

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
(Transmitting Post-Hearing Questions)

The Commission held an evidentiary hearing on January 23, 2018, at its Rockville, Maryland headquarters to receive testimony and exhibits in the captioned proceeding. Northwest Medical Isotopes, LLC (NWMI) and the NRC Staff should file written responses to the post-hearing questions listed in the table below no later than February 6, 2018. The responses should be filed as exhibits, using the previously established numbering scheme. The parties should consult prior to filing their responses and indicate whether there are any objections to admitting the new exhibits into the record. Absent objection, the new exhibits will be admitted. This order is issued pursuant to my authority under 10 C.F.R. § 2.346(a) and (j).

No.	Category	Subject	Directed to	Question
1	Safety	Draft Construction Permit Pre-Hearing Question 8	Staff and Applicant	<p>In response to pre-hearing question 8(e), the Staff has proposed a permit condition requiring NWMI to complete a site-specific geotechnical investigation prior to the beginning of construction. Ex. NRC-004, <i>NRC Staff Revised Responses to Commission Pre-Hearing Questions</i> (Jan. 16, 2018), at 11-12 (Staff Pre-Hearing Responses). Please comment on the redline/strikeout changes to the permit condition, which are intended to broaden the condition to ensure the detection of “any site features that could impact the final design bases of the facility.” <i>Id.</i> at 11. These changes may be made in the event the Commission determines that this condition should be imposed.</p> <p>Prior to the beginning of construction, NWMI shall (a) complete a geotechnical investigation to identify sinkhole <u>any potential voids that may adversely impact the stability of subsurface materials and foundation</u>, soil <u>and rock</u> 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.</p>
2	Safety	Geotechnical Investigation	Applicant	<p>In response to a question at the hearing about the methods that NWMI plans to use for the site-specific geotechnical investigation, NWMI stated that borehole and soil compaction tests will be performed. Although these tests are necessary for characterizing soil and rock and investigating soil liquefaction potential, identifying caves and sinkholes is also one of the major purposes of the site-specific geotechnical investigation. Please clarify the geophysical techniques or other methods that will be employed to detect any potential voids that may adversely impact the stability of subsurface materials and foundations. If such techniques will not be employed, why not?</p>
3	Safety	Pre-Hearing Question 19	Staff	<p>The Staff's response to pre-hearing question 19 stated that no redundancy is incorporated into the preliminary design of the standby electrical power system diesel, but that “NWMI plans to include some level of redundancy in</p>

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		SER Chapter 8		<p>design of the uninterruptible power supplies.” Ex. NRC-004, Staff Pre-Hearing Responses, at 19.</p> <p>Could the Staff further explain its response on the uninterruptible power supplies?</p>
4	Safety	<p>Prehearing Question 26</p> <p>Regulatory Guide 1.145</p> <p>SER Section 13.4.3;</p> <p>PSAR Section 13.2.2.7.2</p>	Staff and Applicant	<p>NWMI takes credit for an elevated release from the Radioisotope Production Facility (RPF) by using a 75-foot exhaust stack. The RPF building is 65 feet tall and the exhaust stack attached to the top of it is 10 feet tall. NRC guidance in Regulatory Guide 1.145, “Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants,” advises that the stack height should be 2.5 times the height of the adjacent structures in order to credit an elevated release under all conditions.</p> <p>Was the applicability of this guidance examined, and, if so, what were the conclusions?</p> <p>For purposes of the guidance, what are considered to be the adjacent structures – the RPF or other buildings in or around the NWMI campus? Would it include buildings on other lots of the research park?</p> <p>Please explain the basis for treating the releases from the proposed facility as elevated releases rather than ground-level releases.</p> <p>Please explain the basis for the conclusion that the maximum dose from an accidental facility release would occur at a distance of 1,100 meters from the facility and not the site boundary.</p> <p>Would a re-analysis of the dose calculations and stack height be required if a multi-story building were constructed on a nearby lot?</p>
5	Environmental	December 18, 2017 Exemption	Staff	<p>The proposed licensing action before the NRC is the 10 C.F.R. Part 50 construction permit that would authorize NWMI to construct an RPF at the Discovery Ridge site. NWMI has indicated the intent to also engage in</p>

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		Request Exhibit NWTMI-010		<p>activities that would be licensed pursuant to 10 C.F.R. Part 70 in the RPF. As was discussed during the hearing, NWTMI has sought an exemption from 10 C.F.R. § 70.21(f), which would apply to the license that will be sought by NWTMI to possess and use special nuclear material at its proposed RPF to fabricate low-enriched uranium targets. Section 70.21(f) provides that such a license application “shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted, and shall be accompanied by an Environmental Report required under [10 C.F.R. Part 51, Subpart A].” Corresponding provisions in 10 C.F.R. §§ 51.101(a) and 70.23(a)(7) “provide a disincentive to early construction by raising the possibility of ultimate denial of the license application should an applicant move forward precipitously, despite open environmental issues.” <i>Nuclear Fuel Services, Inc.</i> (Erwin, Tennessee), CLI-03-3, 57 NRC 239, 247 (2003).¹</p> <p>At the hearing, the discussion of the effect of the proposed exemption on construction of the RPF at times lacked clarity.</p> <p>(a) Recognizing that the exemption request that NWTMI has made pursuant to 10 C.F.R. § 70.21(f) is a licensing action separate from this construction permit proceeding, confirm the relief that the exemption will accord NWTMI if granted. Further, if the</p>

¹ See 10 C.F.R. § 70.23(a)(7) (“Commencement of construction prior to [the conclusion that the action called for is issuance of the proposed license, with any appropriate conditions to protect environmental values] is grounds for denial to possess and use special nuclear material in the plant or facility. Commencement of construction as defined in [10 C.F.R. § 70.4] may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.”); see also Final Rule, Licenses, Certifications, and Approvals for Materials Licensees, 76 Fed. Reg. 56,951, 56,955 (Sept. 11, 2011) (“Although the industry and the NRC frequently refer to the discouraging provision in §§ 30.33(a)(5), 40.32(e), and 70.23(a)(7) as a prohibition for ease of reference, it is more of an admonition of the potential consequences of certain action.”).

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				<p>exemption is granted, confirm that the exemption would not limit the NRC's ability to subject the construction to modification(s) or other condition(s) as may be necessary to ensure the public health and safety or common defense and security, for example, as a result of the Staff's subsequent operating license review and ongoing oversight.</p> <p>(b) Assuming a construction permit is issued to NWMI under 10 C.F.R. Part 50 for construction of the RPF, if NWMI were to commence construction on the portion of the RPF that would house operations requiring a license under 10 C.F.R. Part 70 prior to submitting its application for a Part 70 license and without obtaining exemptions from 10 C.F.R. §§ 70.21(f) or 70.23(a)(7), what is the practical difference, if any, from the circumstance in which NWMI obtained the exemption(s) prior to commencing construction?</p>

IT IS SO ORDERED.

For the Commission

NRC SEAL

/RA/

Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 30th day of January, 2018.

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NUCLEAR REGULATORY COMMISSION

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NORTHWEST MEDICAL ISOTOPES, LLC)
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(Mandatory Hearing))

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **ORDER (Transmitting Post-Hearing Questions)** have been served upon the following persons by Electronic Information Exchange.

U.S. Nuclear Regulatory Commission
Office of Commission Appellate Adjudication
Mail Stop: O-16B33
Washington, DC 20555-0001
ocaamail@nrc.gov

U.S. Nuclear Regulatory Commission
Office of the Secretary of the Commission
Mail Stop: O-16B33
Washington, DC 20555-0001
hearing.docket@nrc.gov

U.S. Nuclear Regulatory Commission
Office of the General Counsel
Mail Stop: O-14A44
Washington, DC 20555-0001
Mitzi Young, Esq.
Jeremy Wachutka, Esq.
Catherine Scott, Esq.
Catherine Kanatas, Esq.
John Tibbetts, Paralegal
mitzi.young@nrc.gov
jeremy.wachutka@nrc.gov
catherine.scott@nrc.gov
catherine.kanatas@nrc.gov
john.tibbets@nrc.gov

Carolyn Haass
Chief Operating Officer
Northwest Medical Isotopes, LLC
22500 Hope Dale Avenue
Parker, CO 80138
carolyn.haass@nwmedicalisotopes.com

[Original signed by Herald M. Speiser]
Office of the Secretary of the Commission

Dated at Rockville, Maryland,
this 30th day of January, 2018