

American Nuclear Society 2018 Annual Meeting  
*Driving the Future of Nuclear Technology*  
Panel on *Licensing of Medical Isotope Production Facilities*

# U.S. Nuclear Regulatory Commission Activities Related to Domestic Molybdenum-99 Production

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# Supporting Domestic $^{99}\text{Mo}$ 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 ( $^{99}\text{Mo}$ ) 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  $^{99}\text{Mo}$  from low enriched uranium targets
- Medical uses of byproduct material
  - Generators for extracting technetium-99m ( $^{99\text{m}}\text{Tc}$ ) from  $^{99}\text{Mo}$

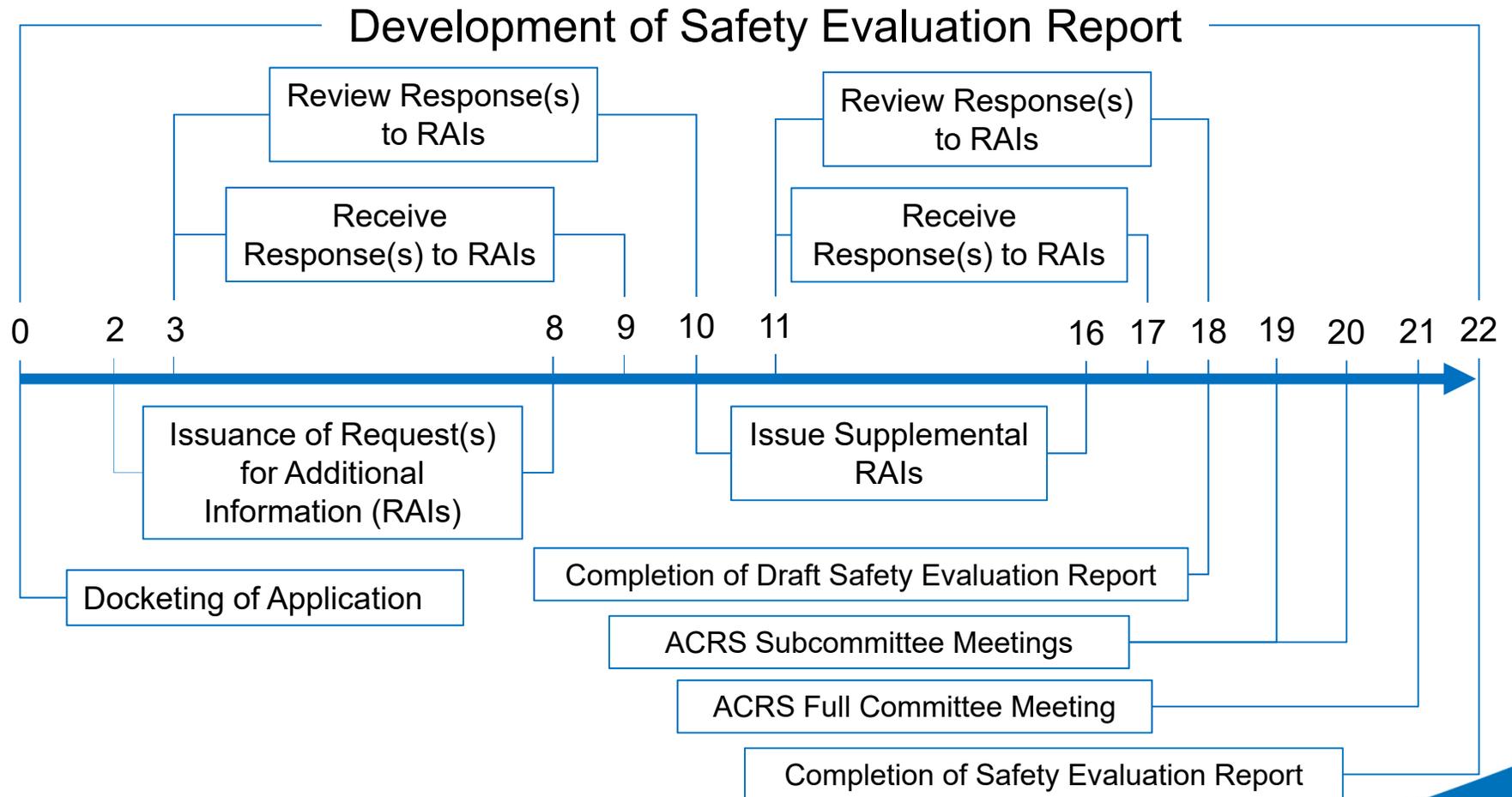
# Medical Radioisotope Licensing Reviews

- Construction permit and operating license applications
  - Northwest Medical Isotopes (NWMI)
  - SHINE Medical Technologies (SHINE)
- License amendment requests anticipated from Oregon State University (OSU) and University of Missouri Research Reactor Center (MURR) in support of NWMI project
- Materials license, and subsequent amendments, issued to Niowave
- Licensing guidance issued for NorthStar RadioGenix generator system

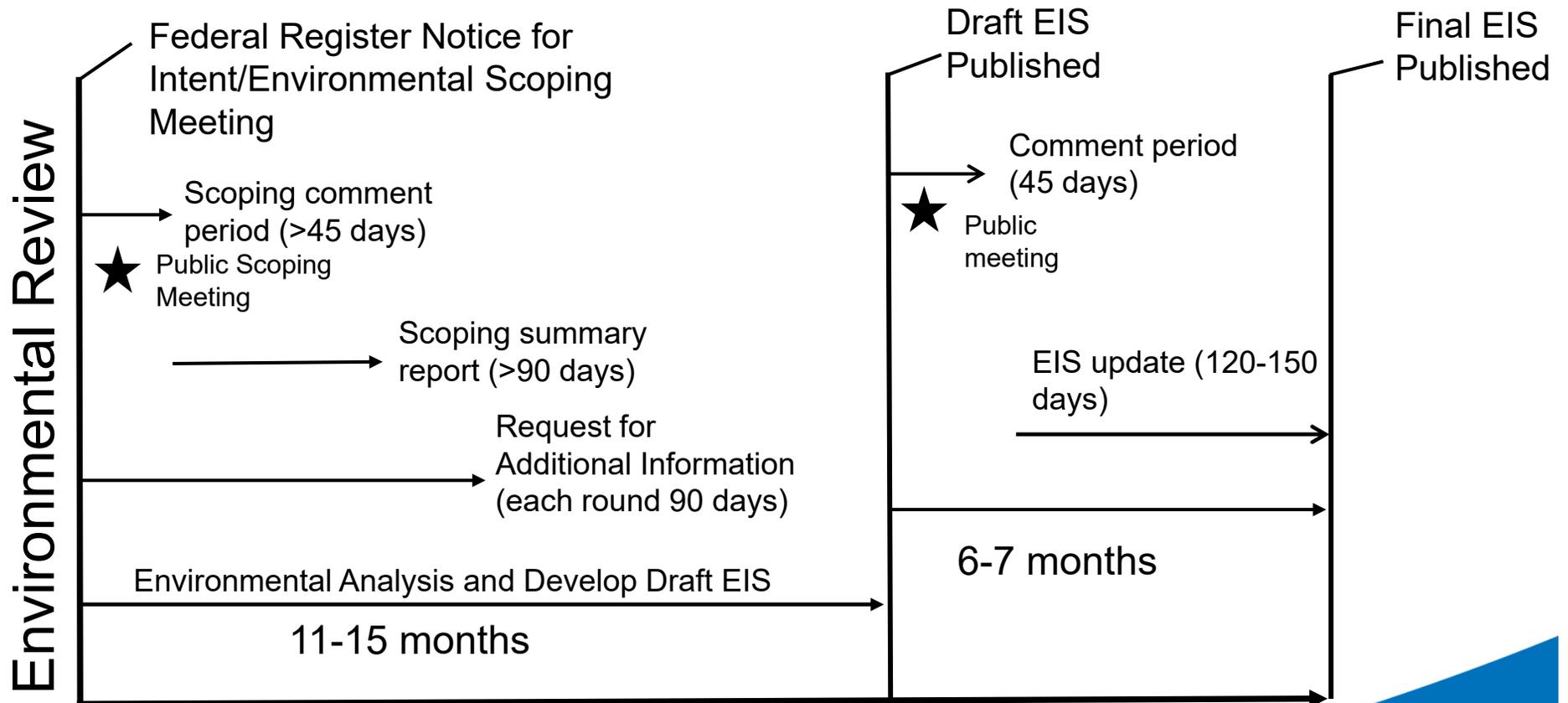
# Construction Permit Review Process

- 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 on 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

# 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

# Northwest Medical Isotopes

- NWMI proposes to manufacture and process low enriched uranium (LEU) targets for  $^{99}\text{Mo}$  production in Columbia, Missouri
  - Target manufacturing to be licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70
  - LEU targets irradiated at existing research reactors
  - Irradiated targets returned to NWMI for processing in a 10 CFR Part 50 *production facility*
- NRC staff applied best practices to support 23-month review
  - Emphasis on most safety-significant technical aspects
  - Focused requests for additional information
  - Weekly status calls

# Status of NWMI Review

- Construction permit application submitted in 2015
- Final environmental impact statement published in May 2017
- Advisory Committee Meeting on Reactor Safeguards full committee meeting held in November 2017
- Safety evaluation report completed in November 2017
- Commission held mandatory hearing in January 2018
  - Staff and applicant presented on unique licensing considerations
- Construction permit issued in May 2018

# SHINE Medical Technologies, Inc.

- SHINE proposes to fission LEU target solution in 8 irradiation units licensed as 10 CFR Part 50 *utilization facilities*
- SHINE proposes to recover  $^{99}\text{Mo}$  by processing irradiated target solution in hot cells licensed as a 10 CFR Part 50 *production facility*
- Construction permit issued in February 2016
  - Periodic reports on permit conditions
  - Annual financial reports
- Pre-construction and pre-application meetings scheduled in April and May 2018
  - Construction expected to begin in 2018
  - Operating license application expected in 2018
- Proposed site: Janesville, Wisconsin

# Facility-Specific Permit Conditions

- SHINE and NWMI construction permits require 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
- The SHINE construction permit contains an additional condition requiring the submission of a periodic report to verify design information related to radiation protection
- The NWMI construction permit contains additional conditions related to the completion of a geotechnical investigation and implementation of its quality assurance program
- SHINE has submitted four periodic reports since the issuance of its construction permit
- 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 three annual financial reports since the issuance of its construction permit
- NRC staff may request additional or more detailed information regarding ability of licensees to continue the conduct of activities authorized by its construction permit

# Reactor License Amendments at MURR

- First of two anticipated amendment requests related to General Atomics (GA) selective gas extraction (SGE) technology submitted in May 2017
  - If granted, would have allowed modification of reactor reflector and installation of supporting systems for LEU target irradiation
  - Second amendment would have supported installation of SGE hot cells to process irradiated targets
- In an April 2018 press release, Nordion, Inc. announced withdrawal of support for medical radioisotope production project partnership with GA and MURR
  - Consequently, GA terminated its contract with MURR, who subsequently withdrew its license amendment request to produce Mo-99 using the GA SGE process

# Materials and Medical Use Licenses

- Materials license issued to Niowave in 2015
  - Production of small amounts of  $^{99}\text{Mo}$  through uranium fission using superconducting linacs for proof of concept
  - NRC staff has issued amendments increasing LEU possession limit and supporting irradiation of natural uranium targets
- NorthStar Medical Radioisotopes
  - Proposes to produce  $^{99}\text{Mo}$  from enriched molybdenum target irradiation
  - Developed RadioGenix  $^{99\text{m}}\text{Tc}$  generator system compatible with lower specific activity  $^{99}\text{Mo}$
  - NRC staff published licensing guidance for medical use applicants and licensees that possess RadioGenix system in February 2018
  - NRC staff currently considering updated information on generator system and potential changes to licensing guidance

# 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
  - Supporting development of 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>