

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

+ + + + +

TUESDAY,

JANUARY 23, 2018

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

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

1 NRC STAFF:
2 ALEXANDER ADAMS, JR., Chief, Research and Test
3 Reactors Licensing Branch, NRR
4 MICHAEL BALAZIK, Project Manager, Research and Test
5 Reactors Licensing Branch, NRR
6 BENJAMIN BEASLEY, Chief, Environmental Review and
7 NEPA Branch, NRR
8 JOSEPH DONOGHUE, Deputy Director, Division of
9 Materials and License Renewal, NRR
10 DAVID DRUCKER, Senior Project Manager, NRR
11 MICHELE EVANS, Deputy Director for Reactor Safety
12 Programs and Mission Support, NRR
13 JAMES HAMMELMAN, Senior Chemical Engineer, Fuel
14 Manufacturing Branch, NMSS
15 STEVEN LYNCH, Project Manager, Research and Test
16 Reactors Licensing Branch, NRR
17 NANCY MARTINEZ, Physical Scientist, NRR
18 MICHELLE MOSER, Biologist, NRR
19 MARY JANE ROSS-LEE, Deputy Director, Division of
20 Materials and License Renewal, NRR
21 APRIL SMITH, Reliability and Risk Analyst,
22 Programmatic Oversight and Regional Support
23 Branch, NMSS
24
25

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

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

6 JEREMY L. WACHUTKA, Counsel for NRC Staff

7

8 NWMI REPRESENTATIVES:

9 ROY BROWN, Curium Pharma

10 MICHAEL CORUM, Senior Technical Advisor, NWMI

11 GARY DUNFORD, Process Engineering Manager, NWMI

12 NICHOLAS FOWLER, CEO, NWMI

13 CAROLYN HAASS, COO, NWMI

14 STEVEN REESE, Irradiation Services Manager, NWMI

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P R O C E E D I N G S

9:02 a.m.

1
2
3 CHAIRMAN SVINICKI: Well good morning,
4 everyone. I call this hearing to order. I want to
5 welcome the applicant, Northwest Medical Isotopes,
6 LLC, the NRC staff, members of the public in the room
7 with us, and those who are observing this proceeding
8 remotely.

9 The Commission convenes today to conduct
10 an evidentiary hearing on Northwest Medical Isotopes'
11 construction permit application for a medical
12 radioisotope production facility in Columbia,
13 Missouri. This hearing is required under Section
14 189(a) of the Atomic Energy Act of 1954, as amended.

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

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

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

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

7 On the safety side, the Commission will
8 determine whether, in accordance with 10 CFR Section
9 50.35(a), (1) the applicant has described the proposed
10 design of the facility, including the principal
11 architectural and engineering criteria for the design
12 and has identified the major features or components
13 incorporated there for the protection of the health
14 and safety of the public; (2) such further technical
15 or design information as may be required to complete
16 the safety analysis, and which can reasonably be left
17 for later consideration, will be supplied in the final
18 Safety Analysis Report; (3) safety features or
19 components, if any, that require research and
20 development have been described by the applicant and
21 the applicant has identified, and there will be
22 conducted, a research and development program
23 reasonably designed to resolve any safety questions
24 associated with such features or components; and (4)
25 on the basis of the foregoing, there is reasonable

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1 assurance that such safety questions will be
2 satisfactorily resolved at or before the latest date
3 stated in the application for completion of
4 construction of the proposed facility and, taking into
5 consideration the site criteria contained in 10 CFR
6 Part 100, the proposed facility can be constructed and
7 operated at the proposed location without undue risk
8 to the health and safety of the public; (5) in making
9 these findings, the Commission also will be guided by
10 the considerations in 10 CFR Section 50.40, which
11 include the Commission's determination as to whether
12 issuance of the construction permit will not be
13 inimical to the common defense and security or the
14 health and safety of the public.

15 On the environmental side, the Commission
16 will: (1) determine whether the requirements of the
17 National Environmental Policy Act Section
18 102(2)(a), (c), and (e) and the applicable regulations
19 in 10 CFR Part 51 have been met; (2) independently
20 consider the final balance among conflicting factors
21 contained in the record of the proceeding with a view
22 to determining the appropriate action to be taken; (3)
23 determine, after weighing the environmental, economic,
24 technical, and other benefits against environmental
25 and other costs, and considering reasonable

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1 alternatives, whether the construction permit should
2 be issued, denied, or appropriately conditioned to
3 protect environmental values; and (4) determine
4 whether the need for review conducted by the NRC staff
5 has been adequate.

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

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

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

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

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1 So counsel for the NRC staff, please
2 introduce yourself.

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

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

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

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

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

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

6 Thank you, you may put your hands down.

7 Are there any witnesses who did not take
8 the oath?

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

11 MS. HAASS: No.

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

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

20 MR. WACHUTKA: There are no changes.

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

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

25 CHAIRMAN SVINICKI: Is there a motion to

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1 admit the exhibits into the record?

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

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

7 MS. HAASS: No, there is not.

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

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

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

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

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

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

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1 read, I would ask that you also stand.

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

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

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

11 Thank you. You may put your hands down.

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

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

18 MR. WACHUTKA: There are no objections.

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

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

25 MS. HAASS: No, there is not.

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

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

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

7 MS. HAASS: Yes.

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

11 MR. WACHUTKA: There are no objections.

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

16 Counsel for the staff is excused.

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

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

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

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

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

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

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

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

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1 introduce yourself, if you have not already done so.

2 So, Ms. Haass, your panel may proceed.

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

6 CHAIRMAN SVINICKI: Thank you. Please
7 proceed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 product.

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

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

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

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

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1 Isotopes as being a significant and anchor tenant.

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

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

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

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

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

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

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

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

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

25 A domestic production capacity for moly-99

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

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

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

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

25 In addition, the novel chemistry of

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

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

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

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

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

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

4 MS. HAASS: No, it does not.

5 CHAIRMAN SVINICKI: Okay.

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

10 CHAIRMAN SVINICKI: Okay, thank you.
11 Please proceed.

12 MS. HAASS: Okay, can we please go to page
13 5?

14 So Northwest Medical Isotopes, what we are
15 doing is we are seeking authorization for us to
16 construction and eventually operate a production under
17 10 CFR Part 50. And in this production facility,
18 there are five primary activities that will be
19 completed under the Part 50. One is we will receive
20 irradiated low-enriched uranium targets from the
21 network of universities that Nick has indicated
22 previously. We would then process those irradiated
23 LEU targets and that means in processing we would
24 dissolve them. We would recover and purify the moly.
25 Then we would like to recover and recycle the low-

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

6 Page 6, please.

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

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

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

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

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

13 In developing this document, we used
14 NUREG-1537 and the associated Interim Staff Guidance
15 that was developed, as well as NUREG-1520. We
16 completed an ISA for the entire facility. We didn't
17 just focus on the 50. We did it for both the 50 and
18 70 portions of the facility.

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

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

25 Page 7 shows a very high-level schedule

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

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

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

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

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

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

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

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

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

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

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

5 But that is the primary activities of our
6 facility.

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

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

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

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

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

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

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

21 There is a basement area within this
22 52,000 square feet and it's where our tank hot cell
23 is. This is where all our critically-safe tanks are
24 for uranium recycle and recovery, and some other
25 things.

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

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

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

12 Some basic stats on the facility. It's
13 about a 65-foot in height facility. The stack will be
14 75 feet. There is loading docks and it's about 15
15 feet below grade. That's about how far we go under.

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

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

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

25 So we can divide into basically three

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

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

10 And then the final part is radioactive
11 waste.

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

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

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

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

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

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

16 If I may have slide 13, please.

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

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

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

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

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

18 Finally, moving to the last slide, slide
19 14, the last thing we wanted to go over in the
20 overview was quality assurance program. We have a
21 quality assurance program that follows 15.8, which is
22 the Quality Assurance Program Requirements for
23 Research Reactors because that is the group under
24 which we are getting licensed. It follows Reg Guide
25 2.5 which is the associated reg guide for that quality

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 of things, but those things can be worked through.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 COMMISSIONER BARAN: -- for both aspects
20 of it.

21 MR. REESE: Yes.

22 COMMISSIONER BARAN: Okay.

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

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

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

10 MR. REESE: Could you repeat that?

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

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

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

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

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

8 COMMISSIONER BARAN: Okay, thank you very
9 much.

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

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

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

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

25 We initiated the selection of the sites

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

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

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

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

25 MS. HAASS: Actually, no, I think you

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

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

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

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

22 COMMISSIONER BURNS: Thank you for that.

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

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

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

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

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

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

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

7 COMMISSIONER BURNS: Okay, thanks.

8 MR. FOWLER: And if I could --

9 COMMISSIONER BURNS: Sure, Mr. Fowler.

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

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

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

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

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

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

19 COMMISSIONER BURNS: Okay.

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

25 COMMISSIONER BURNS: Thank you.

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

10 So what I think will likely happen is a
11 Part 50 license will be issued with that, whereby we
12 have to meet all the requirements of Part 70 and Part
13 30 underneath that Part 50 license.

14 But it also was identified that the Part
15 70 area that was shown in the graphic is essentially
16 just doing Part 70 and nothing else.

17 So with that in mind and because there was
18 an ability for one to reasonably and intellectually
19 walk that off, such that there is no activities
20 associated with basically anything other than Part 70,
21 there was a decision made that that section alone
22 would have a separate Part 70 license and only a Part
23 70 license. So we are in a situation where we have
24 one building and we're going to have two licenses, one
25 Part 70 and one Part 50, which is the reason why we've

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1 been using that language back and forth this morning.

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

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

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

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

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

25 Michele, please proceed.

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

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

7 Okay, so with me at the table this morning
8 are Mary Jane Ross-Lee, Joe Donoghue, and Brian Smith.
9 This panel will provide context for the role of the
10 U.S. Regulatory Commission or the NRC in domestic
11 efforts to establish a reliable supply of molybdenum-
12 99, also referred as moly-99.

13 We will introduce the methodology that the
14 NRC staff used in its review of the Northwest Medical
15 Isotopes construction permit application and introduce
16 the unique aspects of the staff's safety and
17 environmental reviews that will be discussed further
18 in the panels to follow.

19 Next slide, please.

20 Moly-99 decays into technetium-99
21 metastable, the most widely used medical radioisotope
22 in the world. Technetium-99m is used in approximately
23 50,000 imaging procedures daily in the United States,
24 accounting for about one-half of the global demand.
25 Technetium-99m is an effective diagnostic tool because

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

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

9 Next slide.

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

14 In 2016, the NRC issued a 10 CFR Part 50
15 construction permit to SHINE Medical Technologies, or
16 SHINE, for the production of moly-99 using up to eight
17 accelerator-driven subcritical irradiation units in
18 one production facility.

19 Since 2015, the staff has been actively
20 reviewing a second medical radioisotope construction
21 permit application submitted by Northwest Medical
22 Isotopes, which going forward we will refer to as
23 Northwest or NWMI. If granted, this construction
24 permit would allow Northwest to build a 10 CFR Part 50
25 production facility in Columbia, Missouri. Once

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1 constructed, this facility would be used to produce
2 moly-99 from low-enriched uranium targets that have
3 been irradiated at existing research reactors.

4 Next slide.

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

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

10 The staff review of the Northwest
11 construction permit application was supported by
12 procedural efficiencies and lessons learned from
13 previous reviews. For example, the staff docketed a
14 Northwest construction permit application in two
15 parts. Part 1 of the application consisted primarily
16 of the Northwest environmental report and general
17 information required by 10 CFR 50.33 and was docketed
18 in June of 2015. Part 2 of the application contained
19 the Northwest Preliminary Safety Analysis Report or
20 PSAR and was docketed in December of 2015.

21 This two-part application process
22 submission enabled the staff to begin its
23 environmental review months before the docketing of
24 the full application and the commencement of the
25 safety review.

1 Additionally, based on its experience with
2 SHINE review, the staff was able to use previously
3 developed document templates to draft its Safety
4 Evaluation Report and Environmental Impact Statement
5 and to issue clear, focused Requests for Additional
6 Information.

7 The staff also applied insights gained
8 from the development of its Non-Power Production and
9 Utilization Facility Construction Oversight Program to
10 the review of the Northwest construction permit
11 application. For example, in December 2015, the staff
12 published Inspection Manual Chapter 2550, establishing
13 a construction inspection program for non-power
14 production and utilization facilities. One of the
15 objectives of this construction inspection program is
16 to verify whether a licensee adequately implements its
17 quality assurance program during the construction of
18 its facility.

19 Therefore, to ensure the implementation of
20 the program and to be consistent with Part 50
21 requirements for other Part 50 facilities, the staff
22 recommends that the Northwest construction permit be
23 conditioned to require the implementation of a quality
24 assurance program described in the Northwest PSAR.

25 The staff completed its review within 23

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1 months from the docketing of the application and spent
2 approximately 10,000 hours reviewing the application.
3 NRC contractors spent an additional 2,000 hours in
4 support of the staff review.

5 Next slide, please.

6 Northwest seeks authorization to construct
7 a 10 CFR Part 50 production facility. NRC regulations
8 require less detail for a Part 50 construction permit
9 application than for a Part 50 operating license
10 application or a Part 52 combined license application,
11 particularly when the applicant does not seek approval
12 of the final design.

13 The required content of a construction
14 permit application is specified in Section 50.34 and
15 includes the preliminary design of the facility; a
16 preliminary analysis of structures, systems, and
17 components; probable subjects of technical
18 specifications; a preliminary emergency plan; a
19 quality assurance; and ongoing research and
20 development.

21 The Northwest application also describes
22 activities to be conducted within a target fabrication
23 area under a 10 CFR Part 70 licensed to be located in
24 the same building as its proposed production facility.
25 Northwest stated that it will submit this Part 70

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1 application at a later date.

2 As part of its construction permit safety
3 review, the staff focused on the interface between the
4 production facility and target fabrication processes,
5 as well as the impact of the target fabrication
6 processes on the production facility. However, the
7 staff's findings and conclusions in its Safety
8 Evaluation Report are limited to whether the Northwest
9 production facility satisfies the Part 50 requirements
10 for the issuance of a construction permit.

11 In its environmental review, the staff
12 considered both the potential environmental impacts
13 from the construction of the Part 50 production
14 facility and also the actions connected to the
15 issuance of a construction permit.

16 As documented in staff's final
17 Environmental Impact Statement or EIS, connected
18 actions, in part, include the construction,
19 operations, and decommissioning related to the Part 70
20 target fabrication area.

21 Based on the information that Northwest
22 has provided to date, Part 70, not Part 50, would
23 govern the possession and use of special nuclear
24 material in the portions of the site where target
25 fabrication activities would occur. If Northwest were

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1 to commence construction on the portions of the site
2 where target fabrication activities would occur, the
3 ability of the staff to conduct future environmental
4 and safety reviews of the Part 70 application for the
5 target fabrication area would not be affected.
6 However, the commencement of construction of the
7 target fabrication area prior to the staff completing
8 its environmental review of a Part 70 license
9 application for the target fabrication activities may
10 be grounds for the denial of a Part 70 license, if
11 Northwest does not obtain an exemption.

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

16 Next slide, please.

17 The staff evaluation of the Northwest
18 construction permit application consisted of two
19 concurrent technical reviews; one, a safety review
20 based on the Northwest PSAR and the other, an
21 environmental review, based on Northwest's
22 environmental report.

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

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1 The staff safety review assessed the
2 sufficiency of the preliminary design, including the
3 principle design criteria and design basis of the
4 proposed Northwest production facility. The staff
5 safety review was also subject to an independent
6 review by the Advisory Committee on Reactor
7 Safeguards. The Committee concluded that the
8 Northwest had demonstrated knowledge of potential
9 hazards and accidents and of safety requirements and
10 that the topics that the committee had identified
11 during its review were documented by the staff and
12 Northwest. The staff will consider those technical
13 areas undergoing final design during its review of a
14 Northwest Final Safety Analysis Report, or FSAR,
15 submitted as a part of an operating license
16 application.

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

20 Next slide, please.

21 The staff safety review of the Northwest
22 construction permit application considered the
23 physical, radiological, chemical, and licensing
24 processes of the proposed facility. Given the
25 similarities between the proposed Northwest Part 50

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1 production facility and existing Part 70 fuel cycle
2 facilities, the staff adapted existing guidance
3 documents to accommodate this unique combination of
4 technical and licensing considerations.

5 Specifically, the staff conducted its
6 review by using guidance contained in NUREG-1537,
7 which is the standard review plan for non-power
8 reactors; the Interim Staff Guidance, or ISG,
9 augmenting NUREG-1537, which contains the standard
10 review plan for medical radioisotope production
11 facilities; and NUREG-1520, which is the standard
12 review plan for fuel cycle facilities.

13 In applying this guidance, the staff
14 exercises judgment to determine the applicability of
15 acceptance criteria and evaluation findings. The
16 staff also exercises judgment determining the level of
17 detail needed for a preliminary versus a final design
18 in the safety review of the Northwest construction
19 permit application.

20 To support the issuance of a construction
21 permit, the staff evaluated the descriptions and
22 discussions of the Northwest structures, systems, and
23 components with special attention to the design and
24 operating characteristics, unusual or novel design
25 features, and principal safety considerations. The

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1 preliminary design of the Northwest production
2 facility was evaluated to assure the sufficiency of
3 principal design criteria, design basis, and
4 information relative to materials of construction,
5 general arrangement, and approximate dimensions as
6 required by 10 CFR 50.34(a).

7 The staff also evaluated the sufficiency
8 of the preliminary design to provide reasonable
9 assurance that the Northwest final design would
10 conform to the design basis.

11 Next slide, please.

12 An important part of the staff's safety
13 review is determining what additional technical and
14 design information not initially provided in the
15 Northwest PSAR was necessary to support the issuance
16 of a construction permit. To this end, the staff
17 requested additional information and Northwest revised
18 its application, as needed, in response to these
19 requests.

20 The staff determined that with the
21 additional information, Northwest has provided the
22 information necessary for the staff to complete its
23 safety review. The staff concluded that a
24 construction permit should be issued, provided that it
25 include certain permit conditions to support the staff

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1 finding of reasonable assurance for the licensing
2 action.

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

13 Additionally, based on the Commission
14 prehearing questions, the staff now recommends that
15 the construction permit be conditioned to require that
16 prior to the beginning of construction, Northwest
17 complete and submit to the NRC the results of a site-
18 specific geotechnical investigation. This condition
19 would require that the results of the geotechnical
20 investigation be available to enable Northwest to
21 identify sinkhole potential, soil characteristics, and
22 liquefaction potential at the site that could impact
23 the design of the facility before Northwest begins
24 construction.

25 Consistent with 10 CFR 50.35, the

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1 recommended conditions would ensure that Northwest
2 conforms to the final design of its -- confirms that
3 the final design of its facility would conform to the
4 design basis as the design matures.

5 In instances where additional information
6 may reasonably be left for later consideration in the
7 FSAR, Northwest has made commitments to provide such
8 information. These commitments are listed in Appendix
9 A of the Safety Evaluation Report and the staff will
10 verify that they have been addressed during its review
11 of the Northwest operating license application.

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

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

17 The environmental review of the Northwest
18 10 CFR Part 50 construction permit application was
19 performed in accordance with the National
20 Environmental Policy Act of 1969, commonly referred to
21 as NEPA. NEPA requires that agency decisionmaking
22 include the consideration of the environmental impacts
23 of federal actions. NEPA also requires federal
24 agencies to follow a systematic approach in evaluating
25 potential impacts and to assess alternatives to their

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1 actions. The NEPA process involves public
2 participation during prescribed periods and public
3 disclosure.

4 The NRC regulations implementing NEPA are
5 set forth in 10 CFR Part 51. These regulations
6 describe when the staff should prepare an EIS, or
7 environmental assessment. NRC regulations do not
8 require the preparation of an EIS for the issuance of
9 a Part 50 construction permit for a medical isotope
10 production facility; however, the staff determined
11 that an EIS would be appropriate for the Northwest
12 Part 50 construction permit and application for two
13 reasons: 1) an environmental assessment might not
14 support a finding of no significant impact; and 2)
15 operation of the Northwest facility, which would be a
16 connected action to the construction of the facility,
17 would include the possession and use of special
18 nuclear material for target fabrication and scrap
19 recovery, processes similar to those used at fuel
20 fabrication facilities.

21 Notably, the issuance of a license to
22 possess and use special nuclear material for scrap
23 recovery requires an EIS to be prepared in accordance
24 with 10 CFR 51.20(b) and (7). The purpose of the
25 environmental review is to identify the environmental

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1 impacts of constructing the proposed facility and the
2 impacts of the connected actions of operating and
3 decommissioning the facility, as well as alternatives
4 for the facilities.

5 In combination with the safety review, the
6 environmental review will inform the staff
7 recommendation to the commission of whether to issue
8 the construction permit.

9 Next slide, please.

10 The environmental review process for
11 preparing an EIS was conducted in accordance with 10
12 CFR Part 51. As depicted on the slide, there was a
13 scoping period to gather input from the public, other
14 governmental agencies, and tribes regarding the scope
15 of the EIS. The staff conducted an environmental site
16 audit to view the environmental features of the
17 proposed site and the alternative sites.

18 In addition, the staff developed Requests
19 for Additional Information to clarify information in
20 the Northwest environmental report and to seek
21 additional information not included in the Northwest
22 environmental report. Based on this information, the
23 staff published the draft EIS for public comment in
24 October of 2016. The staff responded to all comments
25 received in the final EIS, which was published in May

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1 2017. The staff also updated the final EIS in
2 response to the comments.

3 Next slide, please.

4 The proposed site is located approximately
5 three miles southeast of the city of Columbia,
6 Missouri and is owned by the University of Missouri.
7 The proposed site consists of previously disturbed
8 agricultural lands. The proposed site does not
9 contain any surface water features, no threatened or
10 endangered species, or no historical or cultural
11 resources.

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

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

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

24 Section 103 of the Atomic Energy Act
25 authorizes the Commission to issue licenses for

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1 production facilities subject to the Commission
2 regulations. The principal safety requirements
3 applicable to construction permits for production
4 facilities are contained in 10 CFR Parts 20 and 50.
5 The applicable environmental requirements are
6 contained in 10 CFR Part 51.

7 After completing the required safety and
8 environmental reviews, the staff determined that the
9 Northwest application met the applicable requirements
10 in 10 CFR Parts 20, 50, and 51. This determination
11 was reached, in part, by applying the guidance in the
12 ISG augmenting NUREG-1537, the standard review plan
13 for medical radioisotope production facilities. This
14 guidance allows applicants to use the performance
15 requirements of 10 CFR 70.61 to demonstrate adequate
16 safety for a medical radioisotope production facility,
17 particularly with respect to postulated accidents.

18 For example, the performance requirements
19 of 10 CFR 70.61 can be used to establish criteria to
20 protect against chemical hazards and ensure
21 subcriticality under normal and credible abnormal
22 conditions.

23 Next slide, please.

24 The staff review supports the four
25 findings required by 10 CRF 50.35 for the issuance of

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1 a construction permit. The first finding is that the
2 applicant has described the proposed design of the
3 facility. The staff used 10 CFR 50.34(a) and its
4 guidance to evaluate the sufficiency of the Northwest
5 preliminary design, making sure that its proposed
6 design bases and criteria are consistent with NRC
7 regulations and guidance.

8 Based on its review, the staff concludes
9 that Northwest has described the proposed design of
10 the facility, including but not limited to the
11 principal, architectural, and engineering criteria for
12 the design and has identified the major features or
13 components incorporated therein for the protection of
14 the health and safety of the public.

15 The second finding is that the applicant
16 has identified technical or design information that
17 can reasonably be left for later consideration in the
18 FSAR. The PSAR identified such information. This
19 includes, for example, the security and emergency
20 plans, facility operating procedures, and certain
21 design information that Northwest committed to provide
22 in the FSAR. As discussed, these commitments are
23 listed in Appendix A of the Safety Evaluation Report
24 and the staff will confirm that Northwest addresses
25 these items in its FSAR.

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1 The third finding is that the applicant
2 has identified safety features that required further
3 research and development. While Northwest did not
4 identify any structures, systems, or components that
5 require research and development to confirm the
6 adequacy of the facility design, Northwest did
7 describe ongoing validation testing at the University
8 of Missouri, Columbia Research Reactor and, at the
9 Department of Energy National Laboratories, resin
10 testing and ion exchange column testing.

11 As described in the Safety Evaluation
12 Report, the staff is tracking these items and will
13 verify their resolution prior to the completion of
14 construction as part of this review of an operating
15 license application.

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

24 Northwest has stated their latest date of
25 construction would be December 31, 2022. The staff

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1 expects that the Northwest testing programs will be
2 completed in advance of this date. The additional
3 permit conditions related to criticality safety must
4 also be satisfied prior to the completion of
5 construction.

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

14 Northwest intends to design its facility
15 such that potential doses to workers and the public
16 from postulated accidents are within the limits of 10
17 CFR Part 20. Chemical accident consequences would be
18 mitigated consistent with the performance requirements
19 of 10 CFR 70.61.

20 Northwest intends to select items relied
21 on for safety and appropriate management measures
22 based on the results of its integrated safety analysis
23 to mitigate potential radioactive and chemical
24 consequences resulting from accident conditions.
25 Thus, the staff finds that the proposed facility can

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

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

9 Next slide, please.

10 Based on these findings, the staff
11 concludes that there is sufficient information for the
12 Commission to issue the subject construction permit to
13 Northwest, as guided by the following considerations
14 described in 10 CFR 50.40 and 10 CFR 50.50. There is
15 reasonable assurance that the construction of the
16 Northwest Facility will not endanger the health and
17 safety of the public and that construction activities
18 can be conducted in compliance with the Commission
19 regulations.

20 Northwest is technically and financially
21 qualified to engage in the construction of its
22 proposed facility. The issuance of a permit for the
23 construction of the facility would not be inimical to
24 the common defense and security or the health and
25 safety of the public.

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1 After weighing the environmental,
2 economic, technical, and other benefits of the
3 facility against environmental and other costs, and
4 considering reasonable available alternatives, the
5 issuance of this construction permit subject to the
6 conditions for protection of the environment set forth
7 therein is in accordance with Subpart A of 10 CFR Part
8 51 of the Commission regulations and the application
9 meets the standards and requirements of the Atomic
10 Energy Act and the Commission regulations and that
11 notifications, if any, to other agencies or bodies
12 have been duly made.

13 Next slide, please.

14 In the panels that follow, the staff will
15 discuss novel aspects of its review of the Northwest
16 construction permit application. Safety Panel 1 will
17 discuss the unique licensing considerations associated
18 with the co-location of the proposed Northwest
19 production facility and target fabrication area. This
20 panel will also cover the implementation of the
21 Northwest quality assurance program plan and design
22 change management. The information presented in this
23 panel is described in greater detail in Chapters 1, 4,
24 and 12 of the staff's Safety Evaluation Report.

25 Additionally, Safety Panel 1 is also

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1 prepared to discussion Chapters 2, 3, 5, and 6 of the
2 Safety Evaluation Report.

3 Safety Panel 2 will follow this with
4 details on the accident analysis methodology, as
5 described in Chapter 13 of the Safety Evaluation
6 Report. Additionally, Safety Panel 2 is also prepared
7 to discuss Chapters 7, 8, 9, 11, 14, and 15 of the
8 Safety Evaluation Report.

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

14 This concludes the staff overview panel
15 and we are prepared to respond to any questions you
16 may have at this time.

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

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

21 COMMISSIONER BARAN: Thanks. Thank you
22 for your presentations.

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

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

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

8 MS. ROSS-LEE: That is correct.

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

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

20 MR. B. SMITH: Yes, sir.

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

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

25 COMMISSIONER BARAN: Okay. And has the

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

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

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

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

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

20 MR. LYNCH: Yes --

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

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

24 CHAIRMAN SVINICKI: Okay, thank you.

25 MR. LYNCH: My name is Steven Lynch and I

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

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

9 COMMISSIONER BARAN: Okay, great. Thank
10 you.

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

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

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

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

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

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

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

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

19 CHAIRMAN SVINICKI: Thank you very much.
20 Commissioner Burns.

21 COMMISSIONER BURNS: I'm going to follow-
22 up on that. Does the staff anticipate, if we get to
23 this stage, issuing a single license that covers Part
24 50, 70, 30 as it does with respect to power reactors?

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

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1 hesitate there is my history is Part 70 licensing
2 primarily, uranium-enrichment plant licensing, where
3 we issue a single license that cover Parts 30, 40, and
4 70.

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

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

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

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

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

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

24 MR. B. SMITH: Well --

25 COMMISSIONER BURNS: Actually, let me go

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Have I got this correct?

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

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

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

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

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

25 MR. BALAZIK: It's a totally separate

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1 point from the construction permit application.

2 MS. ROSS-LEE: I would -- yes, the action
3 before the Commission is for the Part 50 construction
4 permit. We are not asking, at this point, for
5 Commission consideration of the exemption under Part
6 70.

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

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

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

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

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

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

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

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

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

24 CHAIRMAN SVINICKI: Okay. All right,
25 thank you.

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

10 Two-step licensing is something that NRC
11 has been more focused on one-step licensing in the new
12 reactor area under Part 50 -- 52. So I think for Part
13 50, in some ways our predecessors who had to navigate
14 the level of detail and review for the construction
15 permit versus the level of detail and review for the
16 operating license, I think that organizations may be
17 this is something that we don't do as routinely. So
18 it is something that the staff had to navigate for
19 this application for SHINE and maybe for Watts Bar,
20 too, to a certain degree as well, which was also two-
21 step licensing in the last ten-year history of the
22 agency.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Again, there are any number of issues --

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

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

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

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

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

3 MS. ROSS-LEE: Yes.

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

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

14 CHAIRMAN SVINICKI: Okay, thank you very
15 much.

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

19 COMMISSIONER BURNS: Not now.

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

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

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

3 Thank you.

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

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

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

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

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

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

7 And can you please go to page 2?

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

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

22 Page 3, please.

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

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1 based upon applicable standards, guidance, code, and
2 criteria, such that reasonable assurance can be
3 provided that the structures, systems, and components,
4 SSCs, will perform as intended. So, we have to inform
5 our discussion of the SSCs as they relate to Chapter
6 13 as it relates to accidents and, also, normal
7 operations for protection of public safety and the
8 health environment and, also, occupational safety,
9 too, as well.

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

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

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

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

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

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

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

18 So, slide 6, please.

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

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

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

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

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

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

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

5 I guess my time is up.

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

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

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

16 MR. ADAMS: Good morning, Chairman and
17 Commissioners. My name is Al Adams.

18 This panel will discuss the unique
19 licensing considerations of the proposed Northwest
20 production facility. I will discuss the licensing
21 process and summarize the staff interactions with the
22 Advisory Committee on Reactor Safeguards, or the ACRS.

23 Michael Balazik, Dave Tiktinsky, and Steve
24 Lynch are with me at the table today.

25 Can I have slide 3, please?

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1 The 10 CFR Part 50 regulations define
2 three types of production facilities, one of which is
3 use for the processing of irradiate materials
4 containing special nuclear materials. Northwest seeks
5 to construct a Part 50 production facility that would
6 process irradiated low enriched uranium, or LEU,
7 targets for the recovery and purification of
8 molybdenum 99.

9 The construction permit licensing
10 requirements for the proposed Northwest production
11 facilities are similar to those for other non-power
12 facilities licensed under 10 CFR Part 50, such as
13 research reactors. However, unlike research reactors
14 licensed to perform research and development
15 activities under Section 104 of the Atomic Energy Act,
16 the Northwest production facility would be licensed to
17 commercially produce medical isotopes under Section
18 103 of the Atomic Energy Act. As such, the Northwest
19 construction permit application is also subject to an
20 independent review by the ACRS and a mandatory
21 hearing.

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

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1 Next slide, please.

2 The staff presented the results of its
3 Safety Review at four ACRS subcommittee meetings last
4 summer. As a result of ACRS subcommittee discussions,
5 the staff performed additional independent analysis of
6 the issues of aircraft impacts and seismic response to
7 confirm the adequacy of the Northwest production
8 facility design basis.

9 To confirm the seismic design of the
10 proposed Northwest production facility, the staff
11 developed a general seismic design response spectrum
12 incorporating site amplification factors of the
13 proposed site. The staff found that the seismic
14 response was acceptable for the issuance of a
15 construction permit because large facility structures,
16 components, and equipment would not be impacted.

17 However, the staff did identify a
18 potential high frequency seismic design response that
19 could impact smaller components, such as electrical
20 relays, piping, and instrumentation. The staff is
21 tracking this issue as a regulatory commitment in
22 Appendix A4 of its Safety Evaluation Report.

23 The staff also performed a confirmatory
24 analysis of the Northwest aircraft impact frequencies.
25 The total aircraft impact frequency calculated by the

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1 staff was greater than an order of magnitude of 10 to
2 the minus 7th per year. This is of the same order of
3 magnitude as that calculated by Northwest.

4 The staff finds that Northwest should
5 evaluate the impact of a general aviation crash in its
6 final design. Northwest states in its PSAR that the
7 general aviation crash will be evaluated in the
8 operating license application.

9 The staff presented the results of its
10 review of the Northwest construction permit
11 application to the ACRS full Committee on November
12 2nd, 2017. The ACRS recommended the issuance of a
13 construction permit in its letter dated November 6th,
14 2017, which is contained in Appendix D of the staff's
15 Safety Evaluation Report.

16 Next slide, please.

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

20 MR. BALAZIK: Thank you, Al.

21 My name is Michael Balazik.

22 Northwest proposes to irradiate low
23 enriched uranium targets at existing U.S. research
24 reactors. After irradiation, the targets would be
25 transported back to the Northwest facility. Northwest

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1 would, then, process these irradiated targets and
2 separate the molybdenum 99 from other fission products
3 in a portion of the proposed facility.

4 Because Northwest is proposing to process
5 irradiated special nuclear material in batch sizes of
6 greater than 100 grams of uranium 236, this portion of
7 the facility meets the definition of a production
8 facility as defined in 10 CFR 50.2.

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

14 To support its review, the staff used the
15 guidance in NUREG-1537, also the Interim Staff
16 Guidance augmenting NUREG-1537, and NUREG-1520. In
17 applying this guidance, the staff used its technical
18 judgment to determine the extent to which the guidance
19 was relevant to the review of the Northwest
20 construction permit application, because much of the
21 guidance was originally developed for completed
22 facility designs.

23 Next slide, please.

24 A unique licensing aspect of this review
25 is that the 10 CFR Part 50 construction permit

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1 application describes a single facility where
2 processes subject to different regulatory regimes will
3 occur. One process consists of disassembly and
4 dissolution of irradiated targets, molybdenum 99
5 recovery and purification, uranium recovery and
6 recycle, and waste management. This process
7 constitutes the production facility for which
8 Northwest has requested a construction permit and
9 which is subject to the licensing requirements of
10 10 CFR Part 50.

11 The construction permit application also
12 describes the target fabrication process. This
13 process consists of fabricating low enriched uranium
14 targets containing unirradiated uranium, uranium from
15 previously irradiated targets, and potentially uranium
16 scrap from off-spec targets.

17 Although the construction permit
18 application discusses this process, the Northwest
19 application states that Northwest plans to submit a
20 10 CFR Part 70 application for these activities.
21 Northwest has also stated that it will submit its Part
22 70 application with its Part 50 operating license
23 application, and will request that the NRC issue a
24 single license for the entire facility, which is
25 permissible under NRC regulations.

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

5 Next slide, please.

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

10 MR. TIKTINSKY: Thank you, Michael.

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

13 While the Northwest application described
14 both production facility and target fabrication
15 activities, Northwest only requested a construction
16 permit for a Part 50 production facility. The staff
17 reviewed the entire application, including the
18 Northwest descriptions related to Part 70 activities
19 associated with target fabrication. However, the
20 staff review was to determine whether Northwest
21 satisfies the requirements for the potential issuance
22 of a construction permit for a Part 50 production
23 facility.

24 As part of this review, the staff focused
25 on the interface between the production facility and

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1 target fabrication processes as well as the impact of
2 target fabrication processes on the production
3 facility. Any systems or components that are shared
4 between the two processes were evaluated to support
5 the conclusions of the staff regarding the issuance of
6 a construction permit for the Part 50 production
7 facility only.

8 A Part 50 construction permit, if issued,
9 would only authorize Northwest to construct the
10 production facility portion of its facility. The
11 separate requirements of Part 70 would govern the
12 target fabrication portion of the facility.

13 Next slide, please.

14 Provided that the requirements for the
15 issuance of a construction permit are satisfied, the
16 regulations in 10 CFR Part 50 generally allow the
17 design to mature from a preliminary to a final design
18 without requiring specific NRC approval. Pursuant to
19 10 CFR 50.35, the construction permit does not
20 constitute the NRC approval of the safety of any
21 design feature unless the applicant specifically makes
22 this request. Instead, the approval of the safety
23 design features is made during a staff review of the
24 final design submitted in the operating license
25 application.

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1 The staff determined that permit
2 conditions were necessary regarding criticality
3 safety, quality assurance, and site characteristics in
4 order to confirm adequate design basis and ensure
5 quality.

6 Next slide, please.

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

15 The staff also recommends a permit
16 condition on the subcritical limit to confirm that the
17 Northwest will integrate the revised subcritical limit
18 in the criticality calculations and design analysis of
19 the facility for its final design, because it is
20 possible that some of the Northwest criticality
21 calculations and design analysis will need to redone
22 to incorporate the revised subcritical limit.

23 Based on the Northwest use of conservative
24 modeling practices and its conservative validation
25 methodology, the staff has reasonable assurance that

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1 it's margin of subcriticality is acceptable to ensure
2 subcriticality of the proposed production facility
3 under normal and credible abnormal conditions. These
4 proposed permit conditions are confirmatory and
5 administrative in nature because they are intended to
6 confirm that Northwest considers certain information
7 as it develops and implements its final design, and
8 because their satisfaction is accomplished by the
9 submission of periodic reports. A safety review of
10 the adequacy of the information will await the review
11 of an operating license application.

12 Next slide, please.

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

16 MR. LYNCH: Thank you, David.

17 Good morning, Chairman and Commissioners.

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

20 In order to provide reasonable assurance
21 that the regulatory requirements and licensee
22 commitments for quality assurance are adequately
23 implemented during construction, the staff recommends
24 that the Northwest construction permit include a
25 quality assurance condition similar to the

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1 requirements of 10 CFR 50.55(f), which apply to
2 nuclear power plant and fuel reprocessing plant
3 construction permit-holders.

4 The proposed condition would require
5 Northwest to implement its quality assurance program
6 plan, or QAPP, as described in its PSAR and would
7 support the adequate implementation of licensee
8 commitments in design, procurement, and construction.

9 Specifically, the inclusion of this permit
10 condition would, one, ensure that Northwest implements
11 its QAPP; two, provide for consistency and maintenance
12 of documentation; three, establish criteria for
13 notifying the NRC of changes to the QAPP, and, four,
14 require correction of deficiencies in the
15 implementation of the QAPP.

16 Next slide, please.

17 Based on the staff review of the Northwest
18 Description and Safety Assessment of the Discovery
19 Ridge site, the staff determined that Northwest had
20 satisfied the requirements of 10 CFR 50.34(a)(1)(i),
21 and that the design basis of the facility described in
22 Chapter 3 of PSAR satisfied the requirements of
23 10 CFR 50.34(a)(3).

24 However, in light of the potential for
25 unidentified sinkholes, undesirable soil

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1 characteristics, and liquefaction, Northwest has
2 committed to performing a site-specific geotechnical
3 investigation. Based on the issues raised by the
4 Commission in pre-hearing questions, the staff has
5 reconsidered its decision to track the results of the
6 investigation via regulatory commitments.

7 Since a site-specific investigation could
8 reveal geological features impacting the design basis
9 of the facility, the staff recommends that the
10 Northwest construction permit be conditioned to
11 require that, prior to the beginning of construction,
12 Northwest complete and submit the results of the
13 geotechnical investigation. The results of the
14 investigation would inform Northwest design
15 activities, would inform the staff construction
16 inspection program, and would confirm the adequacy of
17 the Northwest production facility design basis,
18 including any design changes made in accordance with
19 the Northwest QAPP.

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

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

25 We'll begin the question-and-answer period

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1 this time with Commissioner Burns. Please proceed.

2 COMMISSIONER BURNS: Thank you, Chairman.

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

7 Next. There. Keep it there. Thank you.

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

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

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

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

23 MR. REESE: That is correct, sir.

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

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

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

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

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

25 COMMISSIONER BURNS: Yes, yes.

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

4 COMMISSIONER BURNS: Yes.

5 MR. REESE: That's pretty clear.

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

8 COMMISSIONER BURNS: Okay.

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

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

16 COMMISSIONER BURNS: Okay. All right.
17 Thanks.

18 Staff, any comment with respect to that?

19 MR. TIKTINSKY: Yes, I guess --

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

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

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1 the Part 50 part, but what we did look at is the
2 accidents that were identified in the Part 70 target
3 fabrication area and any impact they may have on the
4 10 CFR production facility.

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

10 MR. TIKTINSKY: Yes.

11 COMMISSIONER BURNS: Okay. Thank you.

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

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

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

8 COMMISSIONER BURNS: Okay. All right.
9 Thank you.

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

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

22 MR. LYNCH: Yes. Our understanding is
23 that the quality assurance program developed by the
24 Applicant will be applied to both the Part 50 and Part
25 70 aspects of the facility.

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

3 MR. LYNCH: No, it does not.

4 COMMISSIONER BURNS: Thank you.

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

9 MR. DUNFORD: This is Gary Dunford.

10 So, put slide 2 back up again, please.

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

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

25 COMMISSIONER BURNS: Okay.

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

3 COMMISSIONER BURNS: Okay. All right.
4 Thank you.

5 Thank you, Chairman.

6 CHAIRMAN SVINICKI: Thank you,
7 Commissioner Burns.

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

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

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

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

25 CHAIRMAN SVINICKI: Okay. So, it's just

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

3 MS. HAASS: Correct.

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

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

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

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

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

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

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

19 CHAIRMAN SVINICKI: Okay. Thank you.

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

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

3 CHAIRMAN SVINICKI: Okay. Thank you.

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

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

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

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

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

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

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

19 CHAIRMAN SVINICKI: Okay. Thank you.

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

22 COMMISSIONER BARAN: Thanks.

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

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

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

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

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

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

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

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

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

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

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

25 MS. HAASS: It is.

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

4 MS. HAASS: No, there will not.

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

10 MS. HAASS: Correct.

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

16 MS. HAASS: Yes.

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

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

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

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1 you all have in mind for the geotechnical
2 investigation?

3 MR. LYNCH: Yes, it is.

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

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

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

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

21 MS. HAASS: No.

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

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1 incorporated into the Applicant's quality assurance
2 program?

3 MR. BALAZIK: Yes, there is.

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

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

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

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

14 COMMISSIONER BARAN: Okay, great.

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

22 MS. HAASS: Go ahead.

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

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

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

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

12 COMMISSIONER BARAN: Okay, great. Thank
13 you.

14 CHAIRMAN SVINICKI: All right. Thank you
15 very much.

16 To Commissioner Burns, do you have
17 anything else?

18 COMMISSIONER BURNS: No.

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

21 And we will now enter our lunch break
22 period. We're pretty much right on schedule, which is
23 a good thing. So, we will reconvene this hearing at
24 1:15 p.m. and start again at that time.

25 I would ask all witnesses to please be in

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1 the room promptly. Thank you.

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

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

20 MR. CORUM: Good afternoon Chairman and
21 commissioners. I am Michael Corum with NWMI and I
22 will be providing the integrated safety analysis and
23 criticality safety presentation for them. Slide two,
24 please. Consistent with the ISG augmenting NUREG
25 1537, NWMI used the ISA methodology identified in 10

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1 CFR 70, subpart H to conduct the safety analysis for
2 its radioisotope production facility. Additional
3 guidance from NUREGs 1520 and 1513 was used in the
4 process to apply radiological and chemical
5 consequences and likelihood criteria to meet the
6 performance criteria -- or, requirements in 10 CFR
7 7961.

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

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

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

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

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

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1 If we could skip to slide eight, please.

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

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

25 Because of the uncertainty involved with

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1 the computer code based on stochastic methods like
2 MCNP a code validation was necessary. To prepare for
3 the code validation the NWMI process was investigated
4 to determine the suitable parameters to include in
5 that validation. Critical experiments were selected
6 from the International Handbook of Evaluated
7 Criticality Safety Benchmark Experiments that
8 adequately represent the uranium enrichment, geometry
9 moderator reflector and neutron energy for the NWMI
10 process. The experiments were then modeled using
11 MCNP. Calculations were completed and the results
12 analyzed to determine an upper subcritical limit of
13 0.924 for NWMI. Slide nine, please.

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

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

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

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

3 10 CFR 50.34 alpha 4 requires that a PSER
4 assess the risk to the public health and safety from
5 the proposed facility. The ISG augmenting NUREG 1537
6 provides that an applicant for a medical radioisotope
7 production facility may satisfy this requirement in
8 part by performing an integrated safety analysis, or
9 otherwise known as an ISA. An ISA involves
10 identifying potential accident sequences and facility
11 operations and designing items relied on for safety or
12 IROFS to either prevent or mitigate their consequences
13 to an acceptable level.

14 An ISA is typically required for 10 CFR
15 Part 70, licenses for fuel cycles facilities.
16 However, the ISG augmenting NUREG 1537 provides that
17 an ISA may be used for a medical isotope --
18 radioisotope production facilities because one, part
19 50 does not contain specific requirements for accident
20 analysis for medical radioisotope production
21 facilities, and two, an anticipated radiological and
22 chemical hazards associated with the processes at
23 medical and radioisotope facilities are similar to
24 those associated with fuel cycle facilities.
25 Specifically the ISG states that the use of ISA

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1 methodologies as described in Part 70, the application
2 of radiological and chemical consequences and
3 likelihood criteria are contained in the performance
4 requirements of 10 CFR 70.61, the designation of items
5 relied on for safety and the establishment of
6 management measures in an acceptable way of
7 demonstrating adequate for a medical radioisotope
8 production facility.

9 In its application Northwest used a Part
10 70 ISA methodology for its accident analysis --
11 including the designation of IROFS. Northwest also
12 stated that it will provide a description of
13 management measures and operating license application
14 to demonstrate the availability and reliability of the
15 IROFS. Using the criteria in 10 CFR 70.61, consistent
16 with the ISG augmenting NUREG 1537, the staff
17 evaluated the radiological and chemical consequences
18 that Northwest developed, and found that the Northwest
19 ISA methodology was sufficient for the issuance of a
20 construction permit.

21 In chapter one of its Construction Permit
22 Application, Northwest stated for both normal releases
23 and postulated accident releases it intends to meet
24 the dose standards in 10 CFR 20.1201 and 20.1301.
25 While these dose standards were not intended to be

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1 used to evaluate postulated accident conditions, the
2 staff finds their use for this purpose to be
3 conservative and consistent with applicable guidance.
4 Next slide, please.

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

8 MS. A. SMITH: Thank you, Michael. My name
9 is April Smith. As Michael described, Northwest
10 performed an ISA of the proposed production facility.
11 To support the establishment of the design basis and
12 to identify the major features or components for the
13 protection of the health and safety of the public, the
14 ISA methodology includes an accident analysis of the
15 radiological and chemical hazards of the facility.

16 Northwest submitted the results of the ISA
17 with its application as an ISA summary. The ISA
18 summary describes the ISA methodology and the methods
19 used by Northwest to perform hazard analyses. These
20 methods included standard industry techniques such as
21 hazard and operability analyses. The hazard analyses
22 results facilitate identification of accident
23 sequences that may require additional assessment via
24 quantitative risk analysis. The ISA summary also
25 defines accident sequence likelihood categories,

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1 consequence severity categories and a risk matrix that
2 combine various likelihood and consequence categories
3 to determine acceptable and unacceptable scenarios.
4 The staff determined that these categories and the
5 risk matrix are consistent with staff guidance for
6 fuel cycle facilities conducting similar activities as
7 Northwest.

8 Furthermore, the staff determined that the
9 use of these hazard and risk analyses methods by
10 Northwest is consistent with what has been used in
11 fuel cycle facilities that have prepared ISAs. The
12 staff evaluated the sufficiency of the ISA methodology
13 to identify, analyze and determine the consequences of
14 accident analyses in part by reviewing the processes
15 conducted inside the production facility. The staff
16 determined that the use of an ISA methodology by
17 Northwest is consistent with NUREG 1520 and the ISG
18 augmenting NUREG 1537 for medical isotope production
19 facilities. The staff also reviewed accident
20 sequences related to the loss of confinement, the
21 mishandling or malfunction of equipment, inadvertent
22 nuclear criticality, fires, and external events
23 including natural phenomena and the loss of electrical
24 power.

25 Additionally, the staff considered

1 postulated accident sequences related to the
2 activities within the target fabrication area to
3 determine their potential impact on the Northwest
4 production facility. Next slide, please. 10 CFR
5 70.61 describes the requirements to render accident
6 sequences with high consequences as highly unlikely
7 and accident sequences with intermediate consequences
8 as unlikely. In order to conform to the requirements
9 in 70.61 and the guidances NUREG 1520, Northwest
10 identified IROFS to either prevent accidents or to
11 mitigate the consequence of accidents. Northwest also
12 identified IROFS to prevent inadvertent criticality
13 and to adhere to the double-contingency principle as
14 defined in 10 CFR 70.4.

15 Adhering to the double-contingency
16 principle means that process design should incorporate
17 sufficient factors of safety to require at least two
18 unlikely, independent and concurrent changes in
19 process conditions before criticality accident is
20 possible. As part of the ISA process, after IROFS are
21 identified management measures are applied.
22 Management measures, as Michael described, are quality
23 assurance elements that assure that IROFS are reliable
24 and available when needed. The staff found it
25 reasonable to leave for later consideration the review

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1 of management measures as part of its review of the
2 Northwest Operating License Application.

3 The staff concluded that the Northwest ISA
4 methodology contains the elements that support the
5 adequate identification of capabilities and features
6 to prevent or mitigate potential accidents and to
7 protect the health and safety of the public and
8 workers. Therefore, it is sufficient for the issuance
9 of a construction permit. Next slide, please.

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

13 MR. TIKTINSKY: Thank you, April. My name
14 is David Tiktinsky in the Office of Nuclear Materials
15 Safety and Safeguards. The staff reviewed the
16 Northwest analysis of accidents with radiological and
17 criticality consequences. This analysis included
18 events sequences involving liquid spills, sprays and
19 leaks. Consistent with the ISG augmenting NUREG 1537,
20 Northwest considered the consequence levels as stated
21 in the performance requirements of 10 CFR 70.61 for
22 postulated accidents and the radiological release
23 limits in 10 CFR Part 20.

24 In its review the staff looked at the
25 engineered safety features and IROFS proposed by

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1 Northwest to prevent or mitigate the impacts of
2 identified accident sequences. The staff evaluation
3 of the identified accidents is similar to that
4 previously done in the staff review of fuel cycle
5 facility applications, except for the unique aspect of
6 having to evaluate the radiological impacts of the
7 separation of fission products. The staff reviewed
8 the accident sequences identified by Northwest in the
9 PSAR and determined that Northwest had adequately
10 identified credible accident sequences with potential
11 radiological consequences or that could cause an
12 inadvertent criticality.

13 The staff also found that Northwest had
14 described a nuclear criticality safety program that
15 will, if properly implemented, ensure that all
16 facility processes are subcritical under both normal
17 and credible abnormal conditions and will comply with
18 the double-contingency principle. Next slide, please.
19 James Hammelman will now provide details on the staff
20 evaluation of the Northwest chemical safety
21 evaluation.

22 MR. HAMMELMAN: Thank you, David. The
23 staff reviewed the Northwest process and facility
24 design as well as the Northwest analysis of chemical
25 safety-related accidents and assessment of chemical

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1 safety controls. The review examined the engineer
2 safety features that Northwest identified to protect
3 against the release of licensed material or hazardous
4 chemicals produced from the processing of licensed
5 material.

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

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

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1 evaluations will be integrated into the Operating
2 License Application.

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

10 MR. BALAZIK: Thank you, Jim. Based on
11 the review of the staff, the staff concludes that for
12 the purposes of issuing a construction permit, there
13 is reasonable assurance that the ISA methodology
14 proposed by Northwest is sufficient to identify
15 accident sequences and items relied on for safety.
16 The ISA approach also supports a determination that
17 the facility hazards have been adequately identified
18 and that the preliminary design -- including the
19 engineered safety features -- will protect the health
20 and safety of workers and the public. This concludes
21 the Safety Panel 2 presentation. We are prepared to
22 respond to any questions at this time.

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

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1 this round of questions with my questions. Northwest
2 Medical Isotopes on slide four makes reference to the
3 translation of the IROFS developed under 10 CFR Part
4 70 to tech specs under 10 CFR Part 50 and that that
5 will be developed in the Operating License
6 Application. Could Northwest at a high level describe
7 that translation step and how they approach doing
8 that?

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

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

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

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

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

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

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

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

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

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

15 MR. CORUM: Correct.

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

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

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

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

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

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

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

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

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

3 COMMISSIONER BARAN: Okay.

4 MR. BALAZIK: And the staff agrees with
5 that.

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

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

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

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1 guidance? And if so, what were your conclusions?

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

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

9 (No audible response.)

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

12 (Pause.)

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

15 (Pause.)

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

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

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

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

4 MR. ATCHISON: I am.

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

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

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

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

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

25 MR. ATCHISON: That search area would be

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

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

8 MR. ATCHISON: This is basically a small
9 lot.

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

12 MR. ATCHISON: Yes. Mm-hmm.

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

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

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

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

11 COMMISSIONER BARAN: Okay.

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

17 COMMISSIONER BARAN: Right.

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

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

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

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

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

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

22 MR. DUNFORD: We do, yes.

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

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

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

13 COMMISSIONER BARAN: Any thoughts from
14 Northwest? Or --

15 (Pause.)

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

24 COMMISSIONER BARAN: Okay, thank you.

25 CHAIRMAN SVINICKI: Thank you,

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1 Commissioner Baran. Now we recognize Commissioner
2 Burns.

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

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

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

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

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

9 COMMISSIONER BURNS: Okay. Do you --
10 (Simultaneous speaking.)

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

12 COMMISSIONER BURNS: Go ahead. No -

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

16 COMMISSIONER BURNS: Okay.

17 MR. BALAZIK: But they still are the same.

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

24 MR. BALAZIK: That is correct.

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

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

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

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

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

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

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

25 But, first, let me ask the Applicant to

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1 respond.

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

5 COMMISSIONER BURNS: Okay.

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

7 COMMISSIONER BURNS: Bound what kind of
8 emissions?

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

11 COMMISSIONER BURNS: Okay.

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

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

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

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

5 COMMISSIONER BURNS: Okay. Staff?

6 MR. BALAZIK: Well, also, within Chapter
7 8, as a result of a request for additional
8 information, Northwest updated their peak power
9 supply, and with that, they also have in Chapter 7
10 where they have a capacity of the diesel generator of
11 1,000 kilowatts. So, there's an inconsistency between
12 the peak power that they have in Chapter 7 and the
13 capacity of the diesel.

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

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

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

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

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1 two numbers.

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

6 MR. BALAZIK: No, there's not.

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

9 MR. BALAZIK: There's not.

10 COMMISSIONER BURNS: Okay. Thank you.

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

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

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

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

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

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

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

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

12 COMMISSIONER BURNS: Can the Applicant
13 answer that?

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

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

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

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

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

25 COMMISSIONER BURNS: Yes. Okay.

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

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

5 Thank you. Thank you, Chairman.

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

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

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

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

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

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

6 Okay, great. Thank you very much.

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

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

12 And if we can go to page 2?

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

18 What you see on the last full bullet here
19 is a chronology of what's occurred. We submitted it
20 in February of 2015. The scoping meetings occurred in
21 December of 2015, with the Draft EIS public comment
22 period occurring November 1 through December 29th of
23 2016, with the EIS being published in May of 2007.

24 Page 3, please.

25 The proposed action under this, I think,

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1 as we have stated earlier in this hearing, that the
2 NEPA that was completed or the environmental
3 assessment -- well, the NEPA that was completed was
4 for both portions of the facility. It was for a Part
5 50 and Part 70. So, that means it would be the
6 production facility as well as the target fabrication.

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

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

18 Page 4.

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

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1 Slide 5.

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

11 Next slide.

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

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

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

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

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

9 Next slide.

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

21 Next slide.

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

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1 accelerator-based technology.

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

8 Next slide.

9 I am going to hand it over.

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

20 If you would go to the next slide?

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

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

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

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

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

15 MS. HAASS: Page 11, please.

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

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

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

7 But thank you.

8 CHAIRMAN SVINICKI: Thank you for that
9 presentation.

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

14 MR. BEASLEY: Thank you.

15 CHAIRMAN SVINICKI: Thank you.

16 MR. BEASLEY: Good afternoon --

17 CHAIRMAN SVINICKI: Good afternoon.

18 MR. BEASLEY: -- Chairman and
19 Commissioners.

20 My name is Benjamin Beasley, and I am the
21 Chief for the Environmental Review and National
22 Environmental Policy Act Branch. With me today to
23 discuss the environmental review of the Northwest
24 10 CFR Part 50 construction permit application are
25 Nancy Martinez, a physical scientist; Michelle Moser,

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1 a biologist, and David Drucker, a Senior Environmental
2 Project Manager. We are all from the Division of
3 Materials and License Renewal in NRR.

4 Part of the staff review of the Northwest
5 construction permit application included an
6 environmental review which was conducted in parallel
7 with the safety review that you heard about earlier.
8 The staff performed the environmental review in
9 accordance with the National Environmental Policy Act,
10 commonly referred to as NEPA.

11 In doing its NEPA review, the staff
12 followed the environmental review process for
13 preparing an Environmental Impact Statement described
14 in 10 CFR Part 51 and the Interim Staff Guidance
15 augmenting NUREG-1537. An Environmental Impact
16 Statement is commonly referred to as an EIS.

17 The following presentations provide an
18 overview of the staff environmental review for the
19 Northwest application, while highlighting the unique
20 aspects of this review. The three novel issues that
21 we will highlight today are related action that were
22 included in the scope of the environmental review, the
23 staff decision to prepare an EIS, and staff analyses
24 to determine the range of reasonable alternatives
25 analyzed in the EIS.

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1 Next slide, please.

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

4 MS. MARTINEZ: Thank you, Ben.

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

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

17 Consistent with 10 CFR 51.14(b), in
18 performing its NEPA review, the staff used the Council
19 on Environmental Quality's definition of "connected
20 action" contained in 40 CFR 1508.25. "Actions that
21 are closely related are connected if they, one,
22 automatically trigger other actions that may require
23 Environmental Impact Statements; two, cannot or will
24 not proceed unless other actions are taken previously
25 or simultaneously, or, three, are interdependent parts

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1 of a larger action and depend on the larger action for
2 their justification."

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

7 Next slide, please.

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

14 Construction at the site will include
15 building a target fabrication area, an administration
16 building, a waste management building, a diesel
17 generator building, and support structures. Because
18 the construction of these buildings and support
19 structures is an interdependent part of constructing
20 the proposed Northwest production facility, the staff
21 also considered these environmental impacts.

22 In addition, operations and
23 decommissioning of the proposed production facility
24 are connected actions to production facility
25 construction because they cannot proceed unless a

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1 10 CFR Part 50 construction permit is issued.
2 Therefore, the staff considered the environmental
3 impacts from these actions as part of its
4 environmental review of the Northwest application.

5 Construction of the target fabrication
6 area, which would be co-located with the proposed
7 production facility within one building, is a
8 connected action to the construction of the production
9 facility. Additionally, operations and
10 decommissioning of the target fabrication area, which
11 is to be licensed under Part 70, are connected actions
12 because they would not occur unless a Part 50
13 construction permit is issued. Therefore, the staff
14 considered the environmental impacts from these
15 actions as part of its environmental review of the
16 Northwest application.

17 Furthermore, operation of the proposed
18 Northwest production facility will depend on low
19 enriched uranium, or LEU, targets being transferred to
20 and from and irradiated in one or more research
21 reactors. Because moly 99 production cannot occur
22 until research reactors are licensed to irradiate
23 these targets, and because the environmental impacts
24 from LEU target irradiation at research reactors have
25 not been previously assessed, the staff concluded that

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1 target irradiation at research reactors and
2 transportation of targets to and from the research
3 reactors are an interdependent part of the proposed
4 Northwest production facility operation and,
5 therefore, are also connected actions.

6 Next slide, please.

7 One of the steps in the environmental
8 review process was determining whether to prepare an
9 environmental assessment or an Environmental Impact
10 Statement. Licensing actions that require an EIS are
11 described in 10 CFR 51.20. The proposed issuance of
12 a construction permit for a medical radioisotope
13 production facility is not specifically listed in
14 10 CFR 51.20. However, pursuant to
15 10 CFR 51.20(a)(2), the NRC may exercise its
16 discretion to determine that a licensing action should
17 be covered by an EIS.

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

23 First, the staff determined that operation
24 of the Northwest facility, a connected action to
25 constructing the facility, would include a type of

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1 action that would require an EIS. Specifically, the
2 application describes that, in support of operation,
3 Northwest would fabricate target material that would,
4 then, be encapsulated in metal cladding.

5 The uranium used for the target material
6 would be from a combination of fresh LEU, recovered
7 LEU from material scrubbed during the target
8 fabrication process, and LEU recovered and recycled
9 from the processing of irradiated targets.

10 Therefore, operation of the Northwest
11 facility, as described in the application, would
12 include the use of special nuclear material for
13 processes which require an EIS under
14 10 CFR 51.20(b)(7).

15 Second, the staff determined that in this
16 instance an environmental assessment may not support
17 a finding of no significant impact. An environmental
18 assessment is used to determine whether the impacts
19 from the proposed action may be significant and
20 whether a finding of no significant impact can be
21 made.

22 If, based on the environmental assessment.
23 the staff concludes that the proposed action could
24 result in significant impacts to the human
25 environment, then the staff would prepare an EIS.

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1 Because the staff was not certain that an
2 environmental assessment would have supported a
3 finding of no significant impact for the Northwest
4 application, it determined that direct preparation of
5 an EIS would be the most efficient path forward.

6 Next slide, please.

7 The staff published the Notice of Intent
8 to Prepare an EIS and commenced a 45-day scoping
9 period to provide the public an opportunity to
10 participate in the environmental scoping process in
11 November 2015. Scoping is the process by which the
12 staff identifies the specific impacts and significant
13 issues to be considered in the preparation of an EIS.

14 During this time, the staff held a public
15 scoping meeting in the City of Columbia, Missouri, to
16 gather input from the public; federal, state, and
17 local agencies, and tribes, regarding issues to
18 consider in the EIS. Six attendees provided oral
19 comments at the public scoping meeting. The oral
20 comments expressed the benefits of constructing and
21 operating the proposed facility, mostly focusing on
22 economic development and job growth.

23 In addition, the staff received eight
24 comment letters or emails from federal and state
25 agencies and tribal nations. Written comments were

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1 related to a variety of environmental issues,
2 including the potential impacts to threatened and
3 endangered species from construction of a facility,
4 the potential contamination to groundwater, and the
5 consideration of alternative sites.

6 The staff responded to comments received
7 during the scoping period in a scoping summary report
8 and included relevant information from in-scope
9 comments and the Draft EIS.

10 Next slide, please.

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

14 MS. MOSER: Thank you, Nancy.

15 In developing the EIS, the staff reviewed
16 information included in the Northwest environmental
17 report, visited the proposed site, considered scoping
18 comments, and conducted an independent review to
19 characterize the site.

20 The environmental resources described in
21 the EIS included both the human and natural
22 environment, such as ecological resources, water
23 resources, and the socioeconomic conditions
24 surrounding the proposed site.

25 The proposed site is located within a

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1 shovel-ready industrial par for future development.
2 Past agricultural activities have previously disturbed
3 the area. Common grass species currently cover the
4 site, which provide low-quality habitat for wildlife
5 and birds. The proposed site does not contain any
6 surface water features, threatened or endangered
7 species, or historical or cultural resources.

8 Next slide, please.

9 To evaluate the environmental impacts of
10 the proposed action, the NRC established three levels
11 of significance for potential impacts: small,
12 moderate, and large. The staff determined that the
13 environmental impacts of the proposed Northwest
14 facility, including all connected actions, would be
15 small for all resource areas. Small is defined as
16 environmental effects that are not detectable or are
17 so minor that they would neither destabilize nor
18 noticeably alter any important attribute of the
19 resource.

20 The project-specific activities and site-
21 specific conditions are the basis for the "small"
22 findings, such as the condition of the previously-
23 disturbed site, the low-quality wildlife habitat on
24 the site, the limited ground disturbance that would
25 occur, the use of a public water system to obtain and

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1 discharge water, and adequate controls to ensure that
2 radiological exposures would be within regulatory
3 limits.

4 Next slide, please.

5 Under Section 7 of the Endangered Species
6 Act, the staff must consult with the Fish and Wildlife
7 Service to determine if the proposed action may affect
8 threatened and endangered species. The staff
9 determined that the proposed action would have no
10 effect on threatened and endangered species because
11 the proposed site does not provide suitable habitat.

12 Although Fish and Wildlife Service
13 concurrence on a no effect determination is not
14 required, the staff submitted a copy of the Draft EIS
15 to the Fish and Wildlife Service for its review. In
16 response, the U.S. Department of the Interior, which
17 includes the Fish and Wildlife Service, stated that it
18 had no comments on the Draft EIS. Accordingly, the
19 NRC has fulfilled its consultation obligations under
20 the Endangered Species Act.

21 Under Section 106 of the National Historic
22 Preservation Act, the staff must consult with the
23 Missouri State Historic Preservation Office to
24 determine whether historic properties would be
25 affected by the proposed action. In addition, the

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1 staff consulted with 31 tribes and the Advisory
2 Council on Historic Preservation.

3 The staff determined that the proposed
4 action would have no impact on known historic
5 properties because the staff did not identify any
6 resources on the proposed site that would be eligible
7 for protection under the National Historic
8 Preservation Act. In November 2016, the Missouri
9 State Historic Preservation Office concurred with the
10 staff determination that no historic properties would
11 be affected. Accordingly, the NRC has fulfilled its
12 consultation obligations under the National Historic
13 Preservation Act.

14 Next slide, please.

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

25 Accordingly, the staff considered the

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1 environmental impacts of the no action alternative or
2 if the NRC were to deny the construction permit
3 application. In addition, the staff examined
4 alternative sites by first reviewing the Northwest
5 site selection process.

6 In the first step of its site selection
7 process, Northwest evaluated a variety of
8 environmental and economic factors to narrow down the
9 number of potential alternative sites to four.

10 In the second step of its site selection
11 process, Northwest scored each of these four sites
12 based on 10 criteria to determine which sites would be
13 eliminated from detailed study and which sites would
14 be considered for in-depth study.

15 Northwest determined that the University
16 of Missouri, Columbia, Research Reactor Site would be
17 considered for in-depth study. The staff considered
18 the environmental impacts at that site, which varied
19 from the proposed site because other buildings
20 currently exist on the site, surface water resources
21 and mature trees are adjacent to the site, and the
22 population is greater surrounding the site.

23 Finally, the staff examined alternative
24 technologies to produce moly 99, which was a unique
25 aspect of the staff review of the Northwest

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1 application.

2 Next slide, please.

3 The alternative technologies analysis was
4 novel because several entities have proposed new
5 technologies to produce moly 99 and the proposed new
6 technologies are at various stages of development.

7 The Council on Environmental Quality
8 Regulations implementing NEPA provide guidance when a
9 large number of potential alternatives exist. In such
10 situations, NEPA only requires that an agency analyze
11 a reasonable number of examples covering the full
12 spectrum of alternatives.

13 The staff considered the range of possible
14 alternatives or various methods to fulfill the stated
15 purpose and need of the proposed action, which is to
16 produce moly 99. The staff initially limited the
17 analysis to the five technologies that the Department
18 of Energy's National Nuclear Security Administration
19 awarded cooperative agreements for financial support.
20 The decision to award cooperative agreements was
21 based, in part, on evaluation of the technical
22 feasibility. Thus, these five technologies appear to
23 be reasonable.

24 Additionally, the staff concluded that the
25 five entities awarded cooperative agreements covered

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1 the spectrum of potential alternatives, based on the
2 general land use requirements, power levels, and other
3 environmental factors. The five alternative
4 technologies were: neutron capture, aqueous
5 homogeneous reactor, selective gas extraction, linear
6 accelerator-based, and subcritical fusion.

7 The staff, then, considered whether
8 sufficient environmental data existed to conduct a
9 meaningful alternative analysis for each of the five
10 technologies. For example, the staff looked for
11 publicly-available documents that described the air
12 emissions, estimated dose exposures, water use,
13 building footprints, and other environmental
14 parameters for each technology. The staff determined
15 that sufficient environmental data existed to
16 meaningfully assess the environmental impacts for the
17 subcritical fission technology and the linear
18 accelerator-based technology. The staff did not
19 identify sufficient environmental data for the other
20 three technologies. Therefore, these three
21 technologies were eliminated from further detailed
22 analysis.

23 Next slide, please.

24 David Drucker will now discuss the
25 cost/benefit analysis.

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1 MR. DRUCKER: Thank you, Michelle.

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

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

15 In terms of the benefits considered, the
16 proposed action would result in several societal,
17 medical, and economic benefits. For example, the
18 proposed action is consistent with the U.S. policy of
19 ensuring a reliable supply of medical radioisotopes
20 while minimizing the use of highly-enriched uranium.

21 In addition, the production of moly 99
22 would increase the availability of medical
23 radioisotopes for U.S. public health needs.
24 Furthermore, constructing and operating the proposed
25 Northwest facility would result in economic benefits

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1 such as tax revenue and employment opportunities to
2 communities located near the Northwest site.

3 Next slide, please.

4 In October 2016, the staff issued the
5 Draft EIS for public comment. During this comment
6 period, the staff requested input from the public;
7 other federal, state, and local agencies, and tribes,
8 regarding the data analyses and conclusions in the
9 Draft EIS.

10 The NRC held a public meeting in Columbia,
11 Missouri, at which seven commenters made oral
12 statements. In addition, the staff received five
13 letters or emails which included comments from the
14 Sierra Club and from the U.S. Environmental Protection
15 Agency addressing a variety of environmental issues.
16 The staff did not receive any comments that resulted
17 in significant revisions to the EIS.

18 However, the comments from the Sierra Club
19 and the Environmental Protection Agency did cause the
20 staff to modify the EIS. These comments, and the
21 staff responses to the comments, are provided in the
22 Final EIS, which was published in May 2017.

23 Next slide, please.

24 In accordance with 10 CFR 51.105(a), the
25 staff weighed the environmental, economic, technical,

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1 and other benefits against the environmental and other
2 costs and considered reasonable alternatives to the
3 proposed action. Based on small environmental impacts
4 associated with the proposed Northwest facility and
5 the societal, medical, and economic benefits
6 associated with the proposed Northwest facility, the
7 staff determined that the benefits outweigh the small
8 environmental costs. Therefore, in the EIS the staff
9 recommends the issuance of a construction permit to
10 Northwest.

11 Next slide, please.

12 Future staff NEPA analyses with regard to
13 Northwest are possible for the three items shown on
14 the slide.

15 First, if Northwest were to submit an
16 application for an operating license for a 10 CFR Part
17 50 production facility, the staff would prepare a
18 supplement to the EIS developed for the construction
19 permit, in accordance with 10 CFR 51.95(b). The
20 supplement to the Final EIS would update the
21 environmental review by discussing issues or topics
22 not included in the Final EIS and any different and
23 significant new information regarding matters
24 discussed in the Final EIS.

25 As part of the operating license

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1 application, Northwest would be required to submit a
2 supplemental environmental report. The staff would
3 independently evaluate the information provided in the
4 supplemental environmental report and would conduct
5 its own independent review to determine if any
6 different and significant new information has become
7 available since the publication of the EIS.

8 The staff would follow the environmental
9 review process described in 10 CFR Part 51 in
10 preparing the supplement to the EIS, including
11 scoping, requesting comments on the EIS, and updating
12 the EIS based on the public comments received.

13 Second, if Northwest were to submit a
14 10 CFR Part 70 application for a license to possess
15 and use special nuclear material for target
16 fabrication, including scrap recovery, Northwest is
17 required by regulation to submit an environmental
18 report in support of this application. The staff
19 would evaluate this information as appropriate.

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

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

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1 questions.

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

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

7 COMMISSIONER BARAN: Thank you.

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

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

23 MR. DUNFORD: No.

24 (Laughter.)

25 So, we do have recycle processes for some

1 of our solvents.

2 COMMISSIONER BARAN: Okay.

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

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

11 MR. DUNFORD: Correct.

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

14 MR. DUNFORD: Correct.

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

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

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

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

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

9 CHAIRMAN SVINICKI: Thank you.

10 Commissioner Burns?

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

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

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

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

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

25 MS. HAASS: Well, the cows roam.

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

3 COMMISSIONER BURNS: Oh, okay. Yes, okay.

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

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

8 MS. HAASS: Right.

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

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

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

19 MS. HAASS: Correct.

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

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

5 Ms. Martinez?

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

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

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

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

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1 Yes?

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

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

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

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

18 MR. HOFFMAN: No, we did not.

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

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

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

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

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

21 COMMISSIONER BURNS: Okay. All right.
22 Thank you.

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

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

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

8 MR. DRUCKER: Yes.

9 COMMISSIONER BURNS: -- on what we had
10 done?

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

14 MR. DRUCKER: Their comments have been
15 properly addressed.

16 COMMISSIONER BURNS: Okay. Thank you.

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

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

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

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

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

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

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

3 COMMISSIONER BURNS: Right. And if I were
4 only looking at this as a Part 70 facility, my
5 understanding -- and if you all could confirm that? --
6 is that this would not be, would not likely be able to
7 take advantage of a categorical exclusion for the Part
8 70 aspects. Is that correct?

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

15 COMMISSIONER BURNS: Okay. So, then, let
16 me come back to the question I was going to ask about
17 a minute ago. It is, what have we not done under Part
18 70 in terms of the evaluation of potential
19 environmental impacts? Phrased another way, is there
20 something we haven't looked at, at this point, with
21 respect to the Part 70 aspects of the facility?

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

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

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

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

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

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1 words in your mouth -- in a sense, we've almost done
2 sort of like a bounding analysis with respect to Part
3 70 aspects. And as you say, Mr. Beasley, I think when
4 we come back to -- we want to know what the actual,
5 well, things like in the Part 70 license, what the
6 actual possession limits are, the form of material.
7 Some of those details will come sort of, come to us
8 really more at that Part 70 license stage?

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

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

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

21 MR. BEASLEY: Right.

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

25 MR. BEASLEY: Right.

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

9 MR. BEASLEY: That's correct.

10 COMMISSIONER BURNS: Okay. Thank you.

11 Thank you, Chairman.

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

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

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

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

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

12 Do I have the component pieces of that
13 correct?

14 MR. BEASLEY: Yes.

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

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

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1 component elements.

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

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

11 CHAIRMAN SVINICKI: Okay. Thank you.

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

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

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

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

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

5 CHAIRMAN SVINICKI: Okay.

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

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

11 MS. HAASS: Yes.

12 CHAIRMAN SVINICKI: -- surveys?

13 MS. HAASS: That is correct.

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

18 MS. HAASS: That is correct.

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

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

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

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

11 CHAIRMAN SVINICKI: Okay. Thank you for
12 that.

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

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

19 Thank you all.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 the construction of the proposed Northwest production
2 facility.

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

10 Rather, the Part 70 regulations discourage
11 the commencement of construction as defined in 10 CFR
12 70.4 for certain facilities in which Part 70
13 activities are conducted, including processes similar
14 to fuel fabrication and scrap recovery, until the
15 staff has made its environmental findings.

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

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

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1 permit.

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

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

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

14 10 CFR 50.35(b) states that a construction
15 permit does not constitute approval of safety and any
16 design feature at this point of a preliminary design.
17 With respect to the impact of the stack height on
18 radiological releases, the staff notes that the
19 applicant did not request and the staff has not
20 approved the safety of any design feature at this
21 time.

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

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

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

9 The staff finds that this designation of
10 an item relied on for safety, in combination with
11 Northwest's commitment to meet the Part 20 dose
12 requirements for accident is sufficient for the
13 issuance of a construction permit, and additional
14 information may be reasonably asked for later in
15 review of the final design as provided in 10 CFR
16 50.35(a). Thank you.

17 MS. EVANS: Okay, the staff review of the
18 Northwest construction permit application supports the
19 national policy objectives of establishing a domestic
20 supply of moly-99. The Northwest review presented a
21 number of unique technical and licensing
22 considerations for the staff.

23 The timely completion of this review
24 required the expertise, cooperation, and dedication of
25 staff throughout the Agency. The staff evaluated the

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1 Northwest preliminary design to ensure sufficiency of
2 information to provide reasonable assurance that the
3 final design will conform to the design bases.

4 The staff found that the Northwest's use
5 of integrated safety analysis methodologies, the
6 application of radiological and chemical consequences
7 and likelihood criteria provide reasonable assurance
8 that the Northwest ISA process contains the elements
9 to support the adequate identification of capabilities
10 and features to prevent or mitigate potential
11 accidents and protect the health and safety of the
12 public and the workers.

13 The objective of the staff evaluation was
14 to assess the sufficiency of information contained in
15 the Northwest application for the issuance of a
16 construction permit. As such, the staff evaluation of
17 the preliminary design and analysis of the proposed
18 Northwest production facility does not constitute
19 approval of the safety of any design feature or
20 specification. Such approval will be made following
21 the evaluation of the final design of the facility as
22 described in the final safety analysis report as part
23 of the Northwest operating license application.

24 The staff also considered the potential
25 environmental impact of the proposed facility in

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1 accordance with the National Environmental Policy Act.
2 The staff will continue to engage Northwest on its
3 exemption request that is currently under acceptance
4 review and any future applications it may submit to
5 the NRC.

6 Based on the findings of the staff review
7 as documented in the safety evaluation report and the
8 final environmental impact statement, and in
9 accordance with 10 CFR Parts 50 and 51, the staff
10 concludes that there is sufficient information for the
11 Commission to issue the subject Part 50 construction
12 permit with certain conditions to Northwest Medical
13 Isotopes, and that concludes our closing remarks.
14 Thank you.

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

23 COMMISSIONER BURNS: Yes, Chairman, I do.

24 CHAIRMAN SVINICKI: Yes, Commissioner
25 Burns?

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

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

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

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

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

25 COMMISSIONER BURNS: And what would be

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

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

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

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

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

24 MS. HAASS: We will actually - we are in
25 the process of our documentation and contracts to

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1 start getting those fabricated.

2 COMMISSIONER BURNS: Okay, all right,
3 thank you. Is there some estimate without - I'm not
4 trying to get you to reveal proprietary information,
5 but is there some estimate of what your kind of need
6 would be for numbers of casks?

7 MS. HAASS: I would say that's more on a
8 proprietary nature -

9 COMMISSIONER BURNS: Okay.

10 MS. HAASS: - in what we're doing because
11 it's part of our business model.

12 COMMISSIONER BURNS: Okay, all right,
13 thanks. I'll leave it at that. Thank you, Chairman.

14 CHAIRMAN SVINICKI: Okay, I thought the
15 clarifying statement was very helpful, and now I'm not
16 sure, and Commissioner Baran would also like now to
17 have a follow up question. I'll withhold mine. I'll
18 read the transcript and then I'll look quickly to see
19 if there's a post hearing question.

20 COMMISSIONER BARAN: No, it's a quick
21 question to follow up on Commissioner Burns'
22 questions. So recognizing that the exemption request
23 is a separate licensing action and that you're still
24 in acceptance review on that, would you foresee the
25 analysis of that request relying on the EIS from this

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1 licensing action given that it looked at the Part 70
2 aspects of the facility?

3 MR. LYNCH: Sure, we definitely could
4 leverage our previous environmental impact statement
5 as we consider the environmental aspects associated
6 with the exemption request.

7 COMMISSIONER BARAN: Okay, that was my
8 question. Thanks.

9 CHAIRMAN SVINICKI: Okay, thank you, and
10 so now I would recognize my colleagues for any closing
11 remarks they would like to make, and I'll begin by my
12 list here with Commissioner Burns.

13 COMMISSIONER BURNS: I want to thank both
14 the staff and the applicant for their presentation and
15 testimony here today. We've covered, I think, a
16 number of issues, you know, that bear on the somewhat
17 unique aspects of this facility.

18 I would note, as the staff recognized as
19 one of the things it considers during its NEPA review,
20 that we have national policy that is intended to
21 improve the availability of medical isotopes for
22 protection of public health and their availability in
23 diagnostic and therapeutic treatment. We currently,
24 I think, as the numbers say, we consume more than 50
25 percent of the world's supply.

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1 I would also note beyond national policy,
2 because one of the last things I worked on when I was
3 at the OECD, but under the Organization of Economic
4 Cooperation and Development, sponsored a joint
5 declaration on isotope availability of which the
6 United States was a signatory, as well as a number of
7 other producing and consuming countries. So I think
8 not only is there a national policy, but an
9 international interest in moving forward in this area.

10 Obviously, whether we come to an ultimate
11 decision on operation, there is still some steps ahead
12 of us and ahead of the application, but I think I
13 appreciate the opportunity today to hear from both the
14 applicant and the staff with respect to this facility
15 and the plans for it. Thank you.

16 CHAIRMAN SVINICKI: Thank you.
17 Commissioner Baran?

18 COMMISSIONER BARAN: Before I give a very
19 brief closing, I will just give the staff an
20 opportunity. It looked like you were getting ready to
21 further elaborate on this question, and feel free to
22 do to.

23 MR. TIKTINSKY: Thank you. This is David
24 Tiktinsky of the Office of Nuclear Material Safety and
25 Safeguards. I wanted to just clarify the words of

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1 land disturbance. So construction in 70.4 is defined
2 specifically as any other activity at the site of a
3 facility subject to regulations in this part that has
4 an exception nexus to radiological health and safety
5 and common defense and security.

6 So other areas, they also specifically
7 define things that aren't considered construction, and
8 things like land disturbance, and site exploration,
9 and erection of fences in preparation of the site is
10 not considered construction, so I just wanted to
11 clarify that.

12 COMMISSIONER BURNS: Okay, thank you.

13 MR. TIKTINSKY: Land disturbance is not
14 construction in terms of Part 70.

15 COMMISSIONER BURNS: Building walls and
16 pouring concrete?

17 MR. TIKTINSKY: Yes, that is nexus, yes.

18 COMMISSIONER BURNS: Okay, thank you.

19 COMMISSIONER BARAN: With that, I just
20 want to briefly thank the staff for all their hard
21 work throughout the review of this application, and I
22 want to thank all of today's participants for your
23 thorough preparation for this important hearing. It's
24 very much appreciated, and thanks again.

25 CHAIRMAN SVINICKI: All right, before I

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1 make some brief procedural announcements at the very
2 end, let me also provide some general closing remarks
3 as a member of the Commission.

4 I want to commend the applicant for a very
5 vigorous preparation, and defense, and response to the
6 Commission's questions today. I also thank the NRC
7 staff, all of the witnesses, but also all of the staff
8 who contributed to the work that was discussed here
9 today. It's a tremendous effort.

10 And I always like to acknowledge the hard
11 work of our Office of the Secretary of the Commission
12 and the Office of Commission Appellate Adjudication
13 which are so pivotal to supporting the Commission in
14 its preparation and work to conduct a hearing such as
15 today, and also all of the administrative
16 professionals throughout the Agency who support all of
17 us in the logistics of the important work that's
18 carried on by the Agency.

19 I will also comment as Commissioner Burns
20 did on what Michelle termed the national policy
21 objectives of the United States having some production
22 capability. Consuming over half of something and
23 having no production capability doesn't seem like the
24 most resilient posture for any country, so that is at
25 work here, but -

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1 And whether or not any of us ever walk
2 into a nuclear power plant, the chance that we're
3 going to be a patient having some sort of, if not
4 therapeutic, at a minimum, a nuclear medicine
5 diagnostic procedure is highly likely for any
6 individual in this country because we have such
7 medical access that that's available to us, which is
8 also a great blessing. But in any event, Congress has
9 identified that this is an area that the U.S. should
10 work to rectify.

11 While all of that is going on, however, it
12 is the NRC's unique role and the obligation of the NRC
13 staff to look in a very searching way at the safety of
14 the proposed facility and its environmental impacts at
15 this construction permit stage, and I thank them for
16 the thoroughness with which they responded to the
17 Commission's questions today.

18 To the extent that for members of the
19 public, it looks like confusion reigned a bit on our
20 deep knowledge of the various aspects of our
21 regulations, I think I would observe that our
22 regulations are very thorough. We just want to be
23 sure that we're applying the right components.

24 There aren't really, in my view, any gaps.
25 There's nothing that's falling through the cracks.

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1 It's a very, very rigorous regulatory framework, and
2 we just want to make sure that we are approaching it
3 under the appropriate relevant regulations, so that's
4 been some of the byplay.

5 We do have also our post hearing question
6 opportunities. So it may be as I study the back and
7 forth, I may have some questions that I will submit
8 just for clarification to the record today.

9 Sometimes as I listen to the responses to
10 others' questions, and this tends to happen, is you
11 think you understand it. Someone else phrases a
12 question differently, you hear the response, and then
13 you say, "Okay, that isn't 100 percent what I
14 understood." So we will have a chance to pose those
15 as post hearing questions.

16 So moving to that procedural matter, I
17 will state that in closing and for the information of
18 the parties, the deadline for responses to any post
19 hearing questions will be February 6, 2018 unless the
20 Commission directs otherwise.

21 The Secretary of the Commission plans to
22 issue an order with post hearing questions, if any, by
23 January 30, 2019. The deadline for transcript
24 corrections will be February 5. The Secretary plans
25 to issue an order requesting proposed transcript

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1 corrections by January 29.

2 As I mentioned this morning, the
3 Commission expects to issue a final decision promptly
4 with due regard to the complexity of the issues.
5 Thank you all again, and the hearing is adjourned.

6 (Whereupon, the above-entitled matter went
7 off the record at 3:18 p.m.)

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

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