



Regulatory Information Conference 2014

Medical Radioisotope Production: U.S. Efforts to Establish a Reliable Domestic Supply of Molybdenum-99

Licensing Medical Isotope Production Facilities

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Supporting Domestic ⁹⁹Mo Production

- NRC is prepared to conduct safety reviews on all applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations*
- NRC is coordinating environmental review work with the Department of Energy, in accordance with American Medical Isotopes Production Act

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Regulatory Authority and Mission Statement

- Statutes
 - Atomic Energy Act of 1954, as Amended
 - National Environmental Policy Act
- NRC's mission statement
 - Protect Public Health and Safety
 - Promote Common Defense and Security
 - Protect Environment

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Potential Mo-99 Producers

- Received 8 letters of intent to produce ⁹⁹Mo
 - Babcock and Wilcox Technical Services Group
 - Coquí Radiopharmaceuticals
 - Eden Radioisotopes
 - Flibe Energy
 - General Electric Hitachi Nuclear Energy
 - Northwest Medical Isotopes
 - SHINE Medical Technologies, Inc.
 - University of Missouri-Columbia

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Pre-application Preparation

- Outreach and communication
 - Regulatory Issue Summaries
 - Public meetings
- Inter-office ⁹⁹Mo working group
- Licensing guidance for applicants and reviewers
- Identification of applicable regulations

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Inter-Office Working Group

- Representatives from several offices, including:
 - Office of Nuclear Reactor Regulation
 - Office Nuclear Material Safety and Safeguards
 - Office of Federal and State Materials and Environmental Management Programs
 - Office of Nuclear Regulatory Research
 - Office of Nuclear Security and Incident Response
 - Office of New Reactors

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Licensing Guidance

- NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors"
 - Part 1, Format and Content
 - Part 2, Standard Review Plan
- NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Rev. 1"

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Licensing Guidance

- Interim Staff Guidance Augmenting NUREG-1537
 - Published October 2012
 - Radioisotope production facilities
 - Aqueous homogeneous reactors
 - Incorporates relevant non-reactor guidance

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Applicable Regulations

- Anticipate licensing most facilities under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"
- May license certain facilities under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"

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Applicable Regulations

- Other relevant regulations:
 - Part 20, "...Protection Against Radiation"
 - Part 30, "...Licensing of Byproduct Material"
 - Part 51, "Environmental Protection..."
 - Part 55, "Operators' Licenses"
 - Part 73, "Physical Protection of Plants..."

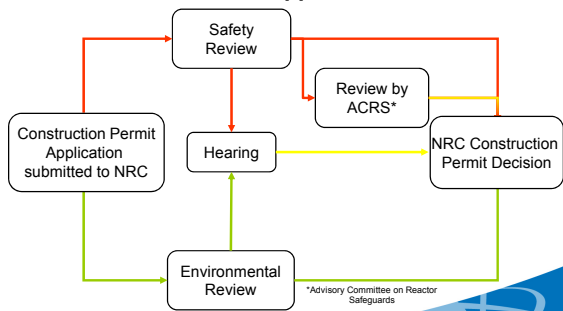
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Application Review

- Construction permit application
 - Environmental report
 - Preliminary safety analysis report
- Concurrent reviews
 - Each approximately 18-24 months
- Operating license application

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Construction Permit Application Review



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Docketing of Application

- Acceptance/sufficiency review
- Review contents of application
 - Summary description of the facility
 - Preliminary design of the facility
 - Preliminary analysis and evaluation of design
 - Environmental Report
- Decision to docket

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Safety Review

- NRC staff review of the application
- Request(s) for additional information, as needed
- Safety Evaluation Report (SER)
- Advisory Committee on Reactor Safeguards
- Hearing
- Decision to grant or deny construction permit

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SHINE Construction Permit Application

- Received two-part construction permit application
 - Environmental Report (March 26, 2013)
 - Preliminary Safety Analysis Report (May 31, 2013)
- Application fully docketed December 2, 2013
- Proposes to produce ⁹⁹Mo from uranium fission
 - Irradiation Facility
 - Radioisotope Production Facility
- Proposes to construct facility in Janesville, WI

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Looking Forward

- Actively reviewing SHINE application
- Anticipate receiving 1 - 2 additional applications within the next year
 - Prepared to review additional applications
 - Encourage early and frequent communication with other potential producers
