29th Annual Regulatory Information Conference
Session T5 - Advanced Non-Light Water Reactors: Addressing the Technical Issues and Challenges

NRC Review of a Novel, Innovative Design: A Case Study in Licensing a Medical Radioisotope Facility

Steven Lynch
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
March 2017

Non-Power Production and Utilization Facilities

- Pursuant to the Atomic Energy Act (AEA), the NRC licenses production and utilization facilities
- All current reactors, both power and non-power, are licensed as utilization facilities
- Two primary classes of non-power licenses:
  - Section 103 Commercial Licenses
  - Section 104 Medical Therapy and Research and Development Licenses

Non-Power Facility Definitions

- *Research reactor:* a nuclear reactor licensed under subsection 104c of the AEA for operation at 10 megawatts or less, and is not a testing facility
- *Testing facility:* a nuclear reactor licensed under subsection 104c of the AEA for operation at:
  1) A thermal power level in excess of 10 megawatts; or
  2) A thermal power level in excess of 1 megawatt, if the reactor is to contain: (i) A circulating loop through the core for fuel experiments; or (ii) A liquid fuel loading; or (iii) An experimental facility in the core in excess of 16 square inches in cross-section

Licensing Comparison

- Testing Facility
  - Occupational dose requirements: 10 CFR 20.1201
  - Public dose requirements: 10 CFR 20.1301
  - Accident dose requirements: 10 CFR 100.11
  - Require Environmental Impact Statement (EIS), hearing, and ACRS Review
- Research Reactor
  - Occupational dose requirements: 10 CFR 20.1201
  - Public dose requirements: 10 CFR 20.1301
  - Accident dose guidance: NUREG-1537
  - No EIS, hearing, or ACRS review required

4

Applicable Regulatory Guidance

- NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors"
- Regulatory Guides
  - Division 2, "Research and Test Reactors"
  - Division 5, "Materials and Plant Protection"
  - Guidance on technical specification development, quality assurance program requirements, and emergency planning
- ANS/ANSI Research Reactor Standards ANS 15 Series (15.1, 15.2, 15.4, 15.8, 15.11, 15.16) referenced by guidance

5

Medical Radioisotope Licensing Reviews

- Majority of proposals involve low enriched uranium fission
  - Reactor and non-reactor technologies
  - Solid clad and aqueous solution targets
  - New and existing facilities
  - Hot cells for separation of fission products
- Initial license and license amendment requests for facilities proposing to manufacture, irradiate, and process low enriched uranium and molybdenum targets
- Facilities involving utilization and production facilities licensed under 10 CFR Part 50

6

10 CFR Part 50 Licensing Process

- Applications contain both general and technical information
- Construction permit application
  - Environmental report
  - Preliminary safety analysis report (PSAR)
- Operating license application
  - Update to environmental report, as necessary
  - Final safety analysis report (FSAR)
  - Physical security plan
  - Safeguards contingency plan
  - Protection against unauthorized disclosure
- May submit applications separately or together
- Testing and commercial facilities may request limited work authorization to allow certain construction activities prior to the issuance of a construction permit

7

SHINE Medical Technologies, Inc.

- SHINE submitted two-part construction permit application
  - General Information and Environmental Report (March 26, 2013)
  - Preliminary Safety Analysis Report (May 31, 2013)
- SHINE proposes to produce ^{99}Mo from fission of low enriched uranium target solution in Irradiation Facility consisting of 8 irradiation units
- ^{99}Mo recovered through irradiated target solution processing in Radioisotope Production Facility consisting of 3 hot cells
- Proposed site: Janesville, WI

8

SHINE Licensing

- Facility to be licensed under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"
  - Target irradiation performed by *utilization facilities*
  - Fission product separation in *production facility*
- Special nuclear material to be licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- Byproduct material to be licensed under 10 CFR Part 30, "…Domestic Licensing of Byproduct Material"
- Source material to be licensed under 10 CFR Part 40, "Domestic Licensing of Source Material"

9

SHINE Irradiation Facility

- Irradiation facility houses eight subcritical irradiation units comparable in power level and safety considerations to existing non-power reactors licensed under 10 CFR Part 50
- However, due to subcriticality, irradiation units did not meet the existing definition of utilization facility in 10 CFR 50.2
- To align licensing process with potential hazards, NRC issued direct final rule modifying 10 CFR definition of utilization facility to include SHINE irradiation units (79 FR 62329)
  - Published October 17, 2014
  - Effective December 31, 2014

10

SHINE Radioisotope Production Facility

- Radioisotope Production Facility consists of three hot cells for ^{99}Mo separation and purification
- Since material processed in batches containing greater than 100 grams U-235, facility considered a production facility as defined in 10 CFR 50.2
- While NRC has historically licensed production facilities, none are currently operating
- Some previously-licensed facilities have conducted similar activities
  - Cintichem (^{99}Mo separation activities licensed under 10 CFR Part 70)
  - West Valley (last licensed 10 CFR Part 50 production facility)

11

Medical Radioisotope Construction Permit Review Process

- Acceptance and docketing of application
- Parallel development of safety evaluation report and environmental impact statement (or environmental assessment)
- Request(s) for additional information, as needed
- Advisory Committee on Reactor Safeguards review
- Potential contested hearing; mandatory Commission hearing (adequacy of staff safety and environmental review)
- Decision to grant or deny construction permit

12

Construction Permit Requirements

- Selected regulations applicable to SHINE construction permit:
  - 10 CFR 50.22, Commercial and industrial facility licenses
  - 10 CFR 50.30, Environmental Report
  - 10 CFR 50.34(a), Preliminary safety analysis report
  - 10 CFR 20.1201, Occupational dose requirements
  - 10 CFR 20.1301, Public and accident dose requirements
  - 10 CFR 50.35, Issuance of construction permits
- Note: 10 CFR Part 50 Appendices A, "General Design Criteria…" and B, "Quality Assurance Criteria…" are only applicable to nuclear power reactors.
- 10 CFR Part 100, "Reactor Site Criteria," siting and accident dose criteria are only applicable to nuclear power reactors and testing facilities

13

Preliminary Safety Analysis Report

- Preliminary design of the facility, including principal design criteria, design bases, general arrangement, and approximate dimensions
- Preliminary analysis of structures, systems, and components, including ability to prevent and mitigate accidents
- Probable subjects of technical specifications
- Preliminary emergency plan
- Quality assurance program
- Description of research and development needed to confirm adequacy of structures, systems, and components by the completion of construction

14

Regulatory Guidance and Acceptance Criteria

- NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors"
- Interim Staff Guidance Augmenting NUREG-1537
  - Radioisotope production facilities
  - Aqueous homogeneous reactors
  - Incorporates relevant non-reactor guidance from NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Rev. 1"
- Other guidance (e.g., regulatory guides and ANSI/ANS standards) and engineering judgment used, as appropriate, to make construction permit findings

15

NUREG-1537 Review Areas

1. The Facility/Introduction
2. Site Characteristics
3. Design of Structures, Systems, and Components
4. Facility Description
5. Coolant Systems
6. Engineered Safety Features
7. Instrumentation and Control
8. Electrical Power Systems
9. Auxiliary Systems
10. Experimental Facilities*
11. Radiation Protection and Waste Management
12. Conduct of Operations
13. Accident Analysis
14. Technical Specifications
15. Financial Qualifications
16. Other License Considerations*
17. Decommissioning*
18. Uranium Conversions*
19. Environmental Review

* Not applicable to the SHINE construction permit application

16

Construction Permit Review Considerations

- Since construction permit may be issued based on preliminary design information, level of detail needed in application is less than for combined operating license or operating license
- Applicant may describe the facility at a functional or conceptual level in the PSAR, leaving detailed design and analysis until the submission of the FSAR
- Review tailored to unique and novel technology described in application using appropriate regulatory guidance and engineering judgment

17

Construction Permit Review Considerations (cont.)

- When the insufficient information is initially provided in an application, the staff may issue requests for additional information (RAIs)
- RAIs may address:
  - Issues that must be resolved prior to the issuance of a construction permit
  - Information deferred to the submission of the FSAR
  - Issues that must be resolved prior to the completion of construction
- Responses to RAIs and other information provided in the application may be tracked as regulatory commitments or license conditions
- If RAIs inadequately addressed by applicant, the staff may deny the application

18

Construction Permit Findings

- A construction permit may be issued per 10 CFR 50.35, if :
  - The applicant has described the proposed design, including the principal architectural and engineering criteria for the design and identified major features or components for the protection of the public health and safety
  - Further technical or design information, which can reasonably be left for later consideration, will be supplied in the FSAR
  - Safety features or components requiring research and development have been identified and the applicant will conduct a research and development program reasonably designed to resolve associated safety questions
  - There is reasonable assurance that safety questions will be resolved prior to the completion of construction and the proposed facility can be constructed without undue risk to the health and safety of the public

19

Construction Permit Findings (cont.)

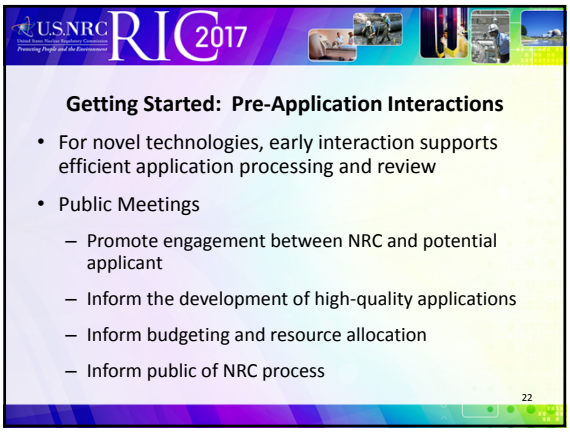
- Issuance of a construction permit also considers whether the following standards in 10 CFR 50.40 and 50.50 have been met:
  - There is reasonable assurance: (i) that construction of the facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations
  - The applicant is technically and financially qualified to engage in the proposed activity
  - The issuance of a construction permit would not be inimical to the common defense and security or to the health and safety of the public
  - The applicable environmental requirements of subpart A of 10 CFR Part 51 have been satisfied
  - The application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made

20

Summary of SHINE Review

- Issued requests for additional information (September 2014, with follow-up requests in January, March, April, and September 2015)
- Issued direct final rule modifying definition of *utilization facility* to include SHINE irradiation units (issued October 2014, effective December 2014)
- Published draft environmental impact statement (May 2015)
- Meetings with ACRS (June, August, September, and October 2015)
- Final environmental impact statement and safety evaluation report completed (October 2015)
- Mandatory Commission hearing on application (December 2015)
- Construction permit issued (February 2016)
- Construction expected to begin in 2017
- Operating license application expected in 2017

21


U.S.NRC
RIC 2017
Getting Started: Pre-Application Interactions
• For novel technologies, early interaction supports efficient application processing and review
• Public Meetings
– Promote engagement between NRC and potential applicant
– Inform the development of high-quality applications
– Inform budgeting and resource allocation
– Inform public of NRC process
22