

March 29, 2016

APPLICANT: Northwest Medical Isotopes, LLC

SUBJECT: SUMMARY OF PUBLIC MEETING WITH NORTHWEST MEDICAL ISOTOPES, LLC REGARDING CONSTRUCTION PERMIT APPLICATION REVIEW STATUS AND LICENSING OF A MOLYBDENUM-99 PRODUCTION FACILITY (TAC NO. MF6138)

On February 18, 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, 11545 Rockville Pike, Rockville, Maryland. The NRC staff arranged this public meeting following NWMI's drop-in meeting with the Office of the Executive Director for Operations on January 16, 2016. This meeting sought to clarify the Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 50 and 70 licensing processes; the applicable regulations and guidance to the NWMI construction permit application; the review status and schedule for NWMI's application; and methods of effective communication between the NRC and NWMI. Presenting on these topics from the NRC staff were Michael Balazik (Office on Nuclear Reactor Regulation [NRR]), Steven Lynch (NRR), Nancy Martinez (NRR), David Tiktinsky (Office of Nuclear Materials Safety and Safeguards), and Alexander Adams (NRR). Nicholas Fowler, Chief Executive Officer, and Carolyn Haass, Chief Operating Officer, were present at the meeting representing NWMI. The meeting notice and agenda, dated February 8, 2016, is available in the Agencywide Documents Access and Management System (ADAMS) under Accession No. ML16049A004. A list of attendees is provided in the enclosure. Also enclosed is the transcription of the meeting and the NRC staff presentation which is available in ADAMS under Accession Nos. ML16083A106 and ML16048A554, respectively. NWMI did not prepare a presentation for the meeting.

NWMI's expressed two objectives for the public meeting. The first objective was to come to a shared understanding of the licensing approach for NWMI's construction permit application. The second objective was to explore mechanisms to expedite the review of NWMI's construction permit application.

The NRC staff addressed both of these topics during their prepared presentations and in response to questions from NWMI. As described below, by the conclusion of the meeting, NWMI agreed that their objectives had been met, noting however that ongoing conversations would be necessary regarding acceleration of the application review schedule.

With respect to the licensing approach for the NWMI facility, the NRC staff clarified the relationship between the NRC's ongoing construction permit review for a 10 CFR Part 50 production facility and 10 CFR Part 70 requirements for possessing and using special nuclear material. The NRC staff and NWMI agreed that NWMI will need to provide additional technical information related to their proposed target manufacturing activities to meet the regulatory requirements of 10 CFR Part 70; however, it is left to NWMI's discretion whether this information is submitted as either part of a 10 CFR Part 50 operating license application for its production facility or an independent 10 CFR Part 70 application.

The staff emphasized that the same technical information would be required regardless of NWMI's selected method of submission. NWMI indicated that it understands its licensing options and will work to convey its intended approach to the NRC through official correspondence.

With respect to the accelerating the NRC staff's review of NWMI's construction permit application, the NRC staff reiterated its commitment to efficiently reviewing the NWMI construction permit application within 18 – 24 months from docketing. To improve transparency in its review process, the NRC staff discussed NWMI's application review schedule, including assumptions and potential impacts to schedule. During the meeting, several factors were discussed that would support efficient application reviews, including:

- The applicant's completeness, timeliness, and responsiveness to requests for additional information (RAIs).
- The applicant's use of established guidance documents.
- Applicant establishment of an electronic reading room for NRC staff to review background information.
- Communication methods, such as:
 - Weekly status calls
 - Standing public meetings
 - Application review audits
 - RAI clarification calls
 - Pre-application meetings on future licensing action requests
- Reduction in expenditure of administrative resources (e.g., establishing standing public meetings reduces time spent on meeting noticing requirements).
- Applicant maintenance of Preliminary Safety Analysis Report (i.e., incorporating necessary updates and changes resulting from responses to RAIs).
- Applicant review of similar past applications (e.g., SHINE construction permit application) and review documents (e.g., SHINE RAIs, safety evaluation report, and environmental impact statement; Advisory Committee on Reactor Safeguards subcommittee and full committee transcripts on SHINE application, etc.).
- Effective project management in that the NRC staff will clearly and regularly communicate progress towards established review milestones, including anticipated dates and subject matter of RAIs.
- NWMI will provide regular updates on the status of responses to RAIs and future applications (e.g., potential exemption and amendment requests, operating license application, etc.).

When offered, the public did not present any questions to the NRC during the public meeting. To close out the meeting, the NRC staff and NWMI agreed to six follow-up items:

- The NRC staff and NWMI will discuss the need for standing public meetings at the next weekly status call.
- NWMI will provide regular updates on the status of its final design, including when and how this information will be provided to the NRC (i.e., as part of construction permit or operating license application).

- NWMI will provide regular updates on the timing of submitting future license applications (e.g., exemptions, licenses amendments for supporting research reactors providing target irradiation, operating license application, etc.).
- The NRC staff will provide advance notification of the timing of documents to be sent to NWMI and allow NWMI an opportunity to conduct pre-reviews of publicly available documents to ensure no proprietary information had inadvertently been included.
- The NRC staff will coordinate future meetings at NWMI's proposed Columbia, MO site with local government (i.e., offer to hold government-to-government meeting).
- The NRC staff will provide regular updates on the status of its review and NWMI will provide regular updates on the status of its responses to requests for additional information.

At the conclusion of the meeting, NWMI stated that the meeting had been a success and indicated an interest in holding similar meetings with NRC management on a quarterly or semi-annual basis. The meeting concluded at approximately 3:00 p.m.

Please direct any inquiries to Michael F. Balazik at 301-415-2856 or by e-mail at Michael.Balazik@nrc.gov.

Sincerely,

/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

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Michael F. Balazik, Project Manager
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 Division of Policy and Rulemaking
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ADAMS Accession Nos. Pkg: ML16083A110, MtgSummary: ML16083A107, NRC Staff Presentation: ML16048A554, Meeting Transcript: ML16083A106, 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/ 21 /2016	3/23/2016	3/ 29 /2016	3/ 29 /2016

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LIST OF ATTENDEES
FEBRUARY 18, 2016, MEETING WITH NORTHWEST MEDICAL ISOTOPES, LLC
REGARDING MEDICAL ISOTOPE PRODUCTION

<u>Name</u>	<u>Organization</u>
Carolyn Haass	Northwest Medical Isotopes, LLC (NWMI)
Nicholas Fowler	NWMI
Michael Balazik	U.S. Nuclear Regulatory Commission (NRC)
Nancy Martinez	NRC
Mirela Gavrilas	NRC
Steven Lynch	NRC
Alexander Adams	NRC
David Tiktinsky	NRC
Robert Johnson	NRC
Shana Helton	NRC
Andrea Keim	NRC
Thomas Matula	NRC
Kevin Morrissey	NRC
Mary Adams	NRC
Lisa London	NRC
Jessica Bielecki	NRC
Joseph Lindell	NRC
Catherine Kanatas	NRC
Mitzi Young	NRC
Linh Tran	NRC
Eben Allen	NRC
James Danna	NRC
Christopher Miller	NRC
Michael Rodriguez	NRC
Michael Flagg	University of Missouri Columbia Research Reactor (MURR)
Les Foyto	MURR
Kara McCullough	NRC
Dave Berick	US Congressional Staff for Senator Ron Wyden
Alison Rivera	NRC
Maitri Banerjee	NRC
Alan Frazier	NRC
Michelle Moser	NRC
Jeff Bartelme	SHINE Medical Technologies, Inc.
Tyrone Naquin	NRC
Charles Teal	NRC
Kevin Folk	NRC
Carl Weber	NRC
William Dean	NRC
Michele Evans	NRC
Lawrence Kokajko	NRC
Craig Erlanger	NRC
Jane Marshall	NRC
Patrick Isaac	NRC
Thomas Grice	NRC
Catherine Scott	NRC

Enclosure