

January 23, 2015

Carolyn C. Haass  
Vice President  
Northwest Medical Isotopes, LLC  
8815 Northwest 9th Street, Suite 256  
Corvallis, OR 97330

SUBJECT: NORTHWEST MEDICAL ISOTOPES, LLC – STATUS OF THE ACCEPTANCE  
REVIEW OF PART ONE OF THE APPLICATION FOR CONSTRUCTION  
PERMIT (TAC NO. MF2288)

Dear Ms. Haass:

By letter dated November 7, 2014, Northwest Medical Isotopes, LLC (NWMI), submitted the first part of a two-part application for a construction permit to build a radioisotope production facility. If granted, the construction permit would allow NWMI to construct a radioisotope production facility to be located in Columbia, Missouri.

An exemption from certain requirements of 10 CFR 2.101(a)(5) granted by the Commission on October 7, 2013 (78 FR 63501), in response to a letter from NWMI dated August 9, 2013 (Agencywide Document Access and Management System Accession (ADAMS) Accession No. ML13227A295), allowed NWMI to submit its construction permit application in two parts. Specifically, the exemption allowed NWMI to submit a portion of its application for a construction permit up to six months prior to the remainder of the application regardless of whether or not an environmental impact statement or a supplement to an environmental impact statement is prepared during the review of its application.

In accordance with 10 CFR 2.101(a)(4), if it is determined that any part of the tendered application and/or environmental report is incomplete, and therefore not acceptable for processing, the applicant will be informed of this determination, and the respects in which the document is deficient. The NRC staff performed an acceptance review to determine whether the application contained sufficient technical information in scope and depth to allow the NRC staff to begin its detailed technical review (both safety and environmental). The NRC staff has identified an apparent deficiency in the application. Specifically, NWMI did not provide sufficient information in the environmental report for the staff to begin its review. A description of the information needed is included in the enclosure.

The NRC staff requests that NWMI provide the requested information, as described in the enclosure, within 30 days of the date of this letter. Should NWMI be unable to provide this information within the 30-day timeframe, the staff will consider the application incomplete and unacceptable for docketing. In the event that such a determination is made, NWMI will be notified of the decision and be provided the opportunity to withdraw, supplement, and resubmit its application for a construction permit. Part one of the NWMI application for a construction permit will be accepted for docketing and a detailed technical review will be commenced only when the NRC staff has determined that the tendered application includes all information required by applicable regulatory requirements.

C. Haass

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If you have any questions regarding this matter, please contact William Schuster at (301) 415-1590.

Sincerely,

***/RA/***

Alexander Adams, Jr., Chief  
Research and Test Reactors Licensing Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

Project No. 0803

Enclosure:  
As stated

Northwest Medical Isotopes

Project No. 0803

cc:

Darrell Liles, CHP, PE  
Senior Health Physicist  
ARCADIS-SENEC  
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Nicholas F. Fowler  
Chief Executive Officer  
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8815 Northwest 9th Street, Suite 256  
Corvallis, OR 97330

C. Haass

- 2 -

If you have any questions regarding this matter, please contact William Schuster at (301) 415-1590.

Sincerely,

**/RA/**

Alexander Adams, Jr., Chief  
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As stated

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**NRR-106**

<b>OFFICE</b>	NRR/DPR/PRLB	NRR/DPR/LA	NRR/DLR/RERB
<b>NAME</b>	WSchuster	DHarrison	DWrona
<b>DATE</b>	12/19/2014	12/23/2014	01/07/2015
<b>OFFICE</b>	OGC	NRR/DPR/PRLB	
<b>NAME</b>	MYoung - NLO	AAdams	
<b>DATE</b>	01/23/2015	01/23/2015	

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DESCRIPTION OF INCOMPLETE INFORMATION IDENTIFIED IN

NORTHWEST MEDICAL ISOTOPES, LLC.

CONSTRUCTION PERMIT APPLICATION

CHAPTER 19 – ENVIRONMENTAL REVIEW

The U.S. Nuclear Regulatory Commission's (NRC's) regulations implementing the National Environmental Policy Act (NEPA) are codified in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." These regulations describe, among other things, information to be submitted by applicants in order for the NRC to conduct environmental reviews that disclose and consider the environmental impacts of a proposed NRC licensing action. Specifically, 10 CFR 51.45(b) states that an environmental report submitted with an application must contain a description of the proposed action and the affected environment, as well as discuss the impacts of the proposed action on the environment.

In determining the scope of its environmental review for the proposed action, the NRC staff, consistent with 10 CFR 51.14(b), uses the definitions in 40 CFR 1508.25 in implementing Section 102(2) of NEPA. Section 1508.25, "Scope," states that actions are connected if they:

- Automatically trigger other actions which may require environmental impact statements;
- Cannot or will not proceed unless other actions are taken previously or simultaneously; or
- Are interdependent parts of a larger action and depend on the larger action for their justification.

Consistent with NRC guidance, Northwest Medical Isotopes (NWMI) submitted an environmental report (Chapter 19 of the construction permit (CP) application) for the NRC to consider in conducting its environmental review of the NWMI CP application. Chapter 19 of the NWMI CP application considers the impacts of construction, operation, and decommissioning of a radioisotope production facility. "Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors" (Agencywide Document Access and Management System Accession No. ML12156A069), states the environmental report should address the likelihood of significant impacts to the human environment posed by the proposed action.

Because radioisotope production by NWMI's proposed facility depends on targets being transferred to and from, and irradiated in, one or more research reactors, transportation of the targets and irradiation at research reactors are connected actions to the proposed action.

ENCLOSURE

While the environmental report contains a discussion on transportation of the targets, it does not contain a discussion of the impacts of target irradiation (at research reactors) on the affected resource areas identified in the ISG augmenting NUREG-1537, Part 1. Therefore, the NRC staff has identified that the environmental report is incomplete in the following two respects.

1. In Chapter 19 of the NWMI CP application, provide a description of the affected environment at all anticipated irradiation locations.
2. In Chapter 19 of the NWMI CP application, provide a discussion of the environmental impacts associated with irradiation of targets.

Until Chapter 19 of the NWMI CP application includes information on the environmental impacts of the connected actions, the CP permit application is incomplete and the NRC staff cannot begin its environmental review.