



February 5, 2015
NWMI-LTR-2015-003

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 1 CONSTRUCTION PERMIT APPLICATION FOR A RADIOISOTOPE PRODUCTION FACILITY – WITHDRAWL OF PART 1 APPLICATION SUBMITTED ON NOVEMBER 7, 2014 AND RESUBMITTAL OF APPLICATION

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-2014-019, dated November 7, 2014.

This letter and Part 1 Construction Permit Application submission supercedes and withdraws the submission dated November 7, 2014 (NWMI-LTR-2014-019, from Northwest Medical Isotopes, LLC to U.S. Nuclear Regulatory Commission) and resubmits the application.

Background

Northwest Medical Isotopes, LLC, (NWMI) is pleased to submit Part 1 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), 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 provides the following:

- 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)
- Chapter 19.0, “Environmental Review,” as required by 10 CFR 50.30(f)
- Agreement limiting access to classified information required by 10 CFR 50.37

Part 2 of NWMI’s application will include the remaining sections of the Construction Permit Application per 10 CFR 50.34(a) and will be submitted in accordance with 10 CFR 2.101 (a)(5).

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NWMI is applying to the NRC to obtain a license for a production facility under Title 10, *Code of Federal Regulations* (CFR) Part 50 (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 (⁹⁹Mo) for medical applications.

NWMI intends to submit a single 10 CFR 50 license application for the radioisotope production facility (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 ⁹⁹Mo, 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.

NWMI’s licensing approach for the RPF defines the following unit processes and areas that fall under the following NRC regulations:

- 10 CFR 50, “Domestic Licensing of Production and Utilization Facilities”
 - LEU Target receipt (from network of university research or test reactors)
 - Irradiated LEU Target disassembly and dissolution
 - ⁹⁹Mo recovery and purification
 - Uranium recovery and recycle
 - Waste management
 - Associated laboratory and support areas
- 10 CFR 70, “Domestic Licensing of Special Nuclear Material”
 - Receipt of fresh LEU (from DOE)
 - LEU target fabrication
 - Associated laboratory and support areas

Any byproduct materials produced or extracted in the RPF will be licensed under 10 CFR 30.

Deliverables

NWMI’s description and safety assessment of the proposed RPF site’s geology, seismology, and geotechnical engineering (Chapter 2.0) was developed using existing data for the Discovery Ridge Research Park in Columbia, Missouri. Although these data are relevant to the overall research park, in some cases, the information is not specific to the exact location of the RPF. NWMI will be completing additional site-specific geotechnical data in support of the facility preliminary safety analysis report (PSAR) and design. NWMI is in the process of collecting geotechnical data specific to the site on which the RPF is proposed to be built. This data will augment the description or analysis of the site’s geology, seismology, or geotechnical engineering, and an amendment to the application will be submitted in accordance with 10 CFR 50.4, “Written Communications.”



The Council for Environmental Quality regulations implementing the National Environmental Policy Act (NEPA) requires that the cumulative impacts of a proposed action be assessed (40 CFR 1500-1508). A cumulative impact is defined by the Council as “the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or nonfederal) or person undertakes such other actions” (40 CFR 1508.7, “Cumulative Impact”). Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time (40 CFR 1508.7).

The Council on Environmental Quality guidance for considering cumulative effects states that NEPA documents “should compare the cumulative effects of multiple actions with appropriate national, regional, State, or community goals to determine whether the total effect is significant.”

Within the Environmental Review (Chapter 19.0), NWMI documented the existing environment at the proposed Columbia, Missouri, site and surround area, and summarized the environmental impacts of construction, operation, and decommissioning. NWMI also considered appropriate impact-mitigation measures and reviewed alternate sites and technologies. The analysis documented within the Environmental Review determined that the impacts associated with construction, operation, and decommissioning of the proposed RPF facility would be small or nonexistent. Extensive consultation with local stakeholders reveals that the facility is non-controversial, and these stakeholders have indicated support for establishment of the facility. Based on these factors, NWMI considers an Environmental Assessment to be the appropriate level of NEPA review for this project.

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 NWMI Part 1 Construction Permit Application; the information is provided on in hard copy
- Attachment 3 – Public (non-proprietary) version of the NWMI Part 1 Construction Permit Application; the information is provided in hard copy

NWMI requests that Attachment 2 be withheld from public disclosure pursuant to 10 CFR 2.390 and Attachment 3 be uncontrolled or can be made available to the public.

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

Sincerely,

Carolyn C. Haass
Vice President and Technical Program Director

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

William Schuster, 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 a Vice President and 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 7, 2014, is proprietary commercial information related to NWMI becoming a domestic supplier of Molybdenum-99 (⁹⁹Mo). The proprietary information (Re-Submission of Part 1 Construction Permit Application, 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

Carolyn C. Haass, Vice President

Subscribed and sworn before me, a Notary Public, in and for the State of Washington, this ___ day of January, 2015.

Witness my hand and Notarial Seal.



Eryn E. Brooks
Notary Public

My commission expires:

9.19.2018

25.15

Date

ATTACHMENT 2

**CONTAINS PROPRIETARY INFORMATION
IN ACCORDANCE WITH 10 CFR 2.390**

Northwest Medical Isotopes, LLC

Part One, Construction Permit Application

Non-Public Version

- **General Information per 10 CFR 50.33, filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21, and Classified Information Agreement in Accordance with 10 CFR 50.37**
- **Chapter 2 – Site Characteristics**
- **Chapter 19 – Environmental Review**

Information is being provided via hard copy

ATTACHMENT 3

Northwest Medical Isotopes, LLC

Part One, Construction Permit Application

Public Version

- **General Information per 10 CFR 50.33, filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21, and Classified Information Agreement in Accordance with 10 CFR 50.37**
- **Chapter 2 – Site Characteristics**
- **Chapter 19 – Environmental Review**

Information is being provided via hard copy