



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

SECRETARY

January 16, 2018

Memorandum to Applicant and Counsel for Staff:

Attached is a revised scheduling note for the U.S. Nuclear Regulatory Commission (NRC) evidentiary session to receive testimony and exhibits in the uncontested proceeding regarding the application from Northwest Medical Isotopes, LLC (NWMI), for a construction permit to construct a medical radioisotope production facility in Columbia, Missouri. The hearing will be held on January 23, 2018, beginning at 9:00 a.m. Eastern Time in the Commissioners' Conference Room on the first floor of the NRC's Headquarters building at One White Flint North, Rockville, Maryland.

The scheduling note will also be posted on our public website at <http://www.nrc.gov/reading-rm/doc-collections/commission/tr/2018/>.

If you have any questions, please contact Ms. Denise McGovern (denise.mcgovern@nrc.gov, 301-415-0681) of my staff.

Sincerely,

/RA/

Annette L. Vietti-Cook

Enclosure:
As stated

FINAL: 1/16/18

SCHEDULING NOTE

Title: HEARING ON CONSTRUCTION PERMIT FOR NORTHWEST MEDICAL ISOTOPES PRODUCTION FACILITY: SECTION 189A OF THE ATOMIC ENERGY ACT PROCEEDING (Public Meeting)

Purpose: To receive testimony and exhibits regarding the application of Northwest Medical Isotopes, LLC, for a medical radioisotope production facility construction permit. The testimony will focus on unique features of the facility or novel issues that arose as part of the review process and other significant technical or policy issues associated with aspects of the staff's review that are important for the Commission to make its final decision. The Commission will determine whether the staff's review has been adequate to support the findings in 10 C.F.R. §§ 50.35(a), 50.40, 50.50, and 51.105(a).

Scheduled: **January 23, 2018**
9:00 am

Duration: 1 day

Location: Commissioners' Conference Room, 1st Floor OWFN

NOTE: Chairman to provide opening remarks, admit exhibits, and swear in witnesses. **20 mins.**

Participants: **Presentation**

(Note: Witnesses seated at the table are listed, other staff available to answer questions will be seated in the well and reserved rows.)

Overview (Northwest Medical Isotopes, LLC) (9:20 am) **30 mins.***

At the table:

Nicholas Fowler, Chief Executive Officer, NWMI
Carolyn Haass, Chief Operating Officer, NWMI
Steven Reese, Irradiation Services Manager, NWMI
Roy Brown, Vice President, Curium Pharma

Topic: Overview

Commission Q & A (round of questions; 6 minutes each) **18 mins.****

Overview (NRC Staff)

30 mins.*

At the table:

Michele Evans, Deputy Director for Reactor Safety Programs and Mission Support, Office of Nuclear Reactor Regulation (NRR)

Mary Jane Ross-Lee, Deputy Director, Division of Licensing Projects, NRR

Joseph Donoghue, Deputy Director, Division of Materials and License Renewal (DMLR), NRR

Brian Smith, Deputy Director, Division of Fuel Cycle Safety, Safeguards and Environmental Review, Office of Nuclear Material Safety and Safeguards (NMSS)

Topic: Overview of the staff's methodology for its review of the NWMI construction permit application and summary of key regulatory findings.

Commission Q & A (round of questions; 6 minutes each)

18 mins.**

BREAK

5 mins.

NOTE: For the remaining panels, the applicant is expected to discuss the contents of the construction permit application while the staff is expected to discuss its review process and regulatory conclusions. Each panel should include a discussion of any permit conditions associated with the subject matter of the panel.

Safety Panel 1 (11:05 am)

Applicant

5 mins.*

At the table:

Carolyn Haass, Chief Operating Officer, NWMI

Steven Reese, Irradiation Services Manager, NWMI

Gary Dunford, Process Engineering Manager, NWMI (AEM Consulting, Inc.)

Michael Corum, Senior Technical Advisor, NWMI

Staff

12 mins.*

At the table:

Alexander Adams, Jr., Chief, Research and Test Reactors Licensing Branch, NRR

Michael Balazik, Project Manager, Research and Test Reactors Licensing Branch, NRR

David Tiktinsky, Senior Project Manager, Fuel Manufacturing Branch (FMB), NMSS

Steven Lynch, Project Manager, Research and Test Reactors Licensing Branch, NRR

Topic: Sections of the application and the following chapters from

the Safety Evaluation Report:

Chapter 1, “The Facility,” and Chapter 4 “Radioisotope Production Facility Description,” including discussion of the unique licensing considerations; Colocation of Production Facility and Target Fabrication Area, and Quality Assurance Implementation.

Note that the panel will not have specific topics to discuss for the following chapters. If the Commission wishes to ask questions on these chapters, this panel would be the appropriate time.

- Chapter 2, “Site Characteristics”
- Chapter 3, “Design of Structures, Systems, and Components”
- Chapter 5, “Coolant Systems”
- Chapter 6, “Engineered Safety Features”
- Chapter 12, “Conduct of Operations”***

Commission Q & A (round of questions; 6 minutes each)

18 mins.**

BREAK (Lunch Break-Approx. 11:45-1:15 pm)

Safety Panel 2 (1:15 pm)

Applicant

5 mins.*

At the table:

Carolyn Haass, Chief Operating Officer, NWMI

Steven Reese, Irradiation Services Manager, NWMI

Gary Dunford, Process Engineering Manager, NWMI (AEM Consulting, Inc.)

Michael Corum, Senior Technical Advisor, NWMI

Staff

12 mins.*

At the table:

Michael Balazik, Project Manager, Research and Test Reactors Licensing Branch, NRR

April Smith, Reliability and Risk Analyst, Programmatic Oversight and Regional Support Branch, NMSS

David Tiktinsky, Senior Project Manager, FMB, NMSS

James Hammelman, Senior Chemical Engineer, FMB, NMSS

Topic: Sections of the application and the following chapters from the Safety Evaluation Report:

Chapter 13, “Accident Analysis,” including discussion of novel application of 10 CFR Part 70 accident analysis methodologies

for radiological and chemical exposure accidents.

Note that the panel will not have specific topics to discuss for the following chapters. If the Commission wishes to ask questions on these chapters, this panel would be the appropriate time.

- Chapter 7, “Instrumentation and Control Systems”
- Chapter 8, “Electrical Power Systems”
- Chapter 9, “Auxiliary Systems”
- Chapter 11, “Radiation Protection Program and Waste Management”
- Chapter 14, “Technical Specifications”
- Chapter 15, “Financial Qualifications”

Commission Q & A (round of questions; 6 minutes each)

18 mins.**

Environmental Panel (1:50 pm)

Applicant

10 mins.*

At the table:

Carolyn Haass, Chief Operating Officer, NWMI

Steven Reese, Irradiation Services Manager, NWMI

Staff

25 mins.*

At the table:

Benjamin Beasley, Chief, Environmental Review and NEPA Branch, NRR

Nancy Martinez, Physical Scientist, NRR

Michelle Moser, Biologist, NRR

David Drucker, Senior Project Manager, NRR

Topic: Final Environmental Impact Statement

- Provide a summary of the process for developing the Final Environmental Impact Statement (EIS) including:
 - The decision to prepare an EIS
 - Scope and connected actions
 - The scoping process
 - The staff’s independent review and analysis
 - Issuance of the Draft EIS, public meeting on the Draft EIS, and solicitation of stakeholder comments on the Draft EIS
 - The environmental impacts of the proposed action on the following resource areas: land use, visual resources, air quality and noise, water resources, ecological resources, historic and cultural resources, socioeconomics, human health, transportation, waste management, and environmental justice
 - Consultations with other Federal, State, and local agencies and Tribes

- Discuss the analysis of alternatives including; Range of reasonable alternatives, Alternative site, Alternative technologies, and the No-action alternative
- Summarize conclusions and recommendation including a summary of the benefits and costs of the proposed action

Commission Q & A (round of questions; 6 minutes each) **18 mins.****

BREAK **5 mins.**

Closing (2:50 pm)

Closing Statement by Applicant 10 mins.*

Nicholas Fowler, Chief Executive Officer, NWMI

Carolyn Haass, Chief Operating Officer, NWMI

Roy Brown, Vice President, Curium Pharma

Closing Statement by Staff 10 mins.*

Michele Evans, Deputy Director for Reactor Safety Programs and Mission Support, NRR

Commission Q & A and Closing Statements 18 mins.**

*For presentation only and does not include time for Commission Q & A's.

**All Commissioners will have an opportunity to ask questions after each panel. Commissioners will start the Q&A with their total time allotted to allocate as they see fit among the panels.

*** Chapter 12, "Conduct of Operations," of the staff's SER includes evaluations of NWMI's quality assurance program description and preliminary emergency plan.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)
)
NORTHWEST MEDICAL ISOTOPES, LLC)
) Docket No. 50-609-CP
)
(Medical Radioisotope Production Facility))
)
(Mandatory Hearing))

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **MEMORANDUM FROM THE SECRETARY PROVIDING REVISED SCHEDULING NOTE** have been served upon the following persons by Electronic Information Exchange.

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[Original signed by Herald M. Speiser]
Office of the Secretary of the Commission

Dated at Rockville, Maryland,
this 16th day of January, 2018