

February 27, 2017

Carolyn C. Haass
Chief Operating Officer
Northwest Medical Isotopes, LLC
815 Northwest 9th Street, Suite 256
Corvallis, OR 97330

SUBJECT: NORTHWEST MEDICAL ISOTOPES, LLC – REQUEST FOR WITHHOLDING
INFORMATION FROM PUBLIC DISCLOSURE (CAC NO. MF6138)

Dear Ms. Haass:

By letter dated November 28, 2016 (Agencywide Documents Access and Management System Accession No. ML16344A052) Northwest Medical Isotopes, LLC (NWMI), submitted an affidavit executed by yourself which requested that the information contained in the following document be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.390:

Attachment 2 – Response to the U.S. Nuclear Regulatory Commission Request for Additional Information Regarding the Preliminary Safety Analysis Report of the Northwest Medical Isotopes, LLC Construction Permit Application
Docket No. 50-609

The affidavit stated that the submitted information should be considered exempt from mandatory public disclosure for the following reasons:

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 10 CFR 2.390(a)(4) for trade secrets and commercial information because:

- i. 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.
- ii. 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.

- iii. The information is being transmitted to the NRC voluntarily and in confidence.
- iv. This information is not available in public sources and could not be gathered readily from other publicly available information.
- v. 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.
- vi. 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, and represents significant efforts 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.
- vii. 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 were 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 windfall, and deprive NWMI of the opportunity to exercise its competitive advantage to seek an adequate return on its large investment.

We have reviewed your application and the material in accordance with the requirements of 10 CFR 2.390 and, on the basis of the statements in the affidavit, have determined that the submitted information sought to be withheld contains proprietary commercial information and should be withheld from public disclosure.

Therefore, the "Attachment 2 - Response to the U.S. Nuclear Regulatory Commission Request for Additional Information Regarding the Preliminary Safety Analysis Report of the Northwest Medical Isotopes, LLC Construction Permit Application Docket No. 50-609," marked as proprietary, will be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the U.S. Nuclear Regulatory Commission (NRC). You also should understand

that the NRC may have cause to review this determination in the future, for example, if the scope of a FOIA request includes your information. In all review situations, if the NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions regarding this matter, I may be reached at 301-415-2856 or by electronic mail at Michael.Balazik@nrc.gov.

Sincerely,

/RA/

Michael F. Balazik, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-609

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DATED: February 27, 2017

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