



November 28, 2016  
NWMI-LTR-2016-012

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
11555 Rockville Pike  
Washington, DC 20555

Mr. Michael Balazik  
Research and Test Reactors Branch A  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

**RE: Docket No. 50-609, Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Regarding the Preliminary Safety Analysis Report Request for Additional information (Letter dated September 29, 2016) (TAC NO. MF6138)**

**References:**

1. Northwest Medical Isotopes, LLC Letter NWMI-LTR-2016-009 to U.S. Nuclear Regulatory Commission, dated September 1, 2016, *Docket No. 50-609, Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Environmental Request for Additional information (Letter dated June 16, 2016) – Additional Clarification on POSA3-1A, POSA3-1B, POSA3-2A, POSA3 3A, NOI3-1B, and PA3-1* (ADAMS Accession No. ML16270A377)
2. Northwest Medical Isotopes, LLC Letter NWMI-LTR-2016-007 to U.S. Nuclear Regulatory Commission, dated July 18, 2016, *Docket No. 50-609, Northwest Medical Isotopes, LLC Responses to Request for Additional Information – Letter dated June 16, 2016* (ADAMS Accession No. ML16210A305)
3. U.S. Nuclear Regulatory Commission letter to Northwest Medical Isotopes, LLC, dated June 16, 2016, *Docket No. 50-609, Request for Additional Information for the Environmental Review of the Northwest Medical Isotopes, LLC Construction Permit Application* (ADAMS Accession No. ML16176A114) (TAC Nos. MF6134 and MF 6135)
4. Northwest Medical Isotopes, LLC Letter NWMI-LTR-20 15-006 to U.S. Nuclear Regulatory Commission, dated July 20, 2015, *NRC Project No. 0803 - Northwest Medical Isotopes, LLC, Submittal Part 2 Construction Permit Application for a Radioisotope Production Facility* (ADAMS Accession No. ML16056A122)
5. Northwest Medical Isotopes, LLC Letter to U.S. Nuclear Regulatory Commission, dated February 5, 2015 (ADAMS Accession No. ML14349A501), *Environmental Report and Associated Part One Submittal* (ADAMS Accession Nos. ML14349A501, ML15210A123, ML15210A128, ML15210A129, and ML15210A131)

Dear Mr. Balazik:

Northwest Medical Isotopes, LLC (NWMI) is providing the response to the U.S. Nuclear Regulatory Commission request for additional information (RAI) dated September 29, 2016.

ADD!  
NRR

The required affidavit to withhold information from public disclosure is provided in Attachment 1. NWMI considers the information in Attachment 2 to be proprietary and requests that the attachment be withheld from public disclosure, pursuant to 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding."

The attachments to this letter include the following:

- Attachment 1 – The required affidavit to withhold information from public disclosure per 10 CFR 2.390
- Attachment 2 – Non-public (proprietary and business sensitive) version of the letter; the information is provided in hard copy
- Attachment 3 – Public (non-proprietary) version of the letter; the information is provided in hard copy

NWMI is submitting this response to the NRC in accordance with 10 CFR 50.30(b), "Oath or Affirmation," and 10 CFR 50.4, "Written Communications."

I solemnly declare and affirm that the foregoing information is true and correct under the penalty of perjury.

Executed on November 29, 2016.

If you have questions, I can be reached at (509) 430-6921 or [carolyn.haass@nwmedicalisotopes.com](mailto:carolyn.haass@nwmedicalisotopes.com).

Sincerely,



Carolyn C. Haass  
Chief Operating Officer

cc: Mr. Alexander Adams  
Research and Test Reactors Branch A  
Office of Nuclear Reactor Regulation



**ATTACHMENT 1**

**AFFIDAVIT TO WITHHOLD PROPRIETARY  
INFORMATION FROM PUBLIC DISCLOSURE**

**(Pursuant to 10 CFR 2.390)**



**10 CFR 2.390**  
**AFFIDAVIT OF Carolyn C. Haass**

I, **Carolyn C. Haass**, hereby affirm and state as follows:

1. I am the Chief Operating Officer of Northwest Medical Isotopes, LLC (NWMI), and I have been authorized to execute this affidavit on behalf of NWMI.
2. The information contained in the enclosed letter dated November 29, 2016, is proprietary commercial information related to NWMI becoming a domestic supplier of molybdenum-99 (<sup>99</sup>Mo). The proprietary information (Response to the U.S. Nuclear Regulatory Agency Request for Additional Information for the Preliminary Safety Analysis Report (Dated September 29, 2016) of the Northwest Medical Isotopes, LLC, Construction Permit Application, Non-Public Version) includes sensitive business information created by or for NWMI. This information should be held in confidence by the U.S. Nuclear Regulatory Commission (NRC) and withheld from public disclosure.
3. In making this application for withholding of proprietary information of which it is the owner, NWMI believes that the information qualifies for withholding under the exemption from disclosure set forth in the Freedom of Information Act (FOIA), 5 U.S.C. Section 552(b)(4), the Trade Secrets Act, 18 U.S.C. Section 1905, and NRC regulations in 10 CFR 2.390(a)(4) for trade secrets and commercial information because:
  - a. This information is owned by NWMI. Specifically, information related to the target dimensions, material composition, and mass or information that would reasonably allow knowledgeable people to deduce this information and experimental results should be withheld from public disclosure. This information is considered proprietary and would significantly affect any competitive advantage that this target configuration creates.
  - b. This information is of a type that is customarily held in confidence by NWMI, and there is a rational basis for doing so because the information includes sensitive business information.
  - c. The information is being transmitted to the NRC voluntarily and in confidence.
  - d. This information is not available in public sources and could not be gathered readily from other publicly available information.
  - e. Public disclosure of this information would create substantial harm to the competitive position of NWMI by disclosing certain business decisions NWMI has made or is considering, and the analysis that went behind those decisions. Development and evaluation of this commercial information was achieved at, and disclosure could lead to additional, significant cost to NWMI.
  - f. Public disclosure of the information sought to be withheld is likely to cause substantial harm to NWMI'S competitive position and foreclose or reduce the availability of profit-making opportunities. The value of the information goes beyond the disclosure of actual information pertaining to NWMI's potential business, and includes substantial time and work towards developing the project by NWMI and its associates. The research, development, engineering, and analytical costs comprise a substantial investment of time and money by NWMI. The precise value of the information is difficult to quantify, but clearly is substantial.

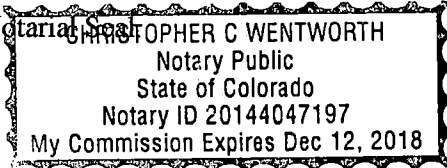


g. NWMI's competitive advantage will be lost if its competitors are able to use the results of NWMI's activities to aid their own commercial activities. The value of this information to NWMI would be lost if the information was disclosed to the public. Making such information available to other entities without their having been required to undertake a similar expenditure of resources would unfairly provide competitors with a significant advantage, and deprive NWMI of the opportunity to exercise its competitive advantage to seek an adequate return on a large investment.

Carolyn C. Haass, Vice President

Subscribed and sworn before me, a Notary Public, in and for the State of Colorado, this 29<sup>th</sup> day of November, 2016.

Witness my hand and Notary Seal



Notary Public

My commission expires: *Dec 12, 2018*

11/30/2016  
Date