



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

October 20, 2016

APPLICANT: Northwest Medical Isotopes, LLC

SUBJECT: SUMMARY OF AUGUST 11, 2016, PUBLIC MEETING WITH NORTHWEST MEDICAL ISOTOPES, LLC (TAC NO. MF6138)

On August 11, 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 to discuss NWMI's planned submittal of an operating license application for its proposed molybdenum-99 (Mo-99) medical isotopes production facility. A portion of this meeting was closed to the public to discuss security-related and 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) Accession No. ML16223A156. A list of meeting attendees is provided as an enclosure.

The NRC staff opened the meeting providing a status update on the environmental and construction permit application review. The NRC staff informed NWMI that the review of the environmental and construction permit application is on schedule. NWMI representatives then provided a general project status update on its proposed medical isotope facility to be located in Discovery Ridge Research Park, Columbia, Missouri. NWMI representatives presented an overview of its proposed change control and design change processes to be implemented prior to and during construction. NWMI representatives also shared some potential project challenges such as licensing strategies, integration of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and change control during construction. The NRC staff and NWMI agreed to conduct a future public meeting regarding a proposed 10 CFR Parts 50 and 70 crosswalk in detail. NWMI also discussed pre-construction activities and what constituted construction and excavation. The NRC staff directed NWMI to the definition of construction in 10 CFR 50.2 and construction activities in 10 CFR 50.10. The NRC staff informed NWMI representatives that they can submit a proposal for non-construction activities for NRC review. During the meeting, NWMI expressed concerns with submitting documents using the Electronics Information Exchange (EIE) system because of certain limitations of the EIE system. During the meeting, the NRC staff endorsed the use of the EIE system for supporting efficient and prompt document submission. NWMI representatives informed the NRC staff that it has not attempted to use the EIE system within the last year. No questions from the public were presented to the NRC staff during the public comment period of the meeting. Further details on the public meeting are included in the presentation slides (ADAMS Accession No. ML16221A037).

During the closed portion of the meeting, NWMI went into proprietary-level detail related to research and development and operating license schedule for its proposed Mo-99 production process. Additionally, the NRC staff discussed security-related information regarding the development of NWMI's safeguards information program physical security plan, and material control and accounting program.

- 2 -

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

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

/RA/

Michael F. Balazik, Project Manager
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Enclosure:
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ADAMS Accession Nos.: ML16288A488 (Summary); ML16216A186 (Presentation);
***concurrence via e-mail** **NRC-001**

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NAME	MBalazik	NParker	AAdams	MBalazik
DATE	10/18/2016	10/18/2016	10/19/2016	10/20/2016

OFFICIAL RECORD COPY

LIST OF ATTENDEES

PUBLIC MEETING WITH NORTHWEST MEDICAL ISOTOPES

AUGUST 11, 2016

9:30 A.M. – 4:15 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
Tim Harris	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Larry Harris	U.S. Nuclear Regulatory Commission
Robert Hoffman	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
Kevin Folk	U.S. Nuclear Regulatory Commission
Jessica Bielecki	U.S. Nuclear Regulatory Commission
Suzanne Ani	U.S. Nuclear Regulatory Commission
Thomas Pham	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
Joseph Anderson	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
Cathy Kanatas	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
James Danna	U.S. Nuclear Regulatory Commission
Tyrone Naquin	U.S. Nuclear Regulatory Commission
Louise Lund	U.S. Nuclear Regulatory Commission
Robert Norman	U.S. Nuclear Regulatory Commission
Gerard Jackson	U.S. Nuclear Regulatory Commission
Steve Reese	Northwest Medical Isotopes
Carolyn Haass	Northwest Medical Isotopes
Michael Corum	Atkins (Northwest Medical Isotopes)
Gary Dunford	AEM Consulting (Northwest Medical Isotopes)
Ryan Molen	McCarthy Building (Northwest Medical Isotopes)

Enclosure