

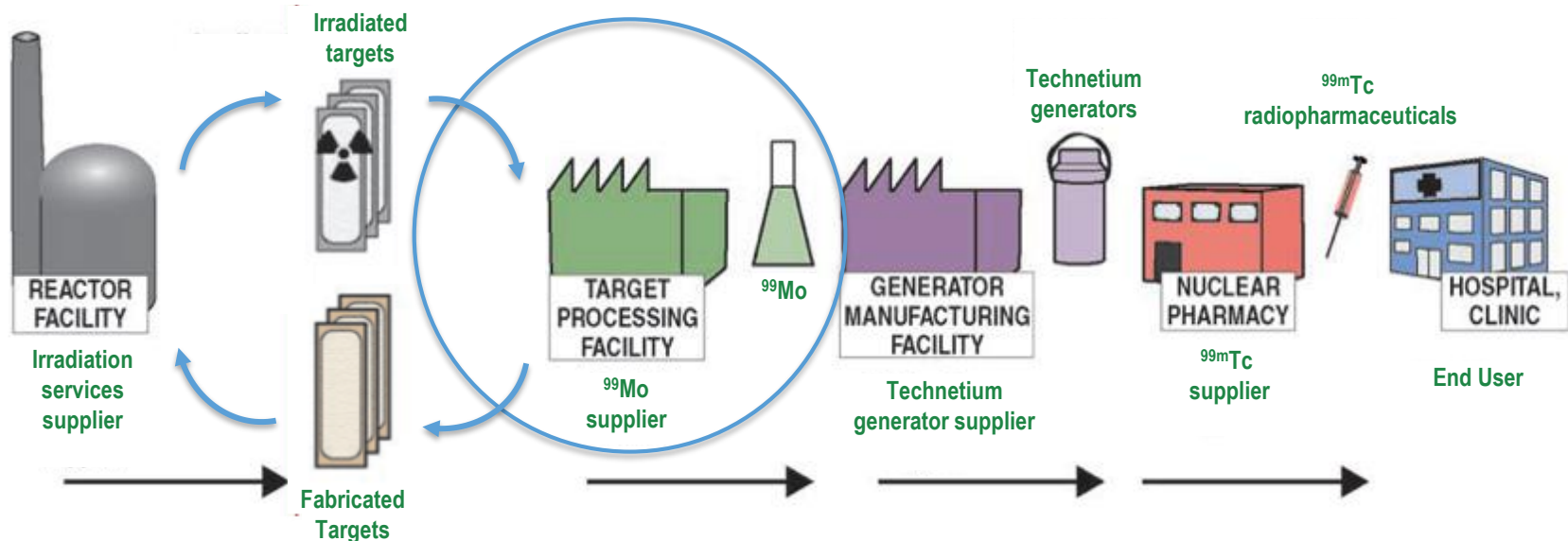
# U.S. Nuclear Regulatory Commission Commission Mandatory Meeting



## Northwest Medical Isotopes, LLC Radioisotope Production Facility Overview January 23, 2018

# NWMI Mission

Assure a Domestic, Secure, and Reliable Supply of Molybdenum-99 (<sup>99</sup>Mo)



- Captive Network of University Research Reactors
  - Reliability/assurance of supply
  - Multiple shipments/week

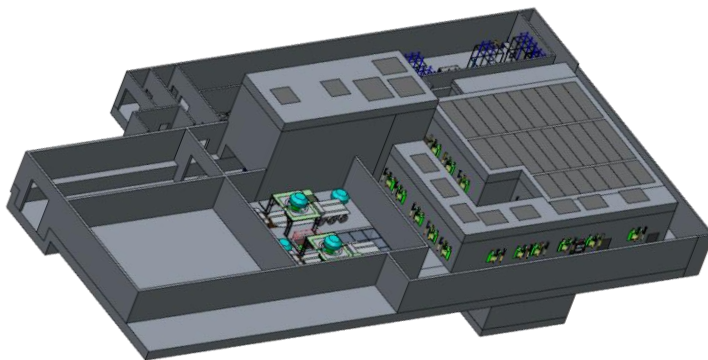
- Radioisotope Production Facility (RPF)
  - Fabrication of LEU targets
  - <sup>99</sup>Mo production
  - Uranium recycle and recovery

- Domestic <sup>99</sup>Mo Generator Distributors
  - Hold FDA Drug Master File
  - No changes to generators
  - No changes to supply chain



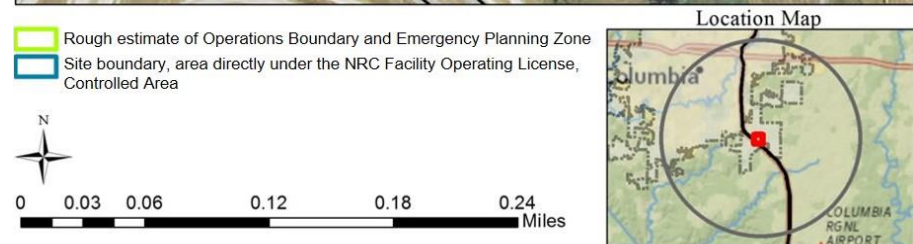
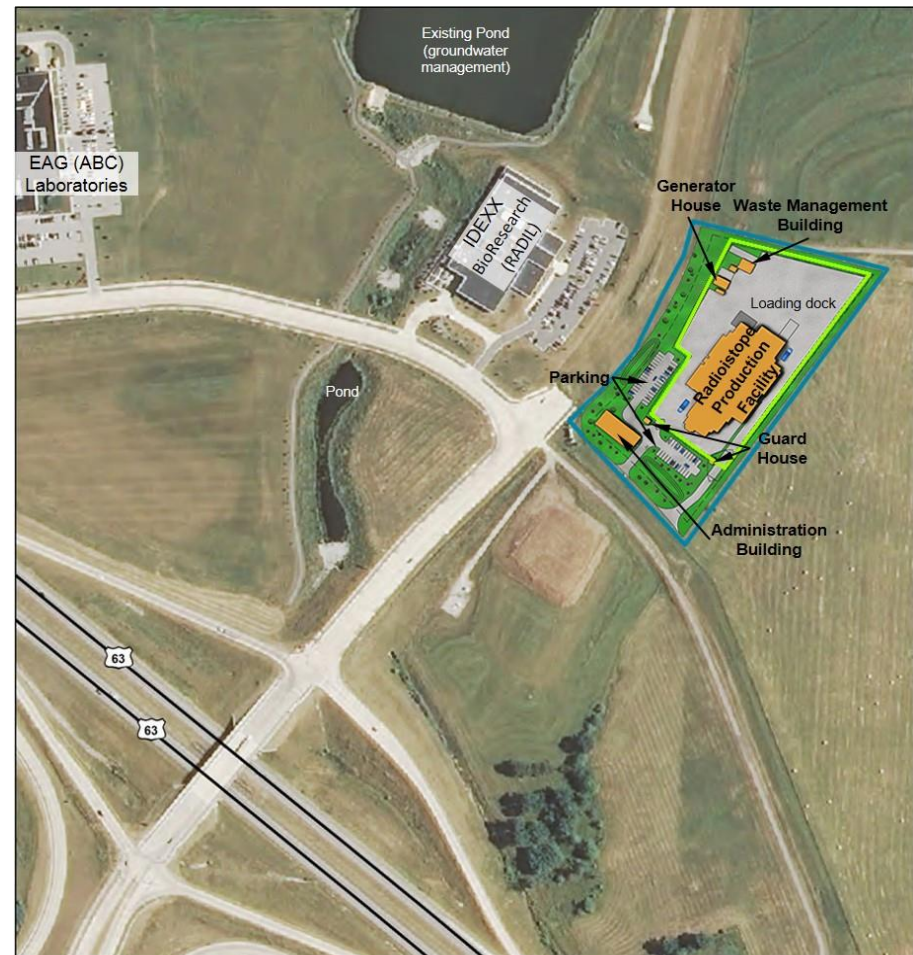
# Primary Assumptions

- Single radioisotope production facility → RPF
  - RPF includes target fabrication,  $^{99}\text{Mo}$  production, and uranium recycle and recovery
  - $^{99}\text{Mo}$  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
- 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

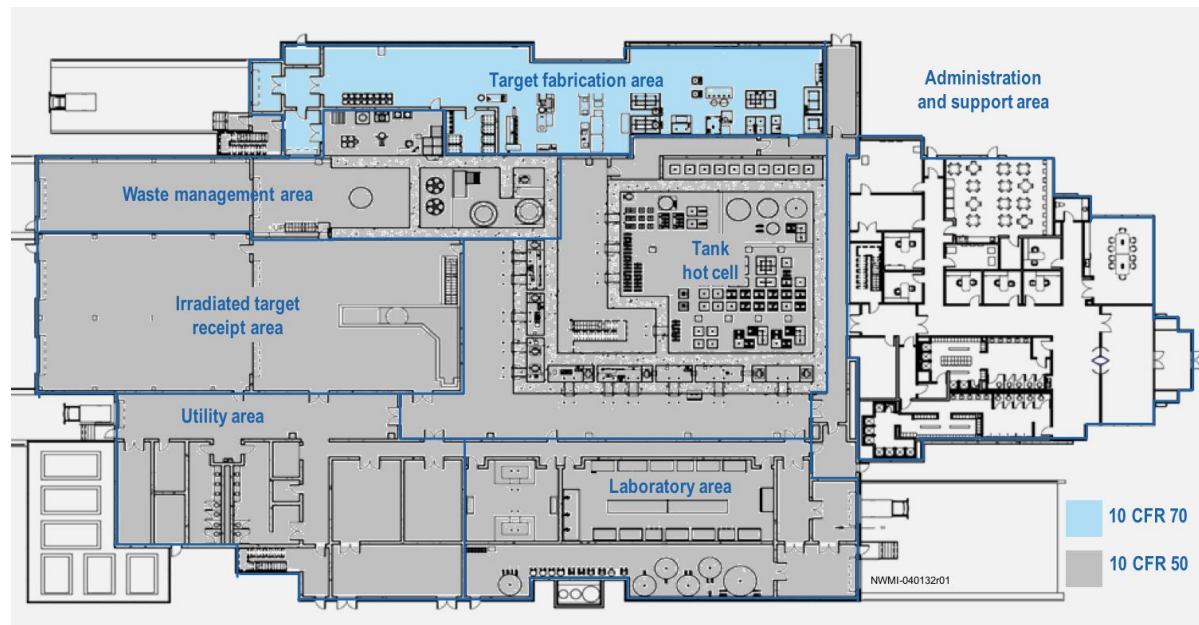


# Licensing Approach

- **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  $^{99}\text{Mo}$  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  $^{99}\text{Mo}$
  - 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 <sup>99</sup>Mo for medical applications
    - Handling of byproduct material
- University reactor(s) and cask licensee(s) will amend their current operating licenses

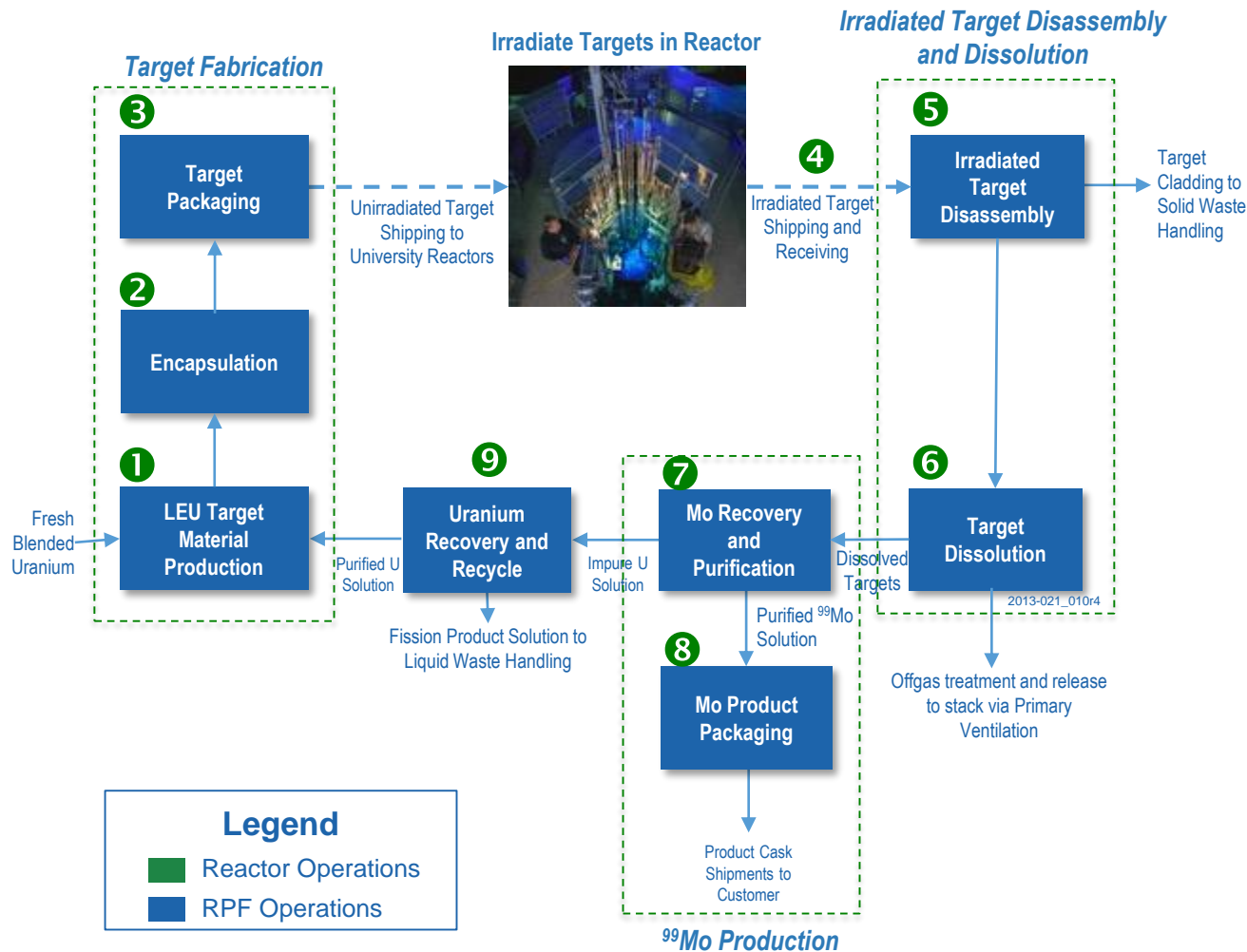


# Proposed Schedule (Calendar Year)

- 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



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

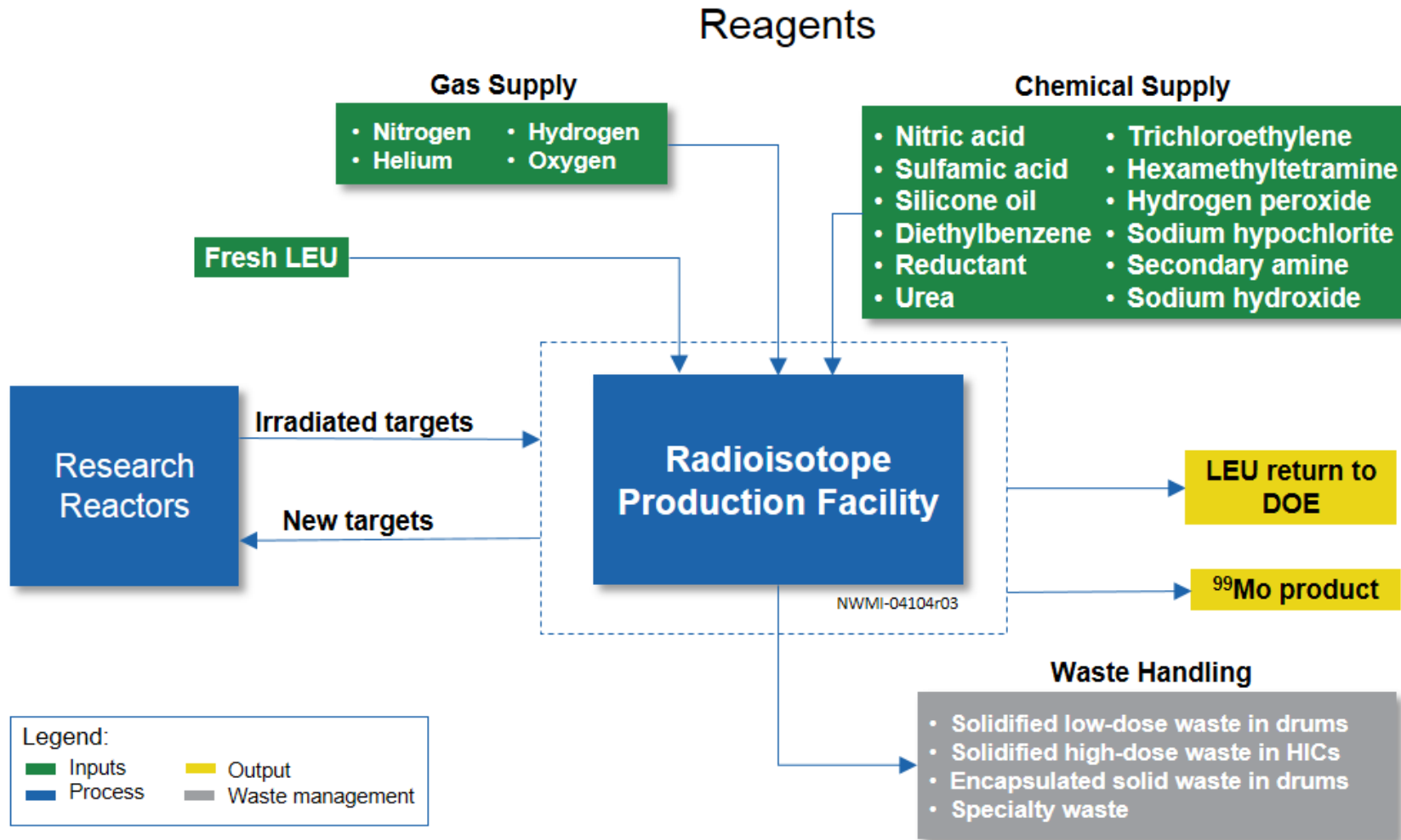
## ➤ Biological Shield

- 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<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 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



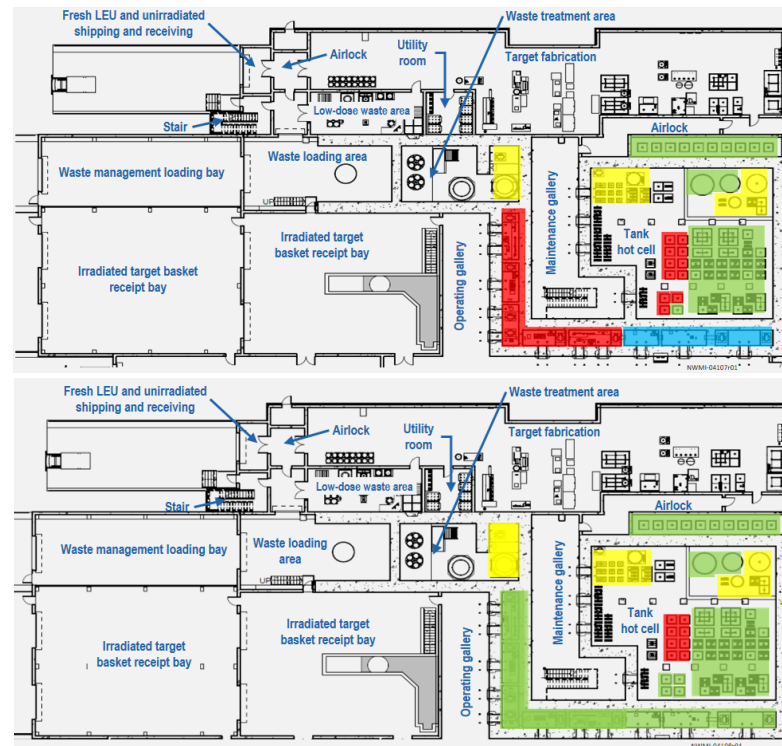
# RPF Consequences and Radionuclide Inventory Summary

- Primary consequences resulting from operation of RPF operations are radiological
  - LEU target material production/fabrication
  - Irradiated LEU target material processing (e.g., extract <sup>99</sup>Mo and recycle and recover <sup>235</sup>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



< 40 hr EOI

**Legend**

	>100K Ci
	>50K Ci
	>10K Ci
	<10K Ci

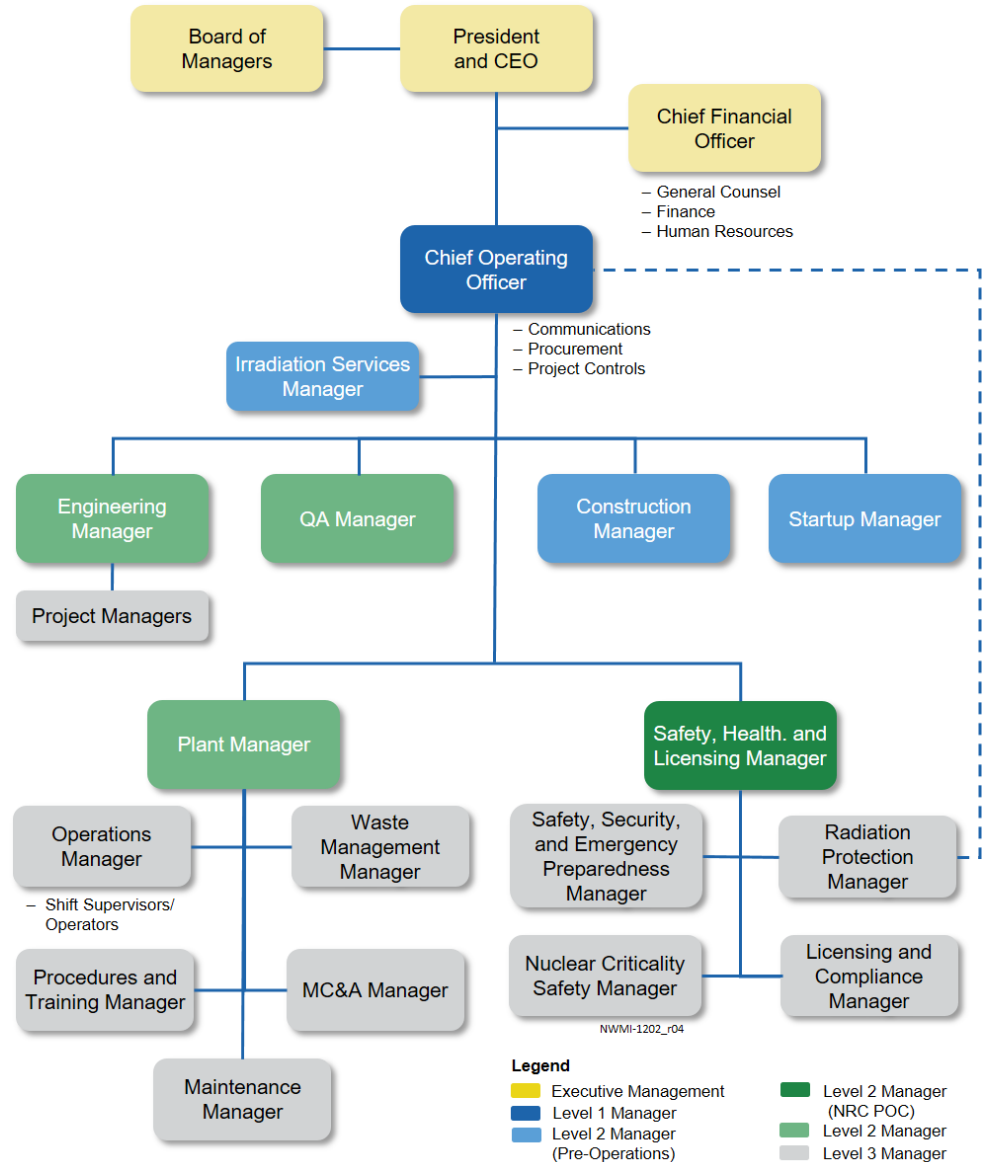
> 40 hr EOI

# 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)
- $^{99}\text{Mo}$  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?

