



July 20, 2015  
NWMI-LTR-2015-006

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

**RE: NRC PROJECT NO. 0803 – NORTHWEST MEDICAL ISOTOPES, LLC, SUBMITTAL  
PART 2 CONSTRUCTION PERMIT APPLICATION FOR A RADIOISOTOPE  
PRODUCTION FACILITY**

**References**

1. Letter from Northwest Medical Isotopes, LLC to U.S. Nuclear Regulatory Commission, "Request for Exemption to Submit a Construction Permit Application in Two Parts as Described in 10 CFR Part 2.101," NWMI-LTR-007, August 9, 2013 (ML13227A295).
2. Letter from U.S. Nuclear Regulatory Commission to Northwest Medical Isotopes, LLC, "Exemption from Certain Requirements of Title 10 Code of Federal Regulations, Section 2.101(a)(5), Regarding the Submission of a Construction Permit Application in Two Parts (TAC No. MF2288)" (ML13238A335).
3. Letter from Northwest Medical Isotopes, LLC to U.S. Nuclear Regulatory Commission, "Submittal of Part 1 Construction Permit Application for a Radioisotope Production Facility," NWMI-LTR-2015-003, dated February 5, 2015.

**Background**

Northwest Medical Isotopes, LLC, (NWMI) is pleased to submit Part 2 of our Construction Permit Application to construct a medical radioisotope production facility (RPF) to be located at the Discovery Ridge Research Park in Columbia, Missouri. NWMI is submitting this application in two parts in accordance with Reference 1, whereby NWMI requested exemption from certain requirements of Title 10, *Code of Federal Regulations* (CFR), Part 50.12 (10 CFR 50.12), "Specific Exemptions," which would allow the submittal of an application for construction permit in two parts, in accordance with 10 CFR 2.101(a)(5). The U.S. Nuclear Regulatory Commission (NRC) granted NWMI the exemption, as noted in Reference 2.

Part 1 of NWMI's Construction Permit Application submitted on February 5, 2015, included the following information: General information required by 10 CFR 50.33; Filing fee required by 10 CFR 50.30(3) and 10 CFR 170.21; Chapter 2.0, "Site Characteristics," as required by 10 CFR 50.34(a)(1); and Chapter 19.0, "Environmental Review," as required by 10 CFR 50.30(f).

Part 2 of NWMI's application includes the Integrated Safety Analysis Summary and the remaining sections of the Construction Permit Application per 10 CFR 50.34(a), and is being submitted in accordance with 10 CFR 2.101 (a)(5). In addition, the Part 2 submittal includes the Part 1 submittal (per NRC's request) to constitute a full application.

NWMI is applying to the NRC to obtain a license for a production facility under 10 CFR 50, "Domestic Licensing of Production and Utilization Facilities." Embedded in the 10 CFR 50-licensed facility will be several activities subject to 10 CFR 70, "Domestic Licensing of Special Nuclear Material," to receive, possess, use, and transfer special nuclear material, and 10 CFR 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," to process and transport molybdenum-99 (<sup>99</sup>Mo) for medical applications.

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NWMI intends to submit a single 10 CFR 50 license application for the RPF following the guidance in NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Format and Content*, that encompasses activities regulated under different NRC requirements (e.g., 10 CFR 70 and 10 CFR 30), in accordance with 10 CFR 50.31, “Combining Applications,” and 10 CFR 50.32, “Elimination of Repetition.”

The NRC has determined that a radioisotope separation and processing facility, which also conducts separation of special nuclear material, will be considered a production facility and as such, will be subject to licensing under 10 CFR 50. A significant portion of the NWMI RPF is focused on the disassembly of irradiated low-enriched uranium (LEU) targets, separation and purification of fission product <sup>99</sup>Mo, and the recycle of LEU that is licensed under 10 CFR 50. The RPF will also include the fabrication of LEU targets, which will be licensed under 10 CFR 70. These targets will be shipped to NWMI’s network of research or test reactors for irradiation (considered a connected action) and returned to the RPF for processing. The LEU used for the production of the LEU target materials will be obtained from the U.S. Department of Energy (DOE) and from LEU reclaimed from processing the irradiated targets. Any byproduct materials produced or extracted in the RPF will be licensed under 10 CFR 30.

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.” NWMI requests that Attachment 3 be uncontrolled or can be made available to the public.

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 NWMI Part 2 Construction Permit Application; the information is provided in hard copy
- Attachment 3 – Public (non-proprietary) version of the NWMI Part 2 Construction Permit Application; the information is provided in hard copy

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

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

**ATTACHMENT 1**

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

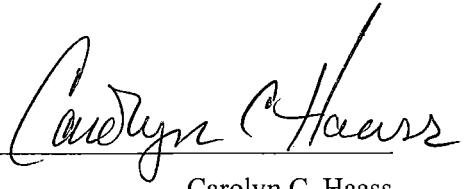
**(Pursuant to 10 CFR 2.390)**



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

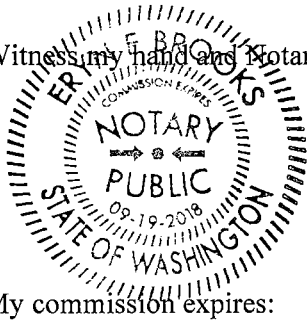
I, **Carolyn C. Haass**, herby affirm and state as follows:

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 July 20, 2015, is proprietary commercial information related to NWMI becoming a domestic supplier of molybdenum-99 (<sup>99</sup>Mo). The proprietary information (Submission of Part 2 Construction Permit Application and Integrated Safety Analysis Summary, Non-Pubic 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 and has been held in confidence by NWMI.
  - 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.

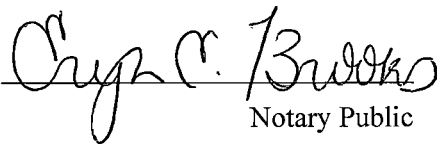
  
Carolyn C. Haass  
Chief Operating Officer

Subscribed and sworn before me, a Notary Public, in and for the state of Washington, this \_\_\_\_ day of July, 2015.

Witness my hand and Notarial Seal.



My commission expires:

  
Notary Public

JULY 20, 2015  
Date

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