



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 27, 2017

APPLICANT: Northwest Medical Isotopes, LLC

SUBJECT: SUMMARY OF NOVEMBER 10, 2016, PUBLIC MEETING WITH NORTHWEST MEDICAL ISOTOPES, LLC

On November 10, 2016, a Category 1 public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) staff and representatives of Northwest Medical Isotopes, LLC (NWMI) at NRC Headquarters, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The purpose of this meeting was for NWMI to discuss with the NRC staff overarching technical topics associated with its construction permit application that may relate to the NRC's request for additional information (RAI) issued on September 29, 2016. A portion of this meeting was closed to the public to discuss proprietary information related to the specifics of design and operation of the proposed medical isotope production facility. The meeting notice and agenda, dated July 29, 2016, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML16223A156. A list of meeting attendees is provided as an enclosure. The information request issued to NWMI is available under ADAMS Accession No. ML16236A013.

NWMI representatives presented an overview of the status of its proposed radioisotope facility project. NWMI indicated that it has initiated final design and development of its future operating license application and the selection of a contractor for construction activities. Additionally, NWMI is continuing research and development of a test generator and the irradiation of a prototype target. NWMI indicated that it plans to submit responses to all RAIs that were issued on September 29, 2016, within the 60 day period and that all of the responses will be incorporated into NWMI's revised preliminary safety analysis report. NWMI briefly described the design objectives of its facility and that specific codes and standards will be included in the operating license application. NWMI presented information on the design criteria of structure, systems, and components. NWMI also explained the different quality levels related to their quality assurance plan. NWMI then discussed proposed changes to the accident analysis methodology. At the close of the meeting, NWMI indicated that NRC staff had an action to determine the applicability of Title 10 of the *Code of Federal Regulations* (10 CFR) 70.21(f) to their future Part 70 license application for target fabrication. The NRC staff will evaluate this action further and will provide NWMI a response. Further details on the public meeting are included in the presentation slides (ADAMS Accession No. ML16309A208).

During the closed portion of the meeting, NWMI went into proprietary-level detail related to criticality validation analysis and facility software demonstration for the proposed Molybdenum-99 production process.

Northwest Medical Isotopes, LLC

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Please direct any inquiries to me at 301-415-2856, or Michael.Balazik@nrc.gov.

/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

Enclosure:
As stated

SUBJECT: SUMMARY OF NOVEMBER 10, 2016, PUBLIC MEETING WITH NORTHWEST
MEDICAL ISOTOPES, LLC DATED: MARCH 27, 2017

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ADAMS Accession Nos.: ML17061A155 (Summary); ML16309A208 (Presentation);

***concurrence via e-mail**

NRC-001

OFFICE	NRR/DPR/PRLB/PM	NRR/DPR/PRLB/LA*	NRR/DPR/PRLB/BC	NRR/DPR/PRLB/PM
NAME	MBalazik	NParker	AAdams	MBalazik
DATE	3/9/17	3/8/17	3/27/17	3/27/17

OFFICIAL RECORD COPY

LIST OF ATTENDEES

PUBLIC MEETING WITH NORTHWEST MEDICAL ISOTOPES

November 10, 2016

9:00 A.M. – 3:30 P.M.

<u>Name</u>	<u>Organization</u>
Jeff Bartelme	SHINE Medical Technologies, Inc.
James Hammelman	U.S. Nuclear Regulatory Commission
Steven Lynch	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Charles Teal	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Mirela Gavrilas	U.S. Nuclear Regulatory Commission
Marilyn Diaz	U.S. Nuclear Regulatory Commission
David Drucker	U.S. Nuclear Regulatory Commission
Robert Johnson	U.S. Nuclear Regulatory Commission
Nancy Martinez	U.S. Nuclear Regulatory Commission
Lisa London	U.S. Nuclear Regulatory Commission
Mollie Semmes	U.S. Nuclear Regulatory Commission
Alex Sapountzis	U.S. Nuclear Regulatory Commission
Kara McCullough	U.S. Nuclear Regulatory Commission
Jenny Weil	U.S. Nuclear Regulatory Commission
Carl Weber	U.S. Nuclear Regulatory Commission
Christopher Tripp	U.S. Nuclear Regulatory Commission
Annie Ramirez	U.S. Nuclear Regulatory Commission
John Adams	U.S. Nuclear Regulatory Commission
Terry Gitnick	Information Systems Laboratories, Inc.
Steve Reese	Northwest Medical Isotopes
Carolyn Haass	Northwest Medical Isotopes
Michael Corum	Atkins (Northwest Medical Isotopes)
Gary Dunford	AEM Consulting (Northwest Medical Isotopes)
James Masterlock	Atkins (Northwest Medical Isotopes)

Enclosure