



**ATTACHMENT 3**

**Northwest Medical Isotopes, LLC**

**U.S. Nuclear Regulatory Commission  
NWMI Technical Meeting Presentation  
March 16, 2016**

**Public Version**



# **NWMI Construction Permit Application Technical Meeting Public Meeting**

**March 16, 2016**

# Agenda

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## *Public Session*

<i>8:30 am</i>	<i>Opening Remarks (NRC)</i>
<i>8:35 am</i>	<i>Introductions (NRC/NWMI)</i>
<i>8:45 am</i>	<i>Licensing Strategy</i>
<i>9:15 am</i>	<i>Integrated Safety Analysis</i>
<i>9:45 am</i>	<i>Chemical Safety</i>
<i>10:15 am</i>	<i>Criticality Control Safety Program Methodology</i>
<i>10:45 am</i>	<i>Radiological Safety</i>
<i>11:00 am</i>	<i>Fire Safety</i>
<i>11:15 am</i>	<i>Transportation Basis Timing from Reactors to Radioisotope Production Facility</i>
<i>11:30 am</i>	<i>Quality Assurance</i>
<i>11:45 am</i>	<i>Environmental Report/NEPA Status (NRC)</i>
<i>11:55 am</i>	<i>Public Q &amp; A</i>
<i>12:00 pm</i>	<i>Meeting Closeout</i>





# Introductions



# Project Organization



## Commercial Irradiation Services University Reactors



## Radioisotope Production Facility

### Engineering Design



### Criticality, Shielding, and Safety Analysis

## ATKINS

### Transportation



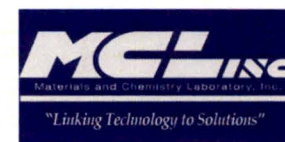
### Licensing and Environmental Permitting



## Technology Demonstration

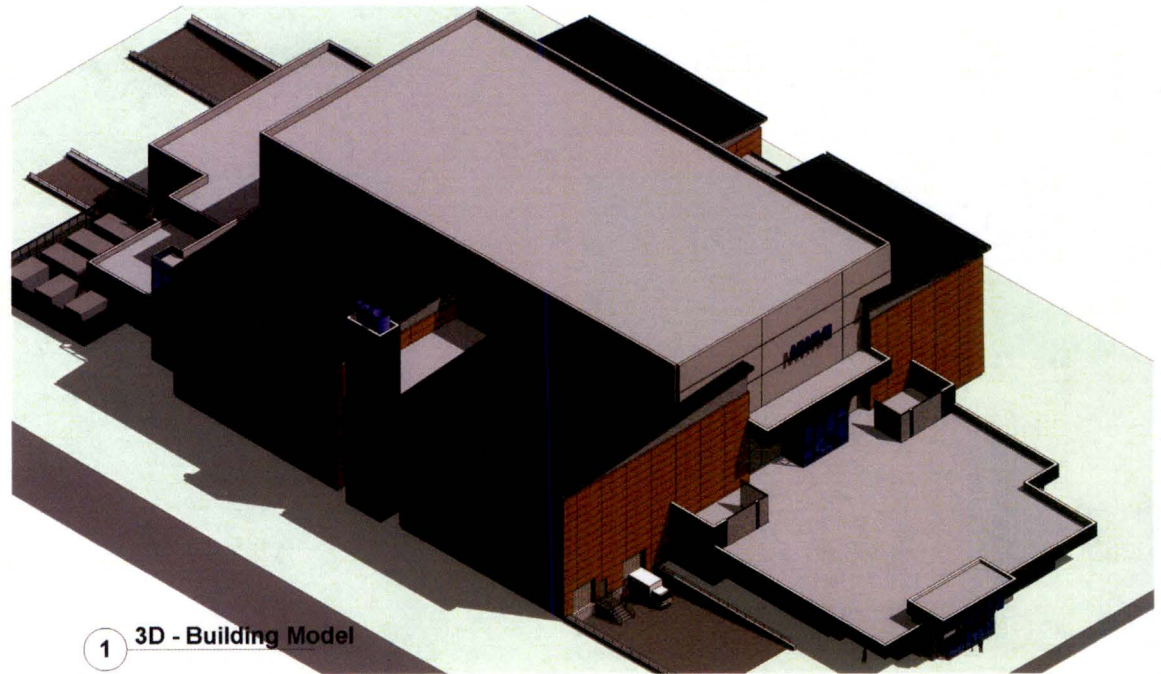


Narodowe Centrum Badań Jądrowych  
National Centre for Nuclear Research  
Świerk



# NWMI RPF Status

- Completed following activities
  - Site Selection – Discovery Ridge Research Park (Columbia, MO)
  - Radioisotope Production Facility (RPF) Preliminary Design and associated Integrated Design Report
  - Construction Permit Application submitted
- Activities through December 2016
  - Selection of general contractor
  - Completion of Final Design
  - Completion of Operating License Application
  - 20 curie (Ci) generator test
  - Irradiation of prototypical target
  - Column parameter optimization testing



1 3D - Building Model





# Licensing Strategy



# NRC Licensing Strategy

- Combine several license activities and submit one application that covers all applicable regulations for construction/operation of the RPF under 10 CFR 50

## 10 CFR 50 Activities

- Irradiated target receipt
- Irradiated target disassembly
- Target dissolution
- $^{99}\text{Mo}$  separations, purification, and packaging
- Uranium (U) recycle and recovery
- Waste management
- Associated laboratory and support

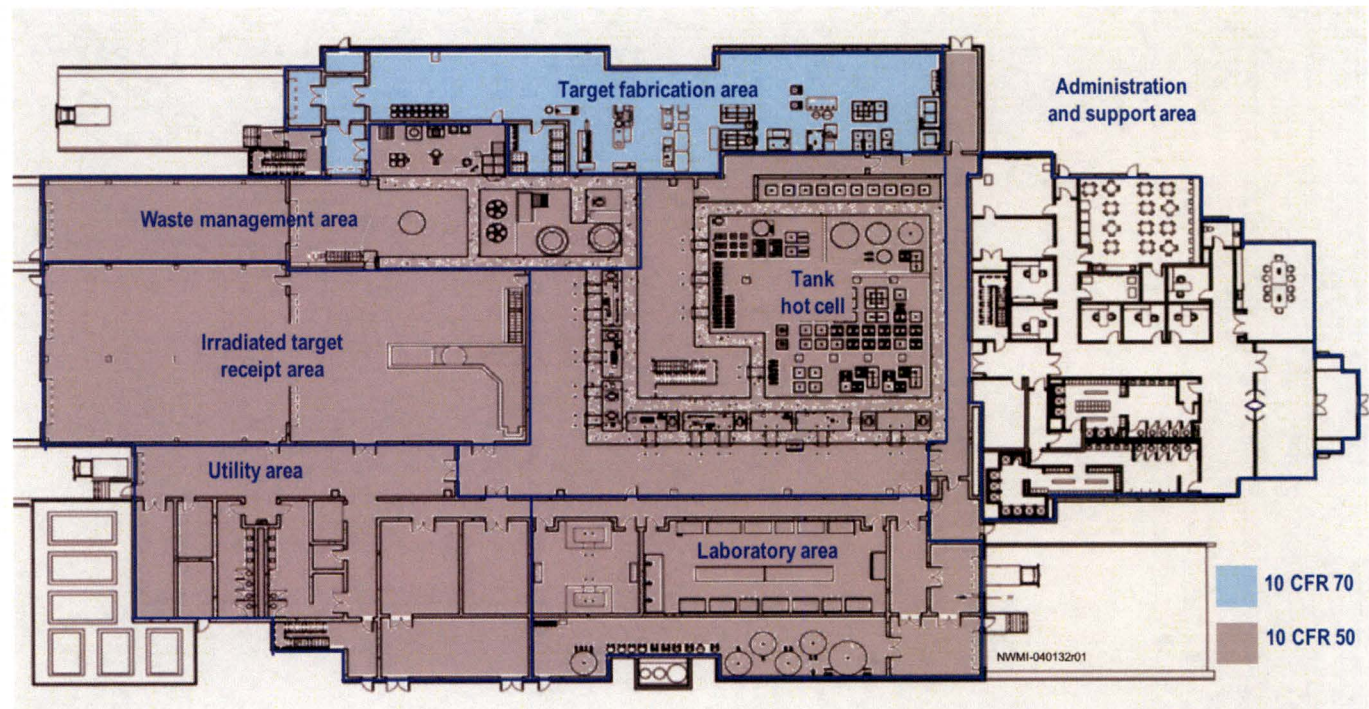
## 10 CFR 70 Activities

- Receipt of low-enriched uranium (LEU) (from DOE)
- Production of LEU microspheres
- Target fabrication and testing
- Shipping/loading of fabricated targets
- Laboratory and support areas

## 10 CFR 30 Activities

- Handling of byproduct material

- University reactor(s) and cask licensee(s) will amend their current operating licenses







# Integrated Safety Analysis

# Integrated Safety Analysis Methodology

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- Accident sequences were evaluated qualitatively to identify likelihood and severity using event frequencies and consequence categories consistent with regulatory guidelines
- Each event with an adverse consequence that involves licensed material or its byproducts has been evaluated for risk using a risk matrix that enables user(s) to identify unacceptable intermediate- and high-consequence risks
  - Items relied on for safety (IROFS) will be developed to prevent or mitigate consequences of events
  - Analysis will be used to demonstrate that risks can be reduced to acceptable frequencies through preventive or mitigative IROFS
- Event trees have been used in certain circumstances to:
  - Provide quantitative failure analysis data (failure frequencies)
  - Quantitatively analyze 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)
- Management measures are identified to ensure that the IROFS failure frequency used in analysis is preserved and IROFS are able to perform the intended function when needed



# Integrated Safety Analysis Methodology (continued)

## **Hazard Analysis**

- Categorize hazards
- Identify initiating events
- Identify preventive/mitigative IROFS, controls, and actions
- List worker hazards, and protective features and controls
- Assess defense-in-depth, worker safety, and environmental protection provisions
- Estimate event likelihood
- Assess qualitative consequences with and without mitigation

## **Evaluation of Results**

- Identify IROFS, technical specifications, and defense-in-depth and work safety items
- Identify environmental protection provisions
- Preliminary selection of accident scenarios (e.g., design basis accidents [DBAs])
- Unique accidents
- Representative accidents

## **Accident Analysis**

- Develop accident scenarios
- Quantify source term and consequence
- Identify analysis assumptions

## **Evaluation of Results**

- Compare to Evaluation Guidelines
- Identify IROFS and technical specifications based on Evaluation Guidelines

## **Describe Facility and IROFS**

- Finalize facility description
- Describe IROFS

## **Develop Technical Specifications**



# Likelihood Categories and Risk Matrix

- “Likelihood of an Occurrence” for each accident scenario will be based on following:
- Frequency of initiating events
  - Historic record of occurrence within similar systems
  - Expert engineering judgment
  - Assessment of number, type, independence, and observed failure history of designated IROFS

	Likelihood Category	Event Frequency Limit
Not Unlikely	3	More than $10^{-3}$ events per year
Unlikely	2	Between $10^{-3}$ and $10^{-5}$ events per year
Highly Unlikely	1	Less than $10^{-5}$ per events per year

➤ Risk Matrix

Severity of Consequences	Likelihood of Occurrence		
	Highly Unlikely (Likelihood Category 1)	Unlikely (Likelihood Category 2)	Not Unlikely (Likelihood Category 3)
High Consequence (Consequence Category 3)	Risk Index = 3 Acceptable Risk	Risk Index = 6 Unacceptable Risk	Risk Index = 9 Unacceptable Risk
Intermediate Consequence (Consequence Category 2)	Risk Index = 2 Acceptable Risk	Risk Index = 4 Acceptable Risk	Risk Index = 6 Unacceptable Risk
Low Consequence (Consequence Category 1)	Risk Index = 1 Acceptable Risk	Risk Index = 2 Acceptable Risk	Risk Index = 3 Acceptable Risk



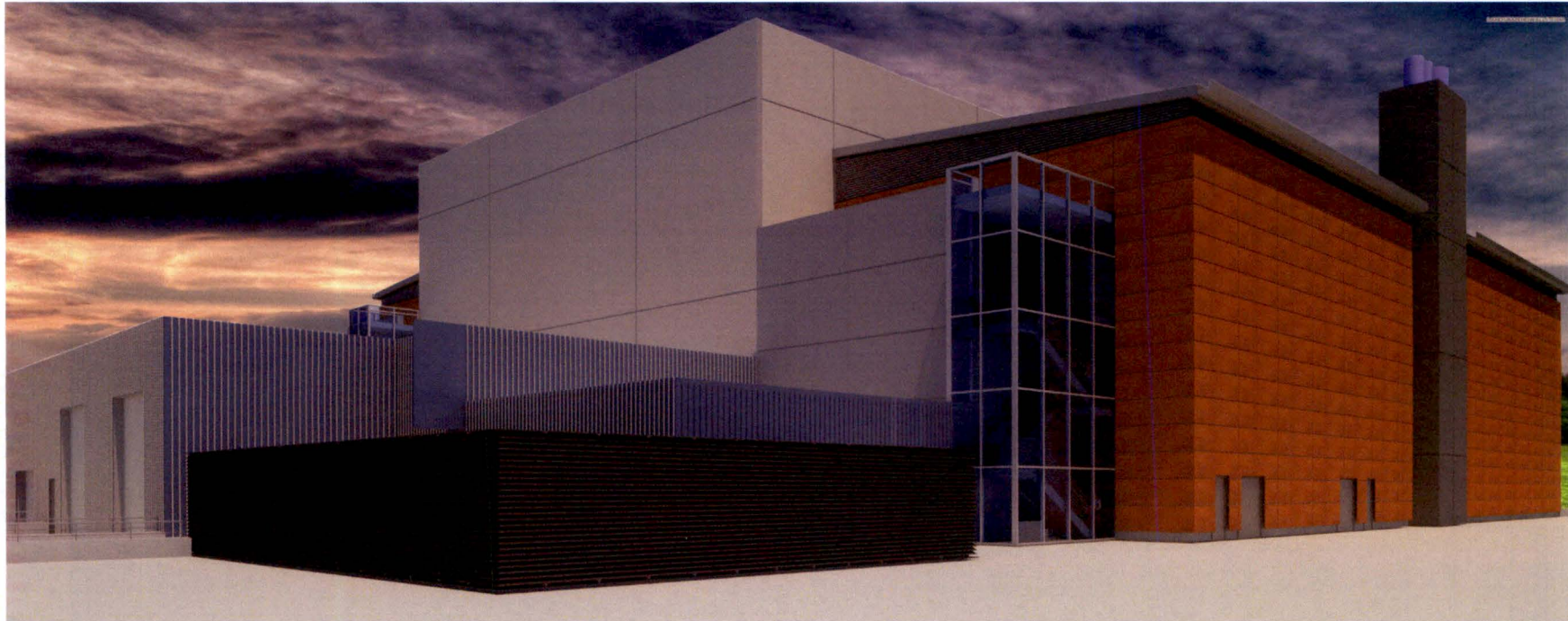
# Consequence Categories

Category Description	Consequence Category	Workers	Off-site Public	Environment
High Consequence	3	<ul style="list-style-type: none"> <li>• Radiological dose &gt; 1 sievert (Sv) (100 rem)</li> <li>• Airborne, radiologically contaminated nitric acid &gt;170 ppm nitric acid (AEGL-3, 10-min exposure limit)</li> <li>• Unshielded nuclear criticality</li> </ul>	<ul style="list-style-type: none"> <li>• Radiological dose &gt; 0.25 Sv (25 rem)</li> <li>• Toxic intake &gt; 30 milligrams (mg) soluble U</li> <li>• Airborne, contaminated nitric acid &gt; 24 ppm nitric acid (AEGL-2, 60-min exposure limit)</li> </ul>	
Intermediate Consequence	2	<ul style="list-style-type: none"> <li>• Radiological dose between 0.25 Sv (25 rem) and 1 Sv (100 rem)</li> <li>• Airborne, radiologically contaminated nitric acid &gt; 43 ppm nitric acid (AEGL-2, 10-min exposure limit)</li> </ul>	<ul style="list-style-type: none"> <li>• Radiological dose between 0.05 Sv (5 rem) and 0.25 Sv (25 rem)</li> <li>• Airborne, contaminated nitric acid &gt; 0.16 ppm nitric acid (AEGL-1, 60-min exposure limit)</li> </ul>	<ul style="list-style-type: none"> <li>• 24-hour radioactive release &gt; 5,000 x Table 2 of 10 CFR 20, Appendix B</li> </ul>
Low Consequence	1	<ul style="list-style-type: none"> <li>• Accidents with lower radiological, chemical, and/or toxicological exposures than those above from licensed material and byproducts of licensed material</li> </ul>	<ul style="list-style-type: none"> <li>• Accidents with lower radiological, chemical, and/or toxicological exposures than those above from licensed material and byproducts of licensed material</li> </ul>	<ul style="list-style-type: none"> <li>• Radiological releases producing lower effects than those listed above from licensed material</li> </ul>



# Hazard and Accident Analysis Summary

- Preliminary Hazard Analysis (PHA) results
- Maximum hypothetical accident
- Qualitative risk assessments (QRA)
- Criticality safety evaluations (CSE)
- IROFS and defense in depth





# Preliminary Hazard Analysis Summary

- Completed PHA on eight “systems”; 107 nodes evaluated
- PHA tables – 290 pages
- ~140 accident sequences identified for additional evaluation
- 75 accident sequences evaluated in QRAs

## RPF PHA Accident Sequence Category Designator Definitions

PHA Top-Level Accident Sequence Category	Definition
S.C.	Criticality
S.F.	Fire/Explosion
S.R.	Radiological
S.M.	Man-Made
S.N.	Natural Phenomena
S.CS.	Chemical Safety

# Preliminary Hazard Analysis Results (continued)

Crosswalk of NUREG-1537 Part 1 ISG Accident Initiating Events versus  
RPF PHA Top-Level Accident Sequence Categories

NUREG-1537 Part 1 ISG Accident Initiating Event Category	PHA Top-Level Accident Sequence Category					
	S.C.	S.F.	S.R.	S.M.	S.N.	S.CS.
Criticality accident	✓	✓			✓	
Loss of electrical power			✓		✓	
External events (meteorological, seismic, fire, flood)	✓	✓		✓	✓	✓
Critical equipment malfunction	✓	✓	✓	✓		✓
Operator error	✓		✓	✓		✓
Facility fire (explosion included in this category)		✓	✓			
Any other event potentially related to unique facility operations	✓		✓	✓		



# Qualitative Risk Assessments

- Eight QRAs completed, covering 75 accidents; 1 QRA addressing chemical accidents

Qualitative Risk Assessment Documents	Document Number
Radioisotope Production Facility Preliminary Hazards Analysis	NWMI-2015-SAFETY-001
Radioisotope Production Facility Integrated Safety Analysis Summary	NWMI-2015-SAFETY-002
Chemical Safety Process Upsets	NWMI-2015-SAFETY-003
Process Upsets Associated with Passive Engineering Controls Leading to Accidental Criticality Accident Sequences	NWMI-2015-SAFETY-004
Criticality Accident Sequences that Involve Uranium Entering a System Not Intended for Uranium Service	NWMI-2015-SAFETY-005
Criticality Accident Sequences that Involve High Uranium Content in Side Waste Stream	NWMI-2015-SAFETY-006
Facility Fires and Explosions Leading to Uncontrolled Release of Fissile Material, High- and Low-Dose Radionuclides	NWMI-2015-SAFETY-007
Radiological Accident Sequences in Confinement Boundaries (including Ventilation Systems)	NWMI-2015-SAFETY-008
Administratively Controlled Enrichment, Mass, Container Volume, and Interaction Limit Process Upsets Leading to Accidental Criticality Accident Sequences	NWMI-2015-SAFETY-009
Receipt and Shipping Events	NWMI-2015-SAFETY-010
Natural Phenomenon and Man-Made Events on Safety Features and Items Relied on for Safety	NWMI-2015-SAFETY-011

- Organization for each sequence

- Description of accident
- Projected consequences
- Initiators for the accident
- Unmitigated likelihood
- Defense in depth
- IROFS to prevent or mitigate
- Mitigated likelihood



# Maximum Hypothetical Accident

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- Maximum hypothetical accident (MHA) is used to bound consequence values for all credible potential accidents
  - MHA is a “non-credible/unmitigated accident” to provide bounding consequence values for all credible potential accidents at the RPF
  - MHA and ISA will serve to satisfy accident analysis requirements of 10 CFR 50.34(a)
- Scenario:
  - Release of all accumulated fission product gases in the dissolver offgas system
  - Dissolution of targets just completed 8 hours end of irradiation
  - Release of radioactive material directly to environment through ventilation system without any safety barrier
- Preliminary model run used Radiological Safety Analysis Computer (RSAC) modeling software
- Intermediate risk, MHA below high consequence category (<25 rem) to the public
- Scoping dose calculations (public) also performed for in-cell spray leak accidents



# IROFS and Defense in Depth

- Shielding
  - Hot cell and waste management walls
  - Cover block
  - Leaded windows
  - Shield doors/plugs
  - Vehicle barriers
  - Cask docking port sensor
- Liquid confinement
  - Hot cell liners
  - Overflow drain/seal pots
  - Double-wall piping
  - Hot cell penetration requirements
- Gaseous confinement
  - Zone 1 exhaust system (e.g., high-efficiency particulate air [HEPA] filters, ducting/flow path, dampers, and stack)
  - Process ventilation iodine removal unit
  - Dissolution system pressure relief tank
- Secondary heating and cooling loops
  - Monitoring and alarm
- High dose liquid out of hot cell
  - Backflow protections
  - Sampling and monitoring on transfers
- Flammable gases
  - Process vessel purge system
  - Steam boiler room blow out panels
  - Reduction furnace hydrogen reduction
- Chemical
  - Defense-in-depth controls only

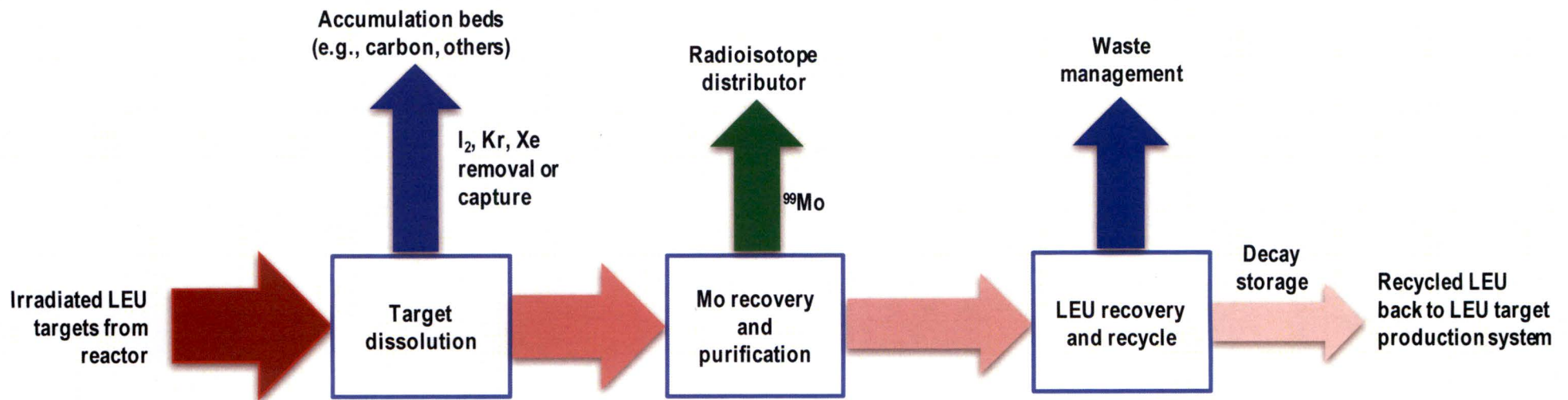


## **Chemical/Process Safety**



# Primary Assumptions

- Single Radioisotope Production Facility
  - $^{99}\text{Mo}$  produced using a fission-based method – “Gold Standard”
  - Nominal capacity 3,500 6-day Ci; surge capacity of 1,500 6-day Ci
  - Use LEU
  - Recover  $^{99}\text{Mo}$  from LEU targets using standard chemical processes
- Use network of university reactors
  - Use same target design for all reactors
- Recycle processed LEU for reuse as target material
- Fission product releases will comply with environmental release criteria
- Generate Class A, B, and C wastes; no greater than Class C (GTCC) waste
- Uranium processing and storage will meet all required safeguards and security requirements





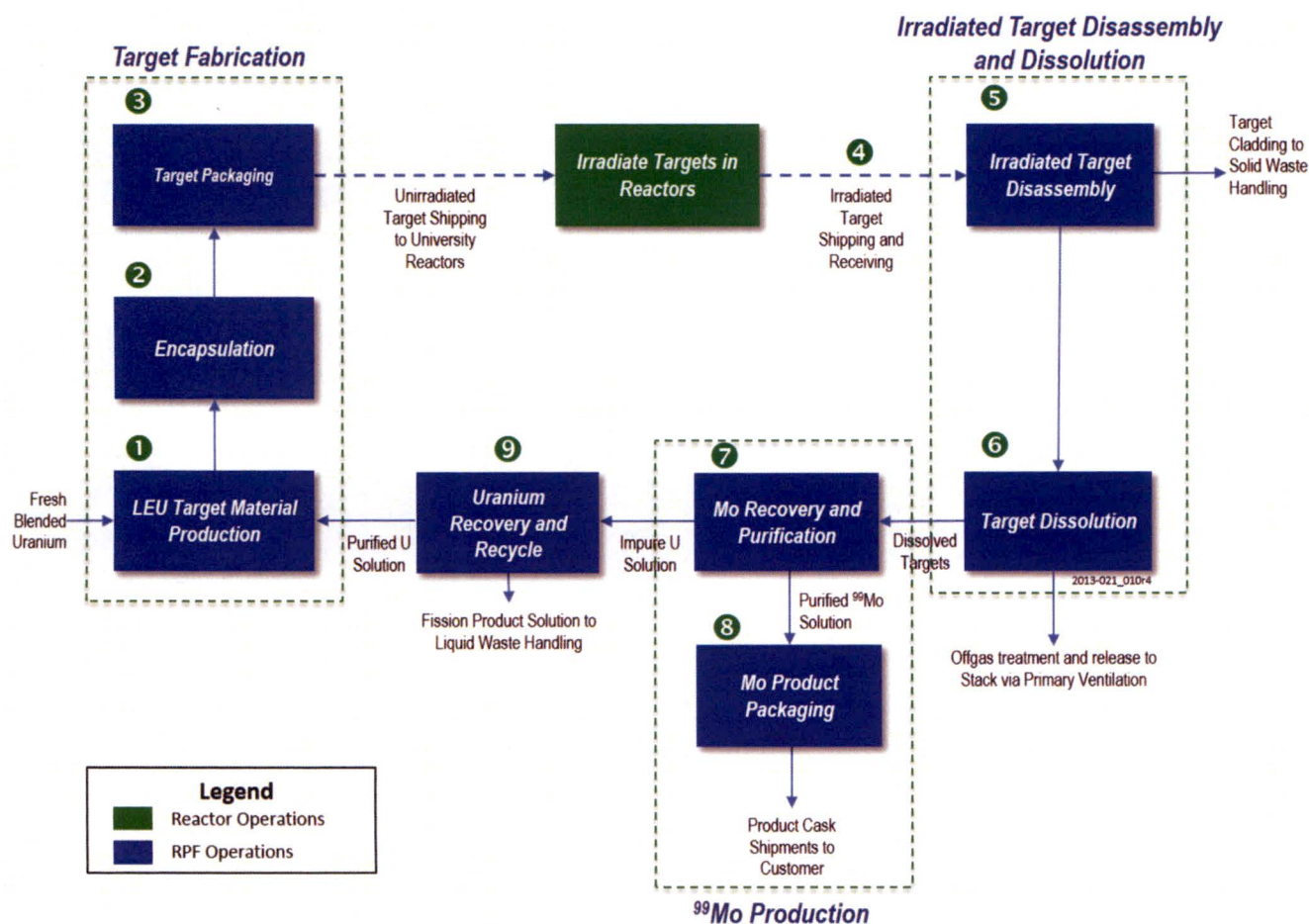
# Facility Description

- First level footprint ~52,000 ft<sup>2</sup>
  - Target fabrication area
  - Hot cell processing area (dissolution, <sup>99</sup>Mo, and <sup>235</sup>U recovery)
  - Waste management, laboratory and utility areas
- Basement ~2,000 ft<sup>2</sup> (tank hot cell, decay vault)
- Second level ~17,000 ft<sup>2</sup> (utility, ventilation, offgas equipment)
- Waste Management Building ~1,200 ft<sup>2</sup>
- Administration Building (outside of secured RPF area) ~10,000 ft<sup>2</sup>
- 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



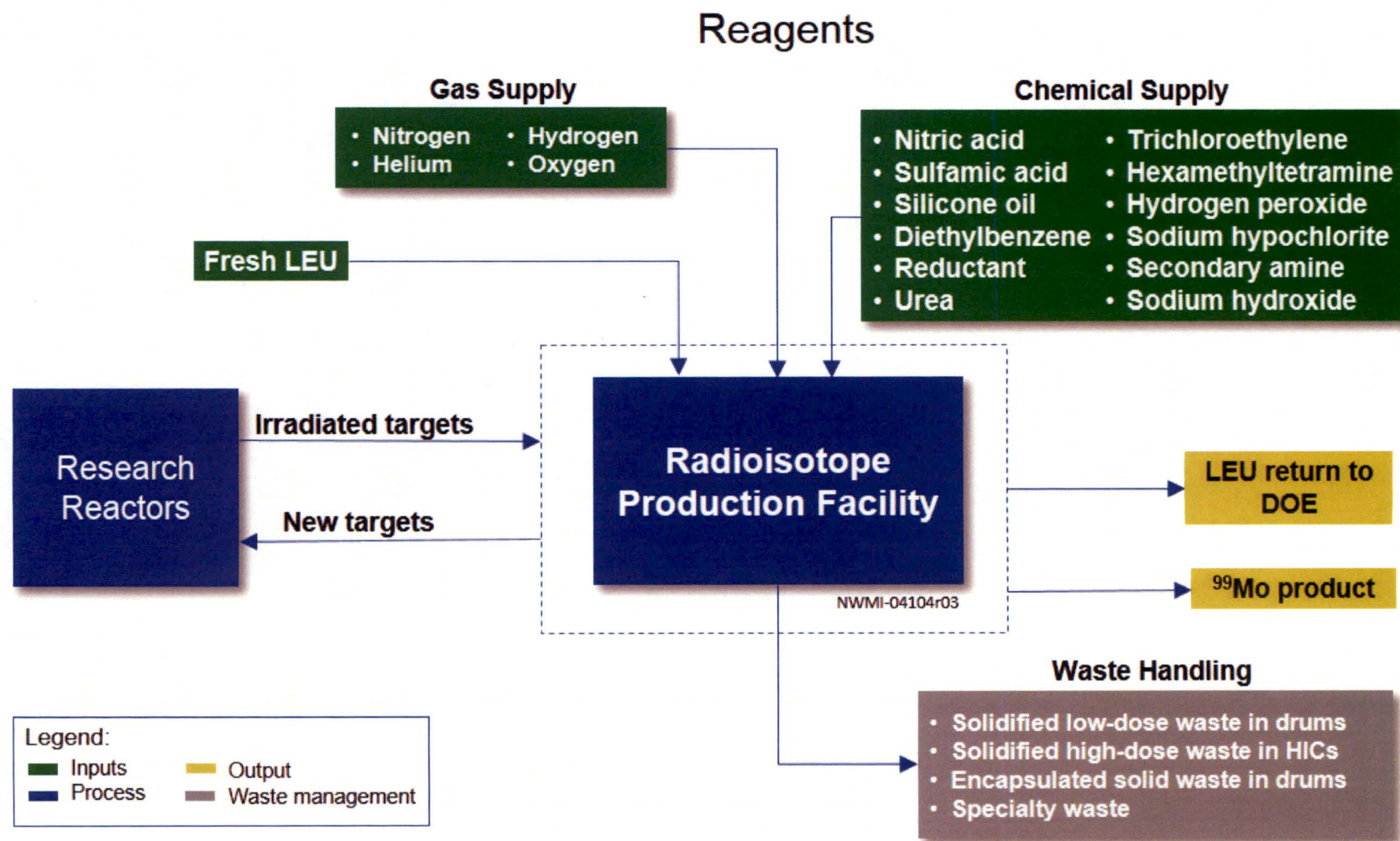


# RPF Process Flow Diagram



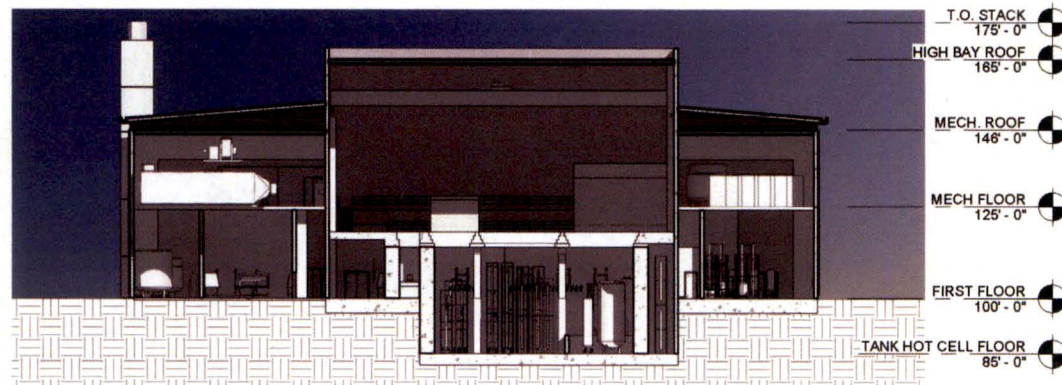
- 1 LEU target material is fabricated (both fresh LEU and recycled U)
- 2 LEU target material encapsulated using metal cladding → LEU target
- 3 LEU targets are packaged and shipped to university reactors for irradiation
- 4 After irradiation, targets are shipped back to RPF
- 5 Irradiated LEU targets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

# Reagent, Product, and Waste Summary Flow Diagram

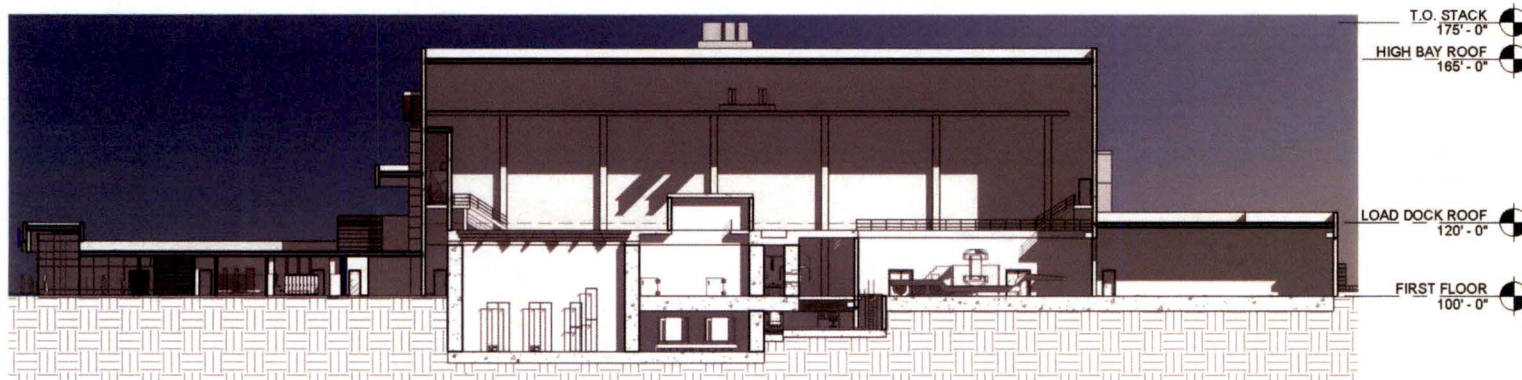




# Facility Cross-Sections



1 Building Section



2 Building Section



# Criticality Control Program Methodology



# Criticality Overview

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- RPF presents a number of differing challenges to nuclear criticality safety
- Used “first principles” and guides as bases for conceptual equipment design and process area layouts
  - Geometry constraints (e.g., pencil tank diameters)
  - Tank array spacing (conservative)
  - Consideration of transition from “safe-geometry” process equipment to less-restricted waste staging and processing equipment
- Evaluations and analysis
  - Monte Carlo N-Particle (MCNP) code validation and upper subcritical limits for all areas of applicability
  - Develop project-specific single-parameter criticality limits for U enrichment, forms, and basic geometries
  - Completed six calculation analyses
  - Completed 13 CSEs



# **Radiological Safety**



# Radiation Protection Methodology

- Designed to meet requirements of 10 CFR 20
- Follows historical standard ANSI/ANS 15.11, *Radiation Protection at Research Reactor Facilities*
- Procedures and engineering controls will be used to extent practicable to achieve occupational doses and doses to members of the public that are ALARA
- Radiation Protection autonomous/independent from Operations
- Radiation monitoring will be conducted to:
  - Determine radiation levels and concentrations of radioactive materials, and identify radiological hazards that could be present in the RPF
  - Detect releases or radioactive materials from RPF operations and equipment
- Radiation surveys will focus on areas of RPF where occupational radiation dose limits could potentially be exceeded
- Measurements of airborne radioactive materials and/or bioassays will be used to determine that occupational exposures to radiation do not exceed the dose limits specified in 10 CFR 20

ALARA program objective is to make every reasonable effort to maintain exposure to radiation as far below dose limits of 10 CFR 20.1201 and 10 CFR 20.1301 as possible

Worker ALARA goal: Total Effective Dose Equivalent → 1 rem/year

General public (requirement): Total Effective Dose Equivalent → <100 mrem/year



# Radiation Exposure Control and Dosimetry

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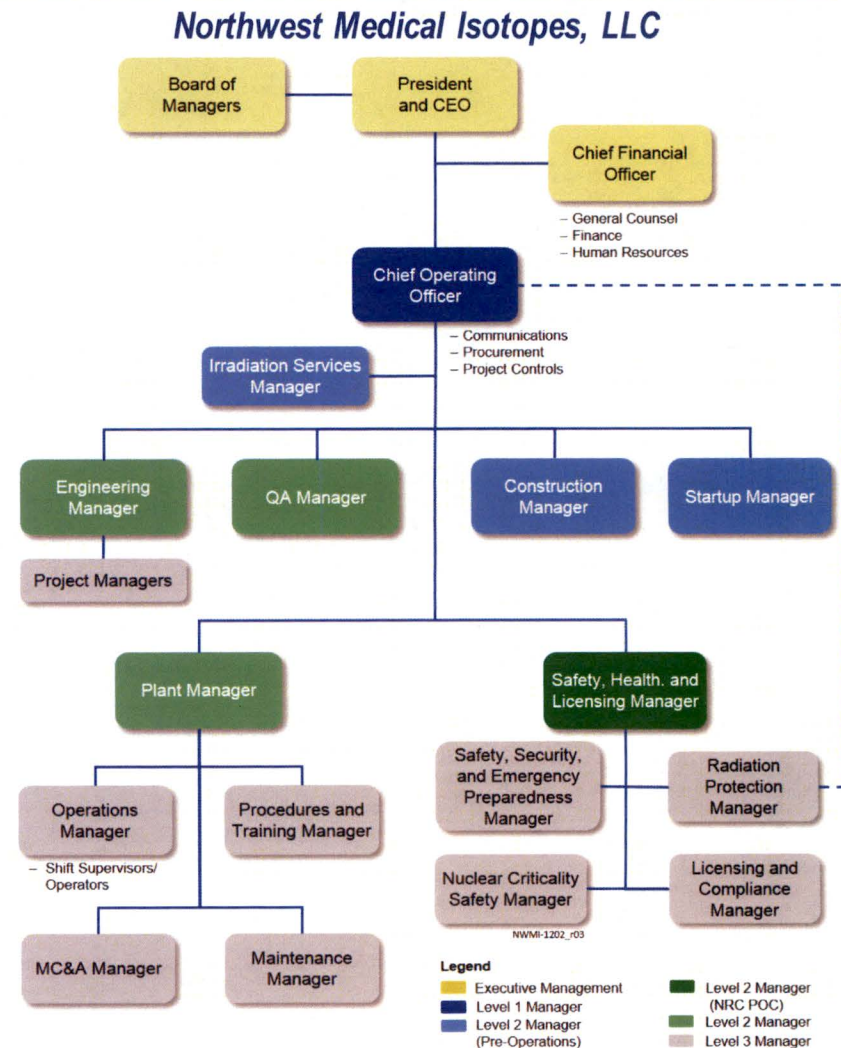
- Radiological areas are established to control spread of contamination, control personnel access to avoid unnecessary exposure of personnel to radiation, and control access to radioactive sources present in the RPF
  - Unrestricted
  - Controlled
  - Restricted
- Personnel monitoring
  - Friskers
  - Hand and foot monitors
  - Portal monitors
  - Personal dosimetry (e.g., thermoluminescent dosimeters [TLD])
  - Bioassay, as necessary
- Radiation surveys
  - Ascertain radiation levels, concentrations of radioactive materials and potential radiological hazards that could be present in facility
  - Detect releases of radioactive material from facility equipment and operations
- Environmental monitoring
  - Effluent release pathways (e.g., direct radiation, airborne)
  - Community Environmental Monitoring Program (e.g., groundwater, soil, surface water, vegetation)
  - Preoperational baseline monitoring



# Radiation Protection Program Organization

NWMI management is committed to the ALARA philosophy for radiological operations. Our policy is to conduct radiological operations in a manner that ensures health and safety of our employees, contractors, coworkers, and general public.

- **Chief Operating Officer** – Overall responsibility for the RPF operations, including radiation protection
- **Plant Manager** – Direct responsibility for RPF safe operations (e.g., protection of all persons from radiation exposure)
- **Environmental, Health, and Safety Manager** – Responsible for development and implementation of the radiation protection program
- **Radiation Protection Manager** – Responsible for matters involving radiological protection, with direct access to Chief Operating Officer
- **Operations Manager** – Responsible for operating RPF safely and in accordance with procedures so that exposures to public, effluents released to the environment, and on-site personnel meet limits specified in applicable regulations, procedures, and guidance documents are met







## Fire Safety



# Fire Hazards Analysis Strategy

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- Demonstrates that the RPF will maintain ability to perform safe-shutdown functions
- Minimizes radioactive material releases to environment in the event of a fire
- Ensures prescriptive fire protection requirements have been applied and are sufficient
  - Minimize potential for occurrence of a fire or related perils
  - Establish and define requirements that will provide an acceptable degree of fire safety and life safety to NWMI personnel, contractor personnel, and public from fire
  - Ensure that fire does not cause an unacceptable on-site or off-site release of hazardous material that will affect public health and safety or the environment
  - Ensure that property damage from fire and related hazards is minimized
- Developed in a stepwise manner
  - Potential in situ and transient fire and explosion hazards
  - Consequences of fire and explosion in any location within the RPF project boundary to minimize and control the release of radioactivity to the environment
  - Measures for fire prevention, detection, suppression, and containment for each fire area containing structures, systems and components (SSC) important to safety
  - Document known deviations and associated approved evaluations, waivers, and equivalences



# Fire Protection System

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- Fire protection (FP) system
  - Designed to provide varying levels of notification of a fire event, suppress small fires, and prevent small fires from becoming large fires
  - Provides detection and suppression of fires within RPF
  - Generation of alarm signals indicating presence and location of fires, and execution of commands appropriate for particular fire location
  - Components have fail-safe features and audible/visual alarms for operability and trouble indication self-contained in that source of protection is water stored in two firewater tanks (TBD)
  - FP system capacity will be ~150,000 to 200,000 gal (TBD in final PHA)
- Fire alarm system (FAS) will be designed with both automatic and manual initiation throughout the RPF
- All alarms (fire, supervisory, and trouble) are transmitted to site FAS and RPF control room
- Redundant on-site dedicated firewater tanks and pumps are provided for water supply
  - Additional makeup water is supplied from the exterior fire hydrant supply via connections to domestic water system
- Firewater booster pumps boost system pressure in fire suppression subsystem piping
- FP system not considered an IROFS but is important to safety



# Fire Protection System

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The RPF fire protection system consists of two subsystems:

## ***Fire Suppression Subsystem***

- Building automatic sprinklers
- HEPA filter plenum deluge (both manual and automatic)
- Fire extinguishers
- Firewater storage and pressure (e.g., firewater tank, fire pumps, water supply piping)
- Fire hydrants
- Inerted gloveboxes/hot cells
- Glovebox/hot cell fire suppression systems

## ***Fire Detection and Alarm Subsystem***

- Controls (e.g., fire alarm control panel, subpanels, devices used for control of devices)
- General area detection (e.g., room smoke and heat detectors, manual pull stations)
- Duct smoke detection for non-nuclear ventilation systems per NFPA 90A
- Glovebox/hot cell heat detection
- HEPA filter plenum heat detection
- Fire suppression subsystem monitoring devices (e.g., water flow switches, tamper switches, fire pump and water storage monitoring devices)
- Occupant notification
- Alarm transmission to central alarm station and control room

# Transportation Timing Basis





# Transportation

- Two high-priority transportation activities can affect 6-day  $\text{Ci}$  delivered
  - Irradiated target to RPF
    - Miles by ground transportation - irradiated targets

*RPF Location: Discovery Ridge/MURR*

Irradiated Target Location	Distance (Time)
Corvallis, OR	2,000 mi (40 hr)
Columbia, MO	6 (30 minutes)

- $^{99}\text{Mo}$  product to distributor
  - Air travel from Discovery Ridge/MURR is ~2 to 4 hours to distributor in Boston, MA;  
no air travel to distributor in St. Louis, MO



## Quality Assurance



# Quality Assurance Program

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- NWMI Quality Assurance Program Plan (QAPP) is based on:
  - Title 10, *Code of Federal Regulations*, Part 50.34 (10 CFR 50.34), “Contents of Applications; Technical Information,” and associated 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”
  - ISO-9001, *Quality Assurance Requirements*
- QAPP will apply to all nuclear, quality-related projects and activities (e.g., design, construction, and operations) that require conformance to a QA Program
- QAPP will be standard for all NWMI personnel to follow for compliance to those requirements
- QA will be autonomous from RPF design, construction, and operations
- QA shall be implemented to following activities:
  - Design
  - Quality-affecting procurement
  - Fabrication
  - Waste treatment
  - Facility and site operations
  - Equipment manufacturing
  - Technical support/consulting
  - Audit, inspection, and surveillance
  - Testing
  - Handling, storage, shipping, and receiving
  - Repairs, modifications, decommissioning, and site remediation

# Quality Assurance Program

*QAPP will be developed to provide safety and reliability during RPF design, construction, and operation activities*

- QA Program will apply to material processing safety, criticality safety, engineered safety features, and applicable radiation monitoring systems
- QA Program will apply a graded approach to items and activities that could affect quality of safety-related SSCs and other components not specifically designated as safety-related
  - Graded approach
    - Process where level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with safety significance
    - Permits implementing organization to focus resources on activities that are deemed, by qualitative analysis, to reduce associated risks and hazards
- Quality level matrix will be used to ensure that quality requirements are understood and specified for each SSC
- Applicable activities will be performed in accordance with a graded approach until a determination is made that the SSC has changed to another quality level



# Quality Assurance Program Plan

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- Ensures that reliability and performance of products and services are maximized through application of effective and prudent business management practices commensurate with risk to workers and the public
- Will be developed and implemented for design, construction, and operation of the RPF
- Will focus on development of appropriate controls to ensure that the RPF is properly designed and constructed and equipment fabricated to the identified design requirements
- Will impose additional requirements during operations phase related to the conduct of operations
- Requires assessments to be planned and performed by qualified assessors, independent contractors, or consultants as determined by the Quality Manager
- Establishes and maintains formal and informal training programs for personnel performing, verifying, or managing activities within the scope of the QAPP to ensure that suitable proficiency is achieved and maintained
- Identifies subcontractor responsibilities:
  - Delegated responsibilities may be performed under a supplier's QA program, provided that supplier is approved in accordance with the QAPP
  - Periodic assessments of supplier QA programs will be performed to ensure compliance with this QAPP and implementing procedures
  - Routine interfaces with supplier personnel provide added assurance that quality expectations will be met



# Procurement of Items and Services

- Controls will be established to ensure that purchased materials or services conform to the procurement documents
- Controls will include, as appropriate, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, periodic source inspection or audit, and examination of the item or service on delivery or completion
- Procurement planning will consider function and complexity of item or service to be procured and will require sufficient advance notice for evaluation and selection of suppliers
- Procurement of QA Level 1 (QL-1) and QA Level 2 (QL-2) items and services will be controlled through procedures to ensure conformance with specified requirements. These controls will provide for the following, as appropriate:
  - Source evaluation and selection
  - Evaluation of objective evidence of quality furnished by the supplier
  - Examination of items or services on delivery or completion
  - Source inspection
  - Audit

## Quality Levels

QL-1: Implement full measure of QA program description and be applied to safety-related SSCs

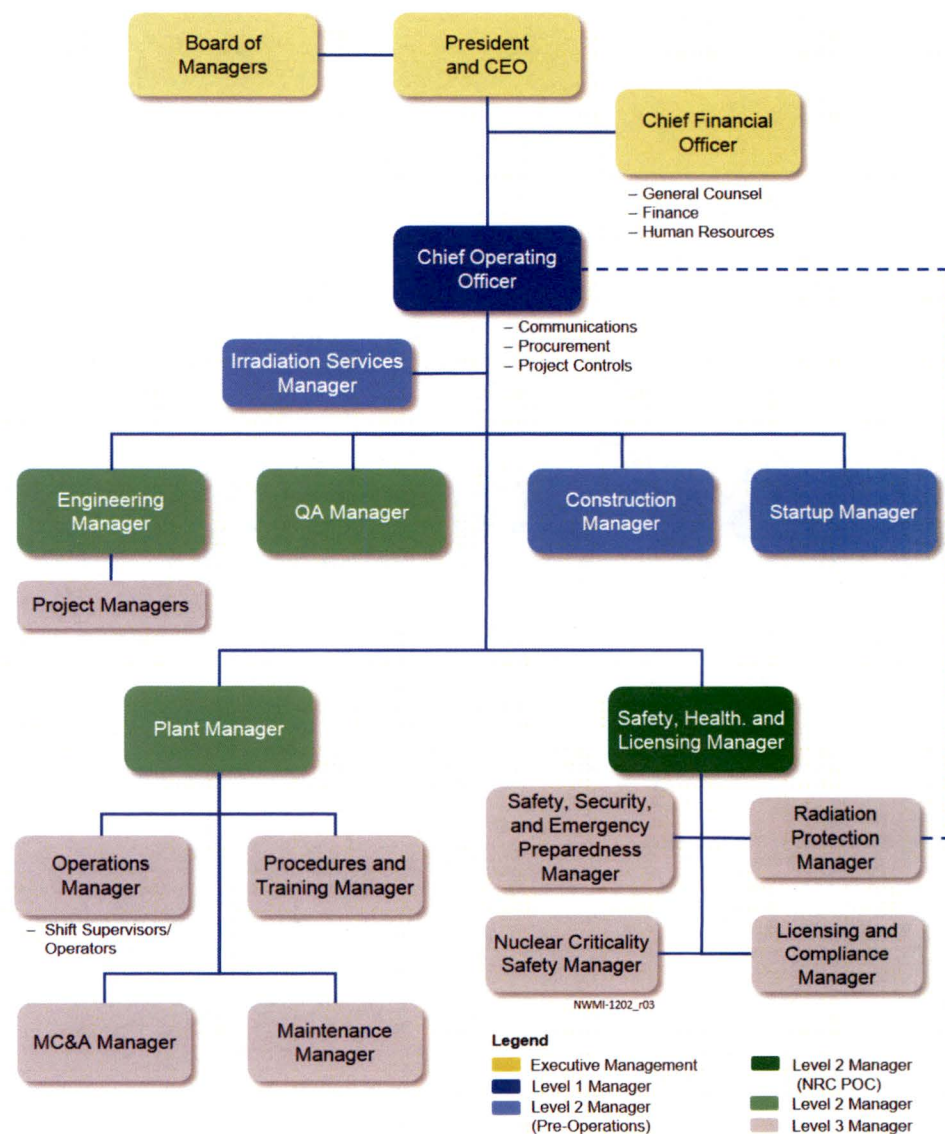
QL-2: Includes quality activities generally on a continuing basis that are applied to ensure that items are available and reliable to perform associated safety functions

QL-3: Non-safety-related quality activities that are deemed necessary to ensure manufacture and delivery of highly reliable products and services to meet customer expectations and requirements

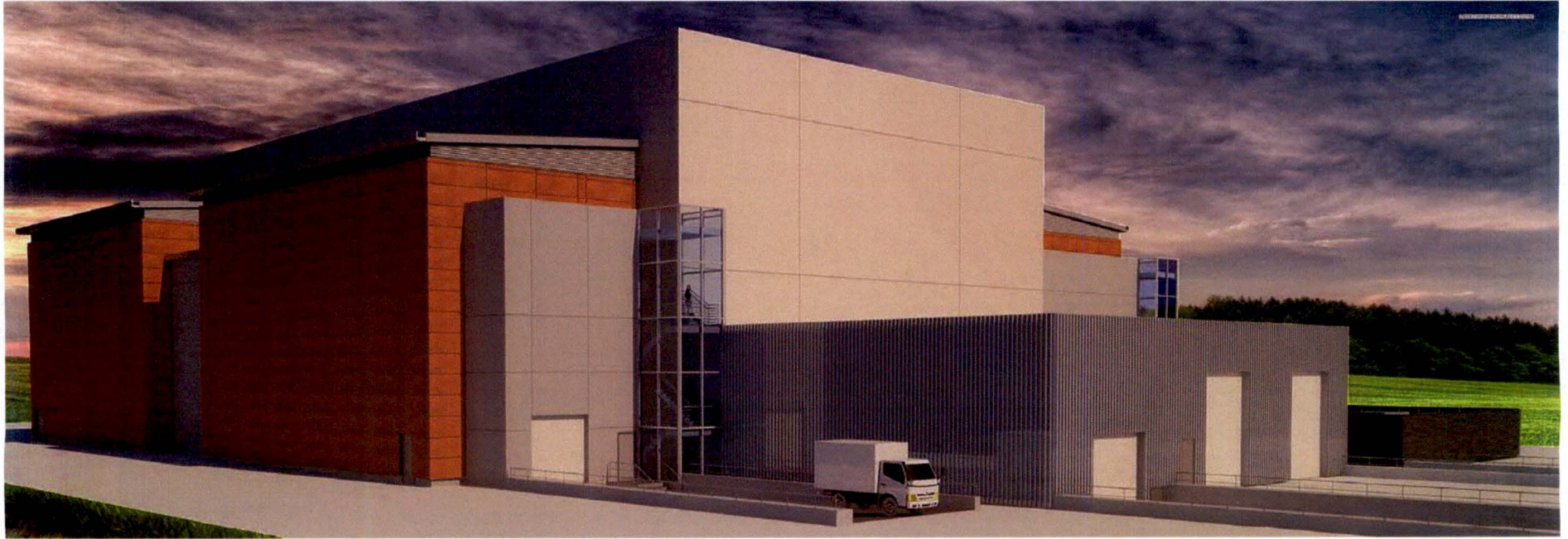


# QA Organization

- Designed to ensure that quality work is safely and cost-effectively performed, and meets or exceeds customer expectations and requirements
- President and senior management responsible for establishing overall expectations for effective implementation of the QAPP and obtaining the desired end result
- QA Manager reports directly to the COO
- Quality Manager with support from all NWMI employees will delineate, manage, and maintain QA procedures
- All employees are individually responsible for achieving and maintaining quality of products and services provided to customers within their respective areas of responsibility
- All employees have authority to stop work







## **Public Questions & Answer Period**