


Northwest Medical Isotopes Construction Permit Application Review

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

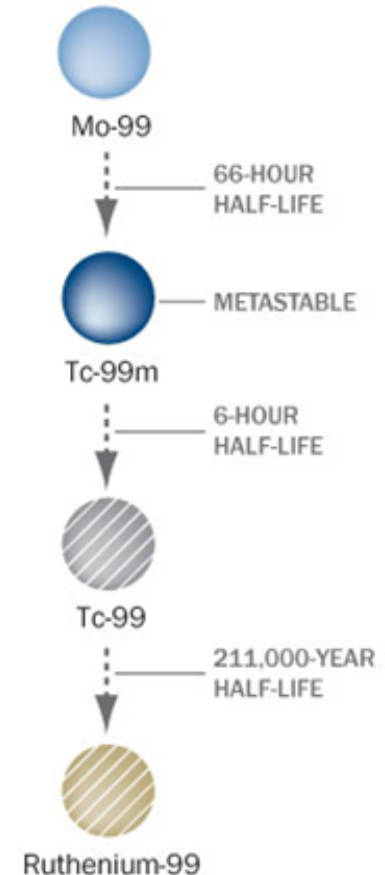
United States Nuclear Regulatory Commission Official Hearing Exhibit	
In the Matter of:	NORTHWEST MEDICAL ISOTOPES, LLC (Medical Radioisotope Production Facility)
Commission Mandatory Hearing	
	Docket #: 05000609
	Exhibit #: NRC-010-MA-CM01
	Admitted: 1/23/2018
	Rejected:
	Other:
	Identified: 1/23/2018
	Withdrawn:
	Stricken:

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

^{99}Mo Overview

- ^{99}Mo decays to $^{99\text{m}}\text{Tc}$
 - Effective diagnosis
 - Minimal exposure
- 50,000 procedures daily
- No domestically-produced supply



Establishing a Domestic Supply of ^{99}Mo

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

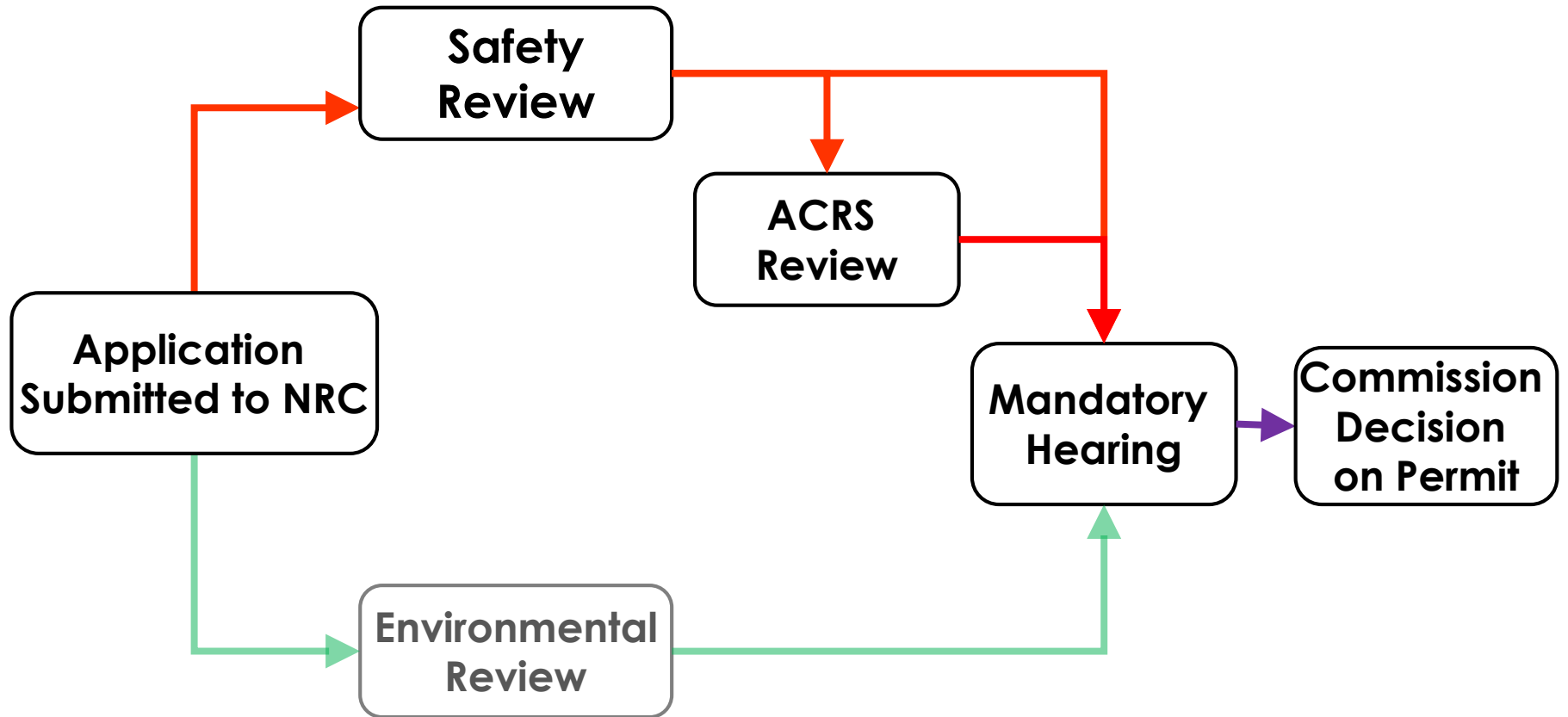
Conducting the NWMI Review

- 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

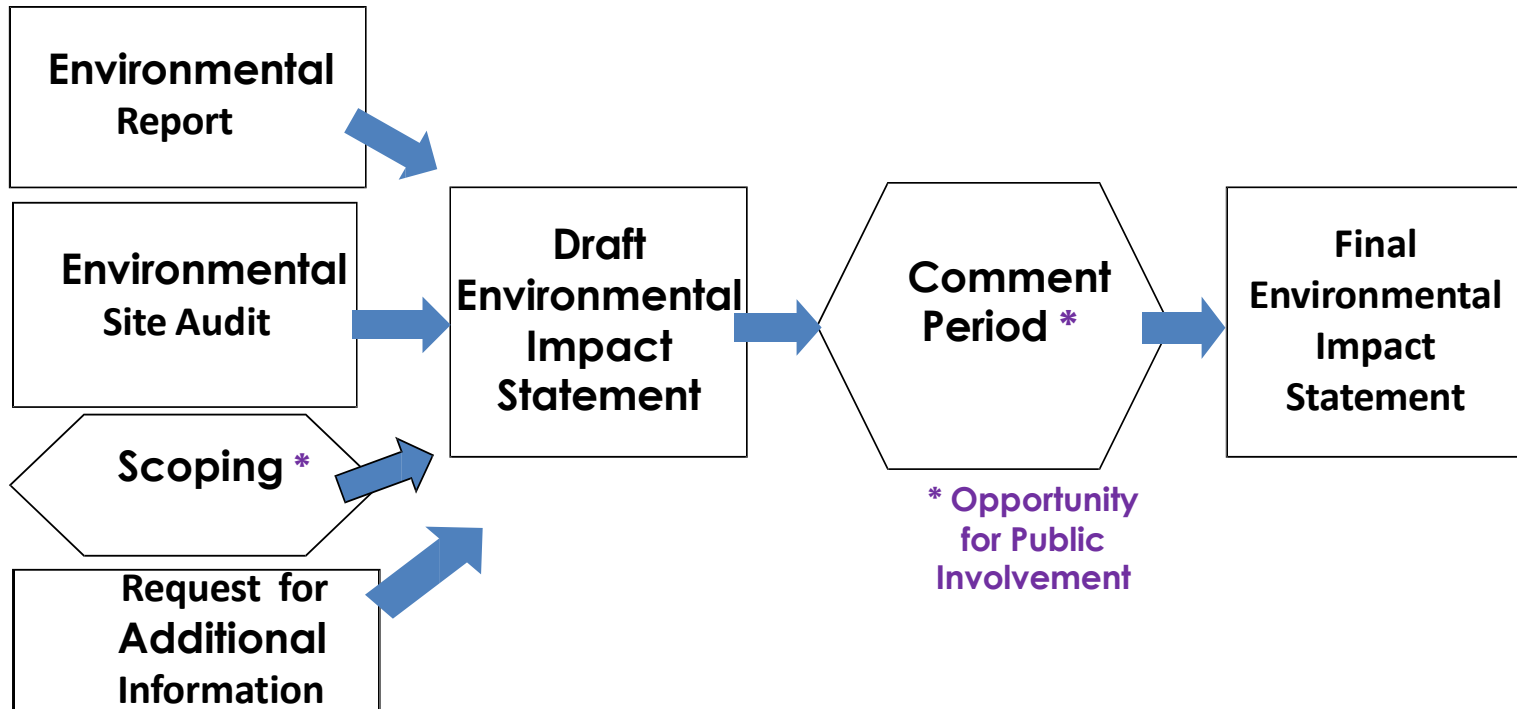
Additional Information

- 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 style="list-style-type: none">• Final Environmental Impact Statement Process• Scope and Connected Actions• Analysis of Alternatives	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

- ^{99}Mo - molybdenum-99
- $^{99\text{m}}\text{Tc}$ - 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