

U.S. National Academy of Sciences  
*Committee on State of Molybdenum-99 Production and Utilization and  
Progress toward Eliminating Use of Highly Enriched Uranium*

# U.S. Nuclear Regulatory Commission Licensing Activities Related to Molybdenum-99 Production (Update)

Steven Lynch  
Office of Nuclear Reactor Regulation  
U.S. Nuclear Regulatory Commission  
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# Supporting Domestic $^{99}\text{Mo}$ Production

- NRC is prepared to conduct reviews on all applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)
- NRC is coordinating environmental review work with the Department of Energy (DOE), in accordance with American Medical Isotopes Production Act
- NRC is supporting the Department of Homeland Security's (DHS) site vulnerability assessments for utilization facilities, in accordance with the provisions of Section 657 of the Energy Policy Act of 2005

# Current and Anticipated Licensing Reviews

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

# Licensing Considerations

- Licensing determinations are facility- and technology-specific and made on a case-by-case basis
- Selection of appropriate licensing process(es) for a facility are based on the following considerations:
  - Type and quantities of material on site (e.g., low enriched uranium or natural molybdenum targets)
  - Type(s) of activities performed at facility (e.g., target manufacturing, irradiation, and/or processing)
  - Method of irradiation (e.g., nuclear reactor, accelerator)
  - Method of target processing, including batch size
  - New or existing facility

# Production Techniques

- 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
- NRC may also license some accelerator-based technologies involving natural molybdenum targets if not under Agreement State jurisdiction

# Licensing Requirements

- Anticipate licensing most facilities under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
  - Target irradiation performed by *utilization facilities*
  - Fission product separation in *production facilities*
- May license certain facilities under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material” or 10 CFR Part 30, “...Domestic Licensing of Byproduct Material”

# Initiating the Licensing Process

- Letters of intent
  - Indicate applicant's level of interest
  - Provide anticipated application submission schedule
  - Introduce proposed technology
- For novel technologies, early interaction supports efficient application processing and review
- Public Meetings
  - Promote engagement between NRC and applicant
  - Inform the development of high-quality applications
  - Inform budgeting and resource allocation
  - Inform public of NRC process

# Applications for Construction and Operation

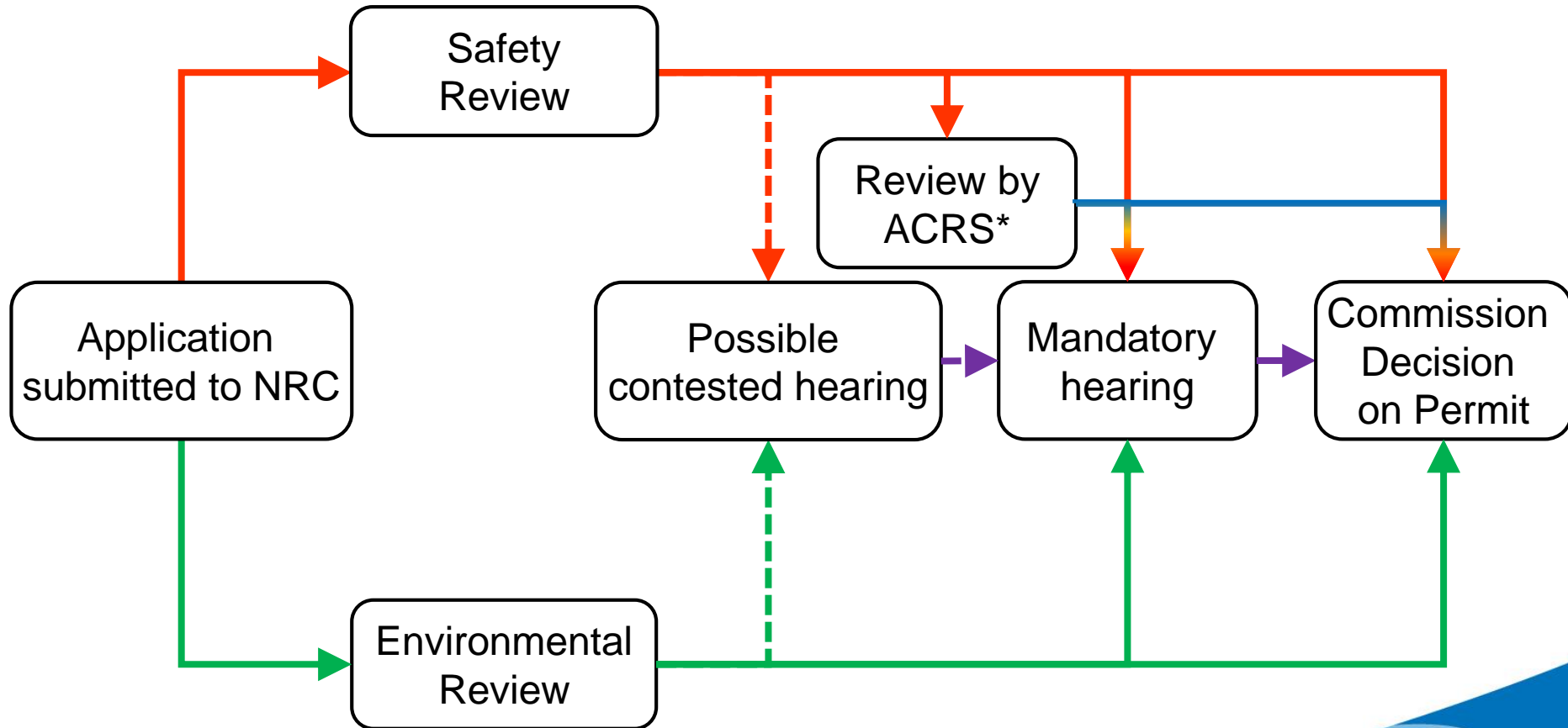
- Applications contain both general and technical information
- Construction permit application
  - Environmental Report
  - Preliminary Safety Analysis Report (PSAR)
- Operating license application
  - Update to environmental report, as necessary
  - Final safety analysis report (FSAR)
  - Physical security plan
  - Protection against unauthorized disclosure
- May submit applications separately or together
- 18 – 24-month review of each application



# Construction Permit vs. Operating License

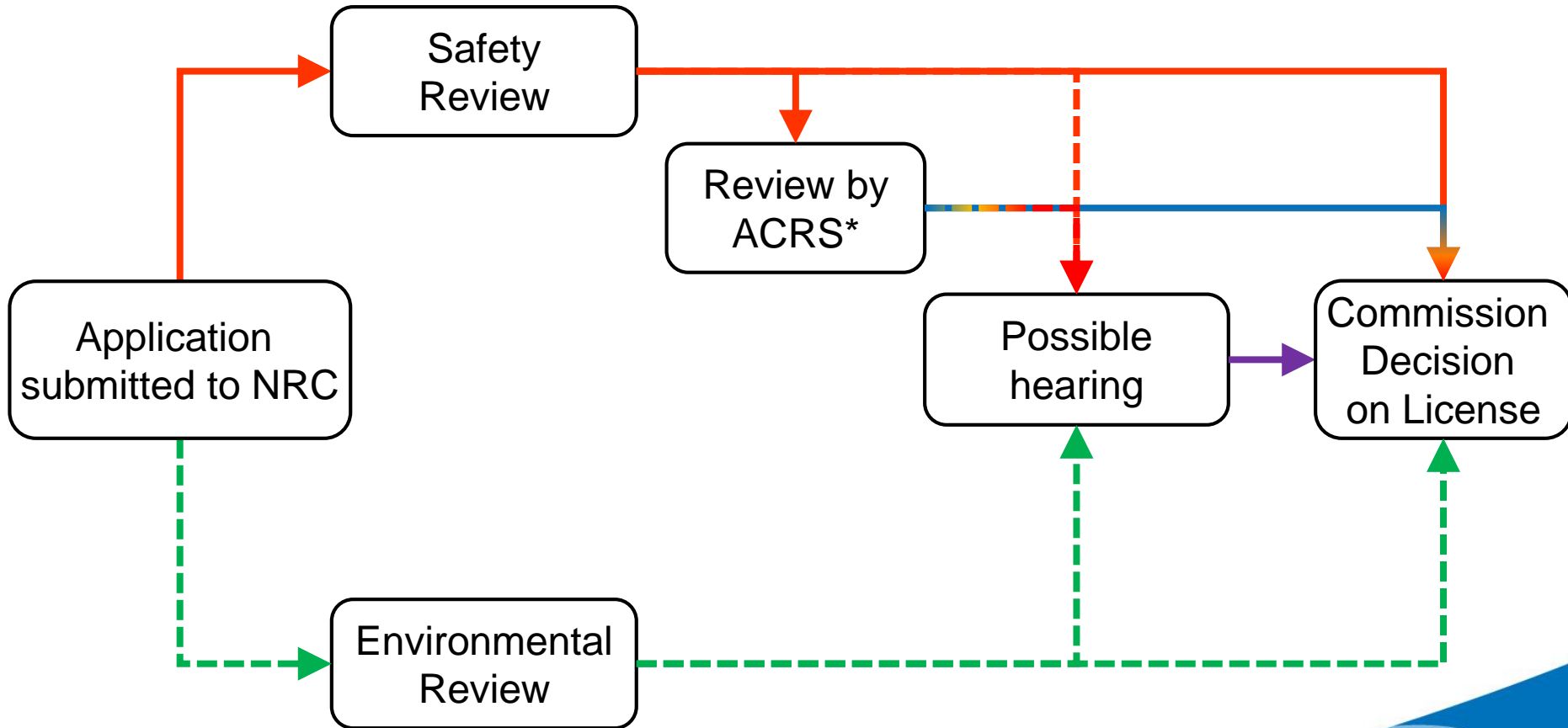
- Construction permit (10 CFR 50.35)
  - Allows licensee to proceed with construction based on preliminary design information (PSAR)
  - Does not approve of the safety of any design feature or specification unless specifically requested by the applicant
- Operating License (10 CFR 50.57)
  - Allows licensee to operate the facility based on final design information (FSAR)
  - Issued when there is reasonable assurance that the activities authorized by the license will not endanger the public health and safety

# Construction Permit Review Process



\* Advisory Committee on Reactor Safeguards

# Operating License Review Process



\* Advisory Committee on Reactor Safeguards

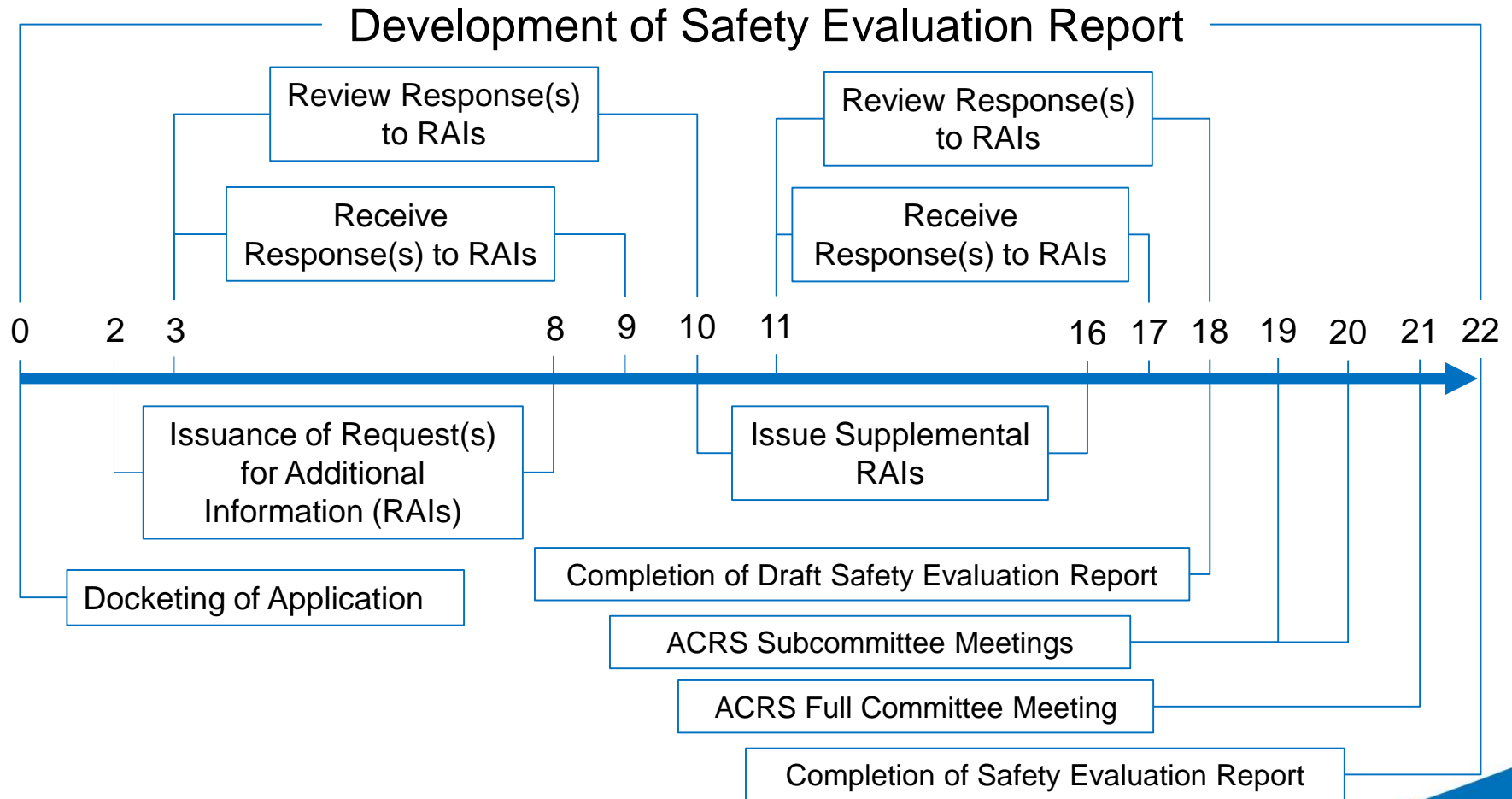
# Safety Review Guidance

- NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”
- Interim Staff Guidance (ISG) 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 judgement used, as appropriate, to determine what is necessary for construction permit

# Safety Review Process

- Acceptance review of SAR
- Docketing of application
- Development of safety evaluation report
- 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 Review Timeline



# Safety Evaluation Report Development

- Assumptions
  - May include multiple rounds of RAIs
  - May require multiple ACRS subcommittee meetings
- Driven by safety significance
  - Confirmatory calculations
  - Cross-disciplinary coordination (vertical slice)
- Document preparation
  - Writing of safety evaluation report
  - Development and issuance of requests for additional information
- Communication with applicant
  - Public meeting(s)
  - Discussion of RAIs

# Impacts to Safety 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



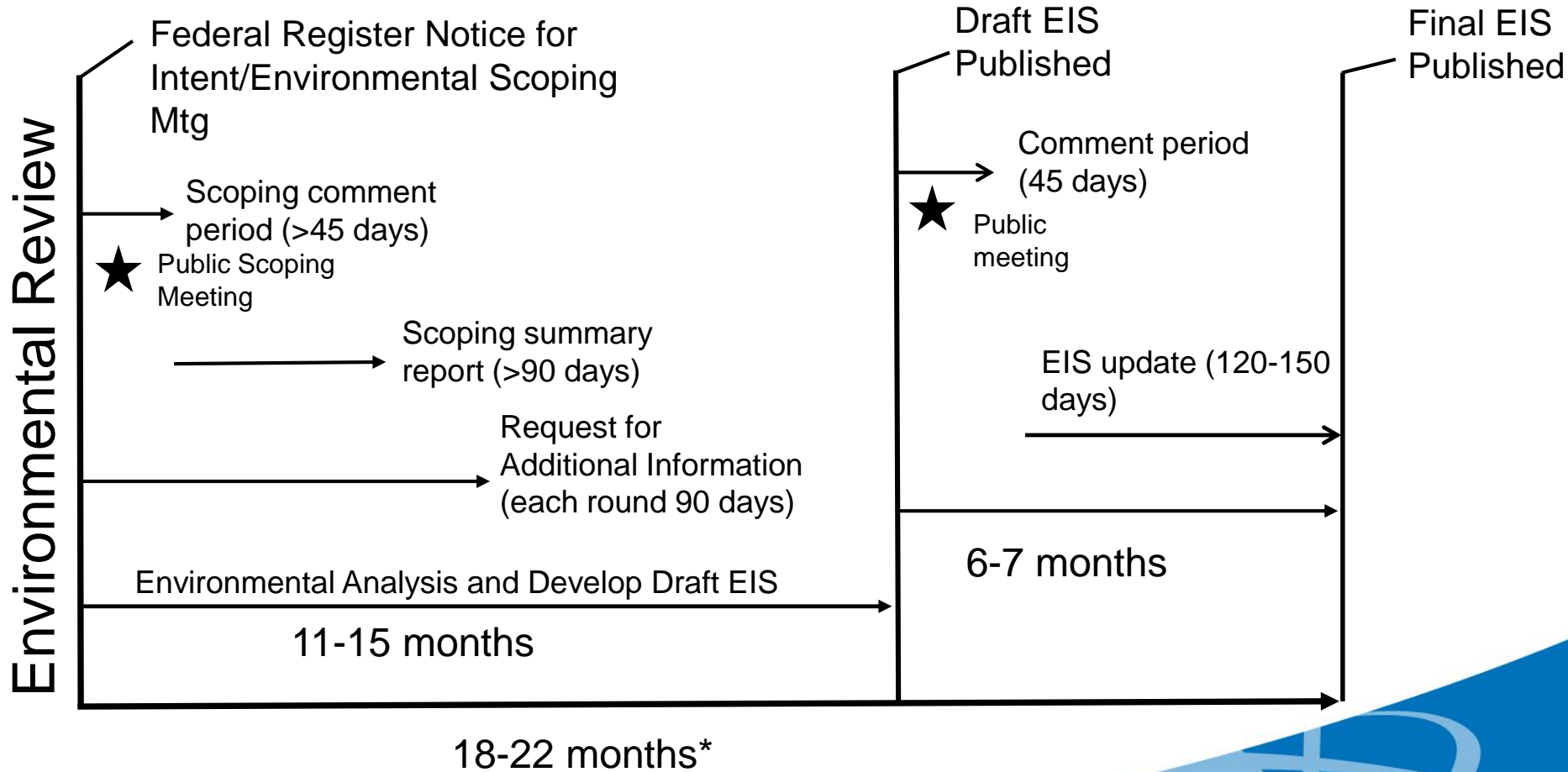
# Other Scheduling Considerations

- 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

# Environmental Review

- National Environmental Policy Act
  - NRC environmental regulations (10 CFR Part 51)
  - Application reviewed using ISG augmenting NUREG-1537
- Environmental scoping period
- Site audit
- Draft Environmental Impact Statement (or environmental assessment)
- Environmental Impact Statement (or environmental assessment)

# Environmental Review Timeline



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

# 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  $^{99}\text{Mo}$  from fission of low enriched uranium target solution in Irradiation Facility consisting of 8 irradiation units
- $^{99}\text{Mo}$  recovered through irradiated target solution processing in Radioisotope Production Facility consisting of 3 hot cells
- Proposed site: Janesville, WI

# 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”

# 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 hearing on application (December 2015)
- Construction permit issued (February 2016)
- Construction expected to begin in 2017
- Operating license application expected 2017

# 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
  - University of Missouri – Columbia (MURR)
  - Oregon State University (OSU)
- $^{99}\text{Mo}$  recovered through processing of irradiated targets
- Proposed site: Columbia, MO

# NWMI Licensing Approach

- Hot cells licensed as *production facility* under 10 CFR Part 50
- Special nuclear material, including target manufacturing, will be licensed under 10 CFR Part 70



# Status of NWMI Review

- Part one of application accepted for docketing (May 2015)
- Environmental site audit (September 2015)
- Issued requests for additional information (November 2015, with follow-up requests January, March, and June 2016)
- Environmental scoping meeting (December 2015)
- Part two of application accepted (December 2015)
- Application supported by license amendments for existing research reactors
  - Prototypical target irradiation (OSU)
  - Commercial target irradiation (OSU, MURR)

# License Amendments and Materials Licenses

- License amendment issued to OSU
  - Demonstration of  $^{99}\text{Mo}$  production in small nuclear reactor with experimental uranium targets
- Materials license issued to Niowave
  - Production of small amounts of  $^{99}\text{Mo}$  through uranium fission using superconducting linacs for proof of concept
- Anticipated licensing request from MURR
  - General Atomics gaseous extraction technology to be used following uranium target irradiation
  - Public Meeting held on June 2, 2016

# Ongoing Infrastructure and Support Activities

- Developing construction and operation inspection programs
- Reviewing regulations and guidance
- Coordinating technical and licensing expertise through inter-office working group
- Maintaining communication with stakeholders
  - Federal government (Office of Science and Technology Policy, National Nuclear Security Administration, DHS)
  - State and local governments
  - Public

# Summary of Licensing Activities

- Issued SHINE construction permit
- Reviewing NWMI construction permit application
- Issued license amendment to Oregon State University
- Anticipate receiving additional applications within the next year
  - Prepared to review additional applications
  - Encourage early and frequent communication with potential producers