

# Northwest Medical Isotopes Construction Permit Application Review

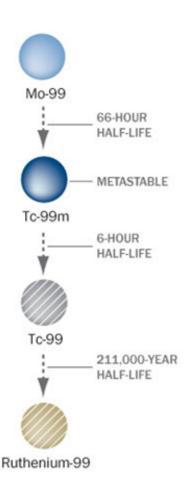
- Mandatory Hearing (Overview Panel)
- January 23, 2018

#### **Panelists**

- Michele Evans
  - Deputy Director for Reactor Safety
     Programs and Mission Support, NRR
- MaryJane Ross-Lee
  - Deputy Director, NRR/DLP
- Joseph Donoghue
  - Deputy Director, NRR/DMLR
- Brian Smith
  - Deputy Director, NMSS/FCSE

#### <sup>99</sup>Mo Overview

- <sup>99</sup>Mo decays to <sup>99m</sup>Tc
  - Effective diagnosis
  - -Minimal exposure
- 50,000 procedures daily
- No domestically-produced supply



# Establishing a Domestic Supply of <sup>99</sup>Mo

- NRC supports U.S. policy objectives to establish domestic <sup>99</sup>Mo production
- First construction permit for domestic <sup>99</sup>Mo production issued to SHINE Medical Technologies in 2016
- Northwest Medical Isotopes would produce <sup>99</sup>Mo by processing irradiated low enriched uranium targets

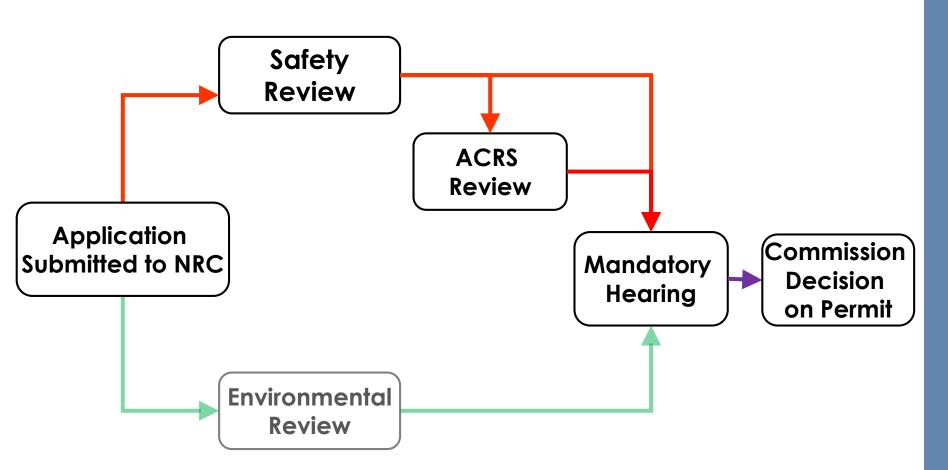
#### Conducting the NWMI Review

- Review of NWMI application supported by procedural efficiencies and previous licensing experience
  - -Two-part application submission
  - Document templates
  - Permit condition supporting quality assurance implementation
- Staff and contractors spent ~12,000 hours reviewing NWMI application

# **Authorizing Construction**

- NWMI seeks authorization to construct
   10 CFR Part 50 production facility
- Staff review based on preliminary design and analysis of facility
  - Design details may be left for operating license application
  - Target fabrication activities to be considered under a 10 CFR Part 70 application

# Conducting the Safety Review



### Tailoring Review Methodology

- Review accommodated unique aspects of the NWMI application
- Staff adapted existing guidance for research reactors, production facilities, and fuel cycle facilities
- Review focused on whether there was reasonable assurance that the final design would conform to design bases

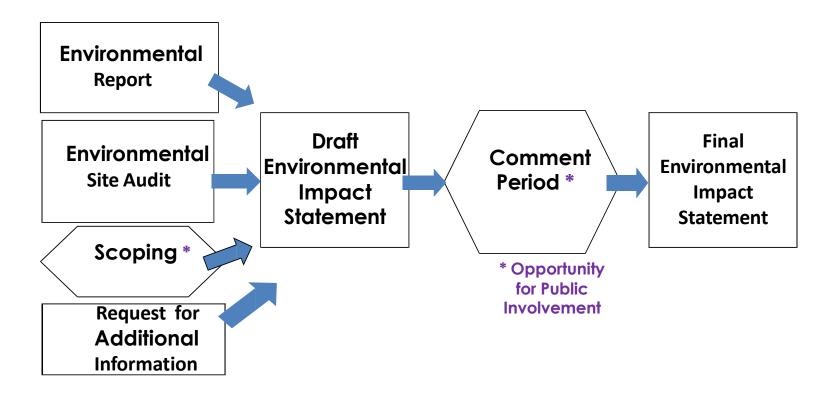
#### **Additional Information**

- In response to staff requests, NWMI provided additional information
- In some cases, permit conditions were necessary to support findings
- Regulatory commitments track items for resolution in Final Safety Analysis Report

#### **Environmental Requirements**

- National Environmental Policy Act
  - Informs Federal decision making
  - Public disclosure
- NRC environmental regulations in 10 CFR Part 51
  - NRC regulations implementing the National Environmental Policy Act

#### **Environmental Review Process**



### Proposed Discovery Ridge Site



- Agricultural land
- Previously disturbed
- No surface water features
- No threatened or endangered species
- No historical or cultural resources

# Statutory and Regulatory Basis for Construction Permit Issuance

- Commission authorized to issue permits by Atomic Energy Act, Section 103
- Applicable requirements in 10 CFR Parts 20, 50, and 51
- Performance requirements in 10 CFR Part 70 also considered

#### **Construction Permit Findings**

- Preliminary facility design described
- Further technical or design information may be left for FSAR
- Ongoing research and development identified
- Facility can be constructed and operated without undue risk

#### **Construction Permit Considerations**

- Construction will not endanger public health and safety
- NWMI is technically and financially qualified
- Environmental requirements have been satisfied

# Introducing the Review Panels

Panel Number	Discussion Topics	Evaluation Areas
Safety Panel 1	Licensing Considerations	Safety Evaluation Report Chapters 1, 4, and 12
Safety Panel 2	Accident Analysis Methodology	Safety Evaluation Report Chapter 13
Environmental Panel	<ul> <li>Final Environmental Impact Statement Process</li> <li>Scope and Connected Actions</li> <li>Analysis of Alternatives</li> </ul>	Final Environmental Impact Statement

#### Acronyms

- NRR Office of Nuclear Reactor Regulation
- DLP Division of Licensing Projects
- DMLR Division of Materials and License Renewal
- NMSS Office of Nuclear Material Safety and Safeguards
- FCSE Division of Fuel Cycle Safety,
   Safeguards, and Environmental Review

#### Acronyms

- <sup>99</sup>Mo molybdenum-99
- 99mTc technetium-99m
- NRC U.S. Nuclear Regulatory Commission
- NWMI Northwest Medical Isotopes
- CFR Code of Federal Regulations
- ACRS Advisory Committee on Reactor Safeguards
- FSAR final safety analysis report