

# Regulatory Preparations for Licensing Medical Radioisotope Production Facilities

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# Introduction

- Received 5 letters of intent to produce Mo-99
  - Babcock and Wilcox Technical Services Group
  - Coquí Radiopharmaceuticals
  - General Electric Hitachi Nuclear Energy
  - SHINE Medical Technologies, Inc.
  - University of Missouri-Columbia



# Pre-application Preparation

- Outreach and communication
  - Regulatory Issue Summaries (RIS)
  - Public meetings
- Inter-office Mo-99 working group
- Licensing guidance
- Regulatory application



# Outreach and Communication

- RIS 2011-06, “Pre-application Communication and Voluntary Submittal of Schedule...”
  - Review budget
  - Review schedule
- Follow-up RIS in May 2013
- Public meetings



# Inter-Office Working Group



- 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

# Licensing Framework

- 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”

# Licensing Framework (Cont.)

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



# Regulatory Application

- Statutory Authority
  - The Atomic Energy Act of 1954, as Amended
  - The Energy Reorganization Act of 1974, as Amended
  - The Energy Policy Act of 2005
- Title 10 of the *Code of Federal Regulations*



## **Regulatory Application (Cont.)**

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



# Regulatory Application (Cont.)

- 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...”



# Application Review

- Construction permit application
  - Environmental report
  - Preliminary safety analysis report (PSAR)
- Concurrent reviews
  - Each take approximately 18-24 months

# Application Review (Cont.)

- PSAR review process
  - Initial NRC staff review of the application
  - Request(s) for additional information (RAI)
  - Safety Evaluation Report (SER)
  - Advisory Committee on Reactor Safeguards (ACRS) SER review



# Application Review (Cont.)

- Environmental review process
  - Environmental assessment (EA) or environmental impact statement (EIS)
    - Preparation and issuance of an EA
    - Preparation and issuance of an EIS
      - Environmental scoping period
      - Environmental site audit
      - RAIs

# Application Review (Cont.)

- Expect to begin review of first application in April 2013
- SHINE exemption from 10 CFR 2.101(a)(5)
- SHINE two-part application submittal
  - Environmental Report
  - PSAR



# Conclusion

- NRC staff prepared to receive and review applications
- Encourage early and frequent communication
- Guidance for application preparation available



# Questions?

