SCHEDULING NOTE

Title: **HEARING ON CONSTRUCTION PERMIT FOR NORTHWEST MEDICAL ISOTOPES PRODUCTION FACILITY: SECTION 189A OF THE ATOMIC ENERGY ACT PROCEEDING (Public Meeting)**

Purpose: To receive testimony and exhibits regarding the application of Northwest Medical Isotopes, LLC, for a medical radioisotope production facility construction permit. The testimony will focus on unique features of the facility or novel issues that arose as part of the review process and other significant technical or policy issues associated with aspects of the staff's review that are important for the Commission to make its final decision. The Commission will determine whether the staff's review has been adequate to support the findings in 10 C.F.R. §§ 50.35(a), 50.40, 50.50, and 51.105(a).

Scheduled: **January 23, 2018**
9:00 am

Duration: 1 day

Location: Commissioners' Conference Room, 1st Floor OWFN

NOTE: Chairman to provide opening remarks, admit exhibits, and swear in witnesses. **20 mins.**

Participants: **Presentation**

(*Note: Witnesses seated at the table are listed, other staff available to answer questions will be seated in the well and reserved rows.)*

Overview (Northwest Medical Isotopes, LLC) (9:20 am) **30 mins.***

At the table:
Nicholas Fowler, Chief Executive Officer, NWMI
Carolyn Haass, Chief Operating Officer, NWMI
Steven Reese, Irradiation Services Manager, NWMI
Roy Brown, Vice President, Curium Pharma

Topic: Overview

Commission Q & A (round of questions; 6 minutes each) **18 mins.****

Overview (NRC Staff) **30 mins.***

At the table:
Michele Evans, Deputy Director for Reactor Safety Programs and Mission Support, Office of Nuclear Reactor Regulation (NRR)
Mary Jane Ross-Lee, Deputy Director, Division of Licensing Projects, NRR
Joseph Donoghue, Deputy Director, Division of Materials and License Renewal (DMLR), NRR
Brian Smith, Deputy Director, Division of Fuel Cycle Safety, Safeguards and Environmental Review, Office of Nuclear Material Safety and Safeguards (NMSS)

Topic: Overview of the staff's methodology for its review of the NWMI construction permit application and summary of key regulatory findings.

Commission Q & A (round of questions; 6 minutes each) **18 mins.****

BREAK ***5 mins.***

NOTE: For the remaining panels, the applicant is expected to discuss the contents of the construction permit application while the staff is expected to discuss its review process and regulatory conclusions. Each panel should include a discussion of any permit conditions associated with the subject matter of the panel.

Safety Panel 1 (11:05 am)

Applicant **5 mins.***
At the table:
Carolyn Haass, Chief Operating Officer, NWMI
Steven Reese, Irradiation Services Manager, NWMI
Gary Dunford, Process Engineering Manager, NWMI (AEM Consulting, Inc.)
Michael Corum, Senior Technical Advisor, NWMI

Staff **12 mins.***
At the table:
Alexander Adams, Jr., Chief, Research and Test Reactors Licensing Branch, NRR
Michael Balazik, Project Manager, Research and Test Reactors Licensing Branch, NRR
David Tiktinsky, Senior Project Manager, Fuel Manufacturing Branch (FMB), NMSS
Steven Lynch, Project Manager, Research and Test Reactors Licensing Branch, NRR

Topic: Sections of the application and the following chapters from

the Safety Evaluation Report:

Chapter 1, "The Facility," and Chapter 4 "Radioisotope Production Facility Description," including discussion of the unique licensing considerations; Colocation of Production Facility and Target Fabrication Area, and Quality Assurance Implementation.

Note that the panel will not have specific topics to discuss for the following chapters. If the Commission wishes to ask questions on these chapters, this panel would be the appropriate time.

- Chapter 2, "Site Characteristics"
- Chapter 3, "Design of Structures, Systems, and Components"
- Chapter 5, "Coolant Systems"
- Chapter 6, "Engineered Safety Features"
- Chapter 12, "Conduct of Operations"***

Commission Q & A (round of questions; 6 minutes each) **18 mins.****

BREAK (Lunch Break-Approx. 11:45-1:15 pm)

Safety Panel 2 (1:15 pm)

Applicant **5 mins.***
At the table:
Carolyn Haass, Chief Operating Officer, NWMI
Steven Reese, Irradiation Services Manager, NWMI
Gary Dunford, Process Engineering Manager, NWMI (AEM Consulting, Inc.)
Michael Corum, Senior Technical Advisor, NWMI

Staff **12 mins.***
At the table:
Michael Balazik, Project Manager, Research and Test Reactors Licensing Branch, NRR
April Smith, Reliability and Risk Analyst, Programmatic Oversight and Regional Support Branch, NMSS
David Tiktinsky, Senior Project Manager, FMB, NMSS
James Hammelman, Senior Chemical Engineer, FMB, NMSS

Topic: Sections of the application and the following chapters from the Safety Evaluation Report:

Chapter 13, "Accident Analysis," including discussion of novel application of 10 CFR Part 70 accident analysis methodologies

for radiological and chemical exposure accidents.

Note that the panel will not have specific topics to discuss for the following chapters. If the Commission wishes to ask questions on these chapters, this panel would be the appropriate time.

- Chapter 7, "Instrumentation and Control Systems"
- Chapter 8, "Electrical Power Systems"
- Chapter 9, "Auxiliary Systems"
- Chapter 11, "Radiation Protection Program and Waste Management"
- Chapter 14, "Technical Specifications"
- Chapter 15, "Financial Qualifications"

Commission Q & A (round of questions; 6 minutes each) **18 mins.****

Environmental Panel (1:50 pm)

Applicant **10 mins.***
At the table:
Carolyn Haass, Chief Operating Officer, NWMI
Steven Reese, Irradiation Services Manager, NWMI

Staff **25 mins.***
At the table:
Benjamin Beasley, Chief, Environmental Review and NEPA Branch, NRR
Nancy Martinez, Physical Scientist, NRR
Michelle Moser, Biologist, NRR
David Drucker, Senior Project Manager, NRR

Topic: Final Environmental Impact Statement

- Provide a summary of the process for developing the Final Environmental Impact Statement (EIS) including:
  - The decision to prepare an EIS
  - Scope and connected actions
  - The scoping process
  - The staff's independent review and analysis
  - Issuance of the Draft EIS, public meeting on the Draft EIS, and solicitation of stakeholder comments on the Draft EIS
  - The environmental impacts of the proposed action on the following resource areas: land use, visual resources, air quality and noise, water resources, ecological resources, historic and cultural resources, socioeconomics, human health, transportation, waste management, and environmental justice
  - Consultations with other Federal, State, and local agencies and Tribes

- Discuss the analysis of alternatives including; Range of reasonable alternatives, Alternative site, Alternative technologies, and the No-action alternative
- Summarize conclusions and recommendation including a summary of the benefits and costs of the proposed action

Commission Q & A (round of questions; 6 minutes each) **18 mins.****

BREAK ***5 mins.***

Closing (2:50 pm)

Closing Statement by Applicant 10 mins.*
Nicholas Fowler, Chief Executive Officer, NWMI
Carolyn Haass, Chief Operating Officer, NWMI
Roy Brown, Vice President, Curium Pharma

Closing Statement by Staff 10 mins.*
Michele Evans, Deputy Director for Reactor Safety Programs and Mission Support, NRR

Commission Q & A and Closing Statements 18 mins.**

*For presentation only and does not include time for Commission Q & A's.

**All Commissioners will have an opportunity to ask questions after each panel. Commissioners will start the Q&A with their total time allotted to allocate as they see fit among the panels.

*** Chapter 12, "Conduct of Operations," of the staff's SER includes evaluations of NWMI's quality assurance program description and preliminary emergency plan.

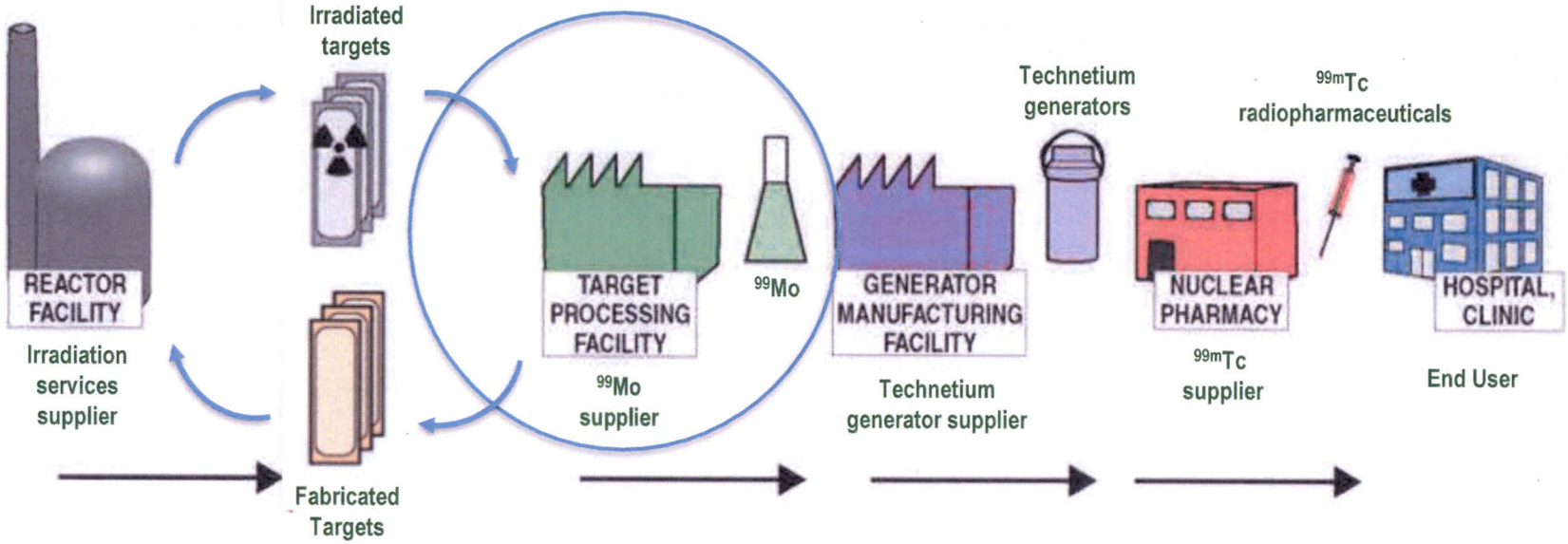
U.S. Nuclear Regulatory Commission
Commission Mandatory Meeting

Northwest Medical Isotopes, LLC
Radioisotope Production Facility Overview

January 23, 2018

NWMI MISSION

Assure a Domestic, Secure, and Reliable Supply of Molybdenum-99 (^{99}Mo)



- Captive Network of University Research Reactors
  - Reliability/assurance of supply
  - Multiple shipments/week
- Radioisotope Production Facility (RPF)
  - Fabrication of LEU targets
  - ^{99}Mo production
  - Uranium recycle and recovery
- Domestic ^{99}Mo Generator Distributors
  - Hold FDA Drug Master File
  - No changes to generators
  - No changes to supply chain

OSU Oregon State University

MISSOURI

Lantheus Medical Imaging

CURIUM LIFE FORWARD

GE Healthcare

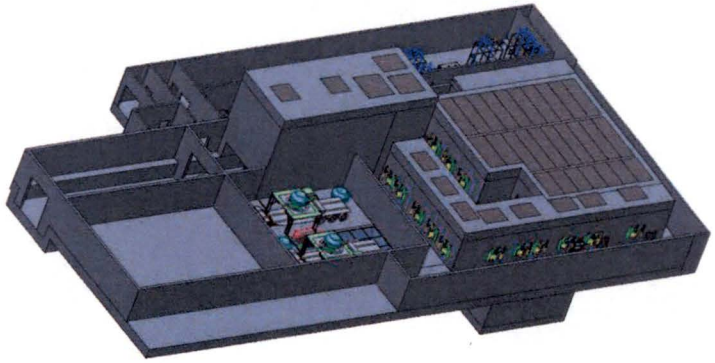
Primary Assumptions

- Single radioisotope production facility → RPF
  - RPF includes target fabrication, ^{99}Mo production, and uranium recycle and recovery
  - ^{99}Mo produced by a fission-based method using LEU
  - Nominal capacity 3,500 6-day curies (Ci); surge capacity of 1,500 6-day Ci
- Use network of university reactors
  - Same target design used for all reactors
  - Intellectual property obtained
    - U.S., Australia, Russia, South Africa, Korea, Europe → Allowed
    - India, China → Pending

OSU Oregon State University

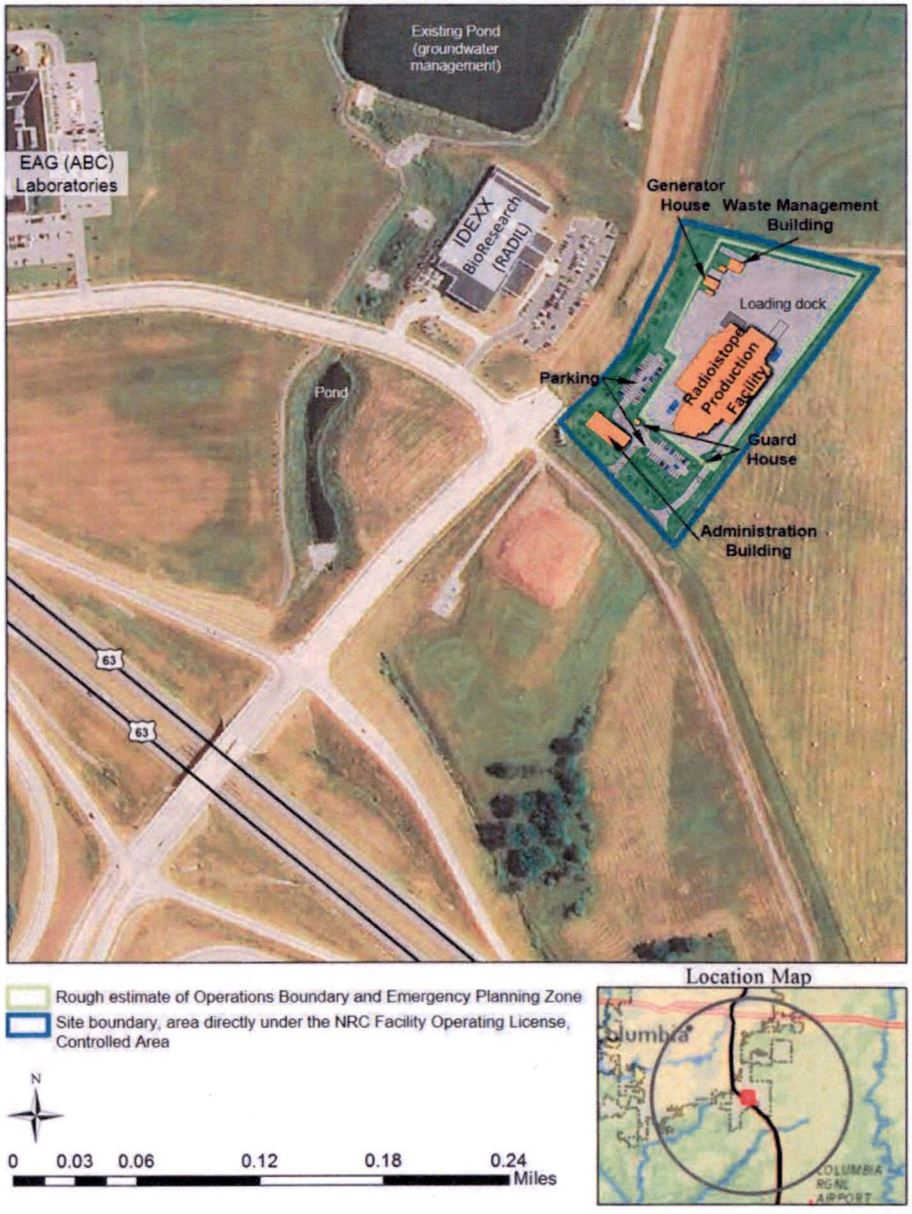
MISSOURI

- Fission product releases will comply with environmental release criteria
- Generate Class A, B, and C wastes; no greater than Class C (GTCC) waste



Site Location and Description

- Site located within Discovery Ridge Research Park → 550 acre
  - University of Missouri (MU)-owned research park in Columbia – Boone County, Missouri
- Discovery Ridge located in central Missouri
  - ~125 miles east of Kansas City and ~125 miles west of St. Louis
  - 4.5 miles south of Interstate-70 and just to north of US Highway 63
  - 3.5 miles to southeast of main MU campus
  - 9.5 miles west of Missouri River
- RPF will be located on Lot 15 → 7.4-acre
  - No existing structures
  - Used for agriculture for past century
- NWMI "anchor" for radioisotope ecosystem; two existing companies

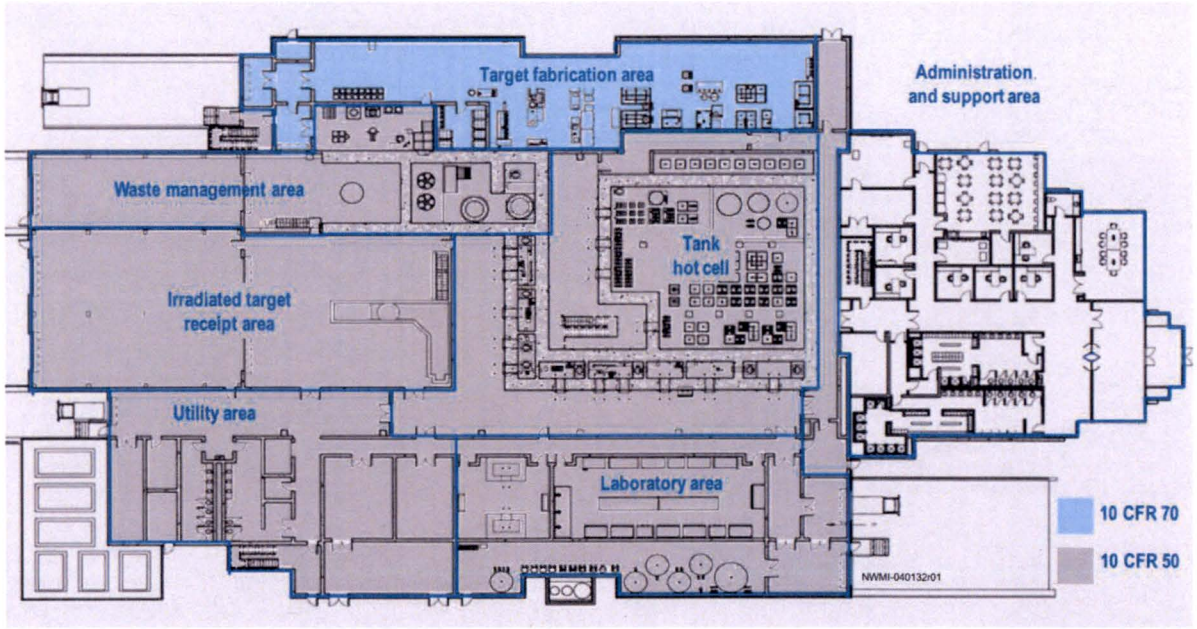


Licensing Approach

- ***License Request:*** NWMI has submitted a Construction Permit Application to obtain a license for a production facility under Title 10, *Code of Federal Regulations*, Part 50 (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities"
  - Using guidance in NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Format and Content*
- ***Proposed Action:*** Issuance of an NRC license under 10 CFR 50 that would authorize NWMI to construct and operate a ^{99}Mo RPF at a site located in Columbia, Missouri
- RPF will:
  - Receive irradiated low-enriched uranium (LEU) targets (from a network of university research or test reactors)
  - Process irradiated LEU targets for dissolution, recovery, and purification of ^{99}Mo
  - Recover and recycle LEU to minimize radioactive, mixed, and hazardous waste generation
  - Treat/package wastes generated by RPF process steps to enable transport to a disposal site
  - Provide areas for associated laboratory and other support activities

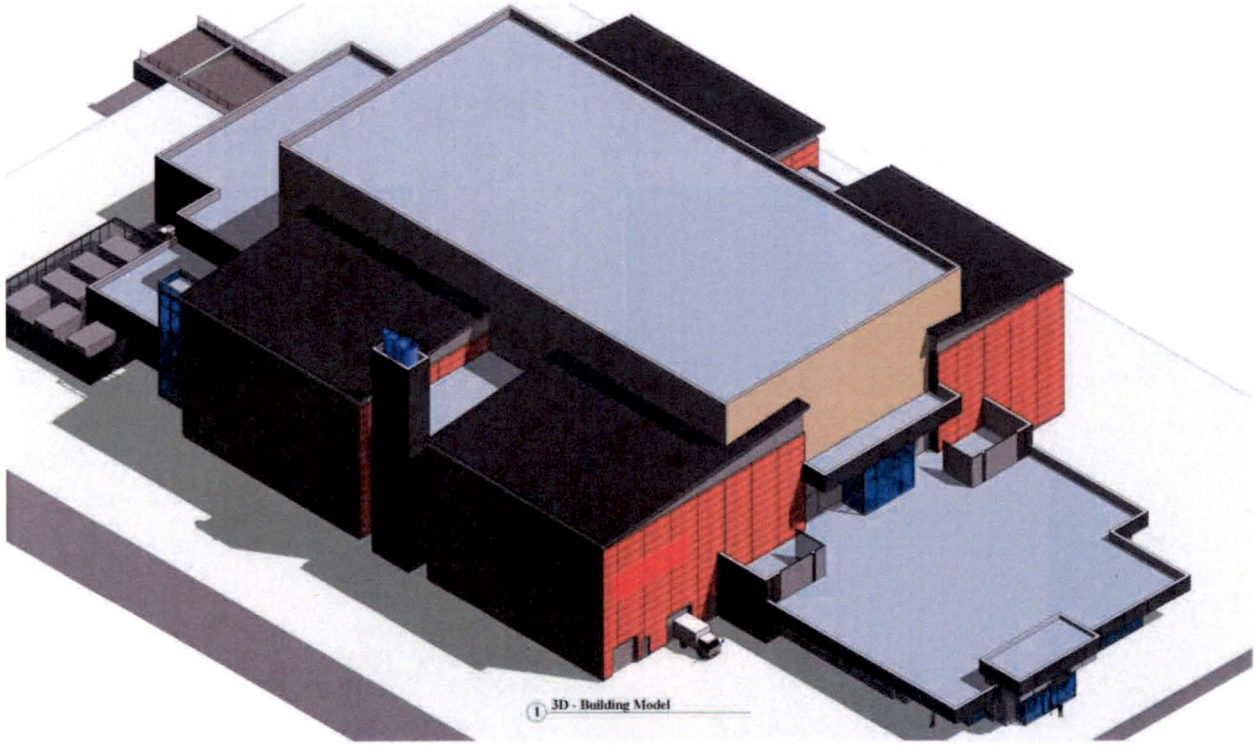
Additional RPF Licensing Activities

- Additional RPF operational activities are subject to other NRC regulations
  - 10 CFR 70, "Domestic Licensing of Special Nuclear Material," to receive, possess, use, and transfer special nuclear material
    - Receiving LEU from U.S. Department of Energy (DOE)
    - Producing LEU target materials and fabrication of targets
  - 10 CFR 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," to process and transport ^{99}Mo for medical applications
    - Handling of byproduct material
- University reactor(s) and cask licensee(s) will amend their current operating licenses

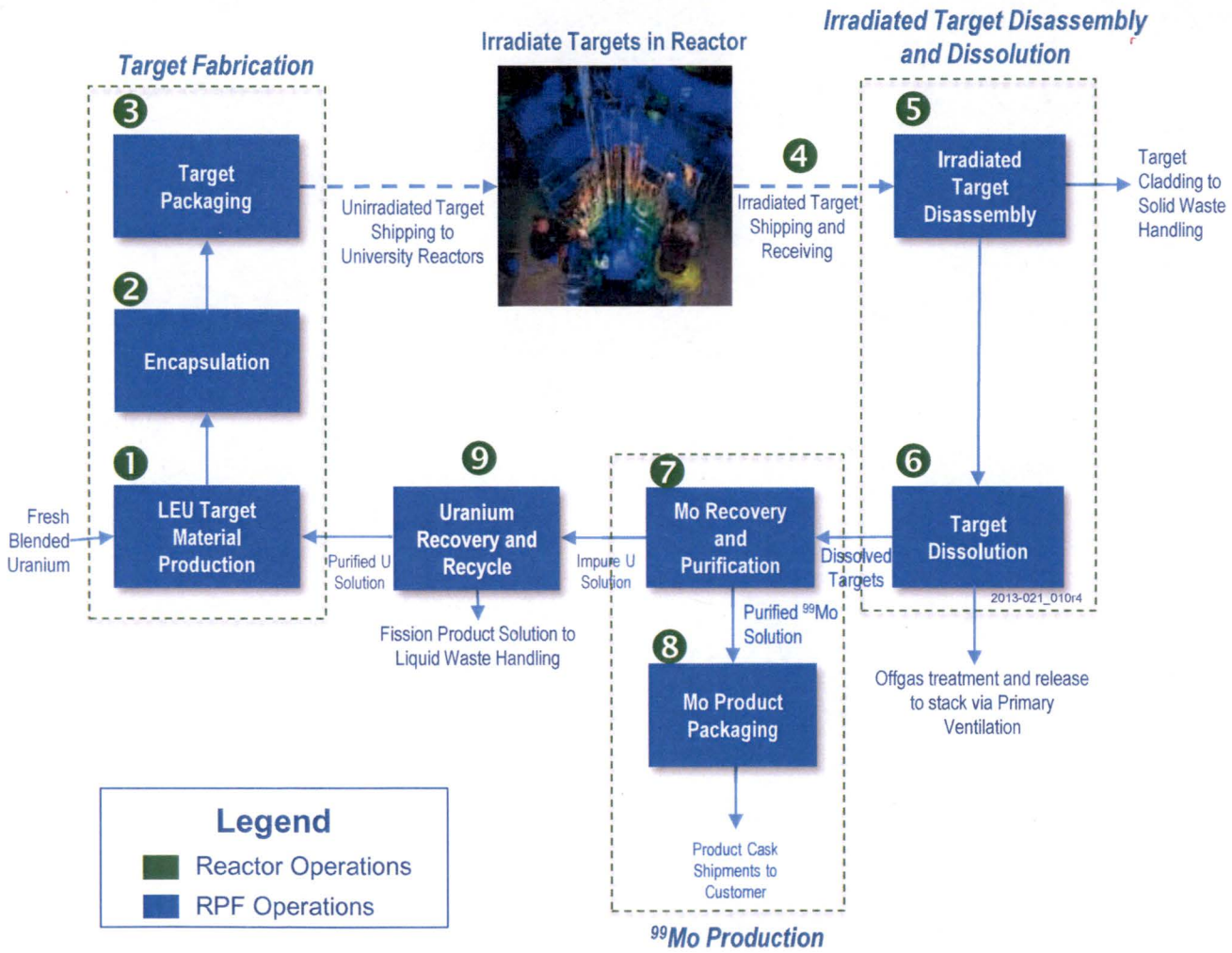


Proposed Schedule (Calendar Year)

- Start date of site preparation/construction → Q2 2018
- End date of construction → Q3 2019
- Start date of facility startup and cold commissioning (pre-operational) → Q4 2019
- Date of hot commissioning and commercial operations → Q1 2020
- Date of decommissioning: 2050



RPF Operating Characteristics

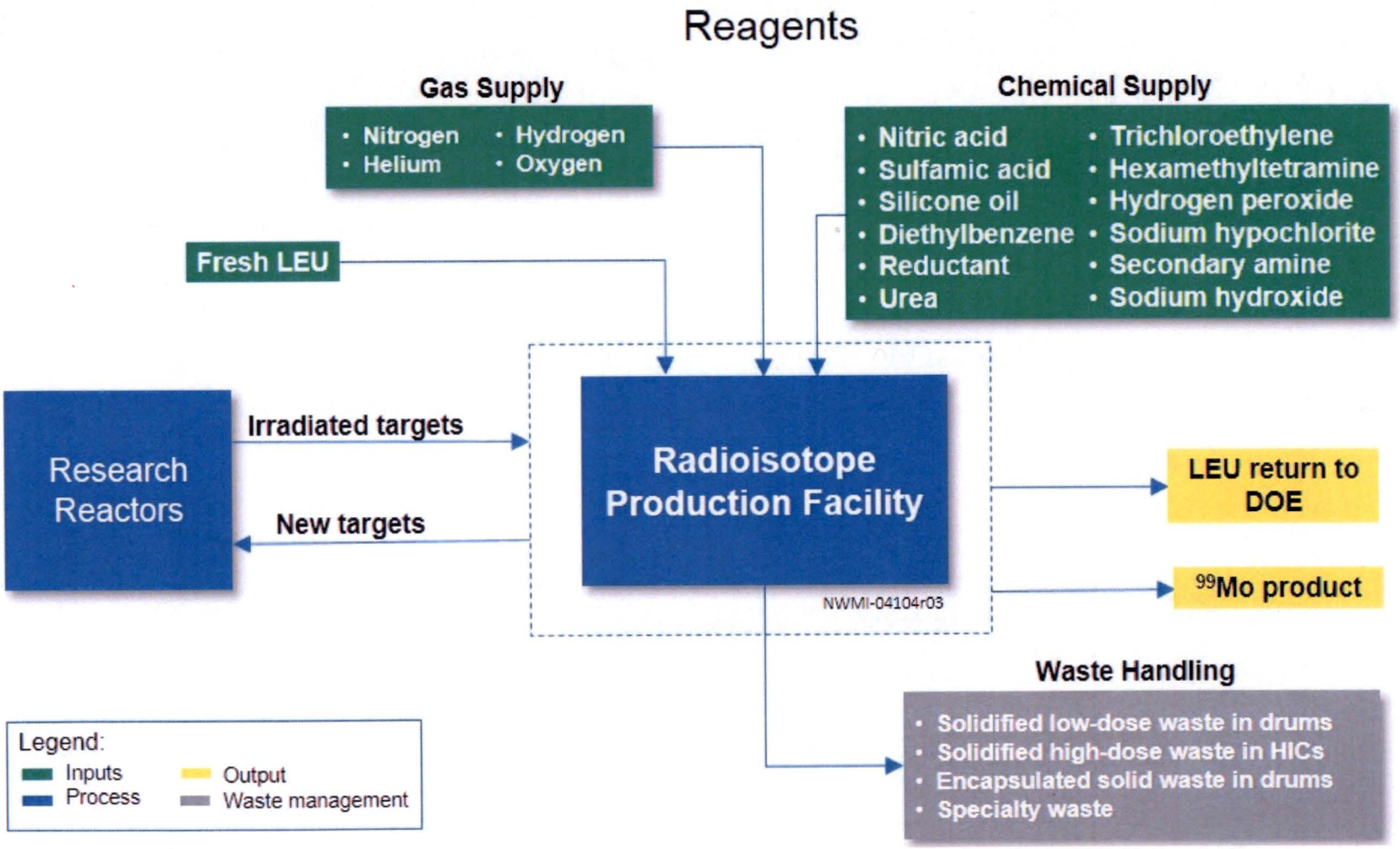


1. LEU target material is fabricated (both fresh LEU and recycled U)
2. LEU target material encapsulated using metal cladding → LEU target
3. LEU targets are packaged and shipped to university reactors for irradiation
4. After irradiation, targets are shipped back to RPF
5. Irradiated LEU targets disassembled
6. Irradiated LEU targets dissolved into a solution for processing
7. Dissolved LEU solution is processed to recover and purify ^{99}Mo
8. Purified ^{99}Mo is packaged/shipped to a radiopharmaceutical distributor
9. LEU solution is treated to recover U and is recycled back to Step 1

RPF Operating Characteristics (continued)

- Ventilation System
  - Ventilation system will be divided into four zones (Zone I, Zone II, Zone III, and Zone IV) → with airflow directed from lowest to highest potential for contamination
  - Zone I ventilation system will be initial confinement barrier (e.g., gloveboxes, tank hot cell, processing hot cells, and Zone I exhaust subsystem)
- Biological Shield
  - Provides an integrated system of features that protects workers from high-dose radiation generated during facility operations
  - Will withstand seismic and other concurrent loads, while maintaining containment and shielding during a design basis event
  - Primary function is to reduce radiation dose rates and accumulated doses in occupied areas to not exceed limits of 10 CFR 20 and RPF ALARA guidelines program
- Engineered Safety Features (ESF)
  - Active or passive features designed to mitigate consequences of accidents and to keep radiological exposures to workers, the public, and environment within acceptable values
  - Confinement is considered a general ESF

Reagent, Product, and Waste Summary Flow Diagram

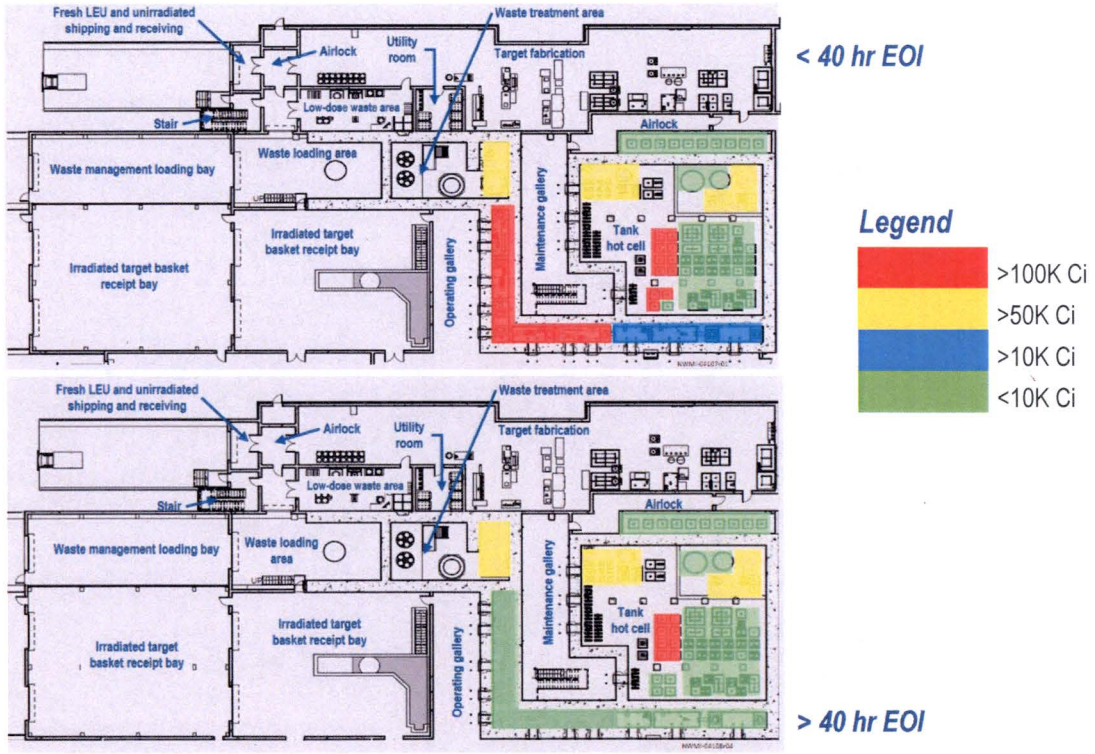


RPF Description

- First level footprint ~52,000 square feet (ft^2)
  - Target fabrication area
  - Hot cell processing area (dissolution, ^{99}Mo, and ^{235}U recovery)
  - Waste management, laboratory, and utility areas
- Basement ~2,000 ft^2 (tank hot cell, decay vault)
- Second level ~17,000 ft^2 (utility, ventilation, offgas equipment)
- Waste Management Building ~1,200 ft^2
- Administration Building (outside secured RPF area) ~10,000 ft^2
- High bay roof – 65 ft
- Mechanical area, second floor – 46 ft
- Top of exhaust stack – 75 ft
- Loading dock (back) roof – 20 ft
- Support and admin (front) roof – 12 ft
- Depth below grade for hot cell/high-integrity container (HIC) storage – 15 ft

RPF Consequences and Radionuclide Inventory Summary

- Primary consequences resulting from operation of RPF operations are radiological
  - LEU target material production/fabrication
  - Irradiated LEU target material processing (e.g., extract ^{99}Mo and recycle and recover ^{235}U)
  - Radioactive waste materials processing
- RPF radionuclide inventory is based on a weekly throughput of irradiated targets
  - MURR → 8 targets
  - OSTR → 30 targets
- Maximum radionuclide inventory is based on accumulation in various systems dependent on process material decay times

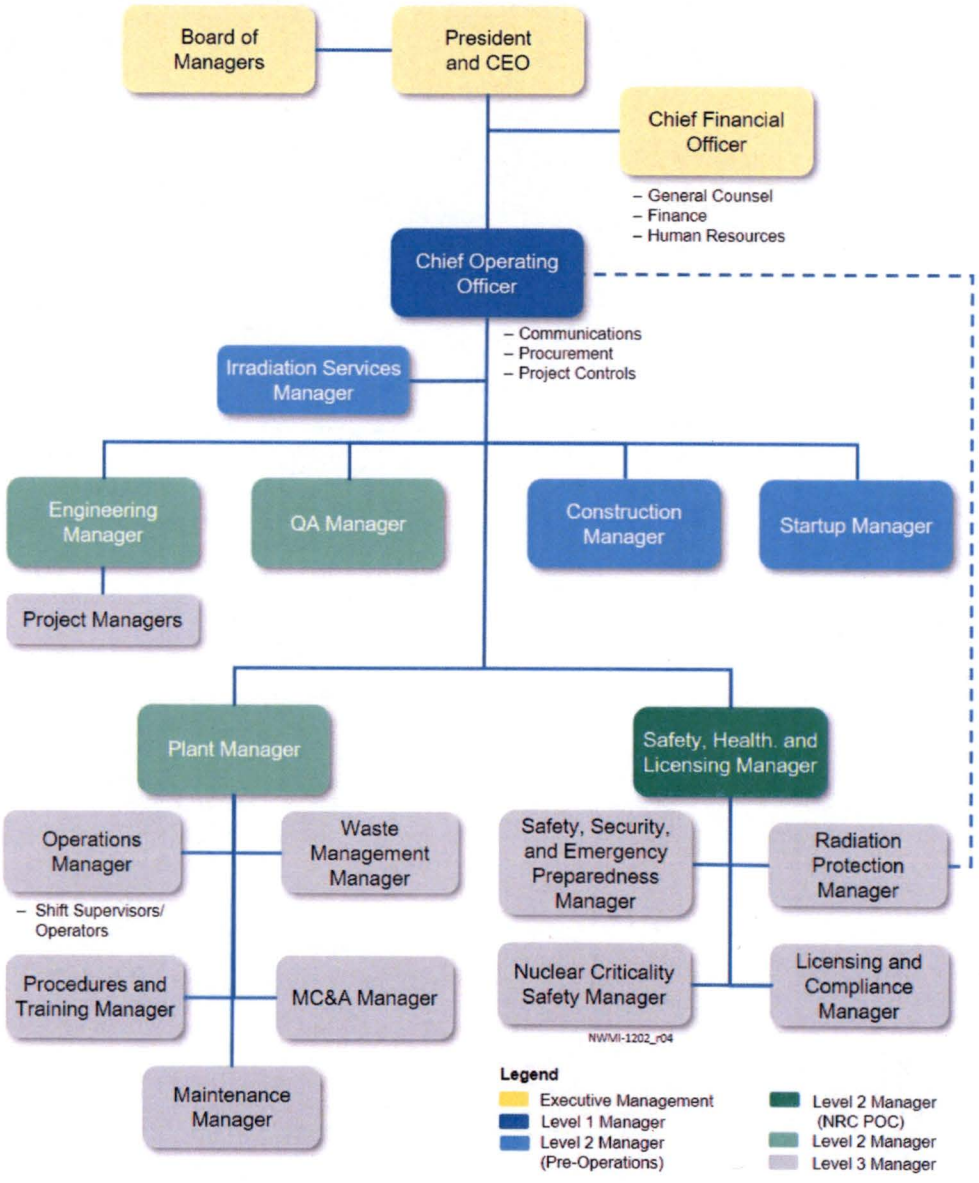


Transportation

- Fresh LEU
  - ES-3100 package (Certificate of Compliance No. 9315)
- Unirradiated targets
  - ES-3100 or similar package
- Irradiated targets
  - BEA Research Reactor cask or similar (Certificate of Compliance No. 9341)
- ^{99}Mo product
  - Medical Isotope Depleted Uranium Shielded (MIDUS) Type B(U) container (Certificate of Compliance USA/9320/B(U)-96)
- Radioactive waste
  - High-dose radioactive waste → High integrity casks (e.g., Model 10-160B cask)
  - Low-dose radioactive waste → 208 liter (L) (55-gallon [gal]) waste drums
- Contact-handled waste
  - Standard industrial waste drums or other appropriate [<2 millisievert (mSv)/hr (200 millirem [mrem]/hr) on contact and 0.1 mSv/hr (10 mrem/hr) at 1 meter (m) (3.3 ft)]

Quality Assurance Program Plan

- NWMI Quality Assurance Program Plan (QAPP) describes policies and requirements necessary to meet applicable Federal regulations
  - ANSI/ANS 15.8, *Quality Assurance Program Requirements for Research Reactors*
  - Regulatory Guide 2.5, *Quality Assurance Program Requirements for Research and Test Reactors*
  - 10 CFR 70.64(a)(1), *Quality Standards and Records*
- QAPP applies to all nuclear, quality-related projects and activities that require conformance to a nuclear quality assurance (QA) program



NWMI RPF Organization

Questions?

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

Northwest Medical Isotopes Construction Permit Application Review

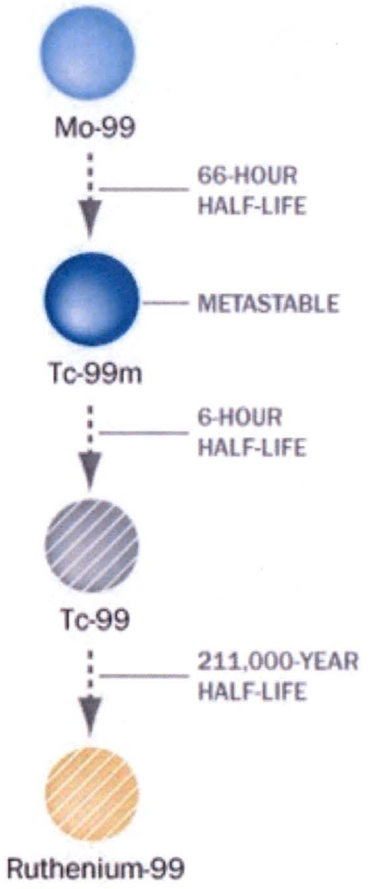
- Mandatory Hearing (Overview Panel)
- January 23, 2018

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

^{99}Mo Overview

- ^{99}Mo decays to ^{99m}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

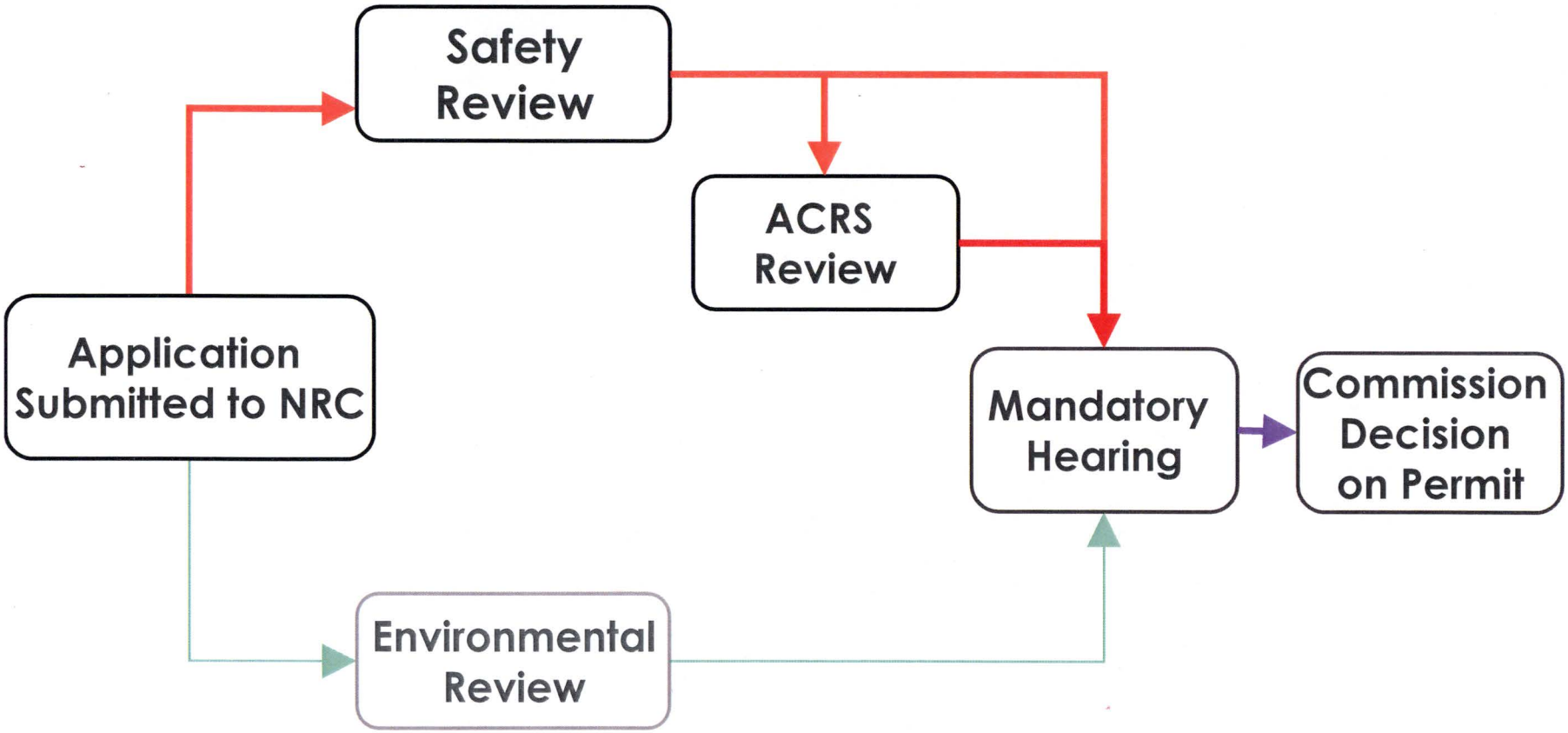
Conducting the NWMI Review

- 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

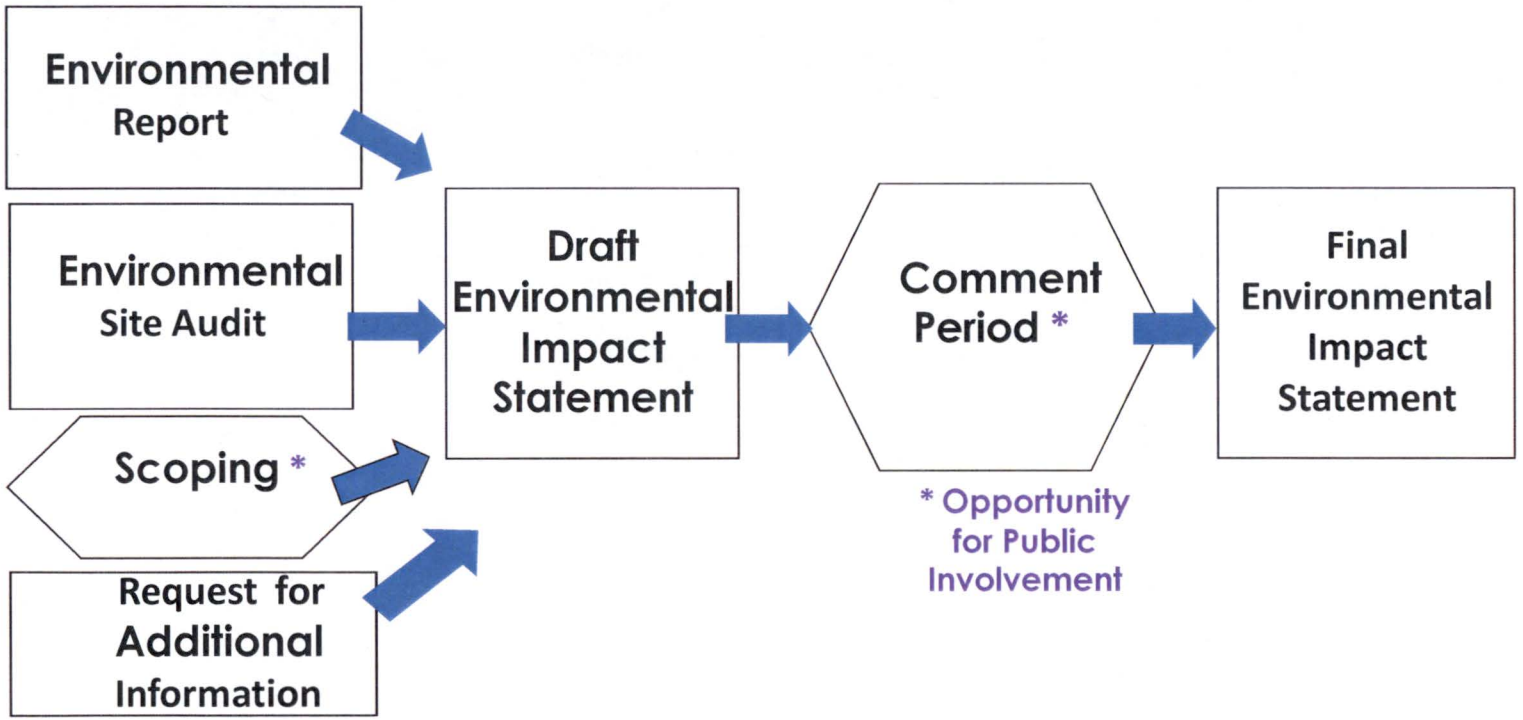
Additional Information

- 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	• 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

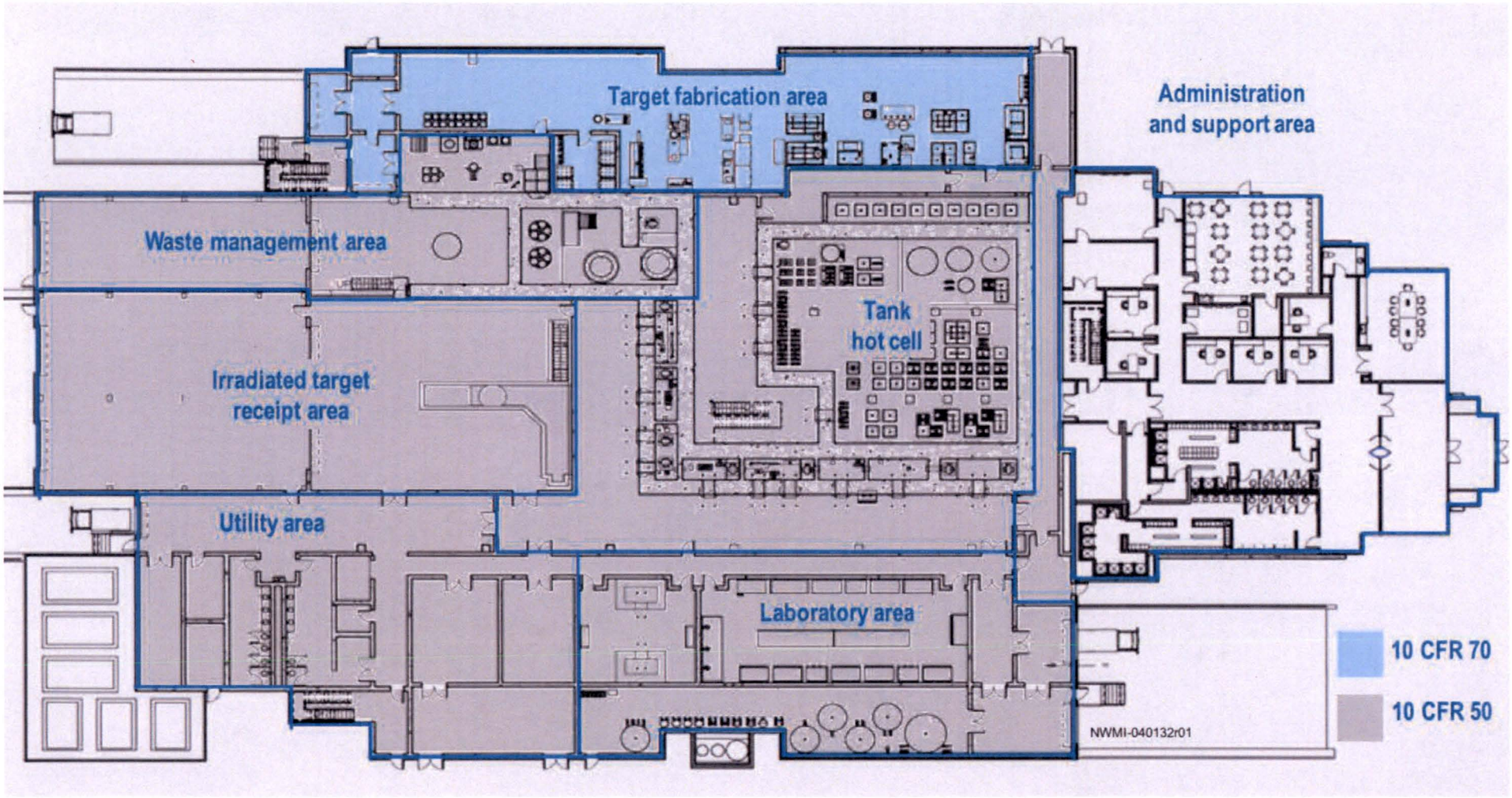
- ^{99}Mo - molybdenum-99
- ^{99m}Tc - technetium-99m
- NRC - U.S. Nuclear Regulatory Commission
- NWMI - Northwest Medical Isotopes
- CFR - *Code of Federal Regulations*
- ACRS - Advisory Committee on Reactor Safeguards
- FSAR - final safety analysis report

U.S. Nuclear Regulatory Commission
Commission Mandatory Hearing

Safety Panel 1 Presentation

January 23, 2018

Radioisotope Production Facility (RPF) Project Overview



RPF Principal Design Criteria

- Design based on applicable standards, guides, codes, and criteria and provides reasonable assurance that structures, systems, and components (SSC):
  - Are built and function as designed and required per NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility*, Chapter 13.0, "Accident Analysis"
  - Provide acceptable protection of public health and safety and the environment
  - Protect against potential hydrological (water) and seismic damage
- Defense-in-depth design philosophy → Applied from outset of facility design through completion of facility design/construction drawings
- Certain systems and components are considered important-to-safety → Perform safety functions during normal operations or are required to prevent or mitigate consequences of abnormal operational transients or accidents
- Safety-related is applied to items relied on to remain functional during or following a design basis event to ensure that the items provide a safety-related function
- Technical specifications will be developed in the Operating License Application

SSC Safety- and Non-Safety Related Definitions

- SSCs are classified as safety-related and non-safety-related:
  - **Safety-related** is a classification applied to items relied on to remain functional during or following a postulated design basis event to ensure:
    - Integrity of facility infrastructure
    - Capability to shut down the RPF and maintain the facility in a safe shutdown condition
    - Capability to prevent or mitigate consequences of postulated accidents identified through accident analyses that could result in potential off-site and worker exposures comparable to applicable guideline exposures set forth in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61 (d) "Performance Requirements"
    - Operation of RPF without undue risk to the health and safety of workers, the public, and environment to meet 10 CFR 20, "Standards for Protection Against Radiation," normal release or exposure limits for radiation doses and applicable limits for chemical exposures
  - **Safety-related items relied on for safety (IROFS)** – SSCs identified through accident analyses as required to meet the performance requirements of 10 CFR 70.61(b), (c), and (d)
  - **Safety-related Non-IROFS** – SSCs that provide reasonable assurance that the RPF can be operated without undue risk to the health and safety of workers, the public, and environment, and includes SSCs to meet 10 CFR 20 normal release or exposure limits
  - **Non-safety-related** – SSCs related to production and delivery of products or services that are not in the above safety classifications

Quality Levels

- **Quality Level (QL) 1** will implement the full measure of the NWMI Quality Assurance Program Plan (QAPP) and will be applied to safety-related SSC IROFS, including items in which failure or malfunction could directly or indirectly result in a condition that adversely affects workers, the public, and/or environment, as described in 10 CFR 70.61
  - Items to prevent nuclear criticality accidents (e.g., preventive controls and measures to ensure that under normal and credible abnormal conditions, all nuclear processes are subcritical)
  - Items credited to withstand credible design-bases external events (e.g., seismic, wind)
  - Items to prevent degradation of structural integrity (e.g., failure or malfunction of facility)
- **QL 2** will be applied to non-QL 1 safety SSCs
  - QAPP is important to acceptability and suitability of item or service to perform as specified (e.g., SSCs to meet 10 CFR 20 normal release or exposure limits, fire protection systems, safeguards and security systems, material control and accountability systems)
- **QL 3** will include non-safety-related quality activities that are deemed necessary to ensure manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements

Seismic Classification for SSCs

- SSCs identified as IROFS will be designed to satisfy general seismic criteria to withstand effects of natural phenomena without loss of capability to perform their safety functions
- Seismic classification methodology used complies with ASCE 7, Chapter 11 (*Seismic Design Criteria*) and Regulatory Guide 1.29 (*Seismic Design Classification)*
  - Demonstrates capability to function during and after vibratory ground-motion associated with safe-shutdown earthquake conditions
- Methodology classifies SSCs into three categories:

1. Seismic Category I (C-I):
   - Applies to IROFS and those SSCs required to support shut down of the RPF and maintain the facility in a safe shutdown condition from both functionality and integrity perspective
2. Seismic Category II (C-II):
   - Applies to SSCs designed to prevent collapse under the safe-shutdown earthquake from an integrity perspective
   - SSCs are classified as C-II to preclude structural failure during a safe-shutdown earthquake, or where interaction with C-I items could degrade the functioning of a safety-related SSC to an unacceptable level or could result in an incapacitating injury to occupants of the main control room
3. Non-seismic (NS):
   - NS SSCs are those that are not classified seismic C-I or C-II

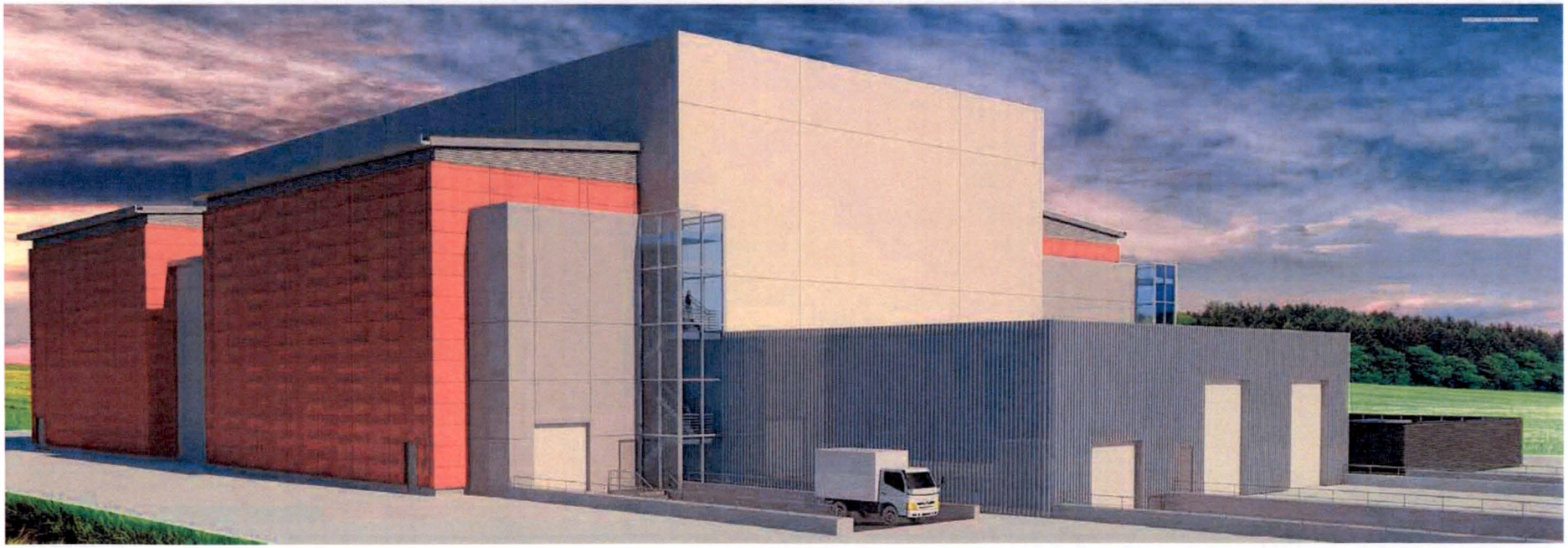
System Safety/Seismic Classification/Quality Level Summary

System Safety and Seismic Classification and Associated Quality Level Group

System name (code)	Highest safety classification	Seismic classification	Quality level group
Facility structure (RPF)	IROFS	C-I	QL-1
Target fabrication (TF)	IROFS	C-I	QL-1
Target receipt and disassembly (TD)	IROFS	C-I	QL-1
Target dissolution (DS)	IROFS	C-I	QL-1
Mo recovery and purification (MR)	IROFS	C-I	QL-1
Uranium recovery and recycle (UR)	IROFS	C-I	QL-1
Waste handling (WH)	IROFS	C-I	QL-1
Criticality accident alarm (CA)	IROFS	C-I	QL-1
Radiation monitoring (RM)	IROFS	C-I	QL-1
Standby electrical power (SEP)	IROFS	C-I	QL-1
Normal electrical power (NEP)	SR	C-I	QL-1
Process vessel ventilation (PVV)	IROFS	C-I	QL-1
Facility ventilation (FV)[c]	IROFS	C-I/II	QL-1/2
Fire protection (FP)	SR	C-II	QL-2
Plant and instrument air (PA)	NSR	C-II	QL-2
Emergency purge gas (PG)	IROFS	C-I	QL-1
Gas supply (GS)	NSR	C-II	QL-2
Process chilled water (PCW)	IROFS	C-I	QL-1
Facility chilled water (FCW)	NSR	C-II	QL-2
Facility heated water (HW)	NSR	C-II	QL-2
Process steam	IROFS	C-I	QL-1
Demineralized water (DW)	NSR	C-II	QL-2
Chemical supply (CS)	IROFS	C-I	QL-1
Biological shield (BS)	IROFS	C-I	QL-1
Facility process control (FPC)	SR	C-II	QL-2

IROFS = items relied on for safety.
NSR = non-safety related.
RPF = Radioisotope Production Facility.
SR = safety-related (not IROFS).

Questions?



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

Northwest Medical Isotopes Construction Permit Application Review

- Mandatory Hearing (Safety Panel 1)
- January 23, 2018

Panelists

- Alexander Adams, Jr.
  - Chief, Research and Test Reactors Licensing Branch, NRR
- Michael Balazik
  - Project Manager, NRR
- David Tiktinsky
  - Senior Project Manager, NMSS
- Steven Lynch
  - Project Manager, NRR

Licensing Process

- NWMI seeks a permit to construct a 10 CFR Part 50 production facility
- Licensing process for NWMI production facility similar to that for other non-power Part 50 facilities
- Unique licensing considerations

Advisory Committee on Reactor Safeguards Review

- Staff presented at subcommittee and full committee meetings
- Staff performed additional independent analysis
- ACRS recommended issuance of construction permit
- Staff documented the NWMI commitments in Safety Evaluation Report

Production Facility Licensing

- Production facility will process irradiated special nuclear material and separate byproduct material
  - Special nuclear material batches contain greater than 100 grams of uranium-235
  - Processes similar to those at existing fuel cycle facilities
- NUREG-1537, Interim Staff Guidance Augmenting NUREG-1537, NUREG-1520

Unique Licensing Considerations

- Two processes described within a single facility
  - Production facility licensed under 10 CFR Part 50
  - Target fabrication licensed under 10 CFR Part 70
- Understanding the interface between the two processes

Relationship Between Production Facility and Target Fabrication

- Both processes described in construction permit application
- Review focused on interface, shared systems, and impact
- Permit would authorize construction of 10 CFR Part 50 production facility

Proposed Permit Conditions

- Construction permit does not constitute approval of the safety of any design feature or specification
- Permit conditions
  - Criticality Safety
  - Quality Assurance
  - Site Characteristics

Criticality Safety Conditions

- Criticality accident alarm system
- Subcritical limit
- Conditions are confirmatory
- Termination of conditions

Quality Assurance Condition

Similar to requirements of 10 CFR 50.55(f), condition would support

- Adequate implementation of commitments in design, procurement, and construction
- Maintenance of documentation
- Approval of certain QAPP changes
- Correction of deficiencies

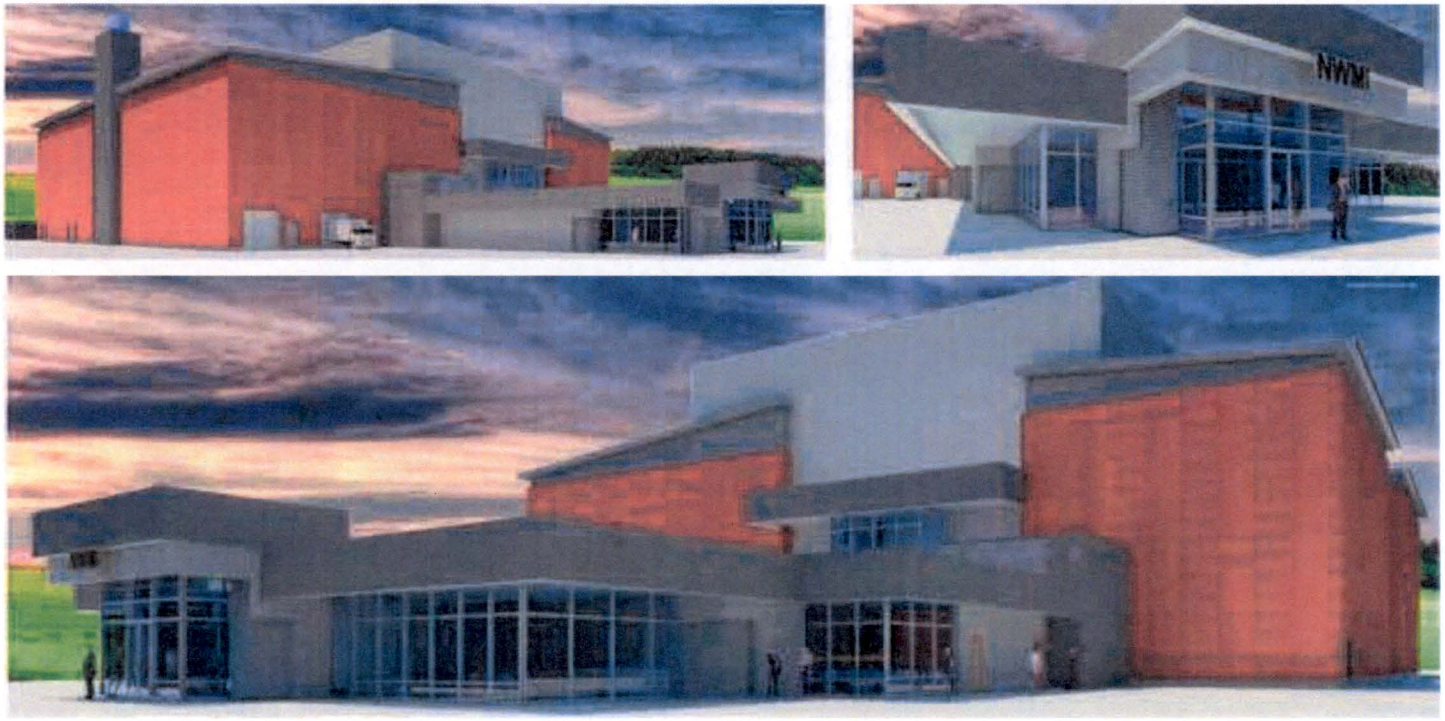
Geotechnical Condition

- NWMI committed to performing site-specific geotechnical investigation
- Since results could impact design bases, Staff recommends NWMI
  - Identify sinkhole potential, soil characteristics, and liquefaction potential
  - Submit design changes based on findings
- Results inform construction inspection

Acronyms

- ACRS - Advisory Committee on Reactor Safeguards
- CFR - Code of Federal Regulations
- NRR - Office of Nuclear Reactor Regulation
- NMSS - Office of Material Safety and Safeguards
- NWMI - Northwest Medical Isotopes
- QAPP - Quality Assurance Program Plan

U.S. Nuclear Regulatory Commission
Commission Mandatory Meeting



Safety Panel 2 Presentation

January 23, 2018

Integrated Safety Analysis

- NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors*, requirements
  - Used integrated safety analysis (ISA) methodologies (per 10 CFR 70 Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," and NUREG-1520, *Standard Review Plan for Fuel Cycle Facilities License Applications*)
  - Applied radiological and chemical consequence and likelihood criteria identified in the performance requirements of 10 CFR 70.61
  - Designated items relied on for safety (IROFS) and established management measures to demonstrate adequate safety for the Radioisotope Production Facility (RPF)
- Evaluated RPF in systematic integrated examination, including processes, equipment, structures, and personnel activities, which ensured that all relevant hazards that could result in unacceptable consequences were adequately evaluated and appropriate protective measures were identified
- Evaluated special nuclear material areas through development of criticality safety evaluations (CSE) to identify double contingencies controls to maintain subcriticality

Integrated Safety Analysis Methodology

- RPF was evaluated using an ISA process
  - Completed process hazards analysis (PHA)
  - Developed quantitative risk assessments (QRA) to address events and hazards identified in PHA as requiring additional evaluation
- Evaluated accident sequences (qualitatively) to identify likelihood and severity using event frequencies and consequence categories consistent with regulatory guidelines
- Assessed each event with an adverse consequence (involving licensed material or its byproducts) for risk using a risk matrix that enables user(s) to identify unacceptable intermediate- and high-consequence risks
  - Developed IROFS to prevent or mitigate consequences of events
  - Reduced risks acceptable frequencies through preventive or mitigative IROFS

Integrated Safety Analysis Methodology (continued)

- Used event trees analysis (certain circumstances)
  - Provided quantitative failure analysis data (failure frequencies)
  - Quantitatively analyzed an event from its basic initiators to demonstrate that quantitative failure frequencies are highly unlikely under normal standard industrial conditions (i.e., no IROFS required)
- Identified management measures to ensure that the IROFS failure frequency used in the analysis was preserved and IROFS are able to perform intended function(s) when needed
- Translation of IROFS (10 CFR 70) to technical specifications (10 CFR 50) will be developed in the Operating License Application

Integrated Safety Analysis Results

- Evaluated accident sequences using both qualitative and quantitative techniques
  - Most of quantitative consequence estimates are for releases to an uncontrolled area (public)
  - Worker safety consequence estimates are primarily qualitative
    - As facility final design matures, quantitative worker safety consequence analyses will be performed
- Accidents for operations with special nuclear material (including irradiated target processing, target material recycle, waste handling, and target fabrication), radioactive materials, and hazardous chemicals were analyzed
- Initiating events for analyzed sequences include operator error, loss of power, external events, and critical equipment malfunctions or failures
- Shielded and unshielded criticality accidents assumed to have high consequences to worker if not prevented
- Updated frequency (likelihood) and worker and public quantitative safety consequences will be provided in Operating License Application

Preliminary Hazard Analysis

- Completed PHA on eight "systems;" 107 nodes were evaluated (PHA tables ~300 pages)
- ~140 accident sequences were identified for additional evaluation; 75 accident sequences were evaluated in QRAs
- 8 QRAs were completed, covering 75 accidents; one QRA addressed chemical accidents

Qualitative Risk Assessment Documents
Radioisotope Production Facility Preliminary Hazards Analysis
Radioisotope Production Facility Integrated Safety Analysis Summary
Chemical Safety Process Upsets
Process Upsets Associated with Passive Engineering Controls Leading to Accidental Criticality Accident Sequences
Criticality Accident Sequences that Involve Uranium Entering a System Not Intended for Uranium Service
Criticality Accident Sequences that Involve High Uranium Content in Side Waste Stream
Facility Fires and Explosions Leading to Uncontrolled Release of Fissile Material, High- and Low-Dose Radionuclides
Radiological Accident Sequences in Confinement Boundaries (including Ventilation Systems)
Administratively Controlled Enrichment, Mass, Container Volume, and Interaction Limit Process Upsets Leading to Accidental Criticality Accident Sequences
Receipt and Shipping Events
Evaluation of Natural Phenomenon and Man-Made Events on Safety Features and Items Relied on for Safety

MCNP Validation (ANSI/ANS 8.24 Requirement)

- Monte Carlo N-Particle Transport Code: MCNP 6.1, Continuous Energy ENDF/B- VII.1 Cross-Section
- Define operation/process to identify range of parameters to be validated
- 92 criticality safety experiments were selected that adequately match uranium enrichment, geometry, moderator, reflector, and neutron energy
- Define area of applicability (AoA) of the validation
- Analyzed data
  - Determined bias and bias uncertainty
  - Identified trends in data → No trends were identified
  - Test for normal or other distribution and select statistical method for data treatment
  - Identify and support subcritical margin – Margin of subcriticality (MoS) of 0.05 Δk
  - Calculate USL – 0.9240

Criticality Analysis

- Used "first principles" as bases for equipment design and process area layouts
  - Geometry constraints (e.g., pencil tank diameters)
  - Tank array spacing (conservative)
  - Transition from "safe-geometry" process equipment to less-restricted waste staging and processing equipment was considered
- Evaluations and analysis
  - MCNP code validation and upper subcritical limits for all areas of applicability
    - Defined operation/process to identify range of parameters
    - 92 criticality safety experiments
    - Defined area of applicability
  - Project-specific single-parameter criticality limits for U enrichment, forms, and basic geometries
- Criticality safety evaluations (CSE)
  - Normal operating conditions described
  - Criticality hazard evaluation
  - Contingency analysis
  - Double contingency controls

Criticality Safety Evaluation Documents
Irradiated Target Handling and Disassembly
Irradiated Low-Enriched Uranium Target Dissolution
Molybdenum-99 Recovery
Low-Enriched Uranium Target Material Production
Target Fabrication Uranium Solution Processes
Target Finishing
Target and Can Storage and Carts
Hot Cell Uranium Purification
Liquid Waste Processing
Solid Waste Collection, Encapsulation, and Staging
Offgas and Ventilation
Target Transport Cask and Drum Handling
Analytical Laboratory
Calculations • *Single Parameter Subcritical Limits for 20 wt% ^{235}U - Uranium Metal, Uranium Oxide, and Homogenous Water Mixtures* • *Irradiated Target Low-Enriched Uranium Material Dissolution* • *55-Gallon Drum Arrays* • *Single Parameter Subcritical Limits for 20 wt% ^{235}U – Low-Enriched Uranium Target Material* • *Target Fabrication Tanks, Wet Processes, and Storage* • *Tank Hot Cell*

Accident Sequences Evaluated and Organization

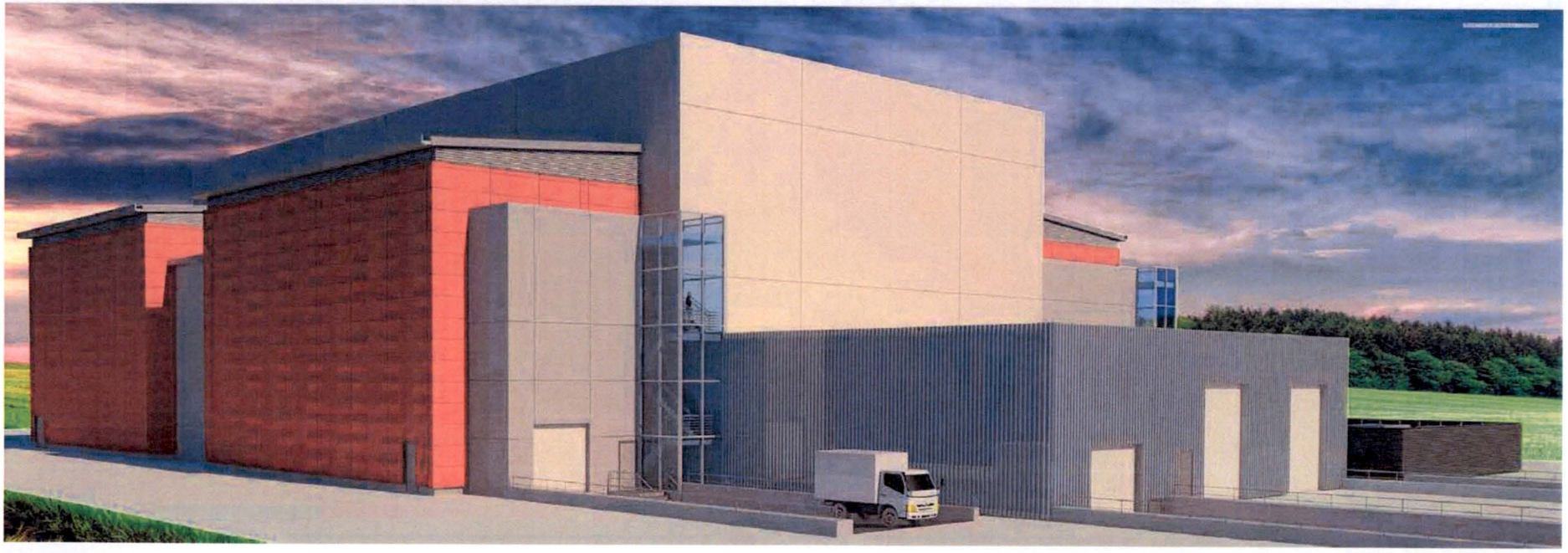
Accident Sequences Evaluated

- Spill and Spray Accidents – Radiological and Criticality (Section 13.2.2)
- Dissolver Offgas Accidents -- Radiological (Section 13.2.3)
- Leaks into Auxiliary Systems – Radiological and Criticality (Section 13.2.4)
- Loss of Electrical Power Accidents (Section 13.2.5)
- Natural Phenomena Accidents (Section 13.2.6)
- Other Accidents (Section 13.2.7)
- Accidents with Hazardous Chemicals (Section 13.3)

Accident-Initiating Events

- Criticality accident
- Loss of electrical power
- External events (meteorological, seismic, fire, flood)
- Critical equipment malfunction
- Operator error
- Facility fire (including explosion)
- Any other event potentially related to unique facility operations

Questions?



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

Northwest Medical Isotopes Construction Permit Application Review

- Mandatory Hearing (Safety Panel 2)
- January 23, 2018

Panelists

- Michael Balazik
  - Project Manager, NRR
- April Smith
  - Reliability and Risk Analyst, NMSS
- David Tiktinsky
  - Senior Project Manager, NMSS
- James Hammelman
  - Senior Chemical Engineer, NMSS

Accident Analysis Methodology

- NWMI used an ISA methodology for its accident analyses
- IROFS and management measures to be selected to demonstrate safety
- Consistent with the ISG Augmenting NUREG-1537, radiological and chemical hazards evaluated against consequence criteria in 10 CFR 70.61

ISA Methodology

- Northwest submitted an ISA Summary of the accident analysis of radiological and chemical hazards
- ISA Summary contains:
  - Hazard analyses results
  - Qualitative assessment of likelihood, consequences, and risk category
  - Identification of accident sequences

ISA Methodology (continued)

- ISA methodology found adequate to identify IROFS to prevent or mitigate accidents and prevent an inadvertent criticality
- Management measures to assure availability and reliability of IROFS will be reviewed in the OL application
- Staff found that ISA process adequate to support identification of hazards and mitigation or prevention of accidents

Radiological and Criticality Safety

- PSAR/ISA Summary presented multiple accident sequences involving liquid spills, sprays and leaks with impacts to radiological and criticality safety
- Staff evaluated engineered safety features including items relied on for safety
- Analysis provides reasonable assurance that credible accident sequences have been identified

Chemical Safety

- Staff reviewed the design, accident analysis, and proposed safety features
- Staff conducted independent analyses of chemical hazards
- NWMI identified additional chemical safety research and development related to ion exchange system
- Staff concludes that the chemical hazards can be adequately managed

Summary of Accident Analysis Findings

- ISA is a sufficient approach to identify accident sequences and IROFS
- Northwest adequately assessed risks to public health and safety for issuance of a construction permit

Acronyms

- IROFS - Items relied on for safety
- ISA - Integrated safety analyses
- PSAR - Preliminary Safety Analysis Report
- NMSS - Office of Nuclear Material Safety and Safeguards
- NRR - Office of Nuclear Reactor Regulation
- NWMI - Northwest Medical Isotopes

U.S. Nuclear Regulatory Commission
Commission Mandatory Meeting

Environmental Panel

January 23, 2018

Development of Environmental Report

- Granted an exemption to submit the Construction Permit Application in two parts [Published in Federal Register (FR) on October 24, 2013 (78 FR 63501)]
- NRC conducted an independent evaluation of Part One of the Construction Permit Application and developed potential impacts of NWMI's proposed action
- Environmental Impact Statement Development Milestones
  - NWMI submitted Part One of Construction Permit Application: February 5, 2015
    - NRC acknowledged receipt: April 21, 2015 (80 FR 22227)
    - NRC published Notice of Docketing: June 8, 2015 (80 FR 32418) (ADAMS Accession No. ML15125A048)
  - Environmental Site Audit/Scoping Meeting: December 8 & 9, 2015 (Columbia, MO)
  - Draft EIS public comment period: November 1 – December 29, 2016 (Public meeting on December 6, 2016 in Columbia, Missouri)
  - Final EIS published May 31, 2017 → NUREG-2209, *Final Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility* (ADAMS Accession No. ML17130A862)

Proposed Action

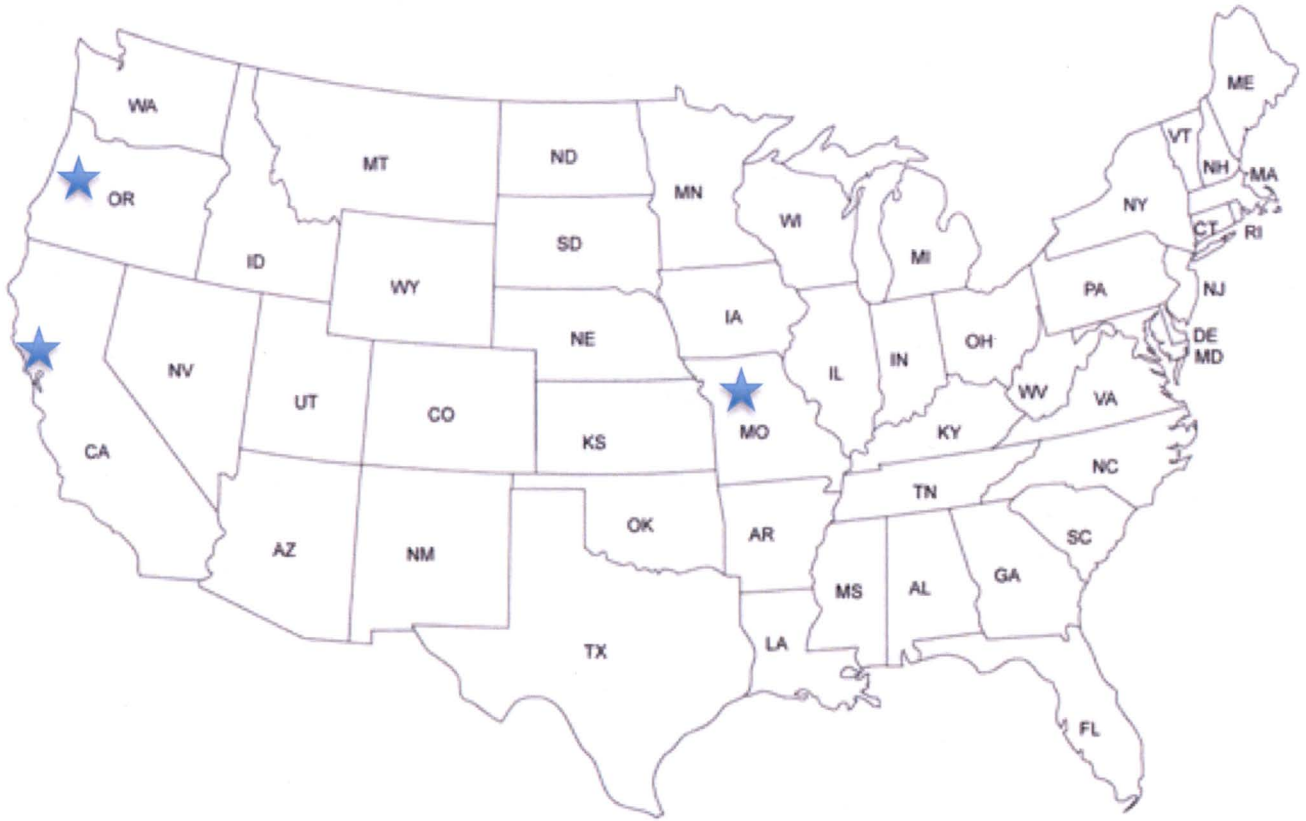
- Decide whether to issue a construction permit under 10 CFR 50 that would allow construction of the NWMI medical radioisotope production facility (RPF)
- If a construction permit is granted by NRC, NWMI could build the proposed facility at the 3 hectare (7.4-acre) Discovery Ridge Research Park (Discovery Ridge) site, in Boone County, Columbia, Missouri
- NWMI RPF activities include:
  - Fabricating low-enriched uranium (LEU) targets (including uranium recycle and recovery)
  - Shipping targets to university research reactors
  - Irradiating LEU targets at university research reactors
  - Returning targets to RPF
  - LEU target dissolution
  - Molybdenum-99 (^{99}Mo) recovery and purification

Consultations

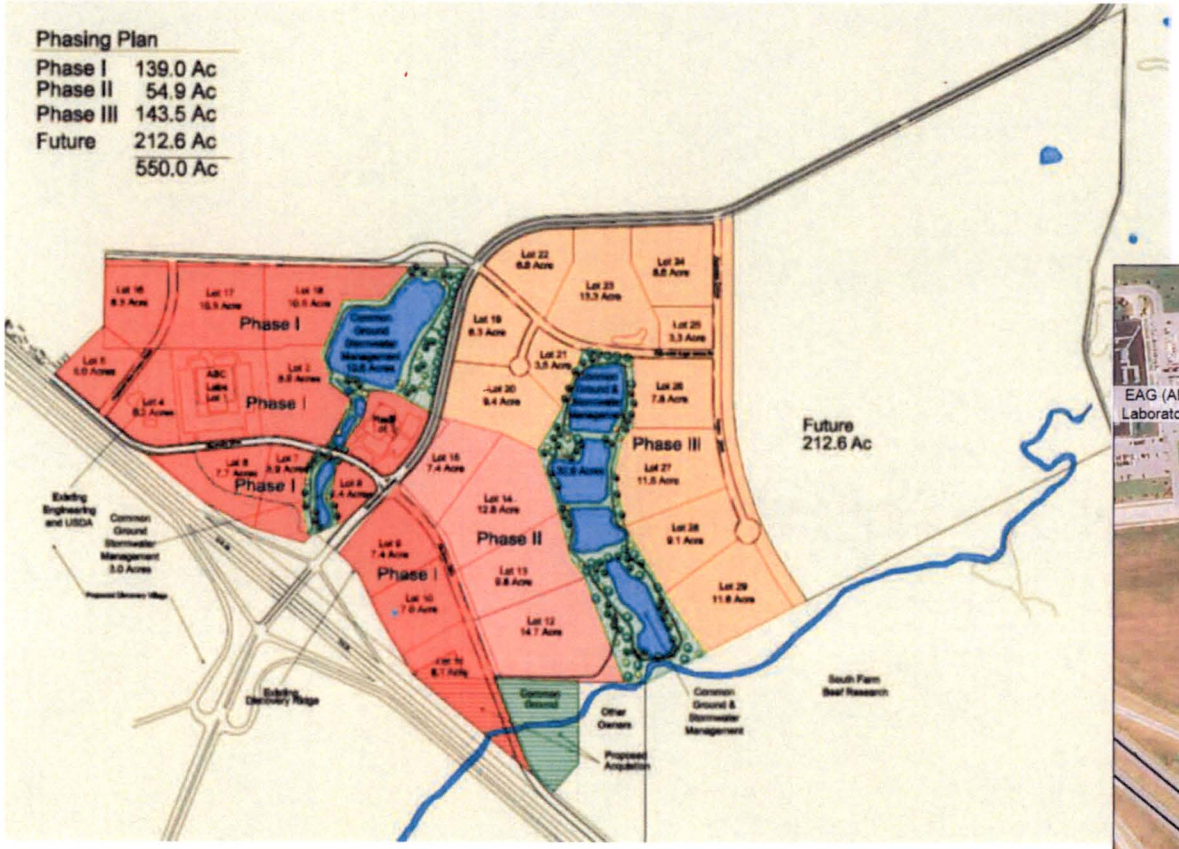
- Advisory Council on Historic Preservation
- Boone County Government Center
- City of Columbia, Missouri
- Mid-Missouri Regional Planning Commission
- Missouri Department of Conservation
- Missouri Department of Health and Senior Services
- Missouri Department of Natural Resources
- Missouri Department of Public Safety
- Missouri Department of Transportation
- U.S. Fish and Wildlife Service
- U.S. Department of Energy
- Tribal Nations → 31

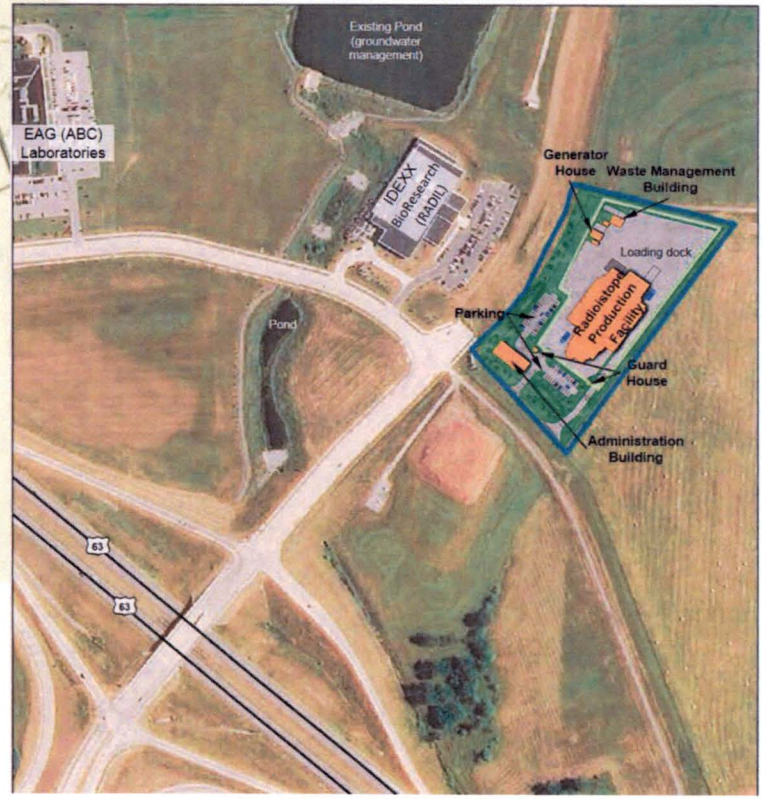
Alternative Site Locations Evaluated by NWMI

- University of Missouri Research Reactor (MURR) – Columbia, MO
- Discovery Ridge Research Park – Columbia, MO
- Oregon State University (OSU) – Corvallis, OR
- McClellan Business Park (McClellan) – Davis, CA
  - University of California at Davis (UC Davis) Research Reactor located at McClellan



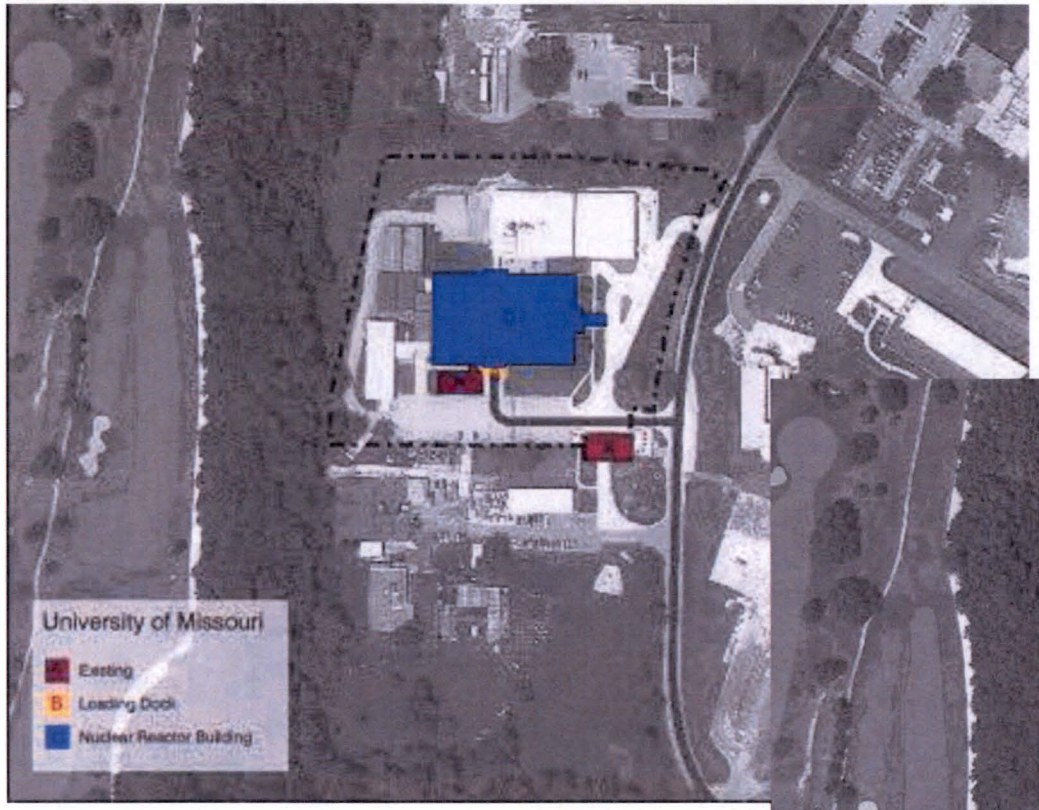
Discovery Ridge Layout





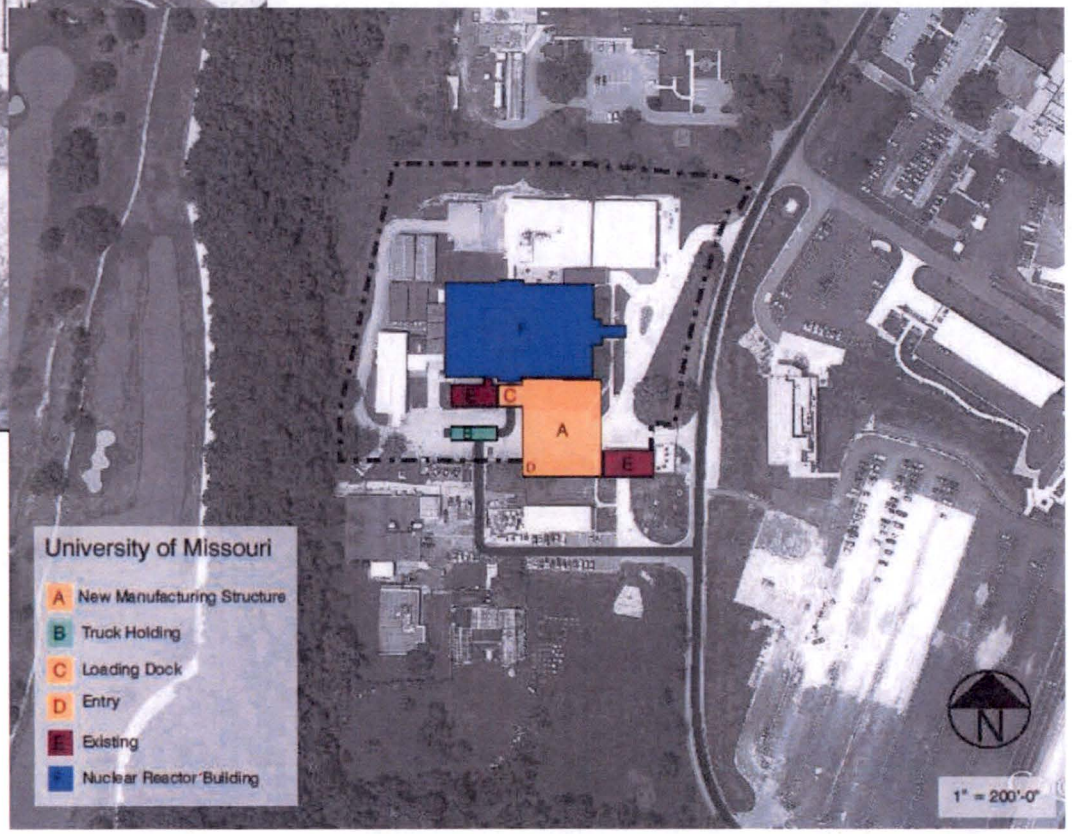
- RPF will be located on Lot 15 → 7.4-acre
  - No existing structures
  - Used for agriculture for past century
- NWMI "anchor" for radioisotope ecosystem; two existing companies

MURR RPF Layout



Current MURR Layout

Preliminary RPF Layout



Alternative Technologies/Alternatives Evaluated by NRC

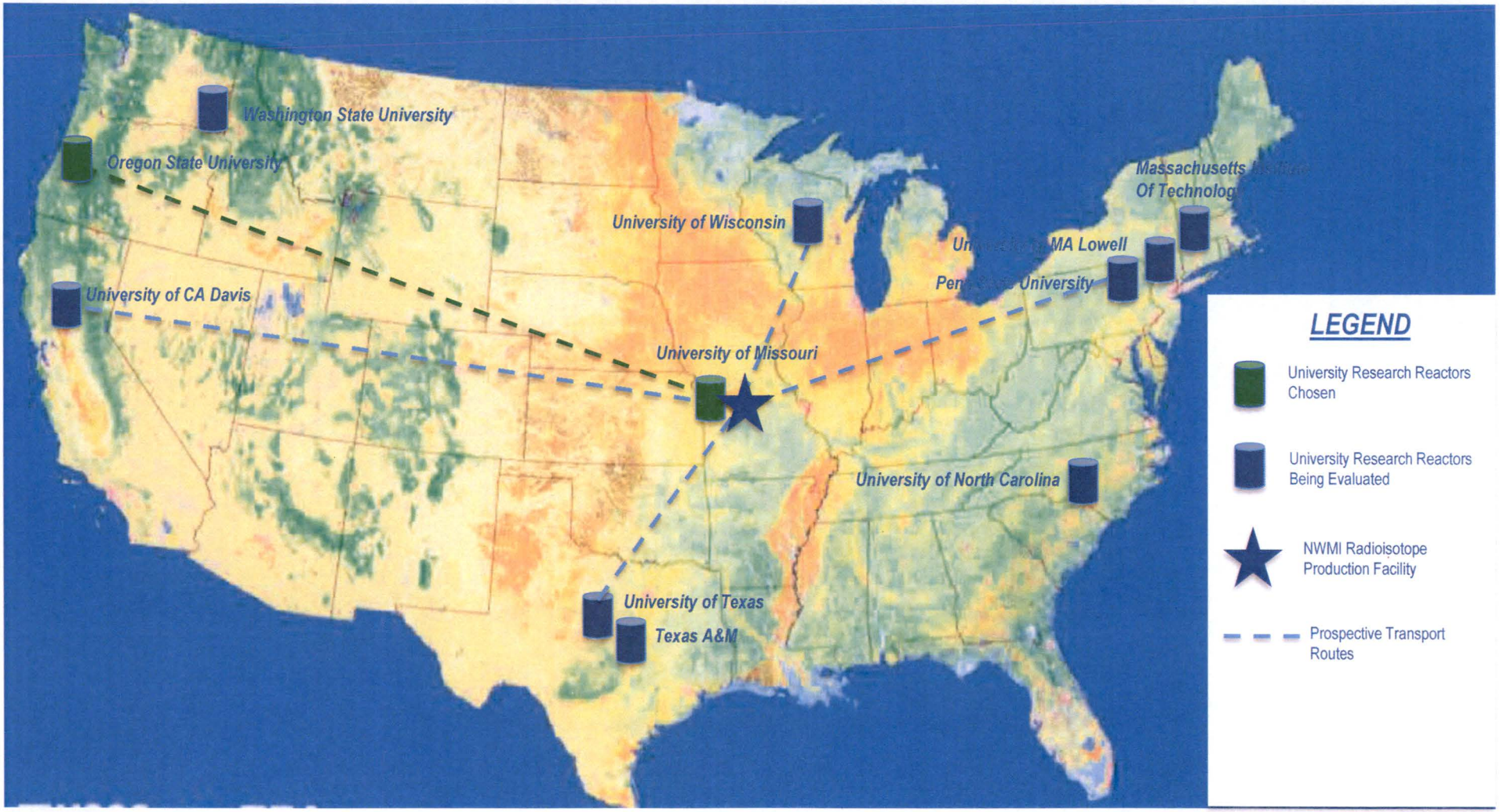
Alternative Technologies

- Neutron capture technology
- Aqueous homogenous reactor technology
- Selective gas extraction technology
- ***Uranium fission technology***
- ***Linear accelerator-based technology***

Alternatives Evaluated

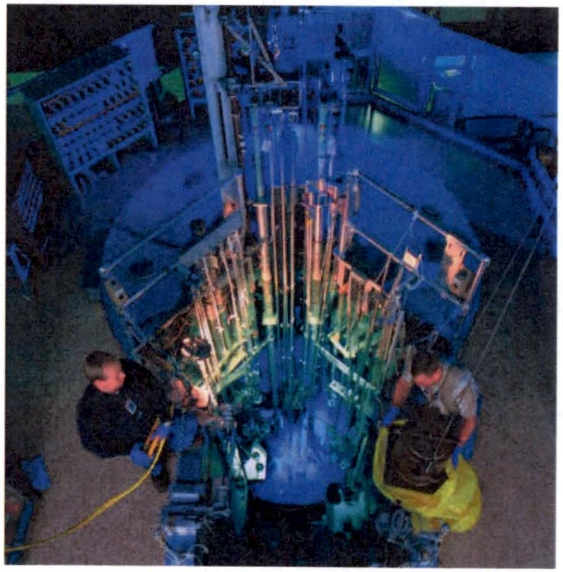
- No-action alternative
- NWMI RPF at University of Missouri Research Reactor site (alternative site)
- Linear accelerator-based facility at Discovery Ridge site (Alternative Technology No. 1)
- Subcritical fission-based facility at Discovery Ridge site (Alternative Technology No. 2)

Connected Actions – University Research Reactor



Connected Actions (continued)

- Few facility modifications will be required
- No exterior construction anticipated for any reactor
- No changes in land use
- Minimal changes in staffing
- Authorization for possession and use of targets will be promulgated under the license amendment process for each facility
  - MURR → early 2018
  - OSU → early 2019
- Third facility has been selected but not socialized

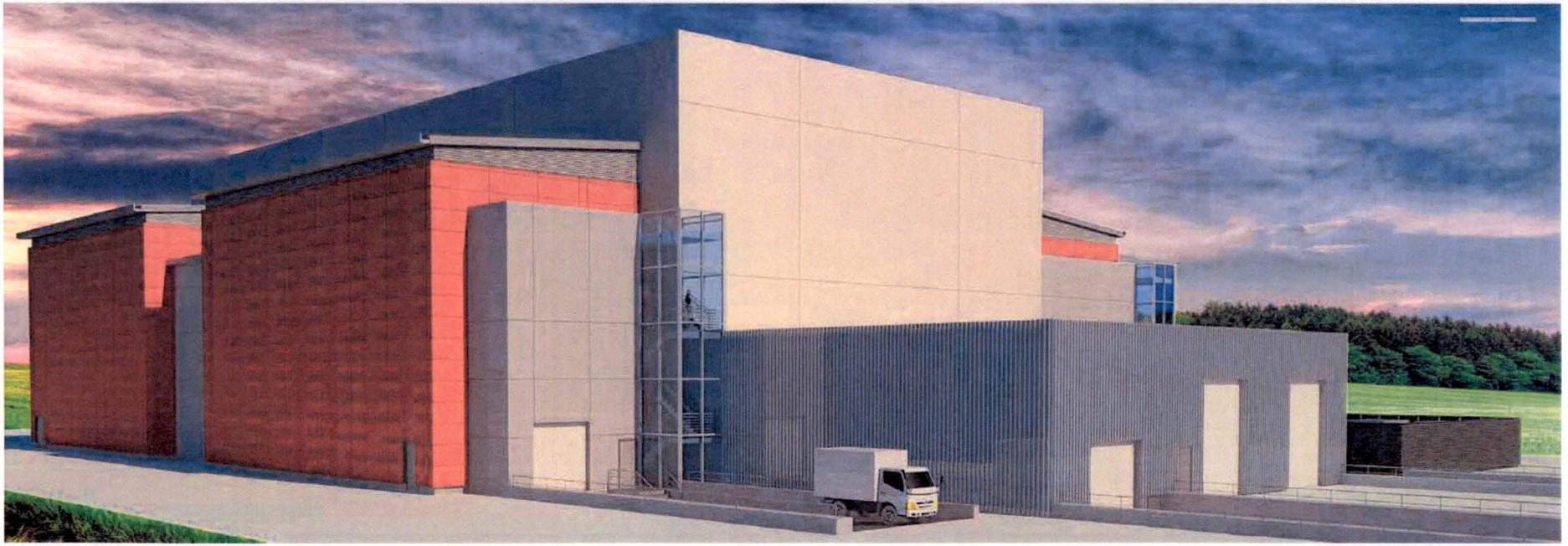


Environmental Impact Summary

Environmental Impact Summary

	NWMI RPF at Discovery Ridge	NWMI RPF at MURR	Linear Accelerator-Based Technology at Discovery Ridge	Subcritical Fission-Based Technology at Discovery Ridge	No Action
Construction Impacts	• SMALL impacts to all resource categories • No historic properties affected	• SMALL to MODERATE impacts to all resource categories • Potential adverse effect to historic properties	• SMALL impacts to all resource categories • No historic properties affected	• SMALL impacts to all resource categories • No historic properties affected	• SMALL impacts to all resource categories • No historic properties affected
Construction Benefits	• ~100 jobs (on average) • Annual tax payment of $2.5M	• ~100 jobs (on average) • Annual tax payment of $2.5M	• ~100 jobs(on average) • Annual tax payment of $2.5M	• ~100 jobs (on average) • Annual tax payment of $2.5M	None
Operation Impacts	• SMALL impacts to all resource categories	• SMALL impacts to all resource categories	• SMALL impacts to all resource categories	• SMALL impacts to all resource categories	• SMALL impacts to all resource categories
Operation Benefits	• ~125 jobs • Reliable source of ^{99}Mo for medical uses • Annual tax payment of $2.5M	• ~125 jobs • Reliable source of ^{99}Mo for medical uses • Annual tax payment of $2.5M	• ~125 jobs • Reliable source of ^{99}Mo for medical uses • Annual tax payment of $2.5M	• ~125 jobs • Reliable source of ^{99}Mo for medical uses • Annual tax payment of $2.5M	None

Questions?



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

Northwest Medical Isotopes Construction Permit Application Review

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

Panelists

- Benjamin Beasley
  - Chief, Environmental Review and NEPA Branch, NRR
- Nancy Martinez
  - Physical Scientist, NRR
- Michelle Moser
  - Biologist, NRR
- David Drucker
  - Senior Project Manager, NRR

Environmental Review

- National Environmental Policy Act
- Environmental review process
  - 10 CFR Part 51
  - Interim Staff Guidance Augmenting NUREG-1537 for Licensing Radioisotope Production Facilities and Aqueous Homogenous Reactors

Scope of the Review: Proposed Action and Connected Actions

Actions are connected if they:

- Automatically trigger other actions that may require environmental impact statements; or
- Cannot or will not proceed unless other actions are taken previously or simultaneously; or
- Are interdependent parts of a larger action and depend on the larger action for their justification

Proposed Action and Connected Actions

- Construction, operations, and decommissioning of the 10 CFR Part 50 production facility
- Construction, operations, and decommissioning related to target fabrication
- Transportation of targets to/from research reactors and irradiation of targets at research reactors

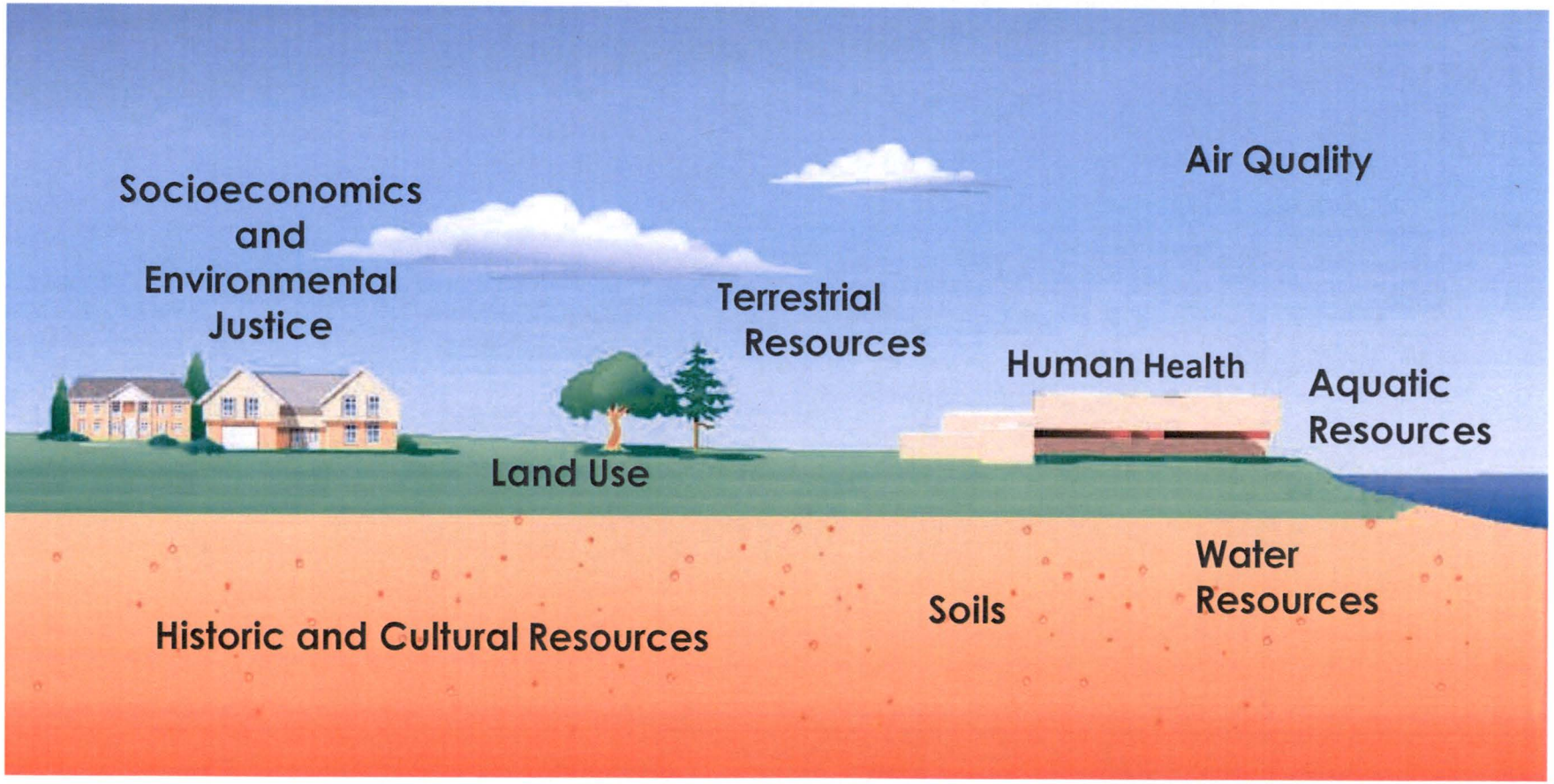
Environmental Impact Statement (EIS)

- 10 CFR 51.20
- Project-specific decision
  - Operation of the proposed Northwest facility would include target fabrication and scrap recovery
  - Environmental assessment might not support a finding of no significant impact

Scoping Process

- Public meeting in Columbia, Missouri
- Six oral commenters
- Eight comment letters or emails

Environmental Review Areas



Environmental Impacts

Resource Area	Impact
Land Use and Visual Resources	SMALL
Air Quality and Noise	SMALL
Geologic Environment	SMALL
Ecological and Water Resources	SMALL
Historic and Cultural Resources	SMALL
Socioeconomics	SMALL
Human Health and Waste	SMALL
Transportation	SMALL

Consultations

Act	Determination
Endangered Species Act, Section 7	No Effect
National Historic Preservation Act, Section 106	No Adverse Effect

Alternatives

- No-action alternative
- Alternative site
- Alternative technologies

Alternative Technologies

- Neutron capture
- Aqueous homogenous reactor
- Selective gas extraction
- Linear-accelerator-based
  - Analyzed in depth
- Subcritical fission
  - Analyzed in depth

Costs and Benefits

- Purpose
  - Inform recommendation to the Commission
- Costs
  - Environmental and financial
- Benefits
  - Societal, medical, and economic

Draft Environmental Impact Statement

- Public meeting in Columbia, Missouri
- Seven oral commenters
- Five comment letters or emails

Staff Conclusion and Recommendation

- Benefits (societal, medical, and economic) outweigh the costs (environmental, economic)
- Considered reasonable alternatives
- Recommend issuance of the construction permit

Future NEPA Analyses

- Application for an operating license
- Application for a license to possess and use special nuclear material for target fabrication and scrap recovery
- License amendment requests from research reactors

Acronyms

- EIS - Environmental Impact Statement
- NEPA - National Environmental Policy Act
- NRR - Office of Nuclear Reactor Regulation