

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY
COMMISSION
BEFORE THE COMMISSION**

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In the Matter of)	Docket No. 50-609-CP
)	
NORTHWEST MEDICAL ISOTOPES, LLC)	
)	
(Medical Radioisotope Production Facility))	February 6, 2018
_____)	

**RESPONSE TO NRC COMMISSION’S PUBLIC POST-HEARING QUESTIONS
NORTHWEST MEDICAL ISOTOPES, LLC
EVIDENTIARY HEARING**

Northwest Medical Isotopes, LLC (NWMI) is providing the following responses to the Commission’s January 30, 2018 Post-Hearing Questions regarding the mandatory hearing for the Construction Permit Application for NWMI’s medical radioisotope production facility. The included responses are limited to those questions directed to NWMI. Questions directed to the NRC staff have been noted in the table that follows. The NRC staff has no objections to admitting NWMI-012 into the record.

**RESPONSE TO U.S. NUCLEAR
REGULATORY COMMISSION
PUBLIC POST-HEARING QUESTIONS**
Docket No. 50-609-CP

February 6, 2018

Prepared by:
Northwest Medical Isotopes, LLC
815 NW 9th Ave, Suite 256
Corvallis, OR 97330

No.	Question
1	<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, NRC Staff Revised Responses to Commission Pre-Hearing Questions (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.” Id. 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 any potential voids that may adversely impact the stability of subsurface materials and foundation, soil and rock 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>

Response: Per our response to the Commission Pre-Hearing Question 8(e) submitted on January 16, 2018, Northwest Medical Isotopes, LLC (NWMI) does not believe the above identified draft permit condition is necessary. However, if the Commission does impose this condition, NWMI has no objection to the above modifications to the permit condition.

2	<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>
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Response: There are several geophysical methods available to qualitatively detect anomalies (e.g., caves, sinkholes) at the radioisotope production facility (RPF) site; however, these methods will not be sufficient for the final design of the NWMI RPF. Ground-penetrating radar is the most common geophysical technique to detect sinkholes, but is limited to subsurface depths that are shallower than needed for a complete investigation of the NWMI RPF site. Either electromagnetic mapping, electrical conductivity and resistivity imaging, or microgravity and surface wave spectral analysis will be used to investigate the NWMI RPF site for subsurface anomalies such as caves or sinkholes. In addition, a complete mapping of the bedrock below the site is planned, in case the NWMI final design warrants facility support using pylons that rest on the bedrock surface.

3	<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 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>
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Response: NRC Staff Response Only.

No.	Question
4	<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>

Response: During the development of the Construction Permit Application, NWMI used NUREG/CR-6410, *Nuclear Fuel Cycle Facility Accident Analysis Handbook*,¹ Section 5.3.5, “Building Wakes.” NWMI concluded that the handbook is consistent with Regulatory Guide 1.145² and defines conditions where an elevated stack height can be used even if the 2.5 rule of thumb (i.e., stack height to adjacent structures) is not met.

4 (cont)	<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>
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Response: NWMI assumed that the RPF (which the stack is attached to) would be considered as an adjacent building, consistent with Regulatory Guide 1.145 and NUREG/CR-6410. Adjacent structures, as referred to in Regulatory Guide 1.145 and NUREG/CR-6410, are buildings that affect the release point, so buildings on other lots would not be considered adjacent structures in this context.

4 (cont)	<p>Please explain the basis for treating the releases from the proposed facility as elevated releases rather than ground-level releases.</p>
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Response: NWMI used the guidance provided in NUREG/CR-6410 during development of the integrated safety analysis (ISA). NUREG/CR-6410, Section 5.3.5, states that if the stack velocity is 5 times greater than the horizontal velocity, then treating the release as an elevated release is allowed. The stack diameter will be designed such that this requirement is met. Based on standard design values, the ratio is expected to be approximately 7.

4 (cont)	<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>
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Response: When a radioisotope production facility accident (e.g., Chapter 13.2.2, “Target Dissolver Offgas Accidents with Radiological Consequences”³) is modeled with an elevated release (i.e., RSAC), the maximum dose occurs at a distance of 1,100 meters (m) (3,609 feet [ft]) from the RPF where the plume reaches ground level.

¹ NUREG/CR-6410, *Nuclear Fuel Cycle Facility Accident Analysis Handbook*, U.S. Nuclear Regulatory Commission, Washington, D.C., 1998.

² Regulatory Guide 1.145, *Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants*, Rev. 1, U.S. Nuclear Regulatory Commission, Washington, D.C., February 1983.

³ NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility*, Rev. 3, Northwest Medical Isotopes, LLC, Corvallis, Oregon, 2017.

No.	Question
4 (cont)	Would a re-analysis of the dose calculations and stack height be required if a multi-story building were constructed on a nearby lot?

Response: While a 10 CFR 50.59⁴ evaluation would be required once the operating license is approved, based on Discovery Ridge Protective Covenants, construction on a nearby lots is unlikely to affect the release calculation. This evaluation will be reanalyzed during the Operating License Application.

5	<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 activities that would be licensed pursuant to 10 C.F.R. Part 70 in the RPF.</p> <p>As was discussed during the hearing, NWMI has sought an exemption from 10 C.F.R. § 70.21(f), that would apply to the license that will be sought by NWMI 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.” Nuclear Fuel Services, Inc. (Erwin, Tennessee), CLI-03-3, 57 NRC 239, 247 (2003).⁵</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 NWMI 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 NWMI if granted. Further, if the 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>
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Response: NRC Staff response only.

⁴ 10 CFR 50.59, “Changes, Tests and Experiments,” *Code of Federal Regulations*, Office of the Federal Register, as amended.

⁵ 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.”).

No.	Question
5. (cont)	(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?

Response: NRC Staff response only.

Respectfully submitted,
Executed in Accord with 10 C.F.R. § 2.304(d)

Signed (electronically) by Carolyn C. Haass
 Carolyn C. Haass
 Northwest Medical Isotopes, LLC – Chief Operating Officer
 815 NW 9th Ave, Suite 256
 Corvallis, OR 97330
 Phone: 509-430-6921
 Email: carolyn.haass@nwmedicalisotopes.com

Dated in Denver, Colorado
 this 6th day of February 2018

CERTIFICATION AND DECLARATION OF WITNESS

I certify that NWMI's responses to the Commission's public post-hearing questions were prepared by me or under my direction; that the responses are true and correct to the best of my information, knowledge and belief; and that I adopt these responses as part of my sworn testimony in this proceeding.

I declare under penalty of perjury that the foregoing written testimony is true and correct to the best of my information, knowledge, and belief.

Executed on February 6, 2018.

Respectfully submitted,

Executed in Accord with 10 C.F.R. § 2.304(d)

Signed (electronically) by Carolyn C. Haass

Carolyn C. Haass
Northwest Medical Isotopes, LLC – Chief Operating Officer
815 NW 9th Ave, Suite 256
Corvallis, OR 97330
Phone: 509-430-6921
Email: carolyn.haass@nwmedicalisotopes.com