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
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*
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”
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?