pressure relief system for mitigating potential exothermic reactions of ion exchange material. Additionally, Northwest will evaluate the potential for the release and thermal decomposition of organic material used in the ion exchange media for uranium purification. The results of these additional

evaluations will be integrated into the Operating License Application.

The staff determined that Northwest preliminary facility design, proposed process operations and engineer safety features can provide adequate protection to the public from chemical hazards at the proposed facility. Next slide, please. Mike Balazik will now provide a summary of the staff's evaluation.

MR. BALAZIK: Thank you, Jim. Based on the review of the staff, 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 items relied on for safety. The ISA approach also supports a 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 at this time.

CHAIRMAN SVINICKI: Well, thank you to the NRC staff witnesses and to Northwest Medical Isotope for the Safety Panel 2 presentations. We will begin

this round of questions with my questions. Northwest Medical Isotopes on slide four makes reference to the translation of the IROFS developed under 10 CFR Part 70 to tech specs under 10 CFR Part 50 and that that will be developed in the Operating License Application. Could Northwest at a high level describe that translation step and how they approach doing that?

MR. REESE: Yes, so this is Steve Reese. At a high level basically on -- most IROFS will end up turning into something akin to limiting condition -- limiting -- excuse me -- an LCO in tech spec world. There will be a couple of -- as an example of a design criteria listed as stack. So the stack would be not necessarily an LCO, but it would be a design criteria. So it's the stack will look like X. So it has to have a certain height and it has to have a certain function. But most of the other IROFS will turn into something akin to an LCO.

CHAIRMAN SVINICKI: Okay. Thank you very much for that. Does the staff have any reaction to that? Or you just await to see how that's brought forward in the Operating License Application?

MR. BALAZIK: At this point we're just waiting to see the -- the approach that Northwest uses

to convert these items relied on for safety for -- for technical specifications.

CHAIRMAN SVINICKI: Okay. Thank you. Northwest Medical Isotopes also presented about its MCNP code validation process that it found to be analytically necessary. Does it -- the NRC staff have an assessment of the adequacy of the approach for the code validation that was taken by Northwest Medical Isotopes? And is -- the criticality I know the staff has identified as an area that will get additional and strong scrutiny in the Operating License Application. But at this point of the review did the staff find that the code validation work for MCNP was sufficient?

MR. BALAZIK: Yes, the staff did find that the code validation for MCNP was sufficient. But we did identify a couple of requests for additional information associated with that review.

CHAIRMAN SVINICKI: Okay, thank you. And on Northwest Medical Isotopes slide nine they have a list of accident-initiating external events. It may be that the list is just illustrative of external events, but sink holes are not explicitly mentioned alongside seismic and other external events. Is the approach to the probability of a sinkhole occurring some time during the operation of the facility more

akin to having done the geotechnical site evaluation, you eliminate that as a probable external event that will occur? Does it become so low probability that it is not one of your accident-initiating external events? Or is -- was the list merely illustrative?

MR. CORUM: No I think we really need the information from the geotechnical in order to -- to better evaluate what -- what that needs to be as far as an analysis space. So.

CHAIRMAN SVINICKI: So when you have that, you would have a better characterization of the probability of a sinkhole developing and therefore you would be able to screen that in and out of various accident scenarios?

MR. CORUM: Correct.

CHAIRMAN SVINICKI: Okay, thank you for that. I think those are my questions, so we will proceed now to Commissioner Baran.

COMMISSIONER BARAN: Thank you. I want to start by following up on pre-hearing question 19 which asked about redundancy in the emergency electrical power system. The staff stated that there is not redundancy in the design of the standby diesel generator but that there is some redundancy in the design of the batteries -- or, the uninterruptible

power supplies. The Applicant stated that there are no plans for redundancy in either the diesel generator or the batteries. So the answers from the staff and the Applicant didn't really line up. Can the Applicant clarify whether you will have a redundancy in the emergency batteries?

MR. DUNFORD: Yes, this is Gary Dunford. Right now we don't -- from the accident analysis we've done and the frequencies, we do not see the need that we need to have a backup set of batteries for our emergency power system at this time.

COMMISSIONER BARAN: And let me ask the staff, is -- is the Applicant's answer today consistent with the information that you evaluated in the application?

MR. BALAZIK: It is -- it is with what we've reviewed in the application. However, when the staff looked at this question we see that the -- the diesel actually provides power to what the UPSs would supply. So therefore there is some level of redundancy in that design.

COMMISSIONER BARAN: I'm seeing some nodding from behind. Do you want to chime in on --

MR. DUNFORD: Well, that's a true statement. But we haven't accredited the diesel from

a safety perspective so we don't take any credit for it in an action space.

COMMISSIONER BARAN: Okay.

MR. BALAZIK: And the staff agrees with that.

COMMISSIONER BARAN: Okay. So from your point of view -- and I ask this question to both -- is there any disagreement between the staff and the Applicant about the status of -- the redundancy of the electrical power supplies?

MR. BALAZIK: With the clarification that the -- Northwest has provided, no.

COMMISSIONER BARAN: Okay. Related to pre-hearing question 26, the Applicant appears to take credit for a high-elevation release from the radioisotope production facility by using a 75-foot exhaust stack. The RPF building is 65 feet tall. The exhaust stack attached to the top of it is 10 feet tall. So 75 total. And RC guidance for atmospheric dispersion states that thee exhaust stack height should be at least two-and-a-half times the height of the adjacent structures in order to credit a high-elevation release under all conditions. And this all relates to the dose calculation for accident analysis. Did the staff examine the applicability of the

guidance? And if so, what were your conclusions?

MR. BALAZIK: Commissioner, I think we will have to get back to you on that question?

COMMISSIONER BARAN: Can I ask you -- is there anyone from the staff here who could chime in on this question of stack height and -- and how that's analyzed for the purpose of -- you know crediting the high -- an elevated release?

(No audible response.)

COMMISSIONER BARAN: Ask the Applicant too if they have any -- any thoughts on this topic.

(Pause.)

MR. BALAZIK: John Atchison, do -- do you have any information that you can provide on that?

(Pause.)

CHAIRMAN SVINICKI: And again, as you approach the podium could you please identify yourself, your affiliation and indicate whether or not you've been sworn as a witness?

MR. ATCHISON: This is John Atchison. I was sworn in this morning. I am supporting the staff on this issue. I think we will have provide an answer later on that question.

COMMISSIONER BARAN: Okay, and -- do -- and if -- if this is too much detail for today, we

need to do post-hearing questions we can do that. Let me just ask, do you -- are you familiar with this reg guide on the -- the atmospheric dispersion question?

MR. ATCHISON: I am.

COMMISSIONER BARAN: Okay. And so do you -- do you have an understanding of when the reg guide talks about adjacent structures, does that apply to the radioisotope production facility itself, or only to nearby buildings on the campus or around the campus?

MR. ATCHISON: My -- my understanding is that would be surrounding buildings.

COMMISSIONER BARAN: So not the 65-foot building that this stack is attached to, but the lower-level buildings around there?

MR. ATCHISON: The -- the building underneath the stack is not in the plume direction.

COMMISSIONER BARAN: Okay. And do -- and again, if this -- if it needs to be follow-up question, we can do that. Do you know how far out you look for adjacent structures for this purpose? So, do you look to buildings on nearby lots, of example in this case? Or -- how far out does that go? That counts as an adjacent structure?

MR. ATCHISON: That search area would be

related to the property boundary and the protected areas and how far away the highest impact public location would be.

COMMISSIONER BARAN: And do you -- do you have a sense of -- or do you know whether that would -- would include other lots in the research park? Or just this lot?

MR. ATCHISON: This is basically a small lot.

COMMISSIONER BARAN: All right. So it may extend beyond that to other lots?

MR. ATCHISON: Yes. Mm-hmm.

COMMISSIONER BARAN: And so earlier we heard a little bit that -- and I give the Applicant a chance to chime in on this too -- broadly speaking. But we heard earlier that some of those lots are vacant right now, but that there's interest in getting folks into some of those lots. So it -- you know, one could imagine there might be buildings that are built down the road in a nearby lot. If -- if one of those buildings were, like, a multi-story building, does that affect this analysis? Would it require some kind of reanalysis of this question?

MR. ATCHISON: I believe the answer is yes, it would -- would have to be reanalyzed.

COMMISSIONER BARAN: I don't know if the Applicant wants to address this issue at all -- or we should save it for post-hearing questions.

MR. DUNFORD: Okay, so we have actually evaluated some scenarios with building wake -- changes in the building wake from the existing RFP building -- with some mixed results, I guess I will say. In -- the nearest receptor that we currently have as our permanent resident, that numbers actually go down under those evaluations.

COMMISSIONER BARAN: Okay.

MR. DUNFORD: So where we are with our -- with our current analysis is we have just stayed with that. And we recognize as part of the FSAR we have to go back and understand that. I am not -- because I -- we actually don't control, obviously, adjacent lots.

COMMISSIONER BARAN: Right.

MR. DUNFORD: So we have to -- I am not sure I would necessarily go say that we would have a ten -- or a 50-59 because someone was going to build a two-story building away from us. So we've got to look at that from that aspect. But as far as nearest resident, we did some -- for -- it was really for the MHA, which we ended up not using in safety analysis space, so -- that's where we are right now.

COMMISSIONER BARAN: Okay, and do you -- do you know this issue enough detail to say whether the way you all looked at it was you were comparing the 75-foot stack height to the low-level buildings around it rather than the production facility itself?

MR. DUNFORD: No, we compared it using the interference of the production facility itself.

COMMISSIONER BARAN: Okay, and did you have a view that about the applicability of this guidance about it being two-and-a-half times taller than the highest adjacent structure in order to get credited?

MR. DUNFORD: We did have discussions about that. And as I said, we were doing this as part of the MHA analysis. When that went away we ended up staying with the numbers because it -- for the maximum hypothetical individuals in something like that, they went down from where we were initially.

COMMISSIONER BARAN: In -- but you are taking credit for it here? Is that -- it read that way.

MR. DUNFORD: We do, yes.

COMMISSIONER BARAN: Okay. All right, well I might have some additional follow-up questions for the staff and the Applicant then in post-hearing

questions where maybe we can get into a little bit more detail on that in whether -- I mean, maybe to kind of close out the discussion here for -- you know, the staff or the Applicant, how do you view the significance of this issue from a -- from a dose calculation point of view? Do you see it as a significant issue or not significant issue? And if so, either way, why?

MR. ATCHISON: I think based -- based on analysis sensitivities, you will find it is not a significant reduction in those by -- by crediting the stack height.

COMMISSIONER BARAN: Any thoughts from Northwest? Or --

(Pause.)

MR. DUNFORD: I guess I want to see the numbers before I tell you what's going to happen. I do know that -- I actually expect as part of the Operating License Application and the conservatism we have right now in some changing control philosophies that we're going forward with, that those numbers are all going to go down anyway. So I guess I want to just leave it at that at this stage.

COMMISSIONER BARAN: Okay, thank you.

CHAIRMAN SVINICKI: Thank you,

Commissioner Baran. Now we recognize Commissioner Burns.

COMMISSIONER BURNS: One question for the staff. There are a number of -- looking at the proposed construction permit, there are a number of provisions including periodic reports. What is the intention of the staff with respect to -- with those reports? What -- is this in effect helping to build the docket as you face potential operating license application? I don't take it -- and if you could confirm it for me, that these reports -- I am looking -- particularly some on -- on the criticality and also on the -- the alarm system and things like that. I take these are not intended as then step -- further step-wise approvals within the construction permit process, but helping to build the record for review later on. Am I --

MR. BALAZIK: Yes, sir. You are correct. We plan to use this information for -- to support our review for the Operating License. And it also -- this information would support the construction inspection process.

COMMISSIONER BURNS: Okay, thank you. We had some discussion -- I think in response to the Chairman's questions with regard to IROFS and tech

specs. And again this is -- you know, use my analogy -- maybe not so far as banging the square peg in the round hole, but -- I mean, it's clear -- I think it's clear that IROFS and technical specifications serve essentially the same purpose. Wouldn't you agree?

MR. BALAZIK: I do agree. Looking at the IROFS, they're just more of the Part 70 world where -- where tech specs are more of the Part 50 world.

COMMISSIONER BURNS: Okay. Do you --

(Simultaneous speaking.)

MR. BALAZIK: And so -- I am sorry.

COMMISSIONER BURNS: Go ahead. No -

MR. BALAZIK: No, I was just saying that right now we're trying to -- to blend the two together.

COMMISSIONER BURNS: Okay.

MR. BALAZIK: But they still are the same.

COMMISSIONER BURNS: Okay. Is there anything that -- have you seen anything to date that would present a particular challenge with respect to -- to doing that at this point? At some point -- I guess because it's Part 50, you have to have tech specs. Is that correct?

MR. BALAZIK: That is correct.

COMMISSIONER BURNS: Okay, so it's -- it's

all a matter of how you describe -- well, you can label them anything. You can -- their IROFS, but you can call them tech specs, I imagine.

You are correct, but at this point we have not seen any transition of IROFs to tech spec, and we're not sure what it would look like at this point.

COMMISSIONER BURNS: Okay. So, I take it we haven't really had any experience with that to date?

MR. BALAZIK: Not that I'm aware of.

COMMISSIONER BURNS: Okay. All right. I want to go to one of the pre-hearing questions. Pre-hearing Question 21, Northwest notes -- this has to do with the power capacity of the diesel generator. And in its response to pre-hearing Question 21, the Applicant says there is no discrepancy in the information. On the other hand, staff documents a discrepancy in the SER.

And I just want to make sure I sort of understand the bases for each of your positions. I also know in that regard, particularly in why this would be identified as a discrepancy from the point of view that the construction permit gives the generator no safety function.

But, first, let me ask the Applicant to

respond.

MR. DUNFORD: So, the purpose of the sizing of the diesel generator in Chapter 19 was to bound emissions.

COMMISSIONER BURNS: Okay.

MR. DUNFORD: And that's so the --

COMMISSIONER BURNS: Bound what kind of emissions?

MR. DUNFORD: Hydrocarbons or fumes coming off of the operation of that generator, gases.

COMMISSIONER BURNS: Okay.

MR. DUNFORD: CO2. So, that's what that purpose was, and they used a very conservative number, right? It's almost twice of what our current number is.

So, when we get to Chapter 4 discussion, and then, that gets translated into the Chapter 8 discussion, where we now have, as part of the preliminary design and size, a generator, that number is quite a bit smaller. And so, that's what's used in the earlier chapters. But Chapter 19, which was really there to bound emissions, CO2, we didn't feel that that needed to be changed.

So, the basis for that, granted, the number is different, right? But the basis for the

number and how it's used really doesn't -- it didn't seem like to us it was a discrepancy. One was just a bounding conservative value and the other one is our current realistic value for operations.

COMMISSIONER BURNS: Okay. Staff?

MR. BALAZIK: Well, also, within Chapter 8, as a result of a request for additional information, Northwest updated their peak power supply, and with that, they also have in Chapter 7 where they have a capacity of the diesel generator of 1,000 kilowatts. So, there's an inconsistency between the peak power that they have in Chapter 7 and the capacity of the diesel.

COMMISSIONER BURNS: Okay. And what's the significance of that?

MR. BALAZIK: It was just pointing out there's a discrepancy between the two numbers.

COMMISSIONER BURNS: Okay. And what's the importance of the numbers? Does it go to this question of emissions?

MR. BALAZIK: It would. Well, not necessarily the emission, but how long the diesel generator would run under a loss of offsite power. There's a certain timing in that they have done. But we're just identifying the inconsistency between the

two numbers.

COMMISSIONER BURNS: Okay, but is there a significance to a finding with respect to the loss of offsite power and availability or the retrievability of this diesel?

MR. BALAZIK: No, there's not.

COMMISSIONER BURNS: So, it doesn't have a significance --

MR. BALAZIK: There's not.

COMMISSIONER BURNS: Okay. Thank you.

A couple of last questions, actually, and I apologize if I should have asked these with respect to the initial panel. But, just to give a context again, we talked a little bit about hazards and all. So, two, just to sort of give me an anchor point.

One, what are the seismic parameters being looked at in terms of the design for the facilities? Is it like a seismic design basis? I don't mean to entreat or introduce and affect power reactor licensing, if I shouldn't be doing so.

MR. BALAZIK: Northwest used the Calloway seismic design for their facility.

COMMISSIONER BURNS: And that's like .2g?

MR. BALAZIK: Yes, sir, you're correct. That's where it's anchored at, .2g

COMMISSIONER BURNS: Okay. The other one is with respect to aircraft hazard. I presume we are analyzing this because of a change to the Commission's rules about 10 years or so ago, which I think introduced this analysis. What is the nature of the aircraft hazard? Where's the nearest airport?

MR. BALAZIK: Steve Morris, can you help us out with that?

I know the nearest airport, it's southeast of the facility, but I'm not exactly sure of the distance.

COMMISSIONER BURNS: Can the Applicant answer that?

MS. HAASS: It's just about five miles southeast of us, of the facility.

COMMISSIONER BURNS: Five miles south? And what's the nature of it? Is it a small --

MS. HAASS: It's a regional airport. I can't remember the exact number of flights on an annual basis. Okay, 20,000.

COMMISSIONER BURNS: Okay. And the type of aircraft? You might have like a 737 come in or --

MS. HAASS: Actually, most of them are just more of the CRJs, you know, the itty-bitty ones.

COMMISSIONER BURNS: Yes. Okay.

MS. HAASS: They do have one annual air show a year, Memorial weekend.

COMMISSIONER BURNS: Okay. Does staff want to add anything? No? Okay.

Thank you. Thank you, Chairman.

CHAIRMAN SVINICKI: Well, thank you to all the presenters for this second Safety Panel.

We will now turn to the Environmental Panel, and we will reset the tables here.

While that is occurring, I will state the following: in this Environmental Panel, both the Applicant and the staff will address the environmental review performed in connection with the construction permit application, with a summary of the staff's process for developing the Final Environmental Impact Statement and a discussion of relevant sections of that document, including the environmental impacts of the proposed action and the staff's analysis of alternatives to the proposed action.

This is another of the combined panels, meaning the Applicant and the staff.

As we continue to reset the table for the NRC staff presenters, I would ask that they make their way to the table because their nameplates are being placed. Thank you.

However, as the staff prepares to be seated off to the sides, to clear our line of sight, we will begin once again with Northwest Medical Isotopes, and I think we're getting close here. We're very close. Thank you.

Okay, great. Thank you very much.

So, again, we will begin with the Northwest Medical Isotopes witnesses. So, please proceed when you're ready.

MS. HAASS: I am Carolyn Haass with Northwest Medical Isotopes.

And if we can go to page 2?

So, as you know, Northwest Medical Isotopes was granted an exemption to submit our construction application in two parts. And we did submit our part one, which included Chapter 19 and Chapter 2, in February of 2015.

What you see on the last full bullet here is a chronology of what's occurred. We submitted it in February of 2015. The scoping meetings occurred in December of 2015, with the Draft EIS public comment period occurring November 1 through December 29th of 2016, with the EIS being published in May of 2007.

Page 3, please.

The proposed action under this, I think,

as we have stated earlier in this hearing, that the NEPA that was completed or the environmental assessment -- well, the NEPA that was completed was for both portions of the facility. It was for a Part 50 and Part 70. So, that means it would be the production facility as well as the target fabrication.

It was to construct -- I mean, the activities associated what that, we have spoken about that, as I have said. I mean, they are more detailed up there, but the material production for the targets, the targets themselves, moly recovery and purification, uranium recovery, recycle and recovery, and that's about it.

Northwest Medical Isotopes did propose that we were going to -- we wanted to construct and operate at the Discovery Ridge Research Park, which is owned by the University of Missouri system.

Page 4.

There was a lot of consultation that occurred for this proposed site. As you noticed, we worked with the city, the county, the State of Missouri -- well, the City of Columbia, the County of Boone, the State of Missouri, as well as with the tribal nations and other federal agencies such as the Department of Energy and U.S. Fish and Wildlife.

Slide 5.

So, when we initially started working and wanting to construct and operate a facility, we evaluated across the country, as Nick Fowler stated earlier in his opening remarks. We did narrow it down to four sites, meaning University of Missouri Research Reactor Site, Discovery Ridge, Oregon State University, and then, McClellan Business Park, which was next to the University of California Davis Reactor.

Next slide.

We did pick that we wanted to be at the Discovery Ridge site. But, prior to doing that, from the four sites, we did narrow it down to the two sites, because we felt it was most beneficial for us to be near the University of Missouri Research Reactor rather than the Oregon State Reactor. So, we narrowed it down to two. Then, we did a detailed analysis of both of those sites.

And what you're seeing here, if you look at the pink, the light pink colors on that graphic, and the furthest one to your left, that is Lot 15, where we will be. And there's only two other facilities that are currently really housed there.

So, there's 550 acres, and we're only 7.5,

or approximately 7.5 acres. So, there is a lot of room to grow.

You'll notice that the areas colored in yellow, there's different phases and that is a very late-stage phase. So, there's not a whole lot that's going to go behind us for quite a bit of time. That's not where the University system is trying to bring people in.

Next slide.

So, one of the reasons I wanted to show you this is, when we looked at potentially being right next to MURR, there was a lot of congestion at that site. There's not a lot of room to do a whole lot, and particularly, you know, they're still building follow-on buildings and other buildings around it, you know, a new cooling tower, those types of things. And logistically, it would have been very difficult, especially from a transportation perspective, you know, getting items in and out. There's just not a lot of room there.

Next slide.

So, I know that the NRC staff will talk a lot more about this, but they went and evaluated five different alternative technologies. They focused on two of them, uranium fission technology and the linear

accelerator-based technology.

From our perspective on the alternatives that were evaluated, we looked at the no action as well as the RPF being at MURR, as the alternative site in Discovery Ridge. They added two additional alternatives that we did not evaluate in our environmental report.

Next slide.

I am going to hand it over.

MR. REESE: Yes. So, this is just a graphic that gives you an idea of the geographical distribution of the different possible reactors that would meet our needs. Again, we looked at, in terms of connected actions, we were looking at transportation issues associated with the movement of both irradiated targets and unirradiated targets as well as any impacts on facility modifications and/or changes in staffing levels, and the impacts thereof, of the irradiations themselves.

If you would go to the next slide?

What we found is that there's actually very little in the way of facility modifications that would be necessary. Certainly no exterior construction would be needed. There are some changes in how the facilities handle the targets themselves,

but that's not unreasonable, nor is it unexpected. Excuse me.

The actual irradiation of the targets themselves don't really result in extra staffing per se because the reactor is running anyway.

And we do know that we are going, as part of the connected actions, going to have to ask for license amendments for the two facilities, though, and we are anticipating MURR to submit sometime this year an OSU to follow up next year.

Now the third facility, as referenced by Nick earlier this morning, we have an idea, but it's not at this time necessary to meet the needs of the business model.

MS. HAASS: Page 11, please.

This is just a summary of the environmental impact. Some of the NRC staff will talk more about it. Since this is their document, I think the only thing to really note here is, on the construction impacts, you do see that the impacts are a bit different at MURR, and it was due to noise. And that's why it went from small at Discovery Ridge to small to moderate.

And when I went and I was looking at this whole summary, I was trying to determine on the two

alternative technologies that were evaluated as well. You know, I summarized that I believed that, from a construction and operation perspective, it was going to be a similar amount of people. It's going to be a similar-type cost. I mean, we don't do linear accelerators, so I had to just make those assumptions.

But thank you.

CHAIRMAN SVINICKI: Thank you for that presentation.

I'll now ask the NRC staff witnesses to please occupy the places behind their name tents. And when the staff is ready, please proceed with your part of the Environmental Panel presentation.

MR. BEASLEY: Thank you.

CHAIRMAN SVINICKI: Thank you.

MR. BEASLEY: Good afternoon --

CHAIRMAN SVINICKI: Good afternoon.

MR. BEASLEY: -- 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.

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 EIS.

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 action 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.

MS. MARTINEZ: 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's definition of "connected action" contained in 40 CFR 1508.25. "Actions that are closely related are connected if they, one, automatically trigger other actions that may require Environmental Impact Statements; two, cannot or will not proceed unless other actions are taken previously or simultaneously, or, three, 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.

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 co-located 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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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 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 fresh LEU, recovered LEU from material scrubbed during the target fabrication process, and 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 the 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 direct preparation of an EIS would be the most efficient path forward.

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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 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 a 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 and the Draft EIS.

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

MS. MOSER: Thank you, Nancy.

In developing the EIS, the staff reviewed 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 included 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 par for future development. Past agricultural activities have previously disturbed the area. Common grass species currently cover the site, which provide 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.

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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.

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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.

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 moly 99, which was a unique aspect of the staff review of the Northwest

application.

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The alternative technologies analysis was novel because several entities have proposed new technologies to produce moly 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 moly 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 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 homogeneous reactor, selective gas extraction, linear accelerator-based, and subcritical fusion.

The staff, then, considered whether sufficient environmental data existed to conduct a meaningful alternative 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.

MR. DRUCKER: 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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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.

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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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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 the publication of the 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 EIS based on the 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.

The concludes the Environmental Panel presentation, and we are prepared to respond to your

questions.

CHAIRMAN SVINICKI: Thank you to all of the witnesses from the Applicant and the NRC for the Environmental Panel presentations.

We'll begin the questions for this panel with Commissioner Baran. Please proceed.

COMMISSIONER BARAN: Thank you.

Last month, on December 18th, the Missouri Department of Natural Resources sent a comment letter to NRC on the construction permit application, and the letter includes about a dozen brief comments. In one comment, the State noted that the treatment of hazardous waste is only allowed under State law in very limited circumstances.

I'm not sure if this is more of a safety question or more of an environmental question, but there's not much difference in the panels for the Applicant. So, I'll ask, can the Applicant discuss whether you're planning to treat non-radioactive hazardous waste as part of the radioisotope production process? That seemed to the focus of a particular comment that Missouri had.

MR. DUNFORD: No.

(Laughter.)

So, we do have recycle processes for some

of our solvents.

COMMISSIONER BARAN: Okay.

MR. DUNFORD: But, as far as treatment for disposal, we would go to a third-party vendor to dispose of non-radioactive hazardous materials that we have at the facility.

COMMISSIONER BARAN: Okay. So, when Missouri flagged that, I don't know if you guys saw that letter. It's really not applicable to what you're doing?

MR. DUNFORD: Correct.

COMMISSIONER BARAN: As far as you can tell? Okay.

MR. DUNFORD: Correct.

COMMISSIONER BARAN: And this is a question for both -- well, I'll start with the staff. Is there anything in the letter from the Missouri Department of Natural Resources that was unexpected or raised concerns for the staff?

MR. BEASLEY: We have reviewed the letter, and it did not raise anything of special concern. We have assessed that it did not affect anything that we had written in the Final Environmental Impact Statement. So, we don't see any edits that would be needed.

COMMISSIONER BARAN: Okay. And I ask just the same question to the Applicant. Assuming you had a chance to review the letter, did it raise any new issues or concerns for you?

MS. HAASS: To our knowledge, no, it has not raised any new issues.

COMMISSIONER BARAN: Okay. All right. Well, that's all I had. Thank you.

CHAIRMAN SVINICKI: Thank you.

Commissioner Burns?

COMMISSIONER BURNS: Yes, a few questions I might have.

How long -- the land on which the facility is being built, you said it had been farmland -- how long has it been dormant?

MS. HAASS: It's been used for agricultural for -- what? -- five, six, seven generations, and it was donated as a farm to the University system.

COMMISSIONER BURNS: Okay. But, basically, there's been no farming on it for some time?

MR. DUNFORD: Well, there are still cows. The pasture --

MS. HAASS: Well, the cows roam.

MR. DUNFORD: There's still pasture in the area.

COMMISSIONER BURNS: Oh, okay. Yes, okay.

MS. HAASS: So, when we talked agricultural, it was really grazing.

COMMISSIONER BURNS: Yes, I misinterpreted you. Agricultural uses can be something else --

MS. HAASS: Right.

COMMISSIONER BURNS: -- and the cows will even eat that lower-quality grass, or whatever somebody described there -- (laughter) -- that, fortunately, the endangered species don't, apparently, like.

MS. HAASS: They don't like cows, either, which is good.

COMMISSIONER BURNS: Okay. Well, that helps. But it's been, as you say, multigenerations it's been basically agricultural land?

MS. HAASS: Correct.

COMMISSIONER BURNS: So, the interesting thing is that, during the contact that's necessary, and certainly appropriate, as part of the National Historic Preservation Act, in consultation with tribal nations, you mentioned there were 31. Are these essentially in that, somewhat within a particular

perimeter or near the site, or are these that may have had an historic affiliation with a site and now might be, say, in Wyoming or somewhere else? Can anyone help me on that?

Ms. Martinez?

MS. MARTINEZ: The 31 tribes that the staff consulted with were, as you said, it's because they had some -- we identified that they may have some historical affiliation or historic ties to the site and area.

COMMISSIONER BURNS: Uh-hum. So, where are they? What I'm trying to understand is where are they. Where are these? Where are the tribal lands or tribal connections now? That's what I'm trying to understand.

MS. MARTINEZ: I would like to ask one of the staff members to please come and address that further.

COMMISSIONER BURNS: Yes. Because the example I would give is, for example, in licensing plants in North Carolina, you typically have consultation with the Cherokee Nation, which, of course, as we know, was forcibly removed in the beginning of the 19th century during the Jackson Administration.

Yes?

CHAIRMAN SVINICKI: And can I ask the NRC staff witness, please identify yourself, give your affiliation, and note if you've been sworn.

MR. HOFFMAN: My name is Bob Hoffman. I'm with NRR, and I have been sworn-in.

All of these tribes, essentially, do not have reservations anywhere near the proposed site, but they do have historic affiliations as far as the range of their tribes in the past. But most of them now are located elsewhere, say in Oklahoma or in the Dakotas or other areas.

COMMISSIONER BURNS: Okay. While you're here, because I'm going to ask a question with regard to the comments of the EPA and Sierra Club, did we receive any adverse comments from the tribal nations with respect to the application?

MR. HOFFMAN: No, we did not.

COMMISSIONER BURNS: Okay. Let me, then, thank you.

Let me go, then, with respect -- actually, it was, I think, Mr. Drucker who mentioned it. If you could briefly say, give a flavor of what the adverse or what the comments of the EPA and of the Sierra Club that led to some modifications in our EIS?

MR. DRUCKER: So, I'll start with the Sierra Club, whose comments were very local. They were very concerned with the local area and the natural areas nearby the proposed facility.

And so, they did propose some modifications and adding -- actually, it required Michelle to add some information from one location to another. They did identify two species. Do you remember? It was the two species that were also -- were not originally included in the EIS, but, then, were added later, is that correct, Michelle?

MS. MOSER: Yes, just to expand upon that, so the Sierra Club identified concerns related to water resources and some of the parks and protected areas near the proposed site. And so, we added a bit more information in terms of those protected areas, both within the land use sections and within the ecological sections, because they provided both recreational use and, then, habitats for some sensitive species.

COMMISSIONER BURNS: Okay. All right. Thank you.

MR. DRUCKER: And for the Environmental Protection Agency, those comments were concerned with things like gaseous effluents and with how we were

going to deal with waste and radioactive dose. And none of those comments required any significant changes. It was mostly just adding information from one place in the EIS to another.

COMMISSIONER BURNS: Okay. So, some clarification? I'll put words in your mouth. Some clarifications or greater transparency --

MR. DRUCKER: Yes.

COMMISSIONER BURNS: -- on what we had done?

So, in the view of the staff, you have adequately dealt with these significant comments from these two organizations?

MR. DRUCKER: Their comments have been properly addressed.

COMMISSIONER BURNS: Okay. Thank you.

Let me go to sort of finish up my questioning with respect to an understanding of the environmental review process as it will relate probably to these other licensing actions. And here, I think we'll touch on an underlying theme of today's discussion, is this interesting marriage of Part 50 and Part 70 licensing, in particular.

So, what you've done, which is what I would expect in an Environmental Impact Statement,

because you really have to take a broad view. This is the directive under NEPA. You cannot sort of chop things up so that you avoid looking at impacts, you know, sort of the natural outcomes of certain activities.

So, what you've done here, as I understand it, is looked at the Part 50 facility, the impacts of construction, operation, et cetera. But, because of the relationship to the Part 70 license, you've also done that. You've taken into account many aspects of what would be contained in a Part 70 license.

So, this is my question. Well, before I ask that question, as I understand it, again -- and I think Ms. Martinez addressed this -- this is not, for the Part 50 piece, this is not clearly specified as you must do an EIS, but we felt, given what we understood, that this was where you make a judgment, and I think an appropriate judgment call, that you go forward with an EIS, correct?

MS. MARTINEZ: It is correct. Specifically, for the Part 50 construction application, an EIS is not required, per our regulations. And we did this, we made this determination based on the operations, which is a connected action that would occur in this facility, as

well as the potential to not reach a finding of no significant impact.

COMMISSIONER BURNS: Right. And if I were only looking at this as a Part 70 facility, my understanding -- and if you all could confirm that? -- is that this would not be, would not likely be able to take advantage of a categorical exclusion for the Part 70 aspects. Is that correct?

MS. MARTINEZ: For the Part 70 aspects, there is an application for possession and use of special nuclear material for target fabrication and scrap recovery. You are correct, this would not apply -- a categorical exclusion would not apply. Our regulations in 10 CFR 51.20(b)(7) require an EIS.

COMMISSIONER BURNS: Okay. So, then, let me come back to the question I was going to ask about a minute ago. It is, what have we not done under Part 70 in terms of the evaluation of potential environmental impacts? Phrased another way, is there something we haven't looked at, at this point, with respect to the Part 70 aspects of the facility?

And I recognize, and let me add the footnote, I recognize that both under Part 50, just as we would with a power reactor license or other license under a two-step process, we would have to do a

supplemental, a supplement to the EIS. But, again, my question is, what haven't we don't here with respect to the environmental impacts of the Part 70 aspects of this application?

MR. BEASLEY: For the current construction permit, we have completed all the reviews that are needed and considered all the information that has been provided. And correct me if I don't get the answer to your question. When they filed the Part 70 application, then we would need to look at an updates. So, if there is updated information or significant new information -- so, if there's not any significant new information and the updates are insignificant, then, conceivably, we would have very little to supplement in the Final Environmental Impact Statement to support the Part 70 application.

COMMISSIONER BURNS: So, if I understand, as I understand it then, in a sense, what we've done -- and again, it's driven by the spirit of NEPA, I would say, that the notion is, notionally, you look at the construction impacts, you look at what the operating license is going to be, but you know you have this other thing that we're calling Part 70 right now that's going to be added on.

So, in a sense, one -- I'll maybe put

words in your mouth -- in a sense, we've almost done sort of like a bounding analysis with respect to Part 70 aspects. And as you say, Mr. Beasley, I think when we come back to -- we want to know what the actual, well, things like in the Part 70 license, what the actual possession limits are, the form of material. Some of those details will come sort of, come to us really more at that Part 70 license stage?

MR. BEASLEY: Yes, that's correct. We didn't intentionally do a review to try to bound a Part 70 application, but we did a comprehensive review. We took a hard look, as guidance requires. And so, that does cover the extent of the facility and the operations proposed and connected action, the decommissioning.

And there was another aspect that you started out with that I'm not sure --

COMMISSIONER BURNS: Yes, I think that, yes, I'm just using sort of colloquially the term "bounding" analysis --

MR. BEASLEY: Right.

COMMISSIONER BURNS: -- since we do that in some other occasions. But I recognize that you're not actually giving any Part 70 permissions.

MR. BEASLEY: Right.

COMMISSIONER BURNS: What you've done is, basically, found that this facility, when you do what NEPA requires and look at it more holistically, what you're saying is there's no showstopper here in terms of the environment or in terms -- and I think, actually, I would go so far to say, or in terms of our regulatory framework, that would prevent us from issuing a license down the road?

MR. BEASLEY: That's correct.

COMMISSIONER BURNS: Okay. Thank you.

Thank you, Chairman.

CHAIRMAN SVINICKI: Well, thank you, everyone, for the presentations.

I will just cover a bit of that ground again, just to be sure that I'm crisp in my thinking on the NEPA analysis that's been done to this point in time and, then, the future analyses.

David, I would return to your slide 16, which was entitled, "Future NEPA Analyses". So, I understand this to be that, going forward, if -- or, since they've indicated they will -- when Northwest submits an application for an operating license for a Part 50 production facility, the staff would look at a supplement to the EIS developed for the construction permit? And then, again, your presentation indicated,

if Northwest were to submit a 10 CFR Part 70 application, which, again, the Applicant has indicated they're going to -- and I think that those would be submitted concurrently -- the Applicant for Part 70 would be required to submit an environmental report. And the staff indicates they would evaluate that as well.

And then, third, the staff would plan to conduct a separate environmental review for each license amendment request that is submitted by the research reactor licensee.

Do I have the component pieces of that correct?

MR. BEASLEY: Yes.

CHAIRMAN SVINICKI: Okay. And so, under the imperative of avoiding two pitfalls, one of which is the segmentation, which we don't want to segment, inappropriately segment the NEPA review or, as Commissioner Burns called it, chopping it up into bits. We don't want to do that inappropriately.

And we also have to consider the connected actions, but there are future licensing actions to come in, in terms of the operating license for Part 50 and the Part 70 application. So, it's quite a bit for the staff to navigate. I think I understand the

component elements.

Is the staff confident that, under the approach they've used, that they have avoided any inappropriate segmentation of all of the actions that are contemplated here? And has considered all of the appropriate connected actions? Are you confident you've done that?

MS. MARTINEZ: Yes, the staff is confident that we have looked at a broad range of connected actions, the proposed action, in this EIS.

CHAIRMAN SVINICKI: Okay. Thank you.

And on a separate matter, in response to a pre-hearing question, the staff indicated that Northwest Medical Isotopes conducted or had conducted a cultural resource survey of the site, at the request of a tribal requester. Maybe it was multiple tribes.

Could I ask Northwest Medical Isotopes, did you conduct that or contract to have that conducted? Could you describe it and the conduct of the cultural resources survey? And did any tribes send observers or participate in the conduct of the survey?

MS. HAASS: I can partially answer that question. So, there were no observers when we did that. We did subcontract that out to a company who

has a lot of experience in doing cultural resource, you know, investigations.

Off the top of my head, I'll be honest, I haven't looked at that in a long period of time.

CHAIRMAN SVINICKI: Okay.

MS. HAASS: I mean, so I can't really describe the document right now.

CHAIRMAN SVINICKI: But this is a, this was a contracted entity that has, to your knowledge, experience in doing these types of cultural --

MS. HAASS: Yes.

CHAIRMAN SVINICKI: -- surveys?

MS. HAASS: That is correct.

CHAIRMAN SVINICKI: And to your knowledge, no tribe, either requesting tribes or other tribes, sent any observers at the time that the survey was conducted?

MS. HAASS: That is correct.

CHAIRMAN SVINICKI: Okay. I think that that's sufficient to answer my inquiry about that.

And my last question would -- I know the staff talked about the scoping process that you went through. But, given that this was a somewhat complex set of actions now and in the future, it was complex to appropriately scope the NEPA evaluation, did the

staff receive any comments through the scoping process that they felt were judgment calls to be analyzed or not analyzed in this particular NEPA review? Was there anything that you felt kind of fell on the line and you struggled with analyzing whether or not you were going to include that in the scope of the NEPA review you conducted?

MS. MARTINEZ: No, during the scoping process we did not identify any comments of that nature.

CHAIRMAN SVINICKI: Okay. Thank you for that.

So, I think that those are my questions for this combined Environmental Panel.

We will now take a shorter break, but I think at five minutes to 3:00 we will reconvene. So, that's about a seven-minute break. And we will reset for the closing statements.

Thank you all.

(Whereupon, the above-entitled matter went off the record at 2:48 p.m. and resumed at 2:57 p.m.)

CHAIRMAN SVINICKI: Okay, I will call the room back to order, and now I will offer each party, the applicant and the staff, an opportunity to make a closing statement. This is also an opportunity, as I

understand, the staff may elect to do to provide additional clarifying response to responses they've given throughout the day.

If you should elect to, please avail yourself of that opportunity, but we will begin with closing statements with Northwest Medical Isotopes. Please proceed.

MR. FOWLER: Thank you, Madam Chair, Commissioner Baran, and Commissioner Burns. Thank you for your time. I'd ask that Mr. Brown begin our summary statements and I'll conclude.

MR. BROWN: Again, I'm Roy Brown with Curium Pharmaceuticals. I want to thank you again for the opportunity to speak with you today. Moly-99 and tech-99m remain the most important radionuclides in nuclear medicine today and will be for quite some time into the future.

Having a domestic, reliable supply of moly-99 is critically important to patients worldwide. Operational issues at foreign reactors and moly-99 processes such as those we're seeing right now today in South Africa and Australia emphasize the importance of increased capacity and domestic production of moly.

As I said in my opening remarks, we have been closely following the development of Northwest

Medical Isotopes' project. Northwest's proposed project will provide a consistent, reliable, and less interrupted supply of moly-99 for U.S. patients.

Curium believes Northwest's technology offers distinct advantages because it is based on a well-proven fission method of moly-99 production and uses existing reactors.

Curium encourages the Commission to issue Northwest their construction permit. Thank you very much.

MR. FOWLER: Thank you, Mr. Brown. Several presenters during the day have established the critical need for moly-99 and its importance to the medical community. I believe several presenters have also established the desirability of a domestic source. Northwest Medical Isotopes desires to be that domestic, secure, and reliable source of moly-99.

We do pride ourselves on professionalism and competency. We hope that is reflected through our submission for a construction permit application in this process.

We intend to be a stalwart member of the city of Columbia community and are very grateful to that community, the city of Columbia, Boone County, the state of Missouri Economic Development

Organization, as well as Senator McCaskill from the state of Missouri and Senator Wyden from the state of Oregon for their letters of support and confirmation of our intended action in Missouri.

On behalf of Northwest Medical Isotopes, we ask respectfully that you provide this application favorable consideration. Thank you for your attention and your questions today.

CHAIRMAN SVINICKI: Thank you very much for those closing statements and to all the witnesses for the applicant. I would now ask the NRC staff to occupy the positions at the table and Michelle, if you would like to lead off the staff in their closing statement, please proceed.

MS. EVANS: Thank you, Chairman. So first of all, we had a few open questions from this afternoon's discussion that we wanted to address, so Steve Lynch and Michael Balazik are joining me here at the table, and I'll turn to Steve to start.

MR. LYNCH: Sure, I just wanted to briefly provide some clarification on the relationship between the 10 CFR Part 50 and 10 CFR Part 70 requirements as they apply to the construction of this facility.

So the issuance of a 10 CFR Part 50 construction permit to Northwest would only authorize

the construction of the proposed Northwest production facility.

The construction permit would not authorize Northwest to construct areas of its facility where target fabrication activities would occur. Instead, the regulations of 10 CFR Part 70 would apply. The 10 CFR Part 70 regulations do not require authorization prior to commencement of construction of the Northwest target fabrication area.

Rather, the Part 70 regulations discourage the commencement of construction as defined in 10 CFR 70.4 for certain facilities in which Part 70 activities are conducted, including processes similar to fuel fabrication and scrap recovery, until the staff has made its environmental findings.

If construction were to begin before such findings were made, there could be grounds for denial of the request to Part 70 license.

To address potential delays associated with the commencement of construction of the Part 70 target fabrication area and the certainty of the staff's consideration of future Part 70 application, Northwest has submitted an exemption request from the requirements of 70.21(f) which are separate from the staff's considerations for the Part 50 construction

permit.

If Northwest proceeds with construction of the Part 70 target fabrication area prior to or without an exemption from 70.21(f), it would do so at its own risk.

The staff expects that any future Part 70 application for its target fabrication area would include all required safety and environmental information to support the issuance of a 10 CFR Part 70 license.

MR. BALAZIK: This is Mike Balazik, and Commissioner Baran, I just want to provide additional information on the stack questions you asked earlier.

10 CFR 50.35(b) states that a construction permit does not constitute approval of safety and any design feature at this point of a preliminary design. With respect to the impact of the stack height on radiological releases, the staff notes that the applicant did not request and the staff has not approved the safety of any design feature at this time.

Based on the staff's review of the potential radiological releases at the Northwest facility, the staff finds that Northwest has provided an adequate preliminary design, including the

identification of structures, systems, and components, and the application of quality level classifications to protect the health and safety of the public.

With respect to the stack, the staff believes that Northwest has appropriately designated this item as an item relied on for safety. Now, however, as this design matures, you may see some changes in those. There is the potential for that.

The staff finds that this designation of an item relied on for safety, in combination with Northwest's commitment to meet the Part 20 dose requirements for accident is sufficient for the issuance of a construction permit, and additional information may be reasonably asked for later in review of the final design as provided in 10 CFR 50.35(a). Thank you.

MS. EVANS: Okay, the staff review of the Northwest construction permit application supports the national policy objectives of establishing a domestic supply of moly-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's use of integrated safety analysis methodologies, the 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 the 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 the 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, and that concludes our closing remarks. Thank you.

CHAIRMAN SVINICKI: Well, thank you to the applicant and the staff for those closing remarks, and in the case of the NRC staff, for those clarifying comments. Prior to recognizing my colleagues for any closing remarks they would wish to make, I would ask if either of my colleagues have questions based on these closing statements or the clarifications that we've heard?

COMMISSIONER BURNS: Yes, Chairman, I do.

CHAIRMAN SVINICKI: Yes, Commissioner Burns?

COMMISSIONER BURNS: I have two or three actually given the explanation Mr. Lynch gave here, so I want to make sure I understand the staff's position.

So assuming that the Commission takes favorable action on the Part 50 construction permit, as I understand it, the staff's position would be that Northwest Medical should not disturb the land on which the Part 70 portion of the facility would exist pending action on its amendment, exemption request, or if it does so, it would do so at its own risk.

MR. LYNCH: With the clarification at the end of your statement there that they would do so at their own risk, that is correct. The staff does not believe that there should be any prohibition placed on Northwest to begin construction or disturb the land.

COMMISSIONER BURNS: Okay, and what is the staff's schedule for acting on the exemption?

MR. LYNCH: So at this time, we are in the process of performing our docketing acceptance review. I believe the application was entered into ADAMS on December 28, and we are working on a 45-day acceptance review schedule, so our next step is to have a call with the applicant to discuss the status of the request.

COMMISSIONER BURNS: And what would be

once - let's assume that the exemption request is accepted for review, what is the staff's typical review period?

MR. LYNCH: In previous exemption requests that are of a more administrative nature, generally the quickest that the staff would review such a request would be in two to three months.

COMMISSIONER BURNS: Okay, finally, this actually goes to Northwest Medical. During your presentation, we talked about, I think, both the environmental, but I think the overview.

There was a discussion on not only the necessity for Oregon State and the University of Missouri for potential amendments of research reactors, but also potential modifications to the Certificate of Compliance on the casks for shipment.

My question actually is not so much about what the complexity of that might be, but is there the cask capacity, if you will, is there, have you assessed the supply of casks and availability that would, from your assessment, if and when the project goes forward and goes into operation, are sufficient casks available for the needs that you would have?

MS. HAASS: We will actually - we are in the process of our documentation and contracts to

start getting those fabricated.

COMMISSIONER BURNS: Okay, all right, thank you. Is there some estimate without - I'm not trying to get you to reveal proprietary information, but is there some estimate of what your kind of need would be for numbers of casks?

MS. HAASS: I would say that's more on a proprietary nature -

COMMISSIONER BURNS: Okay.

MS. HAASS: - in what we're doing because it's part of our business model.

COMMISSIONER BURNS: Okay, all right, thanks. I'll leave it at that. Thank you, Chairman.

CHAIRMAN SVINICKI: Okay, I thought the clarifying statement was very helpful, and now I'm not sure, and Commissioner Baran would also like now to have a follow up question. I'll withhold mine. I'll read the transcript and then I'll look quickly to see if there's a post hearing question.

COMMISSIONER BARAN: No, it's a quick question to follow up on Commissioner Burns' questions. So recognizing that the exemption request is a separate licensing action and that you're still in acceptance review on that, would you foresee the analysis of that request relying on the EIS from this

licensing action given that it looked at the Part 70 aspects of the facility?

MR. LYNCH: Sure, we definitely could leverage our previous environmental impact statement as we consider the environmental aspects associated with the exemption request.

COMMISSIONER BARAN: Okay, that was my question. Thanks.

CHAIRMAN SVINICKI: Okay, thank you, and so now I would recognize my colleagues for any closing remarks they would like to make, and I'll begin by my list here with Commissioner Burns.

COMMISSIONER BURNS: I want to thank both the staff and the applicant for their presentation and testimony here today. We've covered, I think, a number of issues, you know, that bear on the somewhat unique aspects of this facility.

I would note, as the staff recognized as one of the things it considers during its NEPA review, that we have national policy that is intended to improve the availability of medical isotopes for protection of public health and their availability in diagnostic and therapeutic treatment. We currently, I think, as the numbers say, we consume more than 50 percent of the world's supply.

I would also note beyond national policy, because one of the last things I worked on when I was at the OECD, but under the Organization of Economic Cooperation and Development, sponsored a joint declaration on isotope availability of which the United States was a signatory, as well as a number of other producing and consuming countries. So I think not only is there a national policy, but an international interest in moving forward in this area.

Obviously, whether we come to an ultimate decision on operation, there is still some steps ahead of us and ahead of the application, but I think I appreciate the opportunity today to hear from both the applicant and the staff with respect to this facility and the plans for it. Thank you.

CHAIRMAN SVINICKI: Thank you. Commissioner Baran?

COMMISSIONER BARAN: Before I give a very brief closing, I will just give the staff an opportunity. It looked like you were getting ready to further elaborate on this question, and feel free to do to.

MR. TIKTINSKY: Thank you. This is David Tiktinsky of the Office of Nuclear Material Safety and Safeguards. I wanted to just clarify the words of

land disturbance. So construction in 70.4 is defined specifically as any other activity at the site of a facility subject to regulations in this part that has an exception nexus to radiological health and safety and common defense and security.

So other areas, they also specifically define things that aren't considered construction, and things like land disturbance, and site exploration, and erection of fences in preparation of the site is not considered construction, so I just wanted to clarify that.

COMMISSIONER BURNS: Okay, thank you.

MR. TIKTINSKY: Land disturbance is not construction in terms of Part 70.

COMMISSIONER BURNS: Building walls and pouring concrete?

MR. TIKTINSKY: Yes, that is nexus, yes.

COMMISSIONER BURNS: Okay, thank you.

COMMISSIONER BARAN: With that, I just want to briefly thank the staff for all their hard work throughout the review of this application, and I want to thank all of today's participants for your thorough preparation for this important hearing. It's very much appreciated, and thanks again.

CHAIRMAN SVINICKI: All right, before I

make some brief procedural announcements at the very end, let me also provide some general closing remarks as a member of the Commission.

I want to commend the applicant for a very vigorous preparation, and defense, and response to the Commission's questions today. I also thank the NRC staff, all of the witnesses, but also all of the staff who contributed to the work that was discussed here today. It's a tremendous effort.

And I always like to acknowledge the hard work of our Office of the Secretary of the Commission and the Office of Commission Appellate Adjudication which are so pivotal to supporting the Commission in its preparation and work to conduct a hearing such as today, and also all of the administrative professionals throughout the Agency who support all of us in the logistics of the important work that's carried on by the Agency.

I will also comment as Commissioner Burns did on what Michelle termed the national policy objectives of the United States having some production capability. Consuming over half of something and having no production capability doesn't seem like the most resilient posture for any country, so that is at work here, but -

And whether or not any of us ever walk into a nuclear power plant, the chance that we're going to be a patient having some sort of, if not therapeutic, at a minimum, a nuclear medicine diagnostic procedure is highly likely for any individual in this country because we have such medical access that that's available to us, which is also a great blessing. But in any event, Congress has identified that this is an area that the U.S. should work to rectify.

While all of that is going on, however, it is the NRC's unique role and the obligation of the NRC staff to look in a very searching way at the safety of the proposed facility and its environmental impacts at this construction permit stage, and I thank them for the thoroughness with which they responded to the Commission's questions today.

To the extent that for members of the public, it looks like confusion reigned a bit on our deep knowledge of the various aspects of our regulations, I think I would observe that our regulations are very thorough. We just want to be sure that we're applying the right components.

There aren't really, in my view, any gaps. There's nothing that's falling through the cracks.

It's a very, very rigorous regulatory framework, and we just want to make sure that we are approaching it under the appropriate relevant regulations, so that's been some of the byplay.

We do have also our post hearing question opportunities. So it may be as I study the back and forth, I may have some questions that I will submit just for clarification to the record today.

Sometimes as I listen to the responses to others' questions, and this tends to happen, is you think you understand it. Someone else phrases a question differently, you hear the response, and then you say, "Okay, that isn't 100 percent what I understood." So we will have a chance to pose those as post hearing questions.

So moving to that procedural matter, I will state that in closing and for the information of the parties, the deadline for responses to any post hearing questions will be February 6, 2018 unless the Commission directs otherwise.

The Secretary of the Commission plans to issue an order with post hearing questions, if any, by January 30, 2019. The deadline for transcript corrections will be February 5. The Secretary plans to issue an order requesting proposed transcript

corrections by January 29.

As I mentioned this morning, the Commission expects to issue a final decision promptly with due regard to the complexity of the issues. Thank you all again, and the hearing is adjourned.

(Whereupon, the above-entitled matter went off the record at 3:18 p.m.)

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 **ORDER (Setting Deadline for Proposed Transcript Corrections)** have been served upon the following persons by Electronic Information Exchange.

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Office of the Secretary of the Commission

Dated at Rockville, Maryland,
this 29th day of January, 2018