

October 28, 2014

APPLICANT: Northwest Medical Isotopes, LLC

SUBJECT: SUMMALRY OF SEPTEMBER 30, 2014, MEETING WITH NORTHWEST MEDICAL ISOTOPES, LLC REGARDING MEDICAL ISOTOPE PRODUCTION (TAC NO. ME2289)

On September 30, 2014, 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 its proposed medical radioisotope production project. A portion of this meeting was closed to the public to discuss proprietary information related to the specifics of design and operation of NWMI's proposed medical radioisotope production facility. The meeting notice and agenda, dated September 30, 2014, is available in the Agencywide Documents Access and Management System (ADAMS) Accession No. ML14240A610. A list of attendees is provided in the Enclosure.

The NRC staff opened the meeting beginning at 9:00 a.m. by emphasizing the importance of high quality submittals and continued communication between NWMI and the NRC. NWMI then transitioned into a presentation that started with their proposed licensing approach, integrated safety analysis approach and methodology, transportation, and understanding of the regulations in Part 50, "Domestic Licensing of Production and Utilization Facilities," and Part 70, "Domestic Licensing of Special Nuclear Material," of Title 10 of the *Code of Federal Regulations* (10 CFR). These topics transitioned into several discussions on the definition for production facility in 10 CFR 50.2, "Definitions," construction permit requirements, quality assurance, use of Monte Carlo codes in developing safety analysis, use of NRC and industry guidance, and transportation challenges that would likely result in cask owners requesting amendments to Certificates of Compliance for shipments of targets. The presentation materials and discussion during the open portion of the meeting concluded at approximately 10:30 a.m.

Further details on this discussion are included in the presentation slides, which are located in ADAMS, Accession No. ML14268A086.

Three members of the public participated in the open portion of this meeting, but provided no comments.

The NRC staff reconvened for the closed portion of the meeting in the afternoon at 1:00 p.m. During the portion of the meeting closed to the public to discuss proprietary information, NWMI presented material on the technical aspects of its proposed facility. This presentation focused on system processes, operating details, processing details, and a detailed project schedule. During this meeting, NWMI also provided a test electronic submittal on optical storage media (OSM) to the NRC staff. An essential component for the successful receipt and processing of an electronic submittal on OSM to the NRC ADAMS is an XML packing slip. The XML packing slip comprehensively identifies the contents of the submission, in the root folder of the

-2-

submission. To assist applicants in the development of the XML packing slip, the NRC developed the Packing Slip Wizard (<http://www.nrc.gov/site-help/e-submittals.html>). The NRC staff will review the XML packing slip in order to facilitate timely processing of the forthcoming NWMI application into ADAMS.

Please direct any inquiries to William Schuster at 301-415-1590 or by electronic mail at William.Schuster@nrc.gov .

Sincerely,

/RA/

Steven T. Lynch, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 0803

Enclosure:
List of Attendees

cc: See next page

submission. To assist applicants in the development of the XML packing slip, the NRC developed the Packing Slip Wizard (<http://www.nrc.gov/site-help/e-submittals.html>). The NRC staff will review the XML packing slip in order to facilitate timely processing of the forthcoming NWMI application into ADAMS.

Please direct any inquiries to William Schuster at 301-415-1590 or by electronic mail at William.Schuster@nrc.gov.

Sincerely,

/RA/

Steven T. Lynch, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 0803

Enclosure:
List of Attendees

cc: See next page

DISTRIBUTION:

PUBLIC	PRLB r/f	NRR_Moly_99
RidsNrrDprPrta	GWertz, NRR	JBiggins, OGC
RidsNrrDprPrtb	JMunson, NRR	PBlechman, NRR
RidsNrrDpr	RidsOgcMailCenter	

ADAMS Accession Nos. Pkg: ML14276A109, Notice: ML14240A610,
MtgSummary: ML14275A335, Slides Pkg: ML14268A086 NRC-001

OFFICE	DPR/PRLB/NE	DPR/PRLB/LA	DPR/PRLB/BC	DPR/PRLB/PM
NAME	WSchuster	PBlechman	AAdams	SLynch
DATE	10/24/2014	10/27/2014	10/27/2014	10/28/2014

OFFICIAL RECORD COPY

Northwest Medical Isotopes

Project No. PROJ0803

cc:

Darrell Liles, CHP, PE
Senior Health Physicist
ARCADIS-SENES
8310 South Valley Highway Suite 135
Englewood, Colorado, 80112
email: dliles@senesusa.com

Carolyn Haass, Vice President
Technical Program Director
Northwest Medical Isotopes, LLC
815 NW 9th Ave, Suite 256
Corvallis, OR 97330
email: carolyn.haass@nwmedicalisotopes.com

Nicholas F. Fowler
Chief Executive Officer
Northwest Medical Isotopes, LLC
8815 Northwest 9th Street, Suite 256
Corvallis, OR 97330

LIST OF ATTENDEES

SEPTEMBER 30, 2014, MEETING WITH NORTHWEST MEDICAL ISOTOPES, LLC

REGARDING MEDICAL ISOTOPE PRODUCTION

<u>Name</u>	<u>Organization</u>
Carolyn Haass	Northwest Medical Isotopes, LLC (NWMI)
Steve Reese	NWMI
John Beller	NWMI
Michael Washer	NWMI
Michael Corum	NWMI
Marcus Voth	NWMI
Gary Dunford	NWMI
Jim Castidas	SHINE Medical Technologies, Inc.
Dan Cronin	University of Florida
Darrell Liles	Arcadis-Senes
William Schuster	U.S. Nuclear Regulatory Commission (NRC)
Steve Lynch	NRC
Linh Tran	NRC
Alexander Adams	NRC
Mary Adams	NRC
Mirela Gavrilas	NRC
Lawrence Kokajko	NRC
Tim Harris	NRC
Dan Barss	NRC
James Biggins	NRC
Cassandra Frazier	NRC
David Tiktinski	NRC
Eben Allen	NRC
Greg Chapman	NRC
Jeremy Munson	NRC
Rui Li	NRC
Geoff Wertz	NRC
Nancy Martinez	NRC
Alex Sapountzis	NRC
Bernard White	NRC
Larry Harris	NRC
Michael Rodriguez	NRC
David McIntyre	NRC
Deborah Seymour	NRC
Patricia Pelke	NRC

Enclosure