

December 24, 2015

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

SUBJECT: NORTHWEST MEDICAL ISOTOPES, LLC – ACCEPTANCE FOR DOCKETING
OF PART TWO OF THE APPLICATION FOR A PRODUCTION FACILITY
CONSTRUCTION PERMIT (TAC NO. MF6138)

Dear Ms. Haass:

By letter dated July 20, 2015 (NWMI-LTR-2015-006, Agencywide Documents Access and Management System Accession No. ML15210A114), Northwest Medical Isotopes, LLC (NWMI) filed with the U.S. Nuclear Regulatory Commission (NRC), pursuant to Section 103 of the Atomic Energy Act of 1954, as amended (the Act), and Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," the second part of its two-part application for a construction permit for a medical radioisotope production facility. If granted, the construction permit would allow NWMI to construct a production facility in Columbia, Missouri.

On June 8, 2015, NRC published in the *Federal Register* its acceptance of part one of NWMI's application for a construction permit (80 FR 32418).

The staff has completed its acceptance review of part two of NWMI's application for a construction permit for a production facility as defined in 10 CFR 50.2 "Definitions." The staff has determined that part two was submitted in accordance with the requirements of 10 CFR 2.101(a)(5), completes the information required by 10 CFR 50.34(a), and is acceptable for docketing. NWMI's construction permit application, in its entirety, has been placed under Docket No. 50-609. Please reference this docket number in all future correspondence.

The staff expects that NWMI will submit an application for fabricating low enriched uranium targets under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Materials," as stated in paragraph six (page 2) of NWMI's letter dated July 20, 2015.

The staff has started a review of the NWMI construction permit application. The staff will provide NWMI with a schedule that identifies significant milestones and the expected review completion date by January 31, 2016. The schedule will include provisions for staff to request additional information, if necessary.

A copy of the construction permit application will be referred to the Advisory Committee on Reactor Safeguards for a review and report consistent with 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards."

In support of the review of the NWMI construction permit application, a hearing will be conducted by the Commission or a Board designated by the Chief of the Atomic Safety and Licensing Board Panel in accordance with procedures in 10 CFR Part 2, "Agency Rules of Practice and Procedure." A future *Federal Register* notice (FRN) will announce the opportunity to petition for leave to intervene in a hearing on the application as well as the time and place of the hearing.

Additionally, in accordance with 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," the NRC will also prepare an environmental impact statement for the proposed action. The environmental impact statement will evaluate the environmental impacts for construction, operation and decommissioning of NWMI's radioisotope production facility. This review covers all activities at NWMI's radioisotope production facility, including those under 10 CFR Parts 50 and 70.

The docketing of the application does not predict whether the Commission will grant or deny the requested construction permit. If the Commission finds that the NWMI's construction permit application meets the applicable standards of the Act and the Commission's regulations, and that required notifications to other agencies and bodies have been made, the Commission will issue a construction permit for a production facility under 10 CFR Part 50, in the form and containing conditions and limitations that the Commission finds appropriate and necessary.

The NRC will publish an FRN informing the public of the NRC's decision to docket part two of NWMI's application for a construction permit of a production facility under 10 CFR Part 50. This notice only addresses the start of a review to determine whether the NRC will issue a construction permit for the proposed NWMI facility. In order to operate and produce radioisotopes in its facility, a separate application must be submitted by NWMI for NRC review and approval, and, if docketed, would be the subject of a separate FRN.

If you have any questions, please contact me at 301-415-2856, or Michael.Balazik@nrc.gov.

Sincerely,

/RA/

Michael 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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Sincerely,

Michael 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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ADAMS Accession No.: ML15341A112

*concurrence via e-mail

NRR-106

OFFICE	NRR/DPR/PRLB*	NRR/DPR/PRLB/LA*	NMSS/FCSE/FMB/PM*	OGC (Part 50)
NAME	MBalazik	NParker	DTiktinsky	MYoung (NLO)
DATE	12/4/2015	12/7/2015	12/7/2015	12/16/2015
OFFICE	OGC (Part 70)	NRR/DPR/PRLB/BC	NMSS/FCSE/FMB/BC	NRR/DPR/PRLB/PM
NAME	JBielecki (NLO)	AAdams	RJohnson	MBalazik
DATE	12/22/2015	12/10/2015	12/10/2015	12/24/2015

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