

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



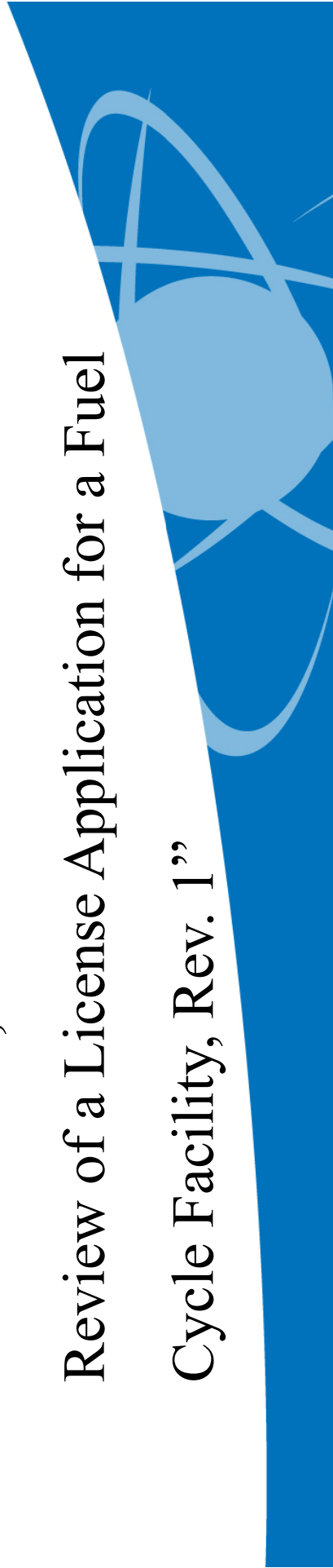
Inter-Office Working Group

- 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”



- 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?

