

January 16, 2018

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

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

NRC STAFF EXHIBIT LIST AND NOTICE OF REVISIONS

The U.S. Nuclear Regulatory Commission (NRC) staff (Staff) hereby files its exhibit list for the mandatory hearing on the construction permit application of Northwest Medical Isotopes, LLC (NWMI). Each exhibit has been listed and marked according to the instructions in the Commission's Scheduling Order, dated January 9, 2018.

The sections below explain changes to documents previously made publicly available in the Agencywide Documents Access and Management System (ADAMS) and changes to the Staff responses to the Commission pre-hearing questions.

A. Changes to Documents Previously Made Publicly Available in ADAMS

The Staff has revised the draft construction permit (CP), the safety evaluation report (SER), and the draft summary record of decision (ROD) to clarify its position consistent with that reflected in the NRC Staff Revised Responses to Commission Pre-Hearing Questions, dated January 16, 2018, and to correct formatting or other minor errors.

1. Revisions to the Draft Construction Permit

The Staff revised the draft CP as follows.

- Inserted the following geotechnical investigation permit condition after the existing quality assurance program condition:

Prior to the beginning of construction, NWMI shall (a) complete a geotechnical investigation to identify sinkhole potential, soil characteristics, and liquefaction potential at the site and (b) submit

the results of this investigation, including any design changes made to the facility based on the findings of the investigation, in a report to the NRC. This condition terminates once NWMI submits the results of the geotechnical investigation in either this report or as part of its final safety analysis report, whichever occurs first.

- Deleted the first clause of permit condition D, and renumbered permit conditions D(1) through D(4) as permit conditions D through F and H, with the new geotechnical investigation permit condition included as permit condition G.
- Inserted “(FSAR)” in paragraph 1.C. and used “FSAR” throughout the document in lieu of the term “final safety analysis report.”

## 2. Revisions to the Safety Evaluation Report

The Staff revised the SER as follows. The revised SER has a different ADAMS Accession Number than the original SER and is available at ADAMS Accession Number ML18016A021.

- On title page, added “(As revised January 2018).”
- On page 2-17, added the following:

Because NWMI must conduct additional geotechnical surveys to further investigate sinkhole potential, liquefaction, and soil characteristics, which could impact the final design bases of the facility, the staff recommends that the construction permit include the following condition:

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

- On page A-1, revised the first paragraph by adding the underlined text and deleting the stricken text:

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) has determined that additional information is needed to address certain matters related to nuclear criticality safety in the Northwest

Medical Isotopes, LLC (NWMI or the applicant) construction permit application. The staff has also determined that a construction permit needs to be conditioned to require that NWMI will implement its quality assurance program during construction and perform a site-specific geotechnical investigation prior to the beginning of construction. Therefore, the staff recommends that, should the application be granted, the construction permit include the conditions set forth below. ~~Conditions 1 and 2 related to nuclear criticality are confirmatory in nature, and must be satisfied prior to the completion of construction.~~ Additional details on the basis for each of these conditions appears in Chapter 2.0, "Site Characteristics," Chapter 6.0, "Engineered Safety Features," and Chapter 12.0, "Conduct of Operations," of the NWMI construction permit safety evaluation report (SER).

- On page A-1 to A-2, renumbered the proposed permit conditions 1 through 3 as 3.D through 3.F.
- On page A-2, added permit condition 3.G as follows:

3.G	2.4.5	Prior to the beginning of construction, NWMI shall (a) complete a geotechnical investigation to identify sinkhole potential, soil characteristics, and liquefaction potential at the site and (b) submit the results of this investigation, including any design changes made to the facility based on the findings of the investigation, in a report to the NRC. This condition terminates once NWMI submits the results of the geotechnical investigation in either this report or as part of its final safety analysis report, whichever occurs first.
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- On page A-4, deleted the regulatory commitments related to the geotechnical investigation permit condition (i.e., regulatory commitments 2.5-1b, 2.5-2, 2.5-3, and 2.5-9).

- On page A-16, changed the second occurrence of "12A-9b" to "12A-9c."

### 3. Revisions to the Draft Summary Record of Decision

The Staff revised the draft ROD as follows.

- On page 1, first paragraph, changed "para" to "a."
- On page 2, fourth paragraph, changed "hosted" to "held."
- On page 5, first paragraph, deleted "at the Discovery Ridge Research Park."
- On page 10, signature block, changed "Environmental Review and Project Management Branch" to "Environmental Review and NEPA Branch."

B. Changes to the Staff Responses to the Commission Pre-Hearing Questions

On January 16, 2018, in order to clarify its position and to correct typographical errors, the Staff filed a revision to its January 2, 2018 responses to the Commission pre-hearing questions that incorporated revised responses to three of the Commission pre-hearing questions. The Staff responses to Commission Pre-Hearing Questions 8.e. and 18 were revised to reflect the proposed permit condition that would require the completion of a geotechnical investigation. The Staff response to Commission Pre-Hearing Question 11 was revised by replacing "RFP" with "RPF," the correct acronym.

The changes described above are reflected in the exhibits NRC-002, NRC-003, NRC-004, and NRC-008 being filed today.

Respectfully submitted,

**/Signed (electronically) by/**

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**Executed in accord with 10 CFR 2.304(d)**

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Dated at Rockville, Maryland  
this 16th day of January, 2018

**Staff Exhibits for NWMI Mandatory Hearing**

<b>Exhibit Number</b>	<b>Sponsoring Witness(es)</b>	<b>Document Description/Title</b>
NRC-001	MaryJane Ross-Lee and Joseph Donoghue	SECY-17-0116, Staff Statement in Support of the Uncontested Hearing for Issuance of a Construction Permit for the Northwest Medical Isotopes, LLC Production Facility (Nov. 16, 2017) (ADAMS Accession No. ML17313A037).
NRC-002	MaryJane Ross-Lee	Draft Construction Permit for Northwest Medical Isotopes, LLC (Nov. 17, 2017) (ADAMS Accession No. ML17313A100) (revised Jan. 16, 2018).
NRC-003	Joseph Donoghue	Draft Summary Record of Decision, Construction Permit Application for the Northwest Medical Isotopes, LLC Radioisotope Production Facility (Nov. 17, 2017) (ADAMS Accession No. ML17313A338) (revised Jan. 16, 2018).
NRC-004	MaryJane Ross-Lee and Joseph Donoghue	NRC Staff Revised Responses to Commission Pre-Hearing Questions (Jan. 16, 2018) (ADAMS Accession No. ML18016A554).
<b>NRC-005</b>	<b>MaryJane Ross-Lee and Joseph Donoghue</b>	<b>NON-PUBLIC - NRC Staff Responses to Non-Public Pre-Hearing Questions and Non-Public Response to Question 36 (Jan. 2, 2018) (ADAMS Accession No. ML18002A546).</b>
NRC-006A	MaryJane Ross-Lee	Northwest Medical Isotopes, LLC, Construction Permit Application – Cover Letter and General and Financial Information (Feb. 5, 2015) (ADAMS Accession Nos. ML15086A262 and ML15086A263 (in part)).
NRC-006B	MaryJane Ross-Lee	Northwest Medical Isotopes, LLC, Construction Permit Application – Preliminary Safety Analysis Report (PSAR), NWMI-2013-021, Rev. 3, Chapters 1 through 2 (Sep. 2017) (ADAMS Accession Nos. ML17257A022 and ML17257A023).
NRC-006C	MaryJane Ross-Lee	Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapter 3 (Sep. 2017) (ADAMS Accession No. ML17257A024).
NRC-006D	MaryJane Ross-Lee	Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapter 4 (Sep. 2017) (ADAMS Accession No. ML17257A025).
NRC-006E	MaryJane Ross-Lee	Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapters 5 through 10 (Sep. 2017) (ADAMS Accession Nos. ML17257A026, ML17257A027, ML17257A028, ML17257A029, ML17257A030, and ML17257A031, respectively).
NRC-006F	MaryJane Ross-Lee	Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3,

		Chapters 11 through 12 (Sep. 2017) (ADAMS Accession Nos. ML17257A032 and ML17257A033).
NRC-006G	MaryJane Ross-Lee	Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapters 13 through 18 (Sep. 2017) (ADAMS Accession Nos. ML17257A034, ML17257A035, ML17257A036, ML17257A037, ML17257A038, and ML17257A040, respectively).
NRC-006H	Joseph Donoghue	Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. OA, Chapter 19, Beginning through 19-130 (Jun. 2015) (ADAMS Accession Nos. ML15210A123 and ML15210A131).
NRC-006I	Joseph Donoghue	Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. OA, Chapter 19, 19-131 through End (Jun. 2015) (ADAMS Accession Nos. ML15210A128 and ML15210A129).
NRC-007A	MaryJane Ross-Lee	<b>NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – General and Financial Information (Feb. 5, 2015) (ADAMS Accession No. ML15086A272 (in part)).</b>
NRC-007B	MaryJane Ross-Lee	<b>NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapters 1 through 2 (Sep. 2017) (ADAMS Accession Nos. ML17257A044 and ML17257A045).</b>
NRC-007C	MaryJane Ross-Lee	<b>NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapter 3 (Sep. 2017) (ADAMS Accession No. ML17257A046).</b>
NRC-007D	MaryJane Ross-Lee	<b>NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapter 4 (Sep. 2017) (ADAMS Accession No. ML17257A047).</b>
NRC-007E	MaryJane Ross-Lee	<b>NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapters 5 through 8 (Sep. 2017) (ADAMS Accession Nos. ML17257A048, ML17257A049, ML17257A050, and ML17257A051, respectively).</b>
NRC-007F	MaryJane Ross-Lee	<b>NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapters 9 through 11 (Sep. 2017) (ADAMS Accession Nos. ML17257A052, ML17257A053, and ML17257A054, respectively).</b>
NRC-007G	MaryJane Ross-Lee	<b>NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapters 12 through 13 (Sep.</b>

		2017) (ADAMS Accession Nos. ML17257A055 and ML17257A056).
NRC-007H	MaryJane Ross-Lee	NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 3, Chapters 14 through 18 (Sep. 2017) (ADAMS Accession Nos. ML17257A057, ML17257A058, ML17257A059, ML17257A060, and ML17257A061, respectively).
NRC-007I	Joseph Donoghue	NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 0A, Chapter 19, Beginning through 19-108 (Jun. 2015) (ADAMS Accession Nos. ML15211A223 and ML15211A224).
NRC-007J	Joseph Donoghue	NON-PUBLIC - Northwest Medical Isotopes, LLC, Construction Permit Application – PSAR, NWMI-2013-021, Rev. 0A, Chapter 19, 19-109 through End (Jun. 2015) (ADAMS Accession Nos. ML15211A225 and ML15211A226).
NRC-008	MaryJane Ross-Lee	Safety Evaluation Report Related to the Northwest Medical Isotopes, LLC Construction Permit Application for a Production Facility (Nov. 2017) (ADAMS Accession No. ML18016A021) (as revised Jan. 2018).
NRC-009	Joseph Donoghue	NUREG-2209, Final Environmental Impact Statement for the Construction Permit for Northwest Medical Isotopes Radioisotope Production Facility (May 2017) (ADAMS Accession No. ML17130A862).
NRC-010	MaryJane Ross-Lee and Joseph Donoghue	Staff Presentation Slides – Overview (Jan. 16, 2018).
NRC-011	MaryJane Ross-Lee	Staff Presentation Slides – Safety Panel 1 (Jan. 16, 2018).
NRC-012	MaryJane Ross-Lee	Staff Presentation Slides – Safety Panel 2 (Jan. 16, 2018).
NRC-013	Joseph Donoghue	Staff Presentation Slides – Environmental Panel (Jan. 16, 2018).

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CERTIFICATE OF SERVICE

Pursuant to 10 C.F.R. § 2.305, I hereby certify that copies of the foregoing "NRC STAFF EXHIBIT LIST AND NOTICE OF REVISIONS," dated January 16, 2018, have been served upon the Electronic Information Exchange, the NRC's E-Filing System, in the above-captioned proceeding, this 16th day of January, 2018.

**/Signed (electronically) by/**

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Dated at Rockville, Maryland  
this 16th day of January, 2018