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 RESPONSES TO COMMISSION POST-HEARING QUESTIONS

Pursuant to the Commission Order (Transmitting Post-Hearing Questions), dated January 30, 2018, the U.S. Nuclear Regulatory Commission (NRC) staff (Staff) hereby files its responses to the questions posed to the Staff by that Order. Northwest Medical Isotopes, LLC does not object to the admission of NRC-014 into the record.

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 6th day of February, 2018

NRC STAFF RESPONSES TO COMMISSION POST-HEARING QUESTIONS

1. 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.

> **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.**

Staff Response: The above redline/strikeout changes to proposed permit condition 3.G appropriately broaden the condition to ensure the detection of site features that could impact the final design bases of the proposed Northwest Medical Isotopes, LLC (NWMI) facility. Should the Commission determine that this condition should be imposed, the Staff will update the construction permit and its safety evaluation report to reflect the revised permit condition.

2. 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?

Staff Response: None. This question was for the applicant only.

3. 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.

> **Could the Staff further explain its response on the uninterruptible power supplies?**

Staff Response: In response to Commission Pre-Hearing Question 19, the Staff attempted to explain that redundancy had been incorporated into the design of the emergency electrical

power system. In this regard, the Staff referred to the preliminary safety analysis report (PSAR), stating that the UPSs will be backed up by the standby electrical power (SEP) system diesel generator. The SEP system diesel generator, however, is not redundant to the UPSs. NUREG-1913, "Design Control," defines redundancy as an alternate, independent, or duplicate method of fulfilling a safety function to mitigate the consequences of a design-basis accident. As described in the NWMI PSAR, the function of the SEP system diesel generator is not safety-related and, therefore, it is not redundant, as that term is defined, to the UPSs.

4. 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.

[a] Was the applicability of this guidance examined, and, if so, what were the conclusions?

Staff Response: No, the Staff did not specifically examine the applicability of Regulatory Guide (RG) 1.145, "Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants," during its review of the NWMI construction permit application, because NWMI used an alternate method to perform its accident analyses.

An NRC RG provides one method by which an applicant can satisfy NRC regulations, but other methods or assumptions may be acceptable if they provide a basis for the requisite licensing findings. NWMI used a computer code, Radiological Safety Analysis Computer Program Version 6.2 (RSAC), to evaluate the consequences of potential target dissolver offgas and dissolver product spray leak accidents at its proposed facility, as discussed below in the Staff's response to Question 4.d. The Staff performed independent confirmatory dose calculations of NWMI's analysis of these accidents using another computer code, Radiological Assessment System for Consequence Analysis (RASCAL), as discussed in the Staff's response to Question 4.c below.

The RG 1.145 recommendation that releases from stacks less than 2.5 times the height of adjacent structures (e.g., short stacks) should be considered ground releases (e.g., releases from a release point with a height of zero) is a conservative, bounding assumption for atmospheric dispersion. This assumption is intended to ensure that building wake effects, which could potentially cause downwash of a plume leaving a short stack and increase ground-level airborne radionuclide concentrations and doses, are adequately considered in analyses of doses to receptors during power reactor accidents.[1] However, this bounding assumption may not be realistic for the NWMI facility because, given the anticipated facility site conditions, including the location of the NWMI site boundary relative to the facility, this assumption could potentially cause postulated accident doses to receptors near the site boundary to be overestimated.

[1] For fuel cycle facilities, building wake effects are discussed in NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," Section 5.3.5.

[b] 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?

Staff Response: RG 1.145 does not define a specific distance from a stack for which a building is considered to be an adjacent structure. However, the building from which a release occurs (whether due to a leak, or a release from a vent or stack on the building), or other nearby buildings on a power reactor site, could be considered adjacent structures as used in RG 1.145. Thus, in addition to the radioisotope production facility (RPF) building itself, other buildings on the NWMI site or on other nearby lots at the Discovery Ridge Research Park could be considered adjacent structures if RG 1.145 were used to review an NWMI application.

[c] Please explain the basis for treating the releases from the proposed facility as elevated releases rather than ground-level releases.

Staff Response: As noted in the Staff's response to Question 4.a above, an applicant can demonstrate it meets NRC regulations by means other than those described in guidance such as a Regulatory Guide. NWMI used an elevated release-level assumption in its accident dose analyses based on the 75 foot height of the stack at the proposed facility. The Staff accepted NWMI's elevated release-level assumption because, based on the siting of the facility as well as the preliminary nature of NWMI's design and proposed facility operation, the Staff found that the dose calculation input parameters, including release-level assumptions, used by NWMI and summarized in the application were sufficiently representative of anticipated site conditions and facility design and operation. As discussed in safety evaluation report (SER) Section 13.4.9 (at 13-23) (Exhibit NRC-008), the Staff performed independent confirmatory dose calculations of NWMI's target dissolver offgas and dissolver product spray leak accidents using the RASCAL code, and obtained comparable dose estimates to NWMI's calculations. The RASCAL code utilizes an algorithm which includes corrections to improve its estimates of dispersion near buildings. As also described in SER Section 13.4.9, the Staff's independent verification of NWMI's preliminary dose calculations allowed the Staff to conclude that there is reasonable assurance that NWMI will develop appropriate models to estimate dose consequences as the design of the facility matures. The Staff will perform additional analysis of NWMI's dose calculations as part of its review of an NWMI operating license (OL) application.

Additionally, as described in PSAR Sections 1.2.2 and 13.2, NWMI intends to select Items Relied on For Safety and appropriate management measures based on the results of its Integrated Safety Analysis (ISA) to mitigate potential releases resulting from accident conditions such that offsite doses would be within the normal operational limits of 10 C.F.R. § 20.1301(d) (*e.g.*, 0.5 rem). Until NWMI finalizes the results of its ISA, and provides more detailed information describing the validation of models, codes, assumptions, and approximations used to estimate radiological release consequences, as part of its final design in a final safety analysis report (FSAR), the Staff finds that it is not necessary for NWMI to provide a dose calculation model that necessarily predicts worst-case values at the site boundary or other locations, or incorporates building wake effects.

[d] 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.

Staff Response: NWMI's conclusion is based on the results of NWMI's RSAC calculations performed for its dissolver product spray leak and target dissolver offgas accident analyses,

which assumed an elevated release through the NWMI facility stack, as discussed in PSAR Section 13.2.3.7 (at 13-57). The Staff notes that RSAC only includes building wake corrections for ground release scenarios. For NWMI's elevated release calculations using RSAC, the maximum accident dose occurs 1,100 meters from the facility because much of the plume passes overhead the receptors located closer to the facility. As discussed above in the Staff's response to Question 4.c, the Staff accepted NWMI's release-level assumptions based on the siting of the facility and the preliminary nature of NWMI's design and proposed facility operation. The Staff found that, for a preliminary analysis, the dose calculation input parameters, including release-level assumptions, used by NWMI and provided in the application were sufficiently representative of anticipated site conditions and facility operation.

[e] Would a re-analysis of the dose calculations and stack height be required if a multi-story building were constructed on a nearby lot?

Staff Response: Yes, 10 C.F.R. § 50.34(b)(4) requires that an FSAR evaluate the performance of the facility design consistent with the objective stated in 50.34(a)(4), which includes consideration of normal and accident conditions. NWMI should re-analyze its dose calculations and stack height if a multi-story building were constructed on a nearby lot prior to the issuance of an OL. The Staff would evaluate NWMI's dose calculations as part of its review of an NWMI OL application, and would also consider whether any multi-story buildings which may have been constructed on nearby lots at the Discovery Ridge Research Park could affect NWMI's dose calculations and the ability to credit its stack. If a multi-story building were constructed nearby after the issuance of an OL, the Staff would consider the matter as part of its inspection program or in response to any NWMI request for a licensing action that could impact radiological releases.

5. 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. As was discussed during the hearing, NWMI has sought an exemption from 10 C.F.R. § 70.21(f), which 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).[1] At the hearing, the discussion of the effect of the proposed exemption on construction of the RPF at times lacked clarity.

(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.

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[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.").

Staff Response: NWMI states in its exemption request that it "submits this exemption request from the requirement of 10 CFR 70.21(f), 'Filing,' for the NWMI Radioisotope Production Facility (RPF)" after which NWMI quotes the entirety of 10 C.F.R. § 70.21(f). Exhibit NWMI-010 at 1. NWMI states that it seeks relief from 10 C.F.R. § 70.21(f) in order to "enable NWMI to initiate construction of the RPF, including 10 CFR [Part] 70 components (e.g., target fabrication), upon authorization of our 10 CFR [Part] 50 construction permit . . . without waiting 9 months after submission of the required Environmental Report (ER), since the ER was covered under the NRC environmental review for the 10 CFR [Part] 50 construction permit application." Exhibit NWMI-010 at 3. *See also* Tr. at 46-47, 53-55 (indicating that, although the RPF may be one building with two parts, NWMI's approach has been to look at the facility as a whole). As the Staff explained in its testimony, the Staff conducted a comprehensive environmental review, including consideration of environmental impacts from proposed Part 70 activities, as part of its Part 50 construction permit application review. *See* Tr. at 196-197. If a Part 70 application is submitted, the Staff would focus its review on any significant new information that is provided in the Environmental Report required by 10 C.F.R. § 70.21(f). *Id*. *See also* Exhibit NRC-001 at 18 n.10 (indicating that the environmental review of a Part 70 target fabrication application would update the environmental review of Part 70 activities documented in the construction permit environmental impact statement).

The Staff is reviewing the exemption request to determine whether or not it contains sufficient information to be docketed for a detailed review. While the Staff has not reached any conclusions on the acceptability for docketing, the Staff notes that NWMI states that the purpose of the exemption request is to allow NWMI to begin construction of the Part 70 portion of the RPF upon issuance of the construction permit, *i.e.*, "without waiting 9 months after submission of the required Environmental Report . . . ." Exhibit NWMI-010 at 3. The exemption request, however, does not specify whether NWMI is seeking an exemption from the requirement of 10 C.F.R. § 70.21(f) that its Part 70 application be filed at least 9 months before commencement of construction and/or the requirement that the application be accompanied by an Environmental Report required under subpart A of 10 C.F.R. Part 51.

Although it is not clear from which specific provision(s) NWMI is requesting the exemption, the Staff can confirm that any exemption granted to the requirements of 10 C.F.R. § 70.21(f) 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 application review and ongoing oversight. The Staff further notes that an exemption request will only be granted if, in

accordance with 10 C.F.R. § 70.17, a determination is made that the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest.

(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?

Staff Response: If NWMI were to commence construction on the target fabrication portion of the RPF before submitting a 10 C.F.R. Part 70 application and without obtaining exemptions from 10 C.F.R. §§ 70.21(f) or 70.23(a)(7), NWMI would do so at risk of adverse regulatory actions for noncompliance with those regulations. Section 70.23(a)(7) provides that commencement of construction prior to completion of the Staff's environmental review[2] could be grounds for denial of the Part 70 license. As explained by the Commission, the purpose of this regulation is not to prohibit construction activities before the NRC has completed an environmental review but to "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, 246-47 (2003). Obtaining exemptions in advance of construction supports regulatory certainty which, from a practical standpoint, could reduce the risk to NWMI's project schedule. *See* Tr. at 43, 52.

[2] Specifically, the regulation refers to commencement of construction before the conclusion of the "Director of Nuclear Material Safety and Safeguards or his/her designee . . . on the basis of information filed and evaluations made pursuant to subpart A of part 51 of this chapter . . . after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values." 10 C.F.R. § 70.23(a)(7).

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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 RESPONSES TO COMMISSION POST-HEARING QUESTIONS," dated February 6, 2018, have been served upon the Electronic Information Exchange, the NRC's E-Filing System, in the above-captioned proceeding, this 6th day of February, 2018.

/Signed (electronically) by/

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Dated at Rockville, Maryland
this 6th day of February, 2018