Regulatory Preparations for Licensing Medical Radioisotope Production Facilities

Steven T. Lynch

Office of Nuclear Reactor Regulation

April 2, 2013

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Introduction

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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

Outreach and Communication

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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.)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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

Regulatory Application

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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.)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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.)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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

Application Review (Cont.)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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.)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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.)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- 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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Questions?