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Isotopes, LLC

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY Commission

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PUBLIC MEETING TO DISCUSS THE CONSTRUCTION PERMIT
PROCESS AND ENVIRONMENTAL SCOPING FOR THE
NORTHWEST MEDICAL ISOTOPES, LLC RADIOISOTOPE
PRODUCTION FACILITY APPLICATION

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TUESDAY

DECEMBER 8, 2015

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The Public Meeting was convened at the
Holiday Inn East, 915 Port Way, Columbia, Missouri at
6:00 p.m., Cheryl Hausman, Facilitator, presiding.

PRESENT:

CHERYL HAUSMAN, Facilitator

MICHAEL BALAZIK, Office of Nuclear Reactor Regulation

NANCY MARTINEZ, Office of Nuclear Reactor Regulation

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P R O C E E D I N G S

(6:00 p.m.)

1
2
3 MS. HAUSMAN: Good evening, everyone.
4 I'd like to welcome you and thank you for participating
5 in the environmental public scoping meeting this
6 evening and providing comments on the NRC's
7 Environmental Impact Statement to evaluate the
8 environmental impacts for the construction, operation,
9 and decommissioning of the proposed Northwest Medical
10 Isotopes radioisotope production facility in Columbia,
11 Missouri.

12 My name is Cheryl Hausman, and I'm going
13 to be the facilitator for the meeting this evening. My
14 role as a facilitator is to help the meeting run
15 smoothly, to ensure that everyone who wishes to speak
16 has an opportunity to do so, and to try to keep us on
17 time.

18 At this time I would like to introduce Al
19 Adams. Al Adams is the NRC chief of research and test
20 reactor licensing. His branch is responsible for
21 review of medical isotope production facilities.

22 MR. ADAMS: Thank you. Good evening.
23 I'd like to also add my welcome. Thanks for coming out
24 tonight, taking time out of your schedule at this busy
25 time of year to spend part of your evening with us.

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1 A couple of things we hope to accomplish
2 tonight. One is we want you to hear about our safety
3 and environmental reviews that we're doing for
4 Northwest Medical facility. Also to give you a brief
5 introduction to Northwest's technology for producing
6 medical isotopes. Plus, the most important part of
7 tonight is hearing from you. Public input is an
8 important part of the NRC licensing process, and we hope
9 that you will take the opportunity to tell us what you
10 consider to be important environmental aspects of the
11 review that we've started on.

12 So, with that, I'll return it to Cheryl.
13 Thank you for coming.

14 MS. HAUSMAN: We'll have two presenters
15 this evening. Michael Balazik. Mike is a safety
16 project manager for Northwest's application. He is in
17 the division of policy and rulemaking, research and
18 test reactor licensing branch. Mike will be
19 presenting an overview of the safety review of the
20 applications.

21 Nancy Martinez. Nancy is the
22 environmental project manager for Northwest's
23 application. She is in the division of license
24 renewal, environmental review and guidance update
25 branch. Nancy will be presenting an overview of the

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1 environmental review.

2 And there are a few other NRC staff.
3 There are -- I'd like for them to introduce themselves.

4 MS. MOSER: Good evening. My name's
5 Michelle Moser. I'm the ecologist working on this
6 project.

7 MR. FOLK: Kevin Folk. I'm an
8 environmental technical reviewer hydrologist in the
9 environmental review branch for NRC.

10 MS. MITLYNG: I'm Viktoria Mitlyng,
11 public affairs officer for the NRC Region III.

12 MS. HAUSMAN: Thank you.

13 This is a Category 3 public meeting to
14 encourage active participation and information
15 exchange with the NRC and members of the public to
16 obtain comments for the EIS. The NRC invites and
17 encourages members of the public to present oral and
18 written comments on the appropriate scope of issues to
19 be considered in and the content of the EIS.

20 Before we begin, I'd like to go over a few
21 ground rules for the meeting this evening. This
22 meeting is being transcribed, so I ask that you keep
23 any background noise to a minimum so the transcriber
24 can produce an accurate recording of the meeting.

25 There are two security officers present

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1 this evening for everyone's safety, and that is
2 standard practice.

3 Please be respectful of others during the
4 meeting so that all participants who have a question
5 or want to make a comment can be heard and have the time
6 to do so.

7 Please turn off all electronic devices or
8 put them on vibrate. If you need to take a phone call,
9 I ask that you step outside the meeting room to take
10 the call so that the audience can hear the proceedings
11 and the transcriber can obtain an accurate recording.

12 There are two exits for the room, one on
13 each side of the room. And the restrooms are down the
14 hall to the left. If we have to evacuate for any
15 reason, please follow the direction of the security
16 officers.

17 The agenda for the meeting include the
18 presentations by NRC staff to present an overview of
19 the NRC's role and mission and a summary of the
20 environmental review process. Following the
21 presentation, we will take time to answer questions
22 from the audience and then open up the floor for
23 comments. Please keep your questions and comments
24 relevant to the topic.

25 Hopefully everybody got signed in and

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1 received copies of the agenda and presentation slide
2 and a feedback form. If you haven't signed in, before
3 you leave, would you please do so at the registration
4 table.

5 When speaking please use the microphone.
6 If you have a question or a comment, you can step up
7 to the podium or raise your hand and I'll bring the
8 microphone to you.

9 And, finally, the NRC is always looking
10 to improve our meetings, and your feedback is important
11 to us. There are some postage-paid public meeting
12 feedback forms available on the table outside, and you
13 can fill it out today and give it to any NRC staff member
14 or drop it in the mail.

15 Any questions about the logistics of the
16 meeting this evening?

17 Okay. With that, I would like to turn the
18 meeting over to Michael for the first slide
19 presentation. Please hold your questions and comments
20 until we begin the Q and A session.

21 Thank you.

22 MR. BALAZIK: Thank you, Cheryl.

23 Good evening. My name is Mike Balazik.
24 I'm a project manager with the Division of Policy and
25 Rule Making at the NRC and coordinating the staff's

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1 review of the Northwest Medical Isotopes construction
2 permit application.

3 Thank you for all taking -- taking time
4 out today to attend this meeting.

5 This evening we'll provide an overview of
6 the construction permit review process, which includes
7 both a safety review and an environmental review.
8 We'll also describe ways in which the public can
9 participate in the Northwest Medical Isotopes
10 construction permit review process.

11 I'd like to reiterate that the most
12 important part of tonight's meeting is receiving any
13 comments that you may have on the scope of the
14 environmental review. We'll also give you information
15 on how you can submit comments, if you prefer not to
16 speak at this meeting. I hope the information that we
17 provide you will help you better understand the
18 construction permit review process and the role that
19 you have in that process.

20 Before discussing the construction
21 permit review process, I'd like to first talk about the
22 regulatory oversight and the mission of the NRC. The
23 NRC is a federal agency that regulates the civilian use
24 of nuclear material. Statutory regulatory authority
25 has been granted to the NRC, primarily by the Atomic

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1 Energy Act of 1954, as amended; the Energy
2 Reorganization Act of 1974, as amended; and the Energy
3 Policy Act of 2005. From this authority the NRC has
4 promulgated the regulations contained in Title 10 of
5 the Code of Federal Regulations, also known as 10 CFR.

6 Another law, the National Environmental
7 Policy Act of 1969, or otherwise known as NEPA,
8 established the national policy for considering the
9 impact of federal decision making on the human
10 environment. Nancy will discuss these in greater
11 detail during her presentation.

12 The NRC mission is to ensure adequate
13 protection of public health and safety and to promote
14 the common defense and security. NRC regulations that
15 implement NEPA also protect the environment.

16 NRC accomplishes these goals through a
17 combination of regulatory programs and processes such
18 as establishing rules and regulations, reviewing
19 license applications, conducting inspections, and
20 issuing enforcement actions and assessing licensee
21 performance. We also evaluate operating -- operating
22 experience from existing nuclear facilities across the
23 country, as well as internationally.

24 Now I'd like to move into a discussion of
25 content and format of a construction permit

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1 application. The NRC received Northwest's application
2 for construction permit in two parts. The first part
3 was submitted on February 5th, 2015, and it consisted
4 of general information in an environmental report.
5 The second part was submitted on July 20th, 2015 that
6 con-- that considered Northwest's preliminary safety
7 analysis report for its proposed facility.

8 The entire application is available
9 online in the NRC's Agency Document Access Management
10 System, otherwise known as ADAMS. The accession
11 number from the application is noted on this slide.
12 The first accession number is associated with the
13 environmental report, and the second accession number
14 is associated with the preliminary safety analysis
15 report.

16 The NRC staff will conduct environmental
17 safety reviews concurrently and expect each
18 one -- review to take approximately 18 to 24 months,
19 depending on the quality of the application.

20 The next several slides I'll provide an
21 overview of the overall construction permit review
22 process, as well as go into additional detail on the
23 review of the preliminary safety analysis report.

24 This flow chart highlights the safety
25 environmental review for a construction permit

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1 application. This is 10 CFR Part 50 review about
2 entering separate aspects of the construction permit
3 application.

4 The chart also indicates that there are
5 other items that precede the Commission's decision on
6 whether or not to grant the construction permit. One
7 of these items is an independent review performed by
8 the Advisory Committee on Reactor Safeguards, commonly
9 referred to as ACRS. Mandated by the Atomic Energy Act
10 the 1954, the ACRS is an independent group of scientists
11 and nuclear safety experts who advise the Commission
12 on safety issues. The ACRS reviews the construction
13 permit application and the NCR staff's safety
14 evaluation. The ACRS reports its findings and
15 recommendations directly to the Commission.

16 As part of the environmental review, the
17 staff consults with local, state, federal, and tribal
18 officials. The staff also holds public meetings like
19 this to receive comments on the draft Environmental
20 Impact Statement. Additionally, a mandatory hearing
21 will be conducted by the Commission. The Commission
22 considers information presented at the hearing in its
23 decision on whether or not to issue a construction
24 permit.

25 Next I'll describe the construction

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1 permit review process in a little bit more detail,
2 starting with the safety review. The first step of the
3 construction permit application review process is to
4 perform an acceptance and sufficiency review of the
5 application. The purpose of this review is to
6 determine if the Applicant has provided all the
7 information required by regulations so that the
8 application can be docketed. Some of the information
9 required to be in a construction permit application
10 include a summary description of the facility, the
11 preliminary design of the facility, and a preliminary
12 analysis and evaluation of the proposed design and
13 performance of structured system and components of the
14 facility.

15 As I stated before, the application also
16 includes an environmental report, which is the
17 Applicant's assessment of the environmental impacts of
18 the proposed facility.

19 If the application has the required
20 information, then it is considered acceptable for
21 docketing, and the staff will begin its technical
22 review of the application. In the case of Northwest's
23 two-part application submittal, separate docketing
24 acceptance reviews are performed for each part of the
25 application.

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1 NRC staff has completed its docketing
2 acceptance review of part one of Northwest Medical
3 Isotopes' application, which I stated earlier
4 primarily consists of the environmental report. The
5 staff found this portion of the application acceptable
6 for docketing and has begun a detailed review of this
7 part of the application.

8 The staff is currently performing its
9 acceptance review of Northwest Medical Isotopes'
10 preliminary safety analysis report provided in part two
11 of the construction permit application.

12 Now I would like to quickly discuss the
13 technology that Northwest proposes to use here in
14 Columbia, Missouri. Northwest is proposing to
15 manufacture low-enriched uranium target at its
16 facility. In the case of Northwest, a target means
17 material subject to neutrons in a nuclear reactor to
18 elicit particulate reaction for the production of
19 molybdenum-99, which is the isotope of interest.

20 Once fabricated, these targets will be
21 transported to existing universities' nuclear reactors
22 for irradiation. Currently Northwest is proposing to
23 use the University of Missouri and Oregon State
24 University research reactors to irradiate its target.
25 After irradiation, the target will be transported back

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1 to Northwest's facility for processing to separate the
2 molybdenum-99 from other isotopes.

3 Additionally, I'd like to add, for each
4 research reactor that would irradiate these targets
5 would need to get NRC approval via license amendment
6 request. Such amendment requests are not part of the
7 Northwest application permit and would be submitted
8 separately by those research reactors for NRC's
9 consideration.

10 Here's a flowchart of the Northwest
11 proposed activities for molybdenum-99. If a license
12 to construct, operate, and receive nuclear material is
13 granted to Northwest, the blue activity would occur at
14 the proposed Northwest facility and the green activity
15 would occur at the nuclear research reactor facility.
16 This flowchart show the three main activities at the
17 proposed facility; target fabrication, target
18 disassembly and dissolution, and molybdenum-99
19 separation.

20 Starting in the lower left corner,
21 low-enriched uranium target material will be
22 fabricated using both fresh uranium and recovered
23 uranium. The target material will be encased in a
24 metal cladding to manufacture a low-enriched uranium
25 target. These targets will be packaged and shipped to

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1 Oregon State University and the University of Missouri
2 research reactor and potentially a third research
3 reactor.

4 After irradiation, targets will be
5 shipped back to the Northwest Medical Isotopes facility
6 for processing. The irradiated low-enriched uranium
7 target would be mechanically disassembled and
8 dissolved in solution processing. The dissolved
9 low-enriched uranium solution would be processed to
10 recover and purify the molybdenum-99. The purified
11 molybdenum-99 would be packaged and shipped to a
12 radiopharmaceutical distributor. The low-enriched
13 uranium solution would be treated to recover uranium
14 and be cycled back to step one of this flowchart.

15 If the NRC staff determines that the
16 remainder of the Northwest Medical Isotopes
17 construction permit application meets all the material
18 parts for docketing, then staff will docket the
19 application and begin a detailed review. Following
20 the initial review of the application, the staff may
21 issue requests for additional information to Northwest
22 to ensure that staff has all necessary technical
23 information to develop a safety evaluation report. The
24 NRC did request additional information for the
25 Environmental Impact Statement.

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1 The safety evaluation report documents
2 the staff's review of the construction permit
3 application and states the bases for the staff's
4 recommendation to either grant or deny the application.
5 The safety evaluation report summarizes the
6 application, the regulatory standards under which the
7 review is being conducted, and the technical evaluation
8 on how the application does or does not meet NRC
9 regulations.

10 As discussed on the previous slide,
11 following the completion of the safety evaluation
12 report, the ACRS reviews the construction permit
13 application and the staff safety evaluation, and then
14 the ACRS reports its findings and recommendations
15 directly to the Commission.

16 Prior to the decision to either grant or
17 deny the construction permit application, a mandatory
18 Commission hearing will be held on the application.
19 The date of the hearing and the explanation of the
20 hearing procedures, including opportunities for the
21 public participation, will be announced with at least
22 30 days notice in a future Federal Register Notice after
23 the full construction permit application has been
24 accepted for docketing.

25 Finally, the Commission will make a

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1 decision to either grant or deny the construction
2 permit based on the NRC staff's safety evaluation
3 report, the recommendation from the ACRS, and the
4 Environmental Impact Statement.

5 More details on the environmental review
6 will be discussed by the environmental project manager,
7 Nancy Martinez.

8 Thank you for your time.

9 MS. MARTINEZ: Thank you, Michael.

10 Good evening. My name is Nancy Martinez.
11 I am the environmental project manager, and I will
12 discuss the environmental review process.

13 The environmental review for the
14 Northwest application will be performed in accordance
15 with the National Environmental Policy Act of 1959,
16 commonly known as NEPA. NEPA requires federal
17 agencies to follow a systematic approach in evaluating
18 potential environmental impacts of the proposed
19 actions and also to assess alternatives to those
20 actions. The NEPA process involves public
21 participation and public disclosure.

22 NRC's environmental regulations
23 implemented in NEPA are contained in 10 CFR Part 51.
24 Our environmental review considers the impact of
25 construction, operation, and decommissioning of the

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1 Northwest facility.

2 We will also consider the impact of
3 alternatives to the proposed action, including
4 alternative sites, alternative technology, and the
5 impact of not issuing a construction permit. We
6 document the review in an Environmental Impact
7 Statement, which is made publicly available.

8 Ultimately the purpose of the
9 environmental review is to take a detailed hard look
10 at the environmental impact of construction,
11 operation, and decommissioning of the Northwest
12 facility, and after balancing the benefits versus the
13 impacts of the proposed project, make a recommendation
14 to the Commission on whether or not to issue the
15 construction permit.

16 This slide presents a high-level overview
17 of NRC's environmental review process, which begins
18 with scoping. Scoping is a process by which the NRC
19 staff identifies the specific impacts and significant
20 issues to be considered in the preparation of the
21 Northwest Environmental Impact Statement.

22 An important part of the scoping process
23 is public involvement. Information that we gather
24 from you today and in the next few weeks will be
25 considered in the development of the Environmental

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1 Impact Statement. Following the scoping process, the
2 NRC staff will prepare a draft of the Environmental
3 Impact Statement for the proposed Northwest facility
4 and issue the draft for public comment. This is the
5 next opportunity for you and other members of the public
6 to participate in the environmental review process.
7 Comments received on the draft will be considered
8 before the NRC staff issues a final Environmental
9 Impact Statement.

10 The Environmental Impact Statement will
11 be available at NRC's website. As you came in, you were
12 asked to fill out a registration card at our reception
13 table. If you included your address on that card, we
14 will mail you a CD copy of the draft and final EIS to
15 you. Once issued, the Northwest Environmental Impact
16 Statement will help to inform the decision on whether
17 or not to issue the construction permit for the
18 Northwest facility.

19 The proposed facility site is located at
20 the Discovery Ridge Research Park in Columbia,
21 Missouri. The site, identified by the red rectangle
22 here, is approximately four-and-a-half miles south of
23 U.S. Interstate 70 and just north of U.S. Highway 63.
24 The site is 7.4 acres and contains no existing
25 structures.

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1 This is a photo of the site taken by the
2 NRC staff during its environmental site visit. The
3 photo was taken looking in a northeast direction of the
4 site. The Discovery Ridge site is a research
5 development and office park. The site is a section of
6 Columbia South Farms, which is primarily agriculture.

7 For an Environmental Impact Statement,
8 the NRC environmental staff looks at a wide range of
9 potential impacts, including potential impacts to air
10 and water resources, land use, human health, fish and
11 wildlife, and environmental justice. As part of the
12 process, the NRC staff consults and coordinates with
13 various federal, state, and local officials, as well
14 as leaders of tribal nations, including the U.S. Fish
15 & Wildlife Service, Environmental Protection Agency,
16 Missouri Department of Natural Resources, Missouri
17 State Historic Preservation Office, and Tribal Nations
18 with historic ties to the site. Consultation helps to
19 make sure that current information that these groups
20 may have is identified and considered in our analysis.

21 The scoping period started on November
22 18th when the notice of intent to prepare an
23 Environmental Impact Statement and conduct scoping was
24 published in the Federal Register. The NRC will accept
25 comments on the scope of the environmental review until

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1 January 4th, 2016. In general, the NRC staff is
2 looking for information about the environmental
3 impacts of construction, operation, and
4 decommissioning of the proposed Northwest facility.
5 You can assist this process by telling us, for example,
6 what aspects of your local community we should focus
7 on; what local environmental, social, and economic
8 issues the NRC should examine during our review; what
9 other major projects are in progress or planned in the
10 area; and what reasonable alternatives are most
11 appropriate for this region. These are just some
12 examples of the information NRC staff seeks. Because
13 you are more familiar with your community than we are,
14 your comments tonight will help us facilitate a
15 thorough NRC staff review.

16 Public comments are an important part of
17 the environmental review process. You may wonder how
18 we collect and use your comments. First I will discuss
19 how we review your comments, and then how you can
20 provide comments. We consider each comment as part of
21 the environmental review. The formal scoping summary
22 report will address comments collected during the
23 scoping period, and comments are used to determine the
24 scope of the Environmental Impact Statement. The
25 Environmental Impact Statement is one of the factors,

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1 as well as several others shown here, that influence
2 the Commission's decision to issue the construction
3 permit.

4 Now I will discuss how to submit comments.
5 Today you can turn in written comments at the
6 registration table or you can provide verbal comments
7 later on in this meeting. A court reporter is here to
8 record all comments provided verbally. In addition to
9 providing verbal and written comments at this meeting,
10 there are other ways that you can submit comments. You
11 can submit comments online using the Federal Rulemaking
12 website, as identified on the slide and with the ID
13 provided. This is a screenshot of the regulations.gov
14 website. You just enter the ID, and this will give you
15 a list of Federal Register Notices. There's an icon
16 on the right-hand side to submit comments.

17 Please note that comments will not be
18 edited to remove any identifying or contact
19 information, such as a phone number or address. Do not
20 include any information in comments that you do not want
21 publicly disclosed.

22 You can also provide written comments by
23 mail at the address provided on this slide. All
24 comments must be submitted by January 4th, 2016.

25 If you are interested in reviewing the

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1 environmental report that Northwest submitted as part
2 of its construction permit, a hard copy can be found
3 at the Daniel Boone Regional Library. Additionally,
4 electronic copies of the environmental report can be
5 viewed on NRC's website, as identified on this slide.

6 Michael and I are the primary points of
7 contact for the NRC for the Northwest application
8 review. Our contact information is provided on this
9 slide.

10 This concludes my presentation. If
11 anyone has questions pertaining to the safety
12 environmental review information provided during this
13 presentation, Michael and I are happy to address them.

14 Thank you.

15 MS. HAUSMAN: Thank you, Michael and
16 Nancy.

17 Does anybody have any questions about the
18 presentation that you've just seen?

19 Okay. Seeing none, no hands raised.

20 Okay. Next we'll move into the public
21 comment period of the meeting. This is the part of the
22 meeting where you have an opportunity to give your
23 comments on the scope and content of the EIS.

24 There are a number of things we can all
25 do to ensure this part of the meeting runs smoothly.

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1 First, as I mentioned earlier, we are transcribing the
2 meeting. So please keep any sidebar conversations
3 down and avoid background noise. In addition,
4 comments can only be heard if you speak into a
5 microphone. Please do not make comments from the
6 audience, because we won't be able to transcribe them
7 accurately.

8 If you have written comments, you can
9 leave them with me or an NRC staff before you leave this
10 evening.

11 And, finally, for those making comments,
12 please step up to the podium and begin by identifying
13 yourself with your name. And, if you would like to
14 mention any organization or who you represent, please
15 do that as well. In addition, if you can be as succinct
16 as possible, we should be able to get to everyone's
17 comments and conclude the meeting in a time -- include
18 the meeting in a timely manner.

19 If you wish to make a comment outside the
20 scope of this meeting, NRC staff will be available
21 following the meeting to answer questions.

22 And if you filled out a yellow comment
23 card, I'll call you up by name. When those comments
24 are finished, I will open up the meeting for any
25 other -- anybody else who has a comment this evening.

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1 First I would like to invite Karen Miller
2 to the podium.

3 MS. MILLER: Good evening. My name's
4 Karen Miller, and I'm associate commissioner here
5 in Boone County. I am here to testify in support of
6 Northwest Medical Isotopes, LLC's proposed project.
7 Because of our wide array of community assets, we
8 believe that Boone County is an excellent location for
9 the proposed facility.

10 One of our community's premier assets is
11 the University of Missouri's nuclear reactor. The
12 physical proximity of the reactor, as well as its
13 history of excellence in performance, combine to make
14 this a perfect partnership between the University of
15 Missouri and Northwest Medical Isotopes.

16 Through this partnership we will
17 be -- which will produce 99-MO, cancer patients
18 throughout the United States will have more
19 opportunities for a better outcome. The proposed
20 location of the facility at University of Missouri's
21 Discovery Ridge Park will provide access to
22 Mid-Missouri Regional Airport. This too is an
23 enormous benefit to the project, since reducing the
24 time between production of the drug and delivery to
25 healthcare professionals will effectively increase the

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1 efficacy of the drug needed by the patients and doctors
2 throughout the United States.

3 Another asset that our community brings
4 to the table is Boone County's ability to utilize our
5 economic development tool, as Chap -- known as Chapter
6 100 Bond. With this tool, in cooperation with our
7 taxing entities, we can make this project successful.

8 This is a community-wide partnership,
9 which has the potential to grow ever stronger through
10 the collaboration created by effectively utilizing our
11 community assets, the University's research reactor,
12 Mid-Missouri Regional Airport, and our ability to
13 utilize the economic tool Chapter 100 Bond.

14 Our community directly benefits from this
15 partnership because this project will bring
16 good-paying jobs and capital investment, and it creates
17 the possibility of pharmaceutical companies joining
18 the research hub of Discovery Ridge, with that enhanced
19 tax base benefiting all citizens.

20 Please accept this testimony made on
21 behalf of the Boone County Commission in support of the
22 Northwest Medical Isotopes, LLC facility location.

23 Thank you.

24 MS. HAUSMAN: Thank you.

25 Next I would like to invite Bob McDan

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1 (sic).

2 MR. MCDAVID: Thank you. My name is Bob
3 McDavid. I'm mayor of the City of Columbia. I
4 appreciate the opportunity to testify before the NRC
5 in support of the Northwest Medical Isotopes proposal.

6 This is an important initiative for
7 obviously several different reasons. One is that we
8 have a highly-skilled workforce in Boone County and can
9 easily support the 80-plus jobs that will be required
10 in the production of Technetium.

11 Secondly, obviously for Boone County, the
12 1,600 workers that will be required to construct the
13 building is very important to the economy here in
14 Mid-Missouri and in the whole state of Missouri.

15 Second -- next, you know, I have -- in my
16 former life I was a physician and have been on staff
17 of both the University of Missouri Hospital and Boone
18 Hospital; and I know how important, you know how
19 important the use of radioisotopes is to the healthcare
20 community, to the men and women who do diagnostic and
21 therapeutic intervention, and you know how important
22 this tool is to continue. And it's -- it's -- I know
23 there are a lot of healthcare providers that are
24 uncomfortable with the prospect that Technetium may be
25 in short supply in the pending near future.

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1 And, last, and really most important in
2 my opinion is the fact that so many of us may be
3 requiring this tool. You know, whether there's -- of
4 the 18 million doses of Technetium a year, which,
5 obviously, do the math, is 50,000 a day, many of us will
6 need this diagnostic tool for heart disease, bone,
7 skin, and other emerging technologies. And it means
8 so much if we're able to bring the production of this
9 very essential radioisotope back into the United States
10 where we can produce it here and deliver it to the
11 300-plus citizens of the United States who continue to
12 need this and will need this in the future.

13 Thank you for your consideration.

14 MS. HAUSMAN: Thank you.

15 Next, Matt McCormick.

16 MR. DOWELL: Actually, Matt is on his
17 way. So I'm going to speak on behalf of our
18 organization, if that's all right.

19 MS. HAUSMAN: Sure. No problem.

20 MR. DOWELL: I'm Jerry Dowell. I'm the
21 director of government affairs for the Columbia Chamber
22 of Commerce, and I wanted to put on record the Columbia
23 Chamber of Commerce's support of the Northwest Medical
24 Isotopes application.

25 I wanted to highlight a couple of items

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1 that we are supportive of. Missouri and Columbia is
2 the home to world-class medical research resources, and
3 Columbia is at the strategic central location of that
4 access point, and it accesses to other critical markets
5 across the country. So we're supportive of that
6 effort.

7 Also, the Discovery Ridge site utilizes
8 the proximity nourished Missouri and its proximity to
9 transport access at the intersections of two major
10 highways and our access to a regional airport. Also,
11 we have an ample workforce available for the
12 construction phase through the decommissioning phase
13 of this facility.

14 So, once again, the Columbia Chamber of
15 Commerce wants to be on record in support of the
16 Northwest Medical Isotopes application.

17 MS. HAUSMAN: Thank you.

18 David Griggs.

19 MR. GRIGGS: I must say that a third of
20 my speech has already been given, so I'm going to spare
21 you in giving it.

22 My name is David Griggs. I reside at 6420
23 North Highway VV in Columbia. Tonight I'm here to
24 represent Regional Economic Development, or REDI,
25 about this great project.

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1 Just a little bit of background on where
2 I'm coming from. I'm a former Boone County
3 Commissioner, a past president of the Columbia Chamber
4 of Commerce, two-time former chair of REDI, and I've
5 operated a business in Columbia for over 40 years. I
6 mention that simply to reinforce the point that this
7 project, Northwest Medical Isotopes, has from the start
8 been the perfect example of a private-public or a
9 public-private partnership. Much like REDI, which is
10 also a public-private partnership, this project is a
11 prime example of a company in the city of Columbia,
12 county of Boone, state of Missouri, and our great native
13 University working together to do whatever's necessary
14 to bring a great project to fruition.

15 You will hear some more and have heard
16 from several folks tonight about more specific
17 information relating to this project. My role is to
18 discuss the overall economic pro-- economic impact of
19 the project and how it will impact our community and
20 state.

21 REDI's worked with Northwest for over two
22 years by assisting Northwest and bringing together the
23 right organizational leadership to help move this
24 project to this point. I mentioned many of them just
25 a second ago, but must stress the critical role of the

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1 University and the University team at the research
2 reactor. This is simply an amazing opportunity for
3 Columbia, the University, Missouri and, in fact, the
4 United States and our citizens.

5 There are approximately 50,000 doses of
6 this drug that will be produced at this proposed
7 facility administered every day in North America.
8 There's no other producer in the United States for this
9 credible diagnostic medical pharmaceutical. Our
10 research reactor, in collaboration between Northwest
11 and the University, are the critical components for
12 this project.

13 It's estimated that construction of this
14 \$70 million radioisotope production facility in fully
15 operational state will require over 180 full-time
16 skilled construction personnel from Central Missouri
17 and take longer than a year. When the facility's in
18 operation, it's estimated to employ 98 full-time
19 employees. I will tell you those positions will range
20 from extremely highly-skilled technical jobs to those
21 tasked with maintenance of equipment in the facilities.
22 I make that point to note the variety of employment
23 opportunities this project brings to our community.

24 Not included in these construction and
25 operational employment and cost estimates are the

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1 ancillary jobs this project will create. Obviously
2 these radiopharmaceuticals require very rapid delivery
3 to the medical facilities that administer them around
4 the country.

5 This project will be located at
6 University's Discovery Ridge Research Park on 7.4
7 acres. Discovery Ridge is another great example of
8 great public-private partnerships, as it houses ABC
9 Laboratories, which is an environmental testing
10 organization serving the pharmaceutical industry, and
11 other clients like IDEXX, a bioscience company serving
12 veterinary and the animal health research industry.

13 This site is critically located within a
14 few miles of Interstate Highway 70, sets immediately
15 adjacent to U.S. Highway 63. This location provides
16 critical north, south, east, west transportation
17 assets from the center of the United States and is only
18 about six miles from Columbia Regional Airport.

19 All necessary utilities and street
20 infrastructures, including an adjacent overpass
21 providing access to Highway 63, is already in place at
22 the lot line for a fast timeline for this project. That
23 fact simply demonstrates our community's long-term
24 commitment to support this very type of development at
25 Discovery Ridge.

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1 In addition to the investment and
2 employment opportunities I've mentioned, it's also
3 anticipated over the life of this project this project
4 will produce over \$76 million in tax revenues to support
5 our school, our city, our county, and our state.

6 In closing, on behalf of REDI and myself,
7 our community, our county, our state, and the thousands
8 of U.S. citizens whose lives will be positively
9 impacted by this project on a daily basis, I give our
10 support and approval. And thank you very much.

11 MS. HAUSMAN: Thank you, David.

12 Terry Maglich.

13 MR. MAGLICH: Good evening. I'm Terry
14 Maglich. I am a project manager with the Department
15 of Economic Development with the State of Missouri.
16 The role of myself and the Department is to provide
17 assistance to business and communities that create
18 opportunities. The opportunities that we look forward
19 to are those that allow for the growth of employment
20 as well as investment.

21 We're very, very pleased to have provided
22 an assistance proposal to Northwest Isotopes
23 approximately a year and a half ago that does just that;
24 creates a number of great jobs, a great deal of
25 investment in one of our targeted industries of life

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1 sciences. It also does something that I consider very
2 important; it creates an opportunity to save lives.

3 Thank you for allowing me to testify.

4 MS. HAUSMAN: Thank you, Terry.

5 Next, Dan Brague.

6 MR. BRAGUE: Thank you. My name is Dan
7 Brague. I'm the vice president and general manager of
8 global medical imaging for Mallinckrodt
9 Pharmaceuticals. I'm responsible for the commercial
10 activities for Mallinckrodt's nuclear medicine
11 business globally, and I have keen interest in the
12 supply of moly-99.

13 Mallinckrodt is the world's largest
14 producer of technetium generators for use of nuclear
15 medicine. These generators use moly-99 with a three-day
16 half-life to provide sterile, pyrogen-free
17 technetium-99 medicine with a six-hour half-life.

18 Mallinckrodt has generator manufacturing
19 operations in Missouri, as well as the Netherlands,
20 which rely on a steady supply of moly-99. Technetium
21 is used in roughly 80 percent of all nuclear medicine
22 procedures nearly 30 million times each year globally
23 to diagnose heart disease, diagnose and stage cancer,
24 and examine organ functions in kidneys, lungs and
25 brain. More than 100 diagnostic procedures are

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1 available to patients using technetium-99
2 radiopharmaceuticals.

3 Large-scale production of moly-99 is
4 currently only completed at five facilities worldwide.
5 Moly-99 has not been produced domestically since 1991.
6 These five facilities rely on aging research reactors,
7 which are periodically subject to planned and unplanned
8 maintenance. Some of these unplanned maintenance
9 outages have led to shortages of moly-99, frequently
10 impacting patient access to technetium for these
11 important diagnostic procedures.

12 Mallinckrodt is also a major producer of
13 moly-99 at our facility in the Netherlands, so we are
14 very familiar with what is needed to produce commercial
15 quantities of this isotope. As the world's largest
16 consumer of moly-99, Mallinckrodt closely follows new
17 efforts to produce this critical isotope and supports
18 construction of new facilities for its production. We
19 are very familiar with Northwest Medical Isotopes' plan
20 to license and construct a facility in Columbia,
21 Missouri for the production of moly-99 and the
22 recycling of their target material. As we understand
23 it, they intend to utilize a network of two to three
24 university research reactors and build a new moly-99
25 production facility, all of which should provide

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1 additional moly-99 capacity.

2 We believe their technology offers
3 distinct advantages because it is based on the
4 well-proven fission method of moly-99 production and
5 uses existing reactors. Their operation will,
6 importantly, also be based upon low-enriched uranium,
7 which meets the objectives of the U.S. Government's
8 nonproliferation policy, as stated at the 2012 Nuclear
9 Security Summit in Seoul, South Korea and in 2014 in
10 the Netherlands.

11 Nuclear medicine procedures performed in
12 the U.S. consume half of the world's supplies of
13 moly-99. A domestic moly-99 production facility will
14 reduce radioactive decay losses in transit from the
15 current suppliers in Europe, South Africa, and
16 Australia. A U.S. supply, if robust enough to supply
17 the entire market, will also eliminate or reduce
18 transport problems we've had in the past relying on
19 shipments from Europe, incidents including volcanic
20 activity in Iceland and flood destructions due to
21 terrorist concerns. Discussions leading up to the
22 passage of the American Medical Isotope Production Act
23 of 2012 cited all of these issues as a reason to
24 encourage domestic production of moly-99.

25 Mallinckrodt applauds Northwest Medical

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1 Isotopes' efforts to build its facility in Columbia and
2 encourages the NRC to provide the necessary resources
3 for an expedient review of their construction permit
4 and operating license applications.

5 Thank you for the opportunity to provide
6 these comments today.

7 MS. HAUSMAN: Thank you, Dan.

8 Does anybody else have a comment that they
9 would like to make this evening?

10 Okay. Going once, twice.

11 We would like to thank everyone for coming
12 to and participating in the meeting this evening, for
13 openness and transparency.

14 The transcript of this meeting will be
15 available publicly on NRC's web page. And the NRC
16 staff will be available for a short time after. If you
17 have questions or comments for us, we will be here.

18 Thank you.

19 (Whereupon, at 6:45 p.m., the proceedings
20 went off the record.)

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