

2017 National State Liaison Officer Conference

U.S. Nuclear Regulatory Commission Activities Related to the Establishment of Domestic Molybdenum-99 Production

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Supporting Domestic ^{99}Mo Production

- NRC is conducting efficient reviews of applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)
- Reviews support U.S. national security interests and nuclear nonproliferation policy objectives by contributing to the establishment of a domestically-available and reliable supply of molybdenum-99 (^{99}Mo) without the use of highly-enriched uranium
- Applications include initial license and license amendment requests for facilities proposing to manufacture, irradiate, and process low enriched uranium and molybdenum targets

Regulated Production Processes

- Target manufacturing
 - Preparation of low enriched uranium targets for irradiation
- Target irradiation
 - Nuclear reactors
 - Subcritical operating assemblies
 - Accelerators
- Target processing
 - Hot cell separation of ^{99}Mo from low enriched uranium targets
- Medical uses of byproduct material
 - Generators for extracting technetium-99m ($^{99\text{m}}\text{Tc}$) from ^{99}Mo

Current and Anticipated Licensing Reviews

- Construction permit and operating license applications
 - Northwest Medical Isotopes (NWMI)
 - Construction permit application under review
 - SHINE Medical Technologies (SHINE)
 - Construction permit issued February 2016
 - Operating license application expected 2018
- License amendment requests from University of Missouri Research Reactor Center (MURR) in support of General Atomics
- Additional license amendment requests anticipated from Oregon State University (OSU) and MURR in support of NWMI project
- Materials license amendment request from Niowave

Northwest Medical Isotopes

- NRC received two-part construction permit application
 - Environmental Report (February 2015)
 - Preliminary Safety Analysis Report (July 2015)
- NWMI proposes to manufacture low enriched uranium targets for irradiation at existing research reactors (MURR and OSU)
- ^{99}Mo recovered through processing of irradiated targets
- Proposed site: Columbia, MO

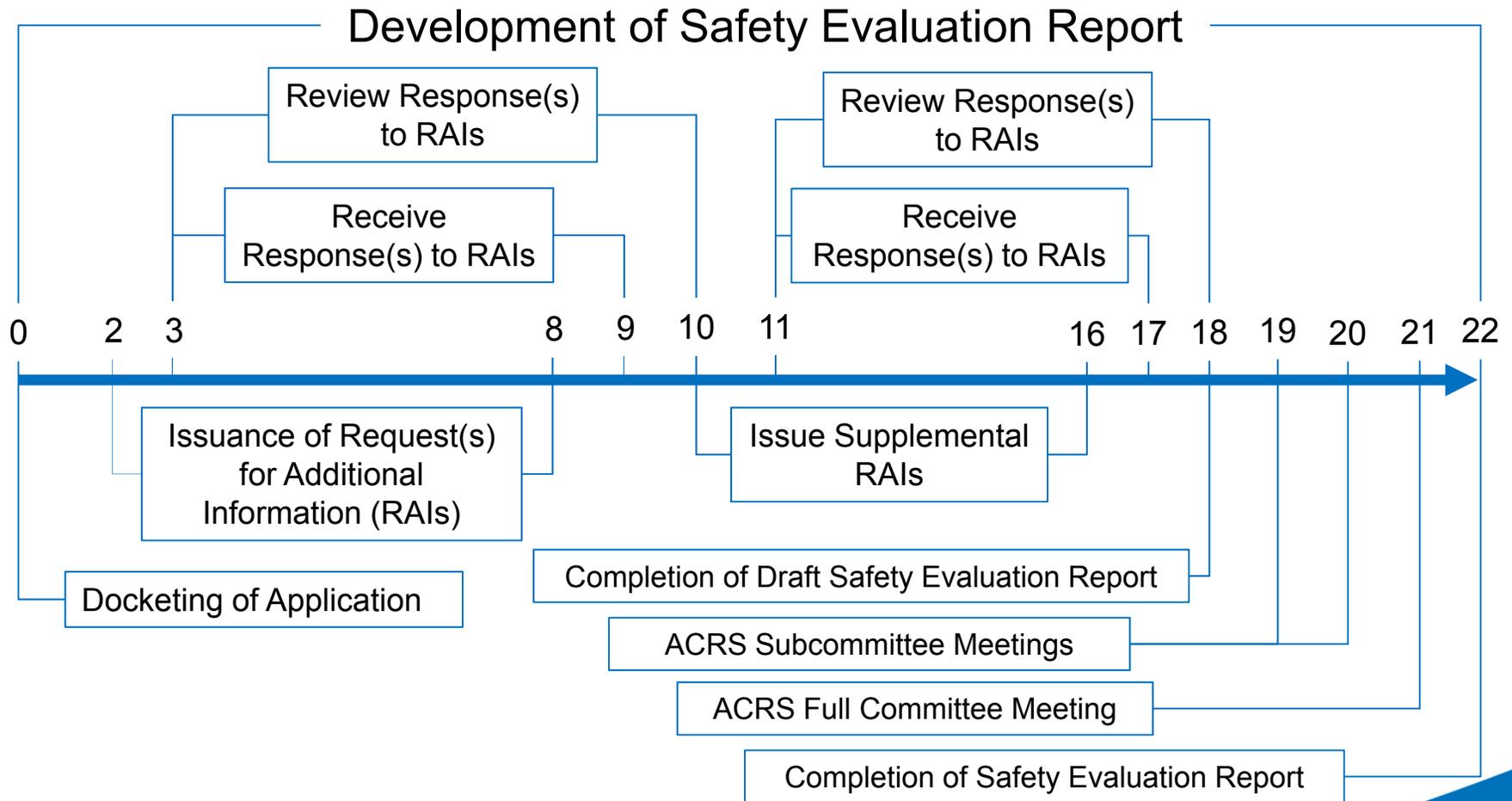
NWMI Licensing Approach

- Hot cells reviewed as *production facility* under 10 CFR Part 50
- Special nuclear material, including target manufacturing, will be licensed under 10 CFR Part 70
- NRC staff applying best practices from SHINE review:
 - Emphasis on most safety-significant technical aspects
 - Focused requests for additional information
 - Weekly status calls
 - Twenty-two month safety review schedule

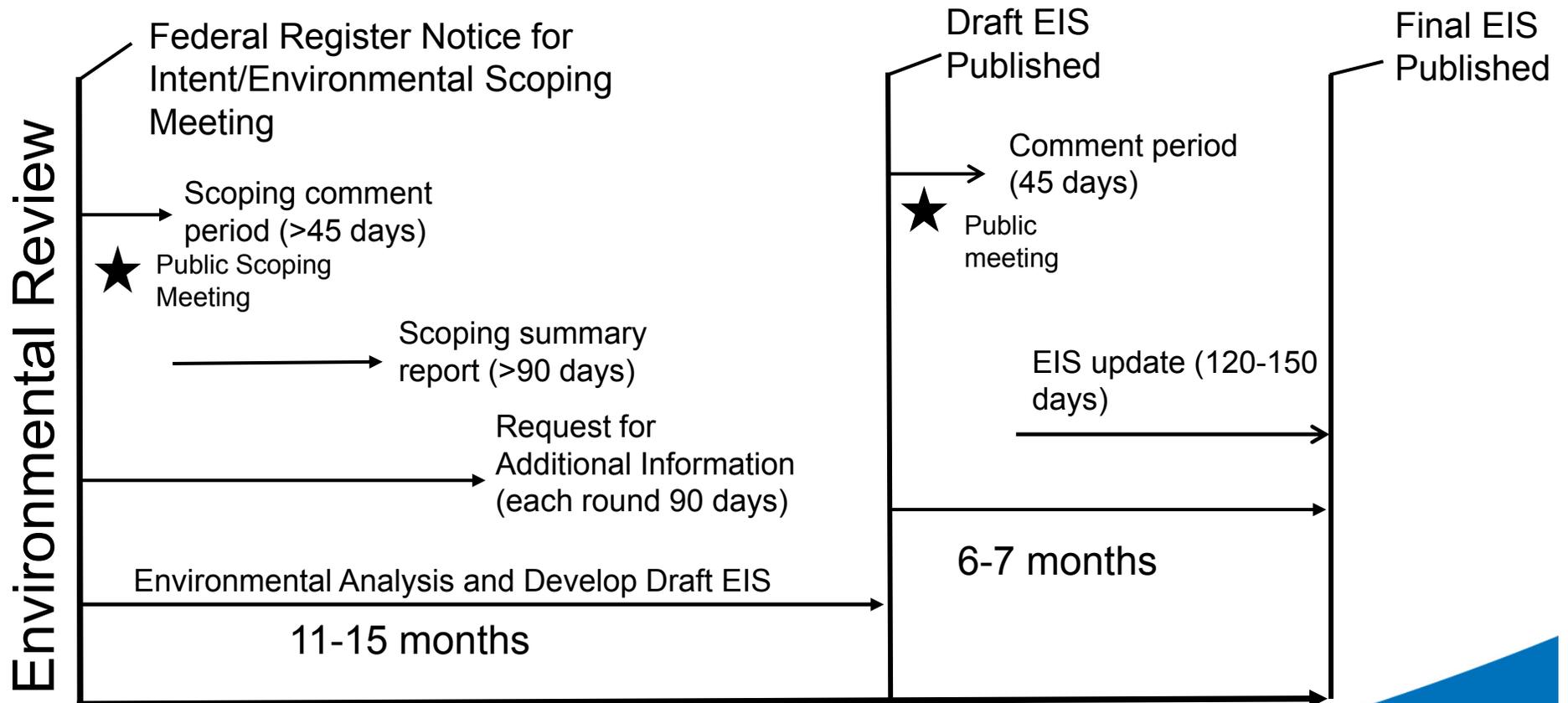
Construction Permit Review Process

- 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 hearing (adequacy of staff safety and environmental review)
- Decision to grant or deny construction permit

Sample 22-month Safety Review Timeline



Sample Environmental Review Timeline



18-22 months*

*estimated time of review based on historical data. Actual time of review may vary based on complexity of application.

Impacts to Review Schedule

- Quality of Application
 - Adherence to regulatory requirements
 - Technical completeness
 - Attention to detail (i.e., organization, format, etc.)
- Requests for Additional Information (RAIs)
 - Completeness, timeliness, and responsiveness to requests
 - Evaluation of new information
 - Number of requests for additional information
 - Number of rounds of RAIs
- Policy Questions
 - Commission involvement to resolve unique considerations
- Advisory Committee on Reactor Safeguards
 - Number of subcommittee meetings
 - Follow-up

Other Scheduling Considerations

- Possible contested hearing(s)
- Mandatory hearing
 - Cannot hold mandatory hearing until completion of Safety Evaluation Report, Environmental Impact Statement, ACRS Review, and contested hearing(s)
- Commission decision to issue or deny construction permit
 - Decision on SHINE construction permit made 2 months following hearing
 - Decisions on combined operating licenses made 2 – 5 months following mandatory hearing

Construction Permit Regulatory Requirements

- Regulatory considerations for NWMI 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 and test reactors

Contents of 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
- Research and development

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
 - 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 judgement used, as appropriate, to determine what is necessary for construction permit

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

NRC Review Methodology

- Since construction permit only allows construction, level of detail needed in application and staff's SER different than for combined operating license or operating license
- For the purposes of issuing a construction permit, the facility may be adequately described at a functional or conceptual level in the PSAR
- Applicants may defer providing many design and analysis details until the submission of its final safety analysis report (FSAR) with its operating license application
- Staff's review tailored to unique and novel technology described in construction permit application using appropriate regulatory guidance

Resolving Technical Issues

- For technical areas requiring additional information, the staff has several options:
 - The staff may determine that such technical issues must be resolved prior to the issuance of a construction permit
 - The staff may determine that such information may be left until the submission of the FSAR
 - The staff may require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit
- In all cases, staff may issue requests for additional information
- In the second and third options, staff may track regulatory commitments or identify necessary license conditions

Basis for Issuing Construction Permit

- The following findings must be made to issue a construction permit, based on 10 CFR 50.35:
 - Facility has been described, including the principal architectural and engineering criteria for the design
 - Further technical or design information may be reasonably left for later consideration in the FSAR
 - Safety features or components requiring research and development have been identified
 - 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
- Staff's conclusions also based on the considerations in 10 CFR 50.40 and 50.50

Status of NWMI Environmental Review

- Part one of application accepted for docketing (May 2015)
- Environmental site audit (September 2015)
- Issued environmental requests for additional information (November 2015, with follow-up requests January, March, and June 2016)
- Environmental scoping meeting (December 2015)
- Draft environmental impact statement (EIS) published (October 2016)
- Public meeting on draft EIS (December 2016)
- Final EIS published (May 2017)

Status of NWMI Safety Review

- Part two of application accepted for docketing (December 2015)
- Issued safety requests for additional information (March 2016, with follow-up requests in September 2016, as well as January and March 2017)
- Participated in Advisory Committee Meeting on Reactor Safeguards (ACRS) subcommittee meetings (June, July, August, and September 2017)
- Completion of staff review anticipated by October 2017
- Next Steps:
 - ACRS full committee meeting
 - Mandatory hearing (with Commission)
- Application supported by license amendments for existing research reactors
 - Prototypical target irradiation (OSU), issued
 - Commercial target irradiation (OSU, MURR), anticipated

SHINE Medical Technologies

- NRC received two-part construction permit application
 - 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

SHINE Irradiation Facility

- Irradiation facility houses eight subcritical irradiation units, which are 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 and could not be licensed under 10 CFR Part 70
- To align licensing process with potential hazards, NRC issued direct final rule modifying 10 CFR definition of utilization facility to include SHINE irradiation units
 - Published October 17, 2014
 - Effective December 31, 2014

SHINE Radioisotope Production Facility

- Radioisotope Production Facility consists of three hot cells for ^{99}Mo separation and purification
- Based on batch size (i.e., greater than 100 grams), facility meets the definition of a production facility as defined in 10 CFR 50.2, “Definitions”
- While NRC has historically licensed production facilities, no such facilities currently operating
- Few previously-licensed facilities have conducted similar activities as SHINE
 - Cintichem (licensed under 10 CFR Part 70)
 - West Valley (licensed as a reprocessing facility)

SHINE Licensing Approach

- SHINE facility licensed under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
 - Irradiation units licensed as *utilization facilities*
 - Hot cells licensed as *production facility*
- Special nuclear material will be licensed under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material”

Periodic Reports on Permit Conditions

- Section 3.D.(1) of SHINE construction permit requires the submission of periodic reports to verify certain design elements related to nuclear criticality safety and radiation protection
 - Criticality accident alarm system
 - Nuclear criticality safety evaluations
 - Design information demonstrating shielding and occupancy times consistent with as low as reasonably achievable practices and dose requirements
- SHINE has submitted three periodic reports since the issuance of its construction permit (August 2016, February 2017, August 2017)
- NRC staff may request clarifying or more detailed information, if necessary, prior to the completion of construction

Annual Financial Reports

- In addition to financial qualifications during initial licensing, NRC requires certain licensees to submit annual financial reports
- While annual financial reports are submitted for informational purposes, NRC staff keeps reports available for future reviews of financial qualifications
- SHINE has submitted two annual financial reports since the issuance of its construction permit
- NRC staff may request additional or more detailed information regarding ability of SHINE to continue the conduct of activities authorized by its construction permit

SHINE Demonstration Unit

- SHINE planning to conduct series of short-duration tests within an accelerator-driven subcritical operating assembly, with less than a critical mass of low enriched uranium (LEU)
- Unlike commercial irradiation units, demonstration unit would not require engineered safety features or physical protection system based on:
 - Thermal power level
 - Effective multiplication factor
 - Potential accident scenarios
 - Quantities of special nuclear material
 - Intended use
- NRC staff determined that proposed demonstration unit would not meet the definition of a “utilization facility” in 10 CFR Part 50 or Atomic Energy Act

Status of SHINE Licensing and Oversight

- Construction permit issued to SHINE in February 2016
- Construction expected to begin in 2018
- Operating license application expected in 2018

Reactor License Amendments at MURR

- First of two anticipated amendment requests submitted in May 2017
 - If granted would allow modification of reactor reflector and installation of supporting systems for LEU target irradiation
 - Initial request for additional information issued in September 2017
 - Completion of technical review anticipated by June 2018
- Second license amendment request would support installation of hot cells to process irradiated targets using General Atomics gaseous extraction technology
 - Hot cells anticipated to be licensed as production facility
 - NRC staff considering licensing questions such as need for construction permit and commercial designation of production facility
 - Public meeting scheduled for October 2017

Materials and Medical Use Licenses

- Materials license issued to Niowave in 2015
 - Production of small amounts of ^{99}Mo through uranium fission using superconducting linacs for proof of concept
 - NRC staff considering amendment request to increase LEU possession limit
- NorthStar Medical Radioisotopes
 - Proposes to produce ^{99}Mo from enriched molybdenum target irradiation
 - Developed RadioGenix $^{99\text{m}}\text{Tc}$ generator system compatible with lower specific activity ^{99}Mo
 - NRC staff developing licensing guidance for medical use applicants and licensees that possess RadioGenix system

Oversight, Infrastructure, and Support Activities

- Developing construction and operation inspection programs
 - Construction inspection program established in December 2015
 - Inspections commensurate with risk of facility, focusing on most safety-significant structures, systems, and components
- Updating regulatory framework
 - Published proposed rule to streamline license renewal in 2017
 - Developing proposed rule for emergency planning
- Coordinating technical and licensing expertise through inter-office working group
- Providing updates on public website:
 - <http://www.nrc.gov/reactors/medical-radioisotopes.html>