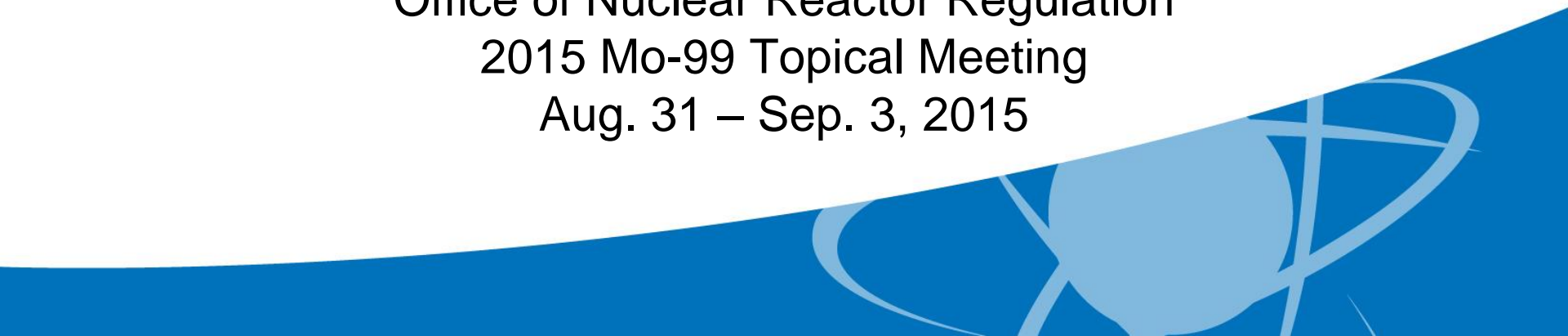


U.S. Nuclear Regulatory Commission Licensing Activities Related to Molybdenum-99 Production

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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}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}Mo from fission of low enriched uranium target solution in Irradiation Facility consisting of 8 irradiation units
- ^{99}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 4th quarter 2015
- Mandatory Commission hearing on application (4th quarter 2015)
- Construction permit determination (1st 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}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}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}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}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}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