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

2018 Mo-99 Topical Meeting on
Molybdenum-99 Production Technology Development

Licensing and Oversight Enhancements and Preparations for Medical Radioisotope Facility Application Reviews and Construction Inspection

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Supporting Domestic ^{99}Mo Production

- NRC staff committed to efficient reviews of applications and inspections in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)

- Licensing and oversight activities support U.S. national security interests and nuclear nonproliferation policy objectives of establishing 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

- Oversight activities focused on preparation for construction inspection of utilization and production facilities

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 irradiated low enriched uranium (LEU) targets
- Medical uses of byproduct material
  - Generators for extracting technetium-99m from ^{99}Mo

Medical Radioisotope Licensing and Oversight

- 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 Medical Radioisotopes RadioGenix generator system
- Inspection preparation for anticipated construction of SHINE and NWMI facilities

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
- Applications may be submitted separately or together
- Testing facilities and commercial facilities may request limited work authorization to allow certain construction activities prior to the issuance of a construction permit

10 CFR Part 50 Licensing Process

- Similar review process for construction permit and operating license applications:
  - Acceptance and docketing review
  - Parallel safety and environmental reviews
    - Construction permit: preparation of safety evaluation report (SER) and environmental impact statement (EIS) (or environmental assessment)
    - Operating license: preparation of SER and supplemental EIS (or environmental assessment)
  - Request(s) for additional information, as needed
  - Advisory Committee on Reactor Safeguards (ACRS) review
  - Hearing(s)
    - Construction permit and operating license: potential for contested hearing(s)
    - Construction permit: mandatory hearing on sufficiency of staff safety and environmental reviews
  - Decision to grant or deny permit or license

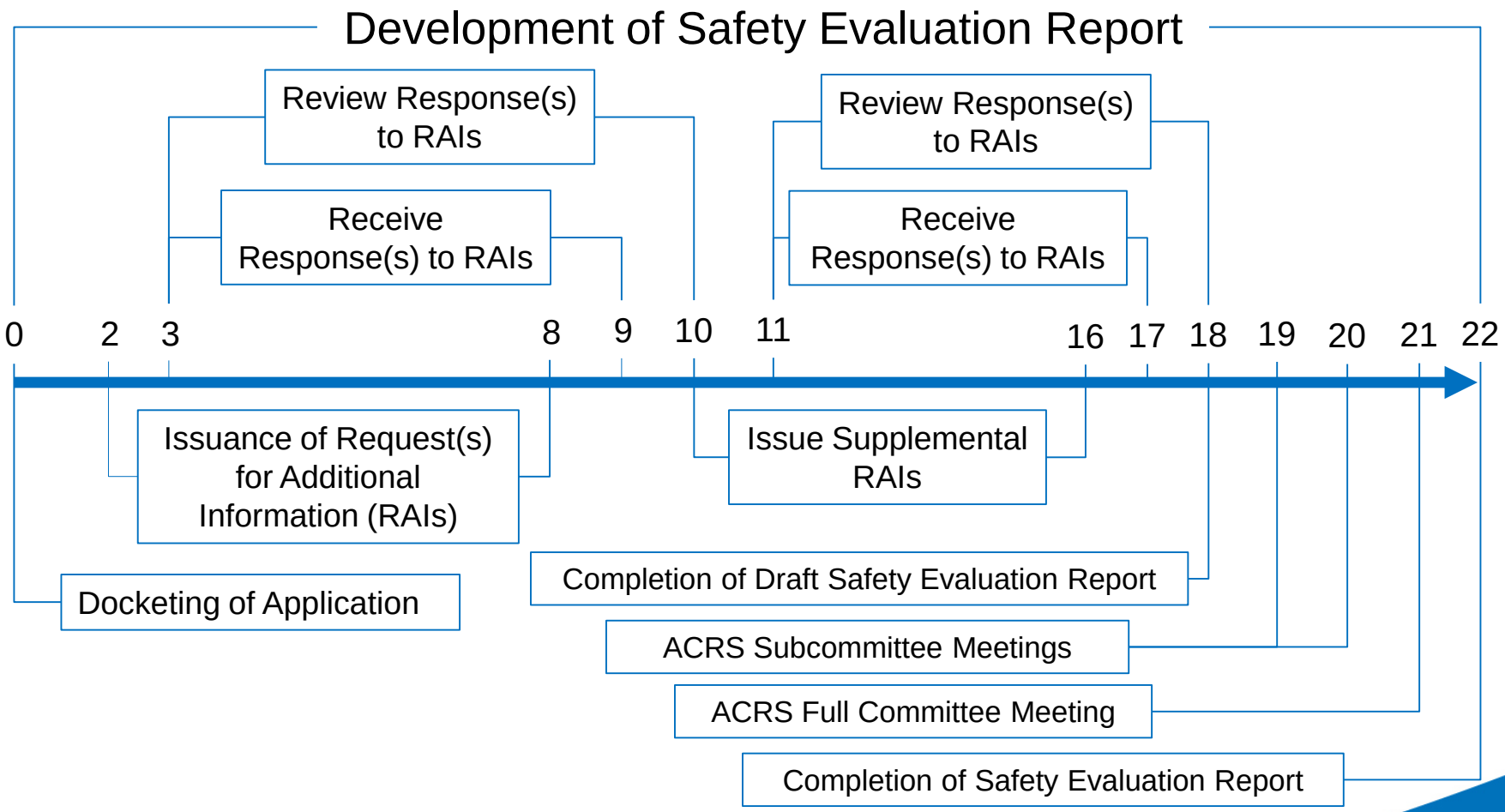
NRC Safety Review Methodology

- Safety reviews for construction permit and operating license applications conducted in accordance with Commission's regulations
- The level of detail needed in a construction permit application and NRC staff's SER different than for combined operating license or operating license
  - The PSAR includes preliminary design of the facility, while the FSAR includes final design of the facility, as well as plans and programs not provided in PSAR
- Staff's review tailored to unique and novel technology described in construction permit application using appropriate regulatory guidance
  - NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors"
  - Interim Staff Guidance Augmenting NUREG-1537
  - Other guidance (e.g., regulatory guides and industry standards) and engineering judgment used, as appropriate

Resolving Technical Issues

- For technical areas requiring additional information, the NRC 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

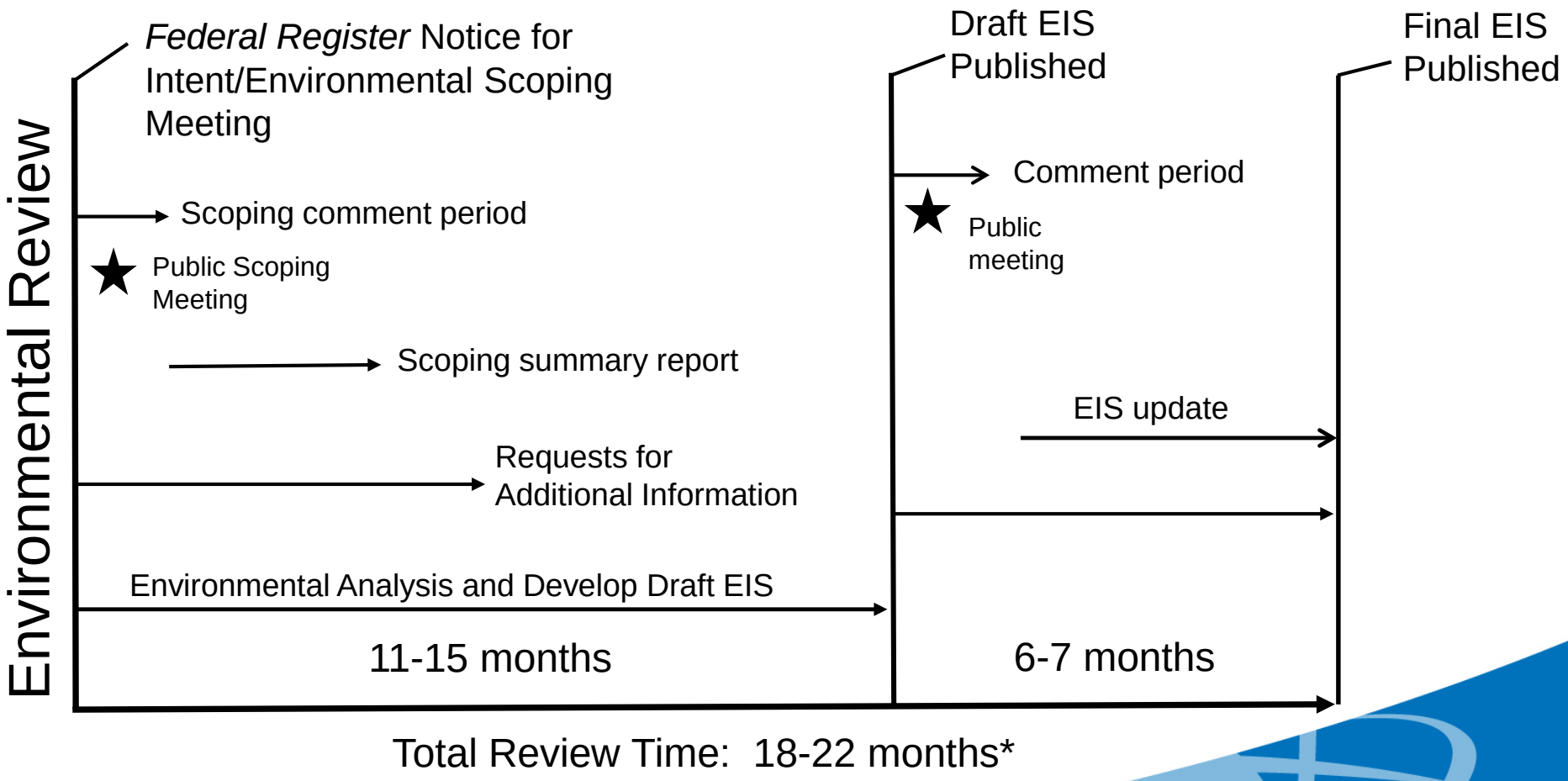
Sample NRC Staff Safety Review Timeline



Environmental Review Process

- Legislation, regulations, and guidance
  - National Environmental Policy Act
  - NRC Environmental Regulations (10 CFR Part 51)
  - Applications reviewed using Interim Staff Guidance Augmenting NUREG-1537
- Applicant submits environmental report for construction permit and operating license applications
- Construction permit application environmental review includes:
  - Environmental scoping period; site audit; and preparation of draft and final EIS (or environmental assessment)
- Operating license application environmental review includes preparation of either Supplemental EIS or environmental assessment
  - Supplemental EIS updates prior review and describes matters that differ or reflect significant new information since publication of EIS
  - Review considers changes in facility design; operation; natural or physical environment; and regulatory environment

Sample Environmental Review Timeline



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

Impacts on Review Schedule

- Quality of application
  - Adherence to regulatory requirements
  - Technical completeness
  - Attention to detail (i.e., organization, format, etc.)
- Requests for additional information (RAIs)
  - Complexity and novelty of technology
  - Completeness, timeliness, and responsiveness to requests
  - Number of RAIs and need for follow-up
  - Evaluation of new information
- Policy questions
  - Commission involvement to resolve unique considerations
- Advisory Committee on Reactor Safeguards
  - Number of subcommittee meetings
  - Follow-up items

Other Scheduling Considerations

- Possible contested hearing for construction permit and operating license applications
- Mandatory hearing only for construction permit application
  - Cannot hold mandatory hearing until completion of Safety Evaluation Report, Environmental Impact Statement, ACRS Review, and any contested hearing
- Commission decision to issue or deny construction permit
  - Decisions on construction permits made 2 – 4 months following mandatory hearing

Licensing Accomplishments

- Issued first two construction permits for non-power utilization or production facilities since 1985
  - SHINE Medical Technologies (February 2016)
  - Northwest Medical Radioisotopes (May 2018)
  - Reviews completed in under two years from time of application docketing
- Published guidance in February 2018 for medical use applicants and licensees possessing the NorthStar Medical Radioisotopes RadioGenix system
  - Supports first anticipated commercial domestic production of ^{99}Mo since Cintichem ceased operations in 1989
- Issued license amendment to OSU in 2016 for demonstration of ^{99}Mo production in small nuclear reactor with experimental uranium targets
- Issued materials license to Niowave in 2015
  - License amendments issued increased LEU possession limit and supported irradiation of natural uranium targets using superconducting linacs for proof of concept

Reflecting Back…

- For novel technologies, early interactions between NRC staff and applicants support efficient application processing and review
- Public pre-application 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
- Best practices from construction permit application reviews:
  - Emphasis on most safety-significant technical aspects
  - Focused requests for additional information
  - Weekly status calls

…And Looking Forward

- Anticipating operating license application reviews and construction inspection activities expected to begin in fiscal year 2019
- Updating licensing framework
- Anticipating technical and licensing challenges
- Engaging with potential construction permit applicants
- Supporting ongoing activities related to materials and medical use licensees
- Preparing for license amendment requests from existing research reactor licensees supporting the NWMI production project
- Continuing interactions with construction permit holders on facility-specific conditions and annual reports

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
- Another SHINE construction permit condition requires the submission of a periodic report to verify design information related to radiation protection
- Other NWMI construction permit conditions require the completion of a geotechnical investigation and quality assurance program implementation
- SHINE has submitted five 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

Construction Inspection Preparation

- Developing construction and operation inspection programs
  - Construction inspection program established in December 2015
  - Inspections to be commensurate with risk of facility, focusing on most safety-significant structures, systems, and components (SSCs)
- Updating construction inspection manual chapter
- Planning for initial construction inspections related to quality assurance and civil engineering
- Working with licensees to identify most safety-significant SSCs to prioritize and focus construction inspections ahead of FSAR submission
  - Information shared through public meetings, site visits, and electronic reading rooms
- Reviewing previous construction inspection reports

Impact of Medical Radioisotope Facility Reviews

- Experience gained from medical radioisotope facility reviews is supporting the creation of a more responsive and efficient technology-inclusive regulatory framework at the NRC
- Review of construction permit applications setting example for future advanced reactor reviews
- Success made possible through technical and licensing expertise provided by inter-office working group
- Stay up-to-date on medical radioisotope facility activities through NRC public website:
  - http://www.nrc.gov/reactors/medical-radioisotopes.html