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

Public Meeting with Northwest Medical Isotopes, LLC.

Office of Nuclear Reactor Regulation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
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Meeting Purpose

- NRC licensing processes
- NRC regulations and guidance
- Review timeline
- Construction permit application (CPA) licensing review/status
- Communications

NRC Licensing Processes

Licensing Considerations for Medical Isotope Facilities

- Licensing determinations are facility- and technology-specific and made on a case-by-case basis
- Selection of licensing process 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

Licensing Regulations

- 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
- 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material”
- 10 CFR Part 30, “…Domestic Licensing of Byproduct Material”
- 10 CFR Part 51, “Environmental Protection Regulations…”

NRC Licensing Process

10 CFR Part 50

Domestic Licensing of Production and Utilization Facilities

10 CFR Part 50 Licenses for Construction and Operation

- Construction permit application
  - Environmental Report
  - Preliminary Safety Analysis Report (PSAR)
- Operating license application
  - Final Safety Analysis Report (FSAR), including: plans for operation, emergencies, and technical specifications
  - Update to Environmental Report, as necessary
  - Physical Security Plan
- 18 – 24-month review of each construction permit and operating license application

Examples of Construction Permit Regulations

- 10 CFR 50.22, “Commercial and industrial facility licenses”
- 10 CFR 50.30(f), “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”
- 10 CFR 50.40, “Common standards”
- 10 CFR 50.42, “Additional standard for class 103 licenses”
- 10 CFR 50.50, “Issuance of licenses and construction permits”

10 CFR 50.35 Construction Permit Findings

- The following safety findings must be made to issue a construction permit:
  - Proposed design of the facility, including the principal architectural and engineering criteria for the design, has been described
  - Further technical or design information may be reasonably left for later consideration and will be supplied in the FSAR
  - Safety features or components, if any, requiring R&D have been described and an R&D program will be conducted to resolve safety questions associated with such features or components
  - Reasonable assurance that safety questions will be resolved prior to the completion of construction and the proposed facility can be constructed and operated without undue risk to the health and safety of the public

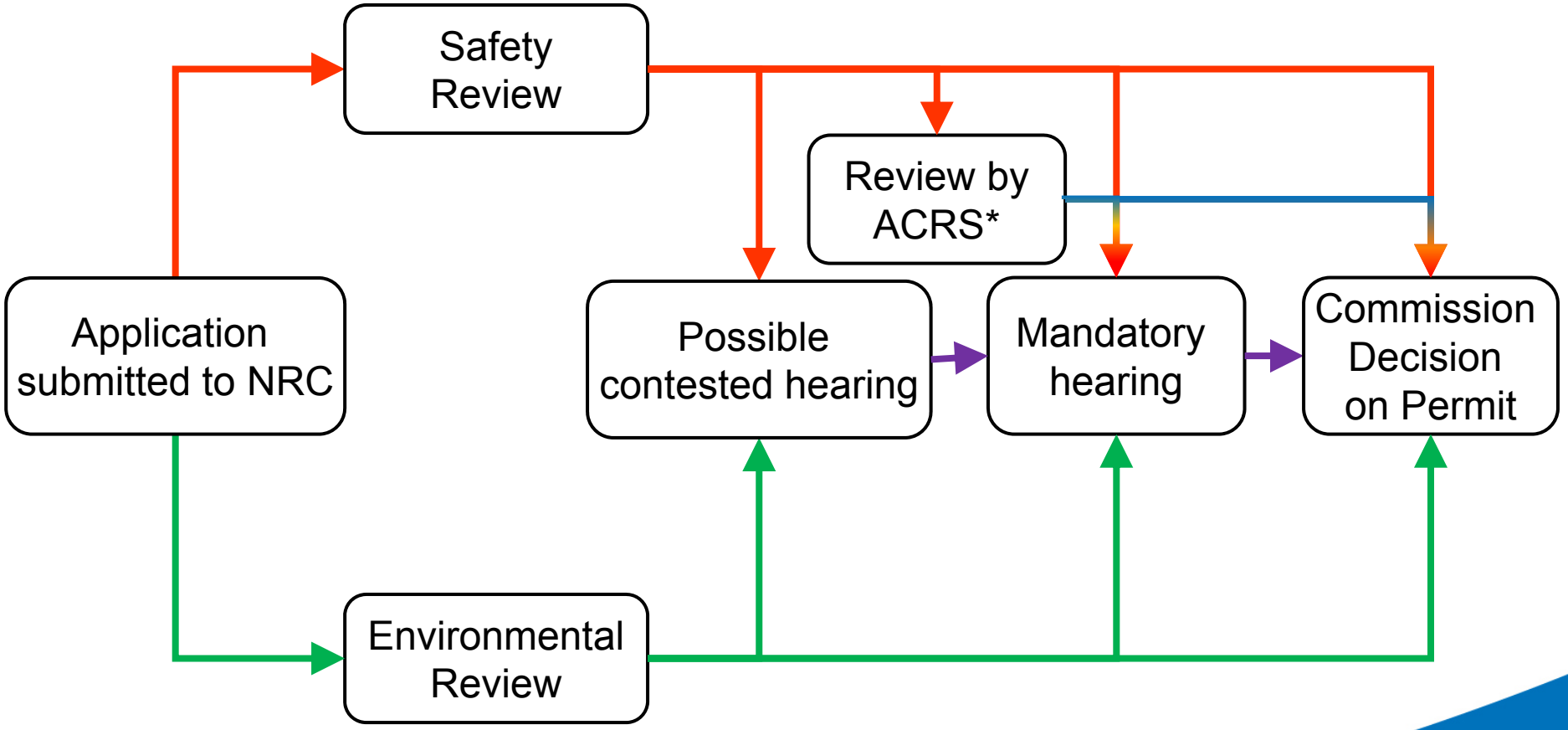
Construction Permit vs. Operating License

- 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

Considerations for Applications

- Atomic Energy Act, Section 161.h authorizes the Commission to "**consider in a single application** one or more of the activities for which a license is required by this Act, **combine in a single license** one or more of such activities, and permit the applicant or licensee to incorporate by reference pertinent information already filed with the Commission"
- Implementing regulations
  - 10 CFR 50.31, Combining applications
  - 10 CFR 50.32, Elimination of repetition
  - 10 CFR 50.52, Combining licenses

Construction Permit Review Process



* Advisory Committee on Reactor Safeguards

NRC Licensing Process

10 CFR Part 51

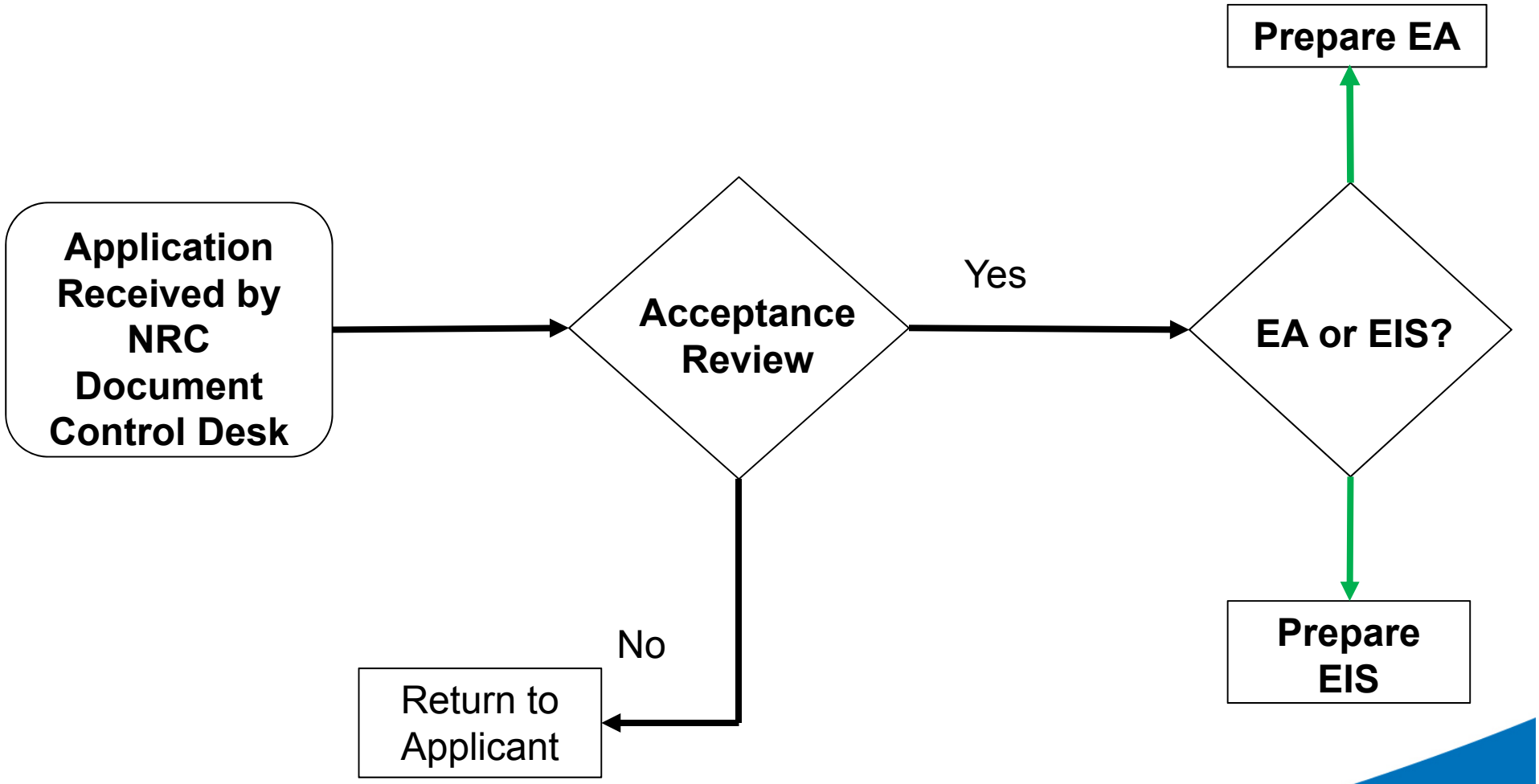
Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions

Environmental Review

- National Environmental Policy Act (NEPA)
  - Informs Federal decision making
  - Public disclosure of environmental impacts and other considerations

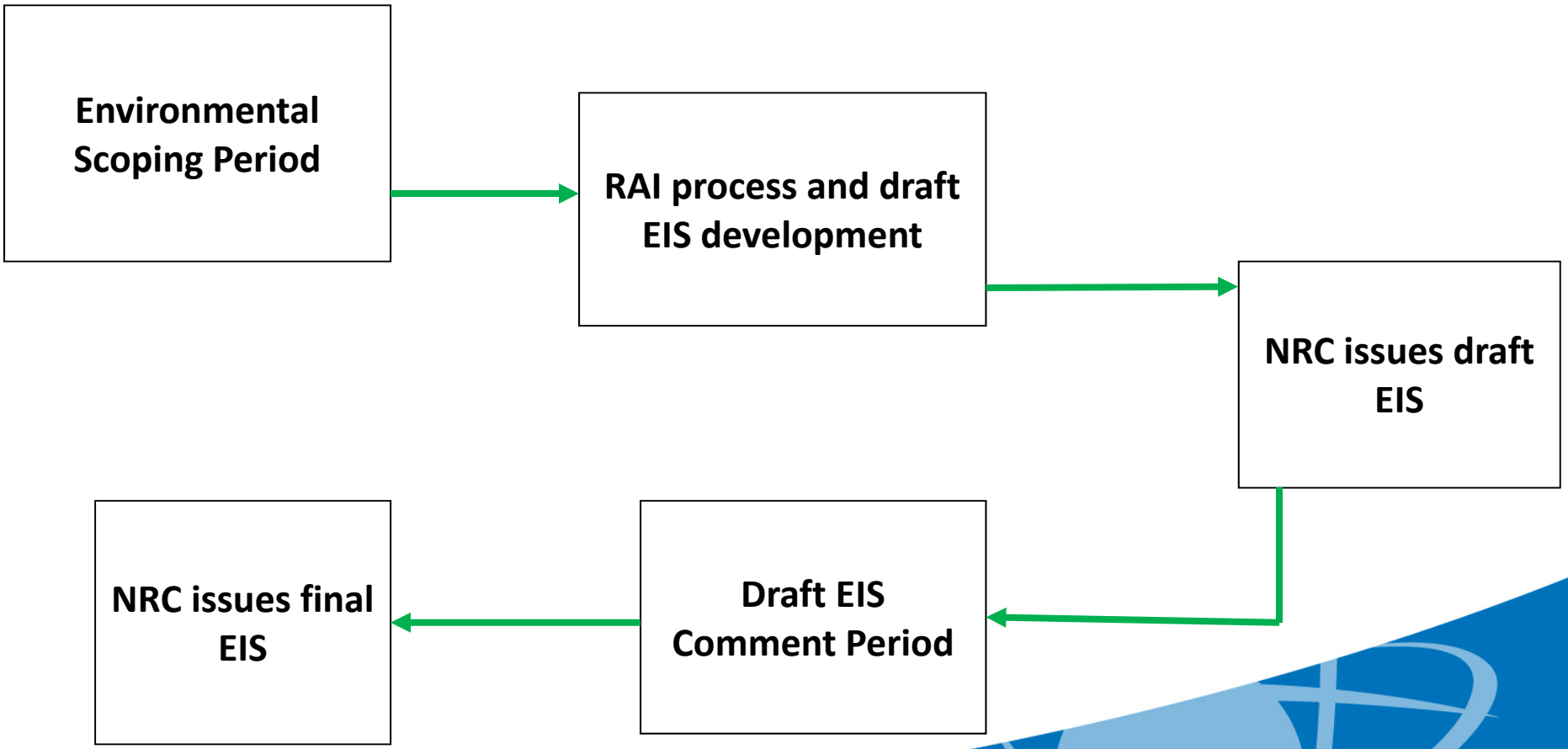
- NRC's Environmental Regulations:
  - 10 CFR Part 51

Environmental Review Process

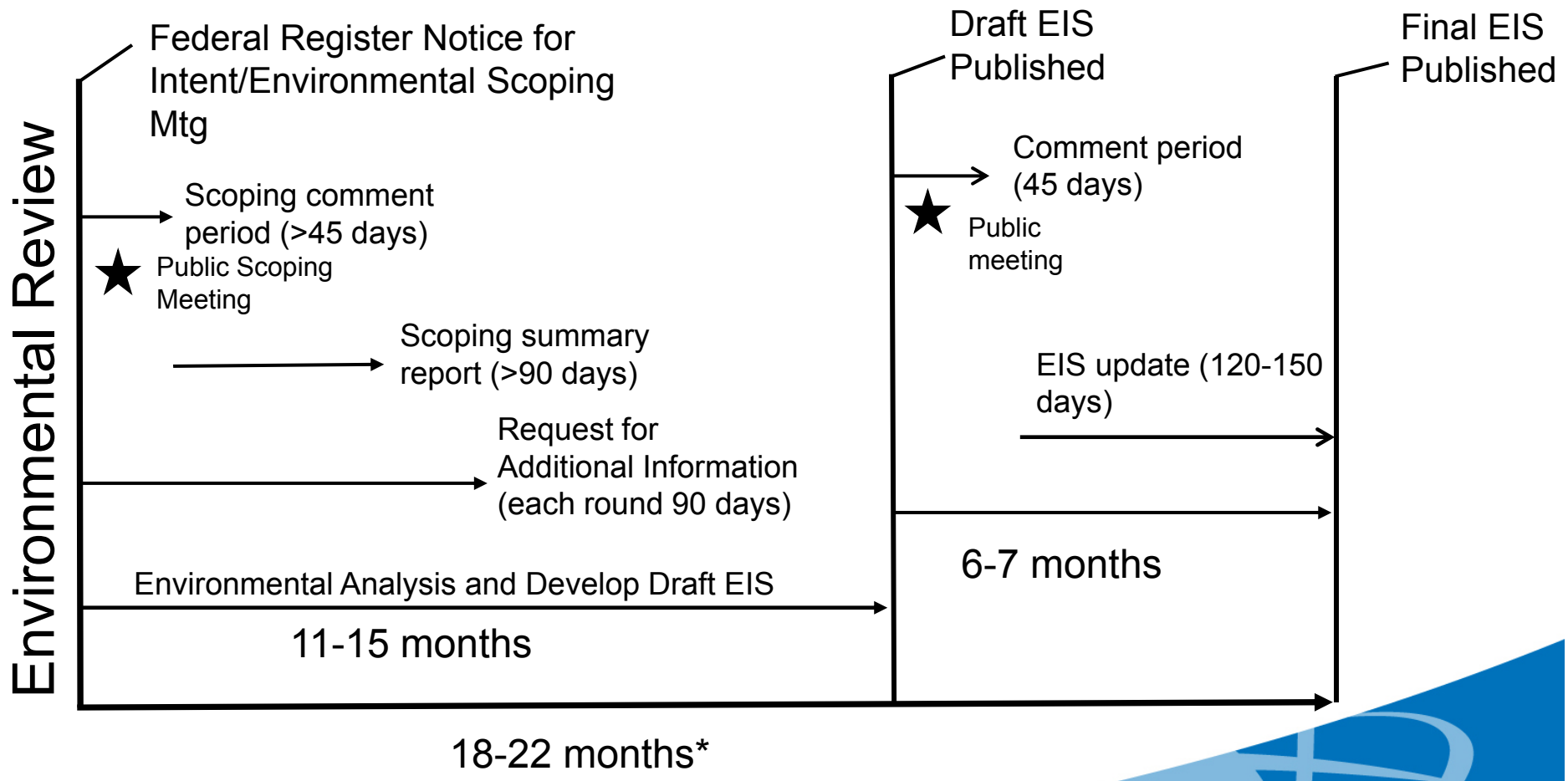


Environmental Review Process

Environmental Impact Statement (EIS)



Environmental Review Timeline



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

Environmental Review

NRC staff performs the environmental review of the application:

- 10 CFR Part 51
- Interim guidance (ISG) augmenting NUREG-1537, "*Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors*"

Acceptance Review

- Application received
  - Public Notice of Receipt and Availability of Part One of the Application (April 21, 2015, 80 FR 22227)
- Acceptance Review
  - Environmental Report acceptance review conducted in accordance with 10 CFR 51.45 and 10 CFR 51.50
  - Acceptance of Part One of the Construction Application issued on June 8, 2015 (80 FR 32418)

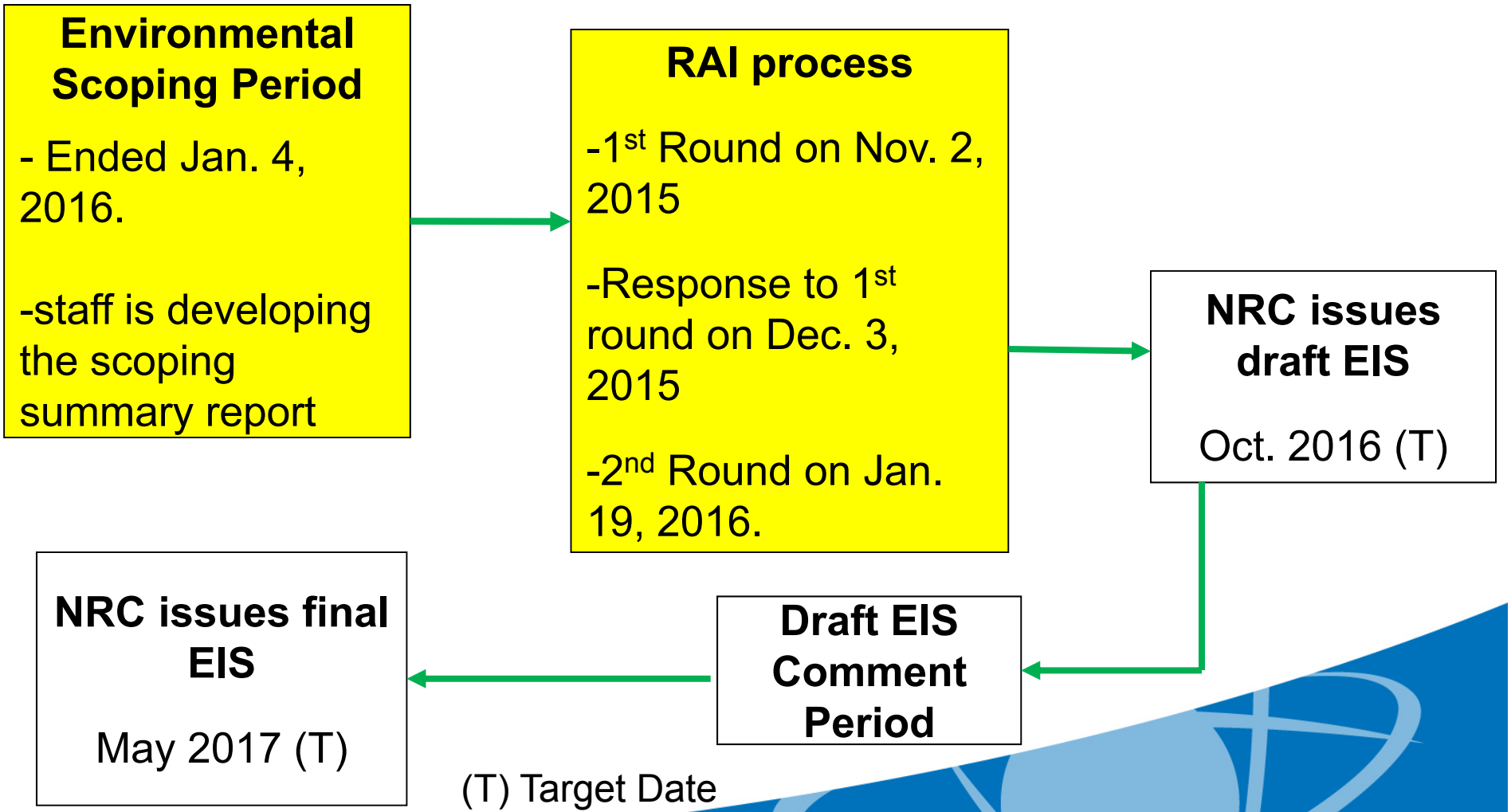
Environmental Impact Statement (EIS) Determination

- In accordance with 10 CFR 51.25, staff had to determine whether an environmental assessment or EIS should be prepared for the proposed action
- Pursuant to 10 CFR 51.20(a)(2), staff determined that an EIS should be developed for the proposed action
  - proposed target fabrication and scrap recovery
  - 10 CFR 51.20(b)(7)

Scope of the NWMI EIS

- Proposed Action
  - Construction of a production facility
- Connected Actions
  - Operation of a production facility and target fabrication
  - Irradiation Services
  - Decommissioning of the facility

NRC Review Schedule - Environmental



NRC Licensing Process

10 CFR Part 50 Construction Permit Safety Review Process

Construction Permit Safety Review

- Consists primarily of preliminary safety analysis report (PSAR), as required by 10 CFR 50.30 and 50.34
- Contents of PSAR include:
  - 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

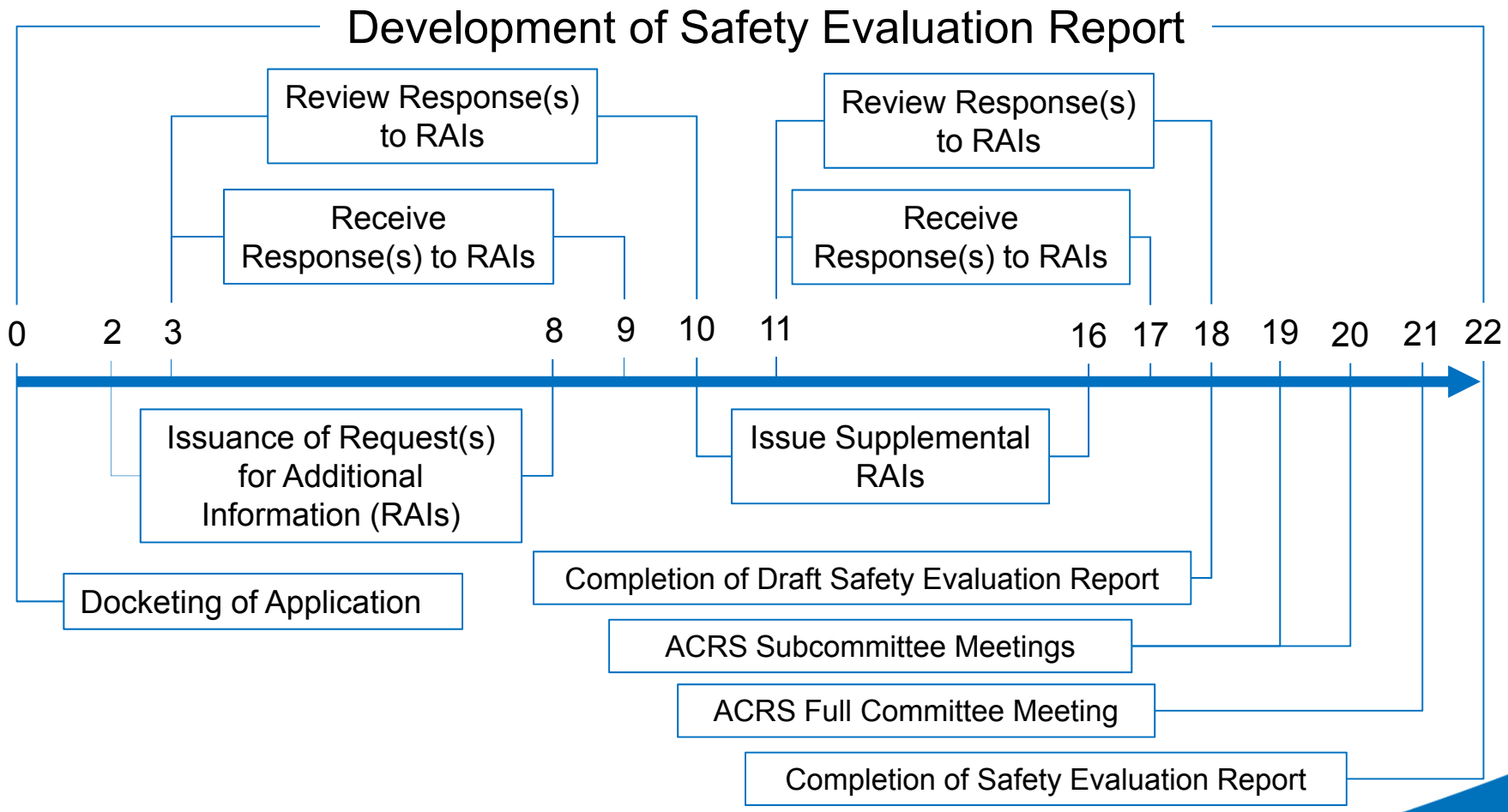
Safety Review Guidance and Acceptance Criteria

- 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 PSAR
- 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 Safety 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
  - Decisions on combined operating licenses made 2 – 5 months following mandatory hearing

NRC CP Review Schedule - Safety

Milestone	Completion Date Actual (A) Target (T)
Receipt of Preliminary Safety Analysis Report (Part Two of Two-Part Construction Permit Application)	July 2015 (A)
Acceptance of Part Two of Application for Docketing	Dec. 2015 (A)
Issuance of Request for Additional Information on Preliminary Safety Analysis Report	Feb. 2016 (T)
Issuance of Supplemental Request for Additional Information on Preliminary Safety Analysis Report	Aug. 2016 (T)
Completion of Draft Safety Evaluation Report	June. 2017 (T)
Advisory Committee on Reactor Safeguards Subcommittee Meeting	July 2017 (T)
Advisory Committee on Reactor Safeguards Subcommittee Meeting	Aug. 2017 (T)
Advisory Committee on Reactor Safeguards Full Committee Meeting	Sep. 2017 (T)
Completion of Safety Evaluation Report	Sep. 2017 (T)
Mandatory Hearing on Construction Permit Application	TBD
Decision on Construction Permit	TBD
NUREG Publication of Safety Evaluation Report	TBD

Docketing

- NWMI submitted Part 1 of its CP application three times (Oct. 15; 29, 2014; Nov. 7, 2014)
- Acceptance review determined that application was incomplete and unacceptable for docketing (30 days to supplement)
- Withdrew and resubmitted application on Feb. 5, 2015
- Delay entering application into ADAMS because of markings
- Entered into ADAMS on Mar. 27, 2015
- Acceptance review approximately 2 months
- Acceptance letter issued on June 1, 2015

Docketing

- NWMI submitted Part 2 of its CP application on July 20, 2015
- Delays associated with document markings
- Entire application added to ADAMS on Sep. 18, 2015
- Submittal not clear on licensing request as required by 10 CFR 50.33(e)
- Acceptance review of approximately 2 months
- Opportunity to supplement request
- Acceptance letter issued on Dec. 24, 2015

NRC Licensing Process

10 CFR Part 70

Domestic Licensing of Special Nuclear Material

10 CFR Part 70 Requirements

Establish procedures and criteria for the issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer special nuclear material (SNM)

- Includes activities related to possession and use of SNM in fuel fabrication and scrap recovery of SNM, and licensing fuel cycle facilities

Examples of Part 70 Regulatory Requirements

- 10 CFR 70.21, “Filing of Application”
  - 70.21(a)(3), Information may be incorporated by reference
  - 70.21 (b), part 70 applications can be considered as applications for other licenses provided the additional activities are specified and regulations met
- 10 CFR 70.22, “Contents of Application”
- 10 CFR 70.23, “Requirements for the Approval of Applications”
- 10 CFR 70.24, – “Criticality accident requirements”
- Subpart H to 10 CFR Part 70, “Additional Requirements for Certain Licensee Authorized to Possess a Critical Mass of Special Nuclear Material”

Review Guidance for Part 70

NUREG-1520, “Standard Review Plan (SRP) for Fuel Cycle Facilities License Applications”, Rev. 2 (ML15176A258)

- ISG augmenting NUREG-1537 contains information that was derived from this document
- Provides guidance to reviewers who perform safety and environmental impact reviews of applications to construct or modify and operate nuclear fuel cycle facilities
- Provides guidance for new facilities, amendments and renewals
  - guidance covers activities similar to those proposed by NWMI
- Makes references to other NRC guidance (e.g., NUREG-1513, ISA guidance document)

SRP (NUREG-1520)

Purpose

- Quality and uniformity of review
- Information and guidance related to the underlying objectives in the regulatory requirements
- Applicants have flexibility to suggest alternative approaches
- Addresses Part 20 “Standards for Protection against radiation” and Part 70

Licensing Decision

- 10 CFR 70.31 – “Issuance of licenses”
  - Upon a determination that an application meets applicable requirements (e.g., 70.23) the NRC will issue a license in such form and containing such conditions and limitations it deems appropriate or necessary
- 10 CFR 70.32 – “Conditions of licenses”

Expected Demonstration

The applicant will demonstrate how applicable regulatory requirements are-met for target fabrication

- Applicant can either prepare a stand-alone application or combine it with the Part 50 production facility application
  - If combined, the application should clearly show how the regulatory requirements are met for target fabrication using tools such as crosswalks

Part 70 Applicability

- From docketed information received so far from NWMI the staff does not have sufficient technical information to conduct a safety review of the target fabrication and scrap recovery activities
  - The activities do not appear to be governed by 10 CFR Part 50
  - These activities appear to be subject to 10 CFR Part 70
- For NRC to conduct a safety review for issuance of a license to conduct those activities, NWMI will need to submit an application meeting applicable regulations
- For a specific licensing question, NWMI can submit a clarification request letter to the NRC

Proposed Schedule

- NRC Part 70 technical reviews typically take approximately 18 months
  - NRC will perform a technical review the a Part 70 application (whether or not submitted as past of a Part 50 application)
  - Request additional information as needed
  - Document safety review in a Safety Evaluation Report
- Review can be in parallel or series with other reviews

NWMI Licensing Review Request

NWMI Request

NWMI Cover Letter for the CP Application, Part 2, dated July 20, 2015 (ML15210A114) states:

> *"NWMI is applying to the NRC to obtain a license for a production facility under 10 CFR 50, Domestic Licensing of Production and Utilization Facilities."*

Staff Determination of NWMI CP Request

Staff determined:

- NWMI submittal letter and application seeks license to construct a facility where it plans to conduct activities to separate Mo-99 from irradiated uranium and other byproduct material was consistent with third definition of Part 50 production facility
  - Any facility designed or used for the processing of irradiated materials containing special nuclear material
- NWMI facility did not fall under exceptions under third definition

Staff Determination of NWMI CP Request

NRC Docketing Acceptance letter dated December 24, 2015 (ML15341A112) states:

> *"The staff has completed its acceptance review of part two of NWMI's application for a construction permit for a production facility as defined in 10 CFR 50.2 "Definitions." The staff has determined that part two was submitted in accordance with the requirements of 10 CFR 2.101(a)(5), completes the information required by 10 CFR 50.34(a), and is acceptable for docketing."*

NWMI Request

NWMI's Cover Letter for the CP Application, Part 2, dated July 20, 2015 (ML15210A114) states:

> *"NWMI intends to submit a single 10 CFR 50 license application for the RPF following the guidance in NUREG-1537, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors - Format and Content, that encompasses activities regulated under different NRC requirements (e.g., 10 CFR 70 and 10 CFR 30), in accordance with 10 CFR 50.31, "Combining Applications," and 10 CFR 50.32, "Elimination of Repetition.""*

10 CFR Parts 50 and 70

- 10 CFR 50.31, "Combining applications," states:

  "An applicant may combine in one his several applications for different kinds of licenses under the regulations in this chapter."

- 10 CFR 50.32, "Elimination of repetition," states:

  "Application, …may incorporate by reference information contained in previous applications, statements or reports filed with the Commission: Provided, That such references are clear and specific."

- 10 CFR 70.21 (a)(3) states:

  "Information contained in previous applications, statements, or reports filed with the Commission may be incorporated by reference if the references are clear and specific."

Review Guidance

- ISG Augmenting NUREG-1537 provides applicable guidance for licensing radioscope production facilities and aqueous homogeneous reactors
- NUREG-1537 contains guidance that materials used in the production facility license need to meet regulatory requirements for the material (i.e., special nuclear material meets Part 70)
- NUREG-1537 contains guidance that materials required to operate the utilization or production facility can be included in the license

NWMI Request

NWMI Cover Letter for the CP Application, Part 2, dated July 20, 2015 (ML15210A114) states:

> *"Embedded in the 10 CFR 50-licensed facility will be several activities subject to 10 CFR 70, "Domestic Licensing of Special Nuclear Material," to receive, possess, use, and transfer special nuclear material, and 10 CFR 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," to process and transport molybdenum-99 (99Mo) for medical applications."*

Part 50 License Included Activities

- Part 50 licenses have included activities under other parts of the regulations (e.g., Parts 30, 40 and 70)
- Included activities need to meet regulatory requirements for each activity

NRC staff needs clarification what NWMI means by "embedded" activities

Example of Part 50 Utilization OL with Included Activities

B. Subject to the conditions and requirements incorporated herein, the Commission hereby licenses:

(1) Pursuant to Section 103 of the Act and 10 CFR Part 50, ... to possess, and to use and operate the facility at the designated location in …, in accordance with the procedures and limitations set forth in this renewed operating license;

(2) Pursuant to the Act and 10 CFR Part 70, … to receive, possess and use at any time special nuclear material as reactor fuel, in accordance with the limitations for storage and amounts required for reactor operation, as described in the licensees' Final Safety Analysis Report, as supplemented and amended and …;

(3) Pursuant to the Act and 10 CFR Parts 30, 40 and 70, … to receive, possess and use at any time any byproduct, source and special nuclear material as sealed neutron sources for reactor startup, sealed sources for reactor instrumentation and radiation monitoring equipment calibration, and as fission detectors in amounts as required;

(4) Pursuant to the Act and 10 CFR Part 30, 40 and 70, … to receive, possess and use in amounts as required any byproduct, source or special.

C. This renewed operating license shall be deemed to contain and is subject to the conditions specified in the Commission's regulations set forth in 10 CFR Chapter I and is subject to all applicable provisions of the Act and to the rules, regulations, and orders of the Commission now or hereafter in effect; and is subject to the additional conditions specified or incorporated below:

NWMI Request

NWMI's Cover Letter for the CP Application, Part 2, dated July 20, 2015 (ML15210A114) states:

> *"The RPF will also include the fabrication of LEU targets, which will be licensed under 10 CFR 70."*

Staff Understanding of NWMI CP Request

- NWMI understands that fabrication of LEU targets is under 10 CFR Part 70
- NRC Acceptance for Docketing letter for NWMI application dated December 24, 2015 (ML15341A112) for the production facility states:

"The staff expects that NWMI will submit an application for fabricating low enriched uranium targets under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Materials," as stated in paragraph six (page 2) of NWMI's letter dated July 20, 2015."

Staff Understanding of NWMI CP Application

- Current application does not seek NRC approval for operating the proposed facility
- Current application does not request a license to possess SNM for the fabrication of LEU targets
- A facility can have multiple licenses (e.g., Part 50, Part 70 and Part 30)

Communications

Communication

- Channels
- Responsiveness
- Quality of Submissions
- Clarifying previous communications
  - No regulatory decisions are made in public meetings
  - Public meetings are not a substitute for submittal or requests for information on the docket
  - Regulatory decisions are not made on phone calls
  - Nonpublic meetings are reserved for information that can be withheld under 10 CFR 2.390