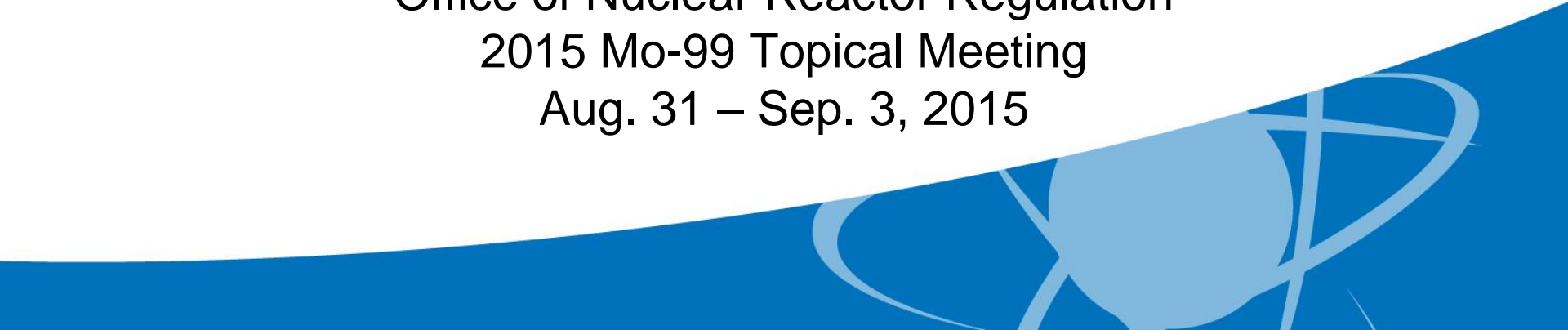


# **U.S. Nuclear Regulatory Commission Licensing Activities Related to Molybdenum-99 Production**

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Office of Nuclear Reactor Regulation  
2015 Mo-99 Topical Meeting  
Aug. 31 – Sep. 3, 2015



# Regulatory Authority and Mission

- Statutes
  - Atomic Energy Act of 1954, as amended
  - National Environmental Policy Act
- Mission
  - The NRC licenses and regulates the Nation's civilian use of radioactive materials to protect public health and safety, promote the common defense and security, and protect the environment

# Supporting Domestic $^{99}\text{Mo}$ Production

- NRC is prepared to conduct reviews on all applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)
- NRC is coordinating environmental review with the Department of Energy (DOE), in accordance with the American Medical Isotopes Production Act
- NRC is supporting the Department of Homeland Security's (DHS) site vulnerability assessments for utilization facilities, in accordance with the provisions of Section 657 of the Energy Policy Act of 2005

# Outreach and Communication

- Public meetings
  - Promote engagement between NRC and applicants
  - Establish working relationship, supporting the development of high-quality applications
  - Allow for appropriate budgeting and resource allocation
  - Keep public informed of NRC licensing actions
- Letters of intent
  - Indicate applicant's level of interest
  - Provide anticipated application submission schedule
  - Introduce proposed technology

# Interest in Mo-99 Production

- Letters of Intent
  - Babcock and Wilcox Technical Services Group
  - Coquí Radiopharmaceuticals
  - Eden Radioisotopes
  - Flibe Energy
  - General Electric Hitachi Nuclear Energy
  - **Niowave, Inc.**
  - Northwest Medical Isotopes, LLC
  - Precision Engineering Consultants, Inc.
  - SHINE Medical Technologies, Inc. (SHINE)
  - University of Missouri-Columbia
  - **Zevacor Molecular**

# Outreach and Communication

- 27th annual Regulatory Information Conference
  - Technical session on regulating research and test reactors
  - Panel discussion focused on status of preparation for current and anticipated application reviews
- Commission meeting (Dec. 2014)
  - Status of implementing licensing approach
  - Status of application review
  - SHINE provided status update on its application and interactions with the NRC

# Outreach and Communication

- Federal, State, and Local Government
  - Office of Science and Technology Policy
  - Congressional staff
  - National Academy of Sciences
  - Wisconsin state, county, and city government

# Regulatory Activities – Current and Anticipated Licensing Reviews

- Construction permit applications (two received, one anticipated)
  - SHINE Medical Technologies (SHINE)
  - Northwest Medical Isotopes (NWMI)
  - Coquí Radiopharmaceuticals (Coquí)
- License amendment request from Oregon State University (OSU)
- License amendment request from University of Missouri Research Reactor Center (MURR) in support of General Atomics
- Materials license request from Niowave



# SHINE Medical Technologies

- NRC received two-part construction permit application
  - Environmental Report (March 26, 2013)
  - Preliminary Safety Analysis Report (May 31, 2013)
- SHINE proposes to produce  $^{99}\text{Mo}$  from fission of low enriched uranium target solution in Irradiation Facility consisting of 8 irradiation units
- $^{99}\text{Mo}$  recovered through irradiated target solution processing in Radioisotope Production Facility consisting of 3 hot cells
- Proposed site: Janesville, WI

# Status of SHINE Review

- Issued requests for additional information (September 2014, with follow-up requests in January, March, and April 2015)
- Issued direct final rule modifying definition of *utilization facility* to include SHINE irradiation units (issued October 2014, effective December 2014)
- Published draft environmental impact statement (May 2015)
- Meetings with the Advisory Committee on Reactor Safeguards in June and August 2015 with meetings scheduled in September and October 2015
- Final environmental impact statement and safety evaluation report scheduled for completion in 4<sup>th</sup> quarter 2015
- Mandatory Commission hearing on application (4<sup>th</sup> quarter 2015)
- Construction permit determination (1<sup>st</sup> quarter 2016)

# Northwest Medical Isotopes

- NRC received two-part construction permit application
  - Environmental Report (February 2015)
  - Preliminary Safety Analysis Report (July 2015)
- NWMI proposes to manufacture low enriched uranium targets for irradiation at existing research and test reactors
  - University of Missouri – Columbia (MURR)
  - Oregon State University (OSU)
- $^{99}\text{Mo}$  recovered through processing of irradiated targets
- Proposed site: Columbia, MO

# Status of NWMI Review

- NRC accepted part one of application for docketing (May 2015)
  - Currently determining whether to perform an environmental impact statement or environmental assessment
- Acceptance review of part two of application
- Environmental site audit scheduled for Sep. 2015
- Application supported by license amendments for existing research reactors
  - Prototypical target irradiation (OSU)
  - Commercial target irradiation (OSU, MURR)

# Coquí Radiopharmaceuticals

- Proposes to construct two INVAP reactors with material testing reactor-type fuel
  - Solid clad low enriched uranium targets
  - Each reactor would operate at approximately 10 MW
  - Approximately 3 MW from uranium targets
- $^{99}\text{Mo}$  recovered through processing of irradiated targets
- Proposed site: Alachua, FL

# Status of Coquí Application

- Public meeting on status of application held in Sep. 2014 and March 2015
- Additional meetings expected in coming months to discuss environmental considerations, licensing requirements (e.g., dose requirements) and technical topics (e.g., security)
- Construction permit application anticipated in 2016

# License Amendments and Materials Licenses

- License amendment request from OSU
  - Demonstration of  $^{99}\text{Mo}$  production in small nuclear reactor with experimental uranium targets
  - Safety evaluation report under development
- Materials license issued to Niowave
  - Production of small amounts of  $^{99}\text{Mo}$  through uranium fission using superconducting linacs for proof of concept
- Anticipated license amendment from MURR
  - General Atomics gaseous extraction technology to be used following uranium target irradiation
  - Public meeting held on April 27, 2015

# Ongoing Infrastructure and Support Activities

- Developing construction and operation inspection programs
- Continuing analysis of applicability of regulations and guidance
- Maintaining and expanding technical and licensing expertise through inter-office working group
- Maintaining communication with stakeholders



# Conclusion

- Frequent and early communication and coordination are essential components of regulatory activities in support of licensing  $^{99}\text{Mo}$  facilities
- Thorough and timely reviews of applications are facilitated by public and applicant engagement
- Ongoing infrastructure development
- Reviews are consistent with the NRC's statutory responsibilities and align with our mission