


U.S. Nuclear Regulatory Commission Commission Mandatory Meeting

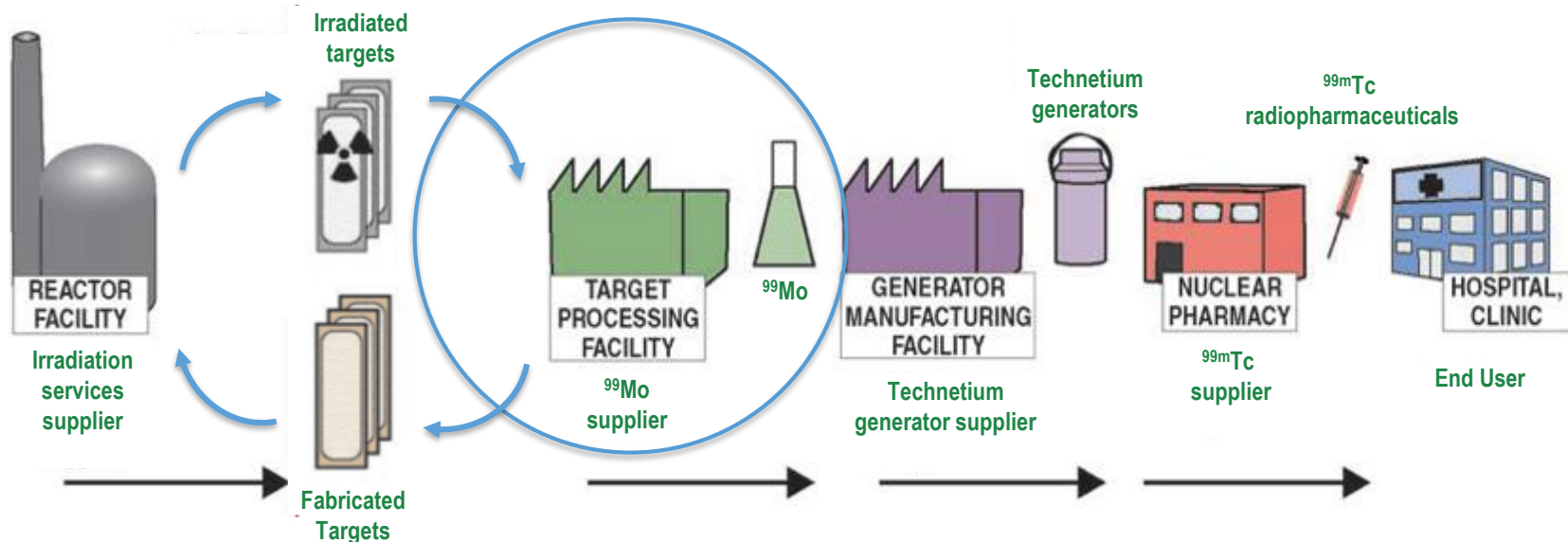


Northwest Medical Isotopes, LLC Radioisotope Production Facility Overview January 23, 2018

		United States Nuclear Regulatory Commission Official Hearing Exhibit In the Matter of: NORTHWEST MEDICAL ISOTOPES, LLC (Medical Radioisotope Production Facility)
Docket #: 05000609 Exhibit #: NWMI-004-R-MA-CM01 Admitted: 1/23/2018 Rejected: Other:	Commission Mandatory Hearing Identified: 1/23/2018 Withdrawn: Stricken:	

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

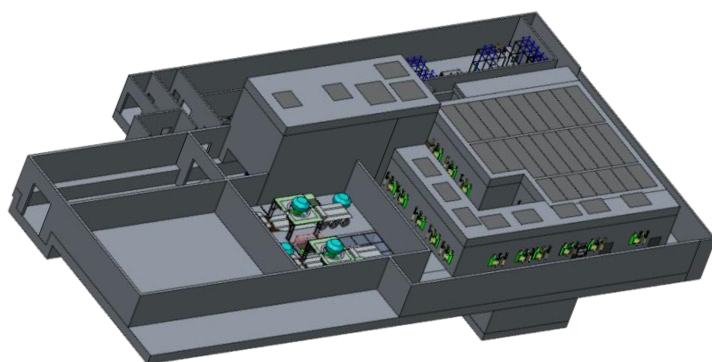
➤ Domestic ^{99}Mo Generator Distributors

- Hold FDA Drug Master File
- No changes to generators
- No changes to supply chain



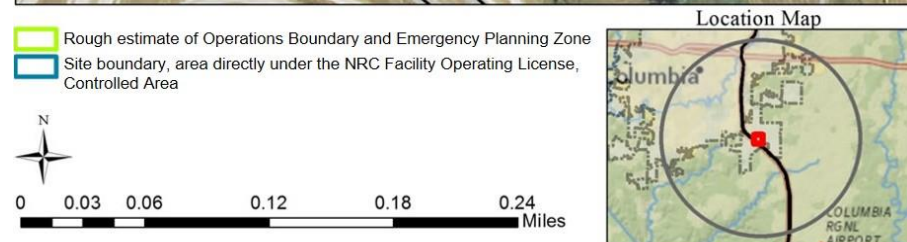
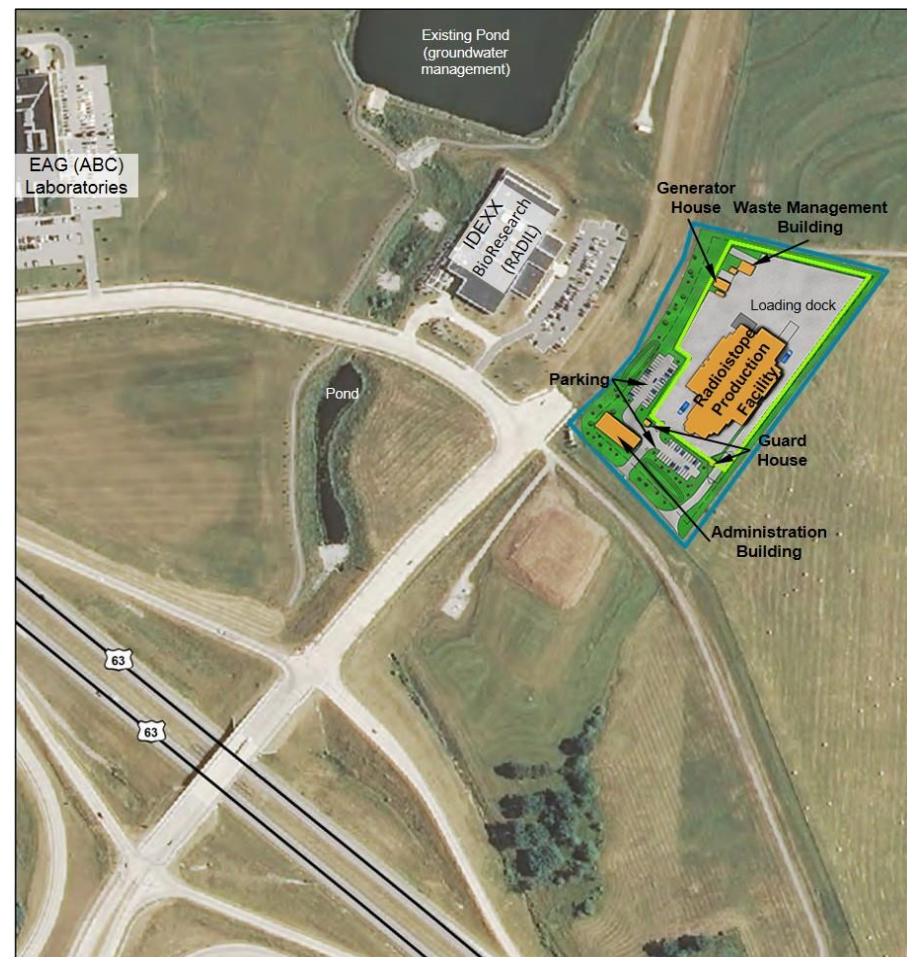
Primary Assumptions

- 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
- 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

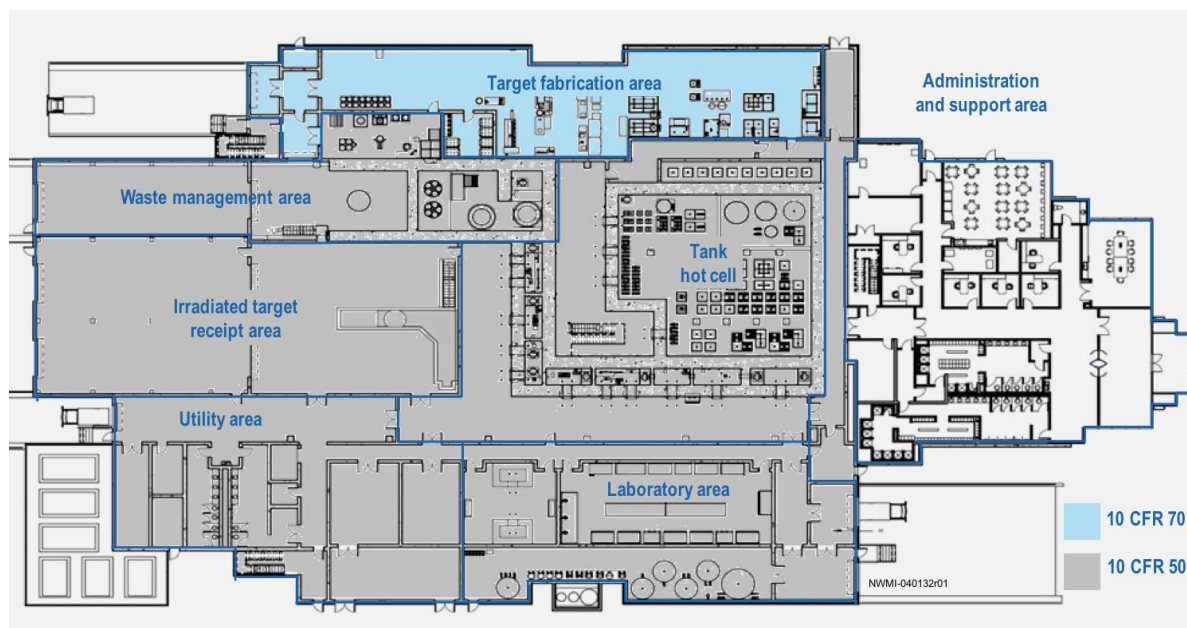


Licensing Approach

- **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

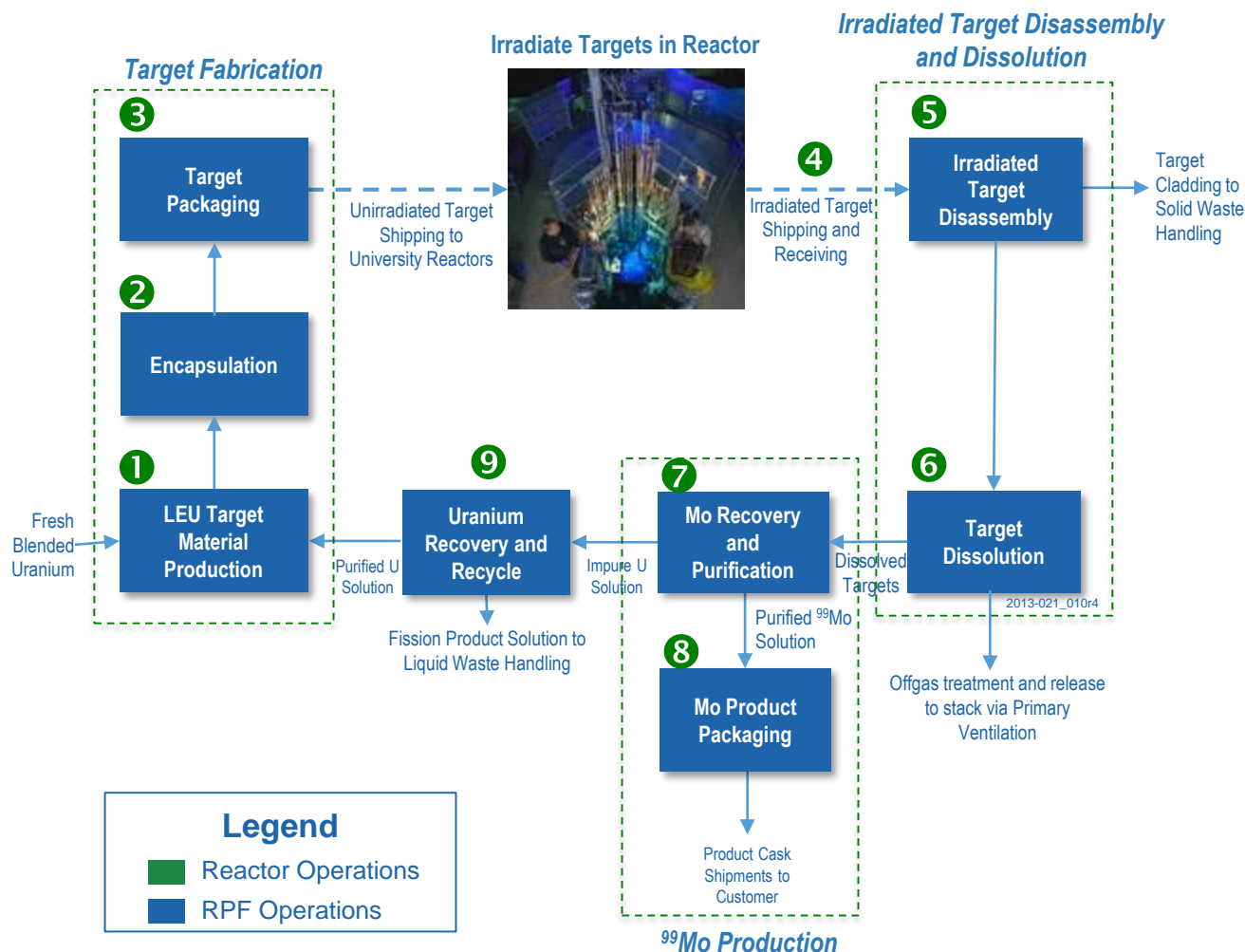


Proposed Schedule (Calendar Year)

- 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

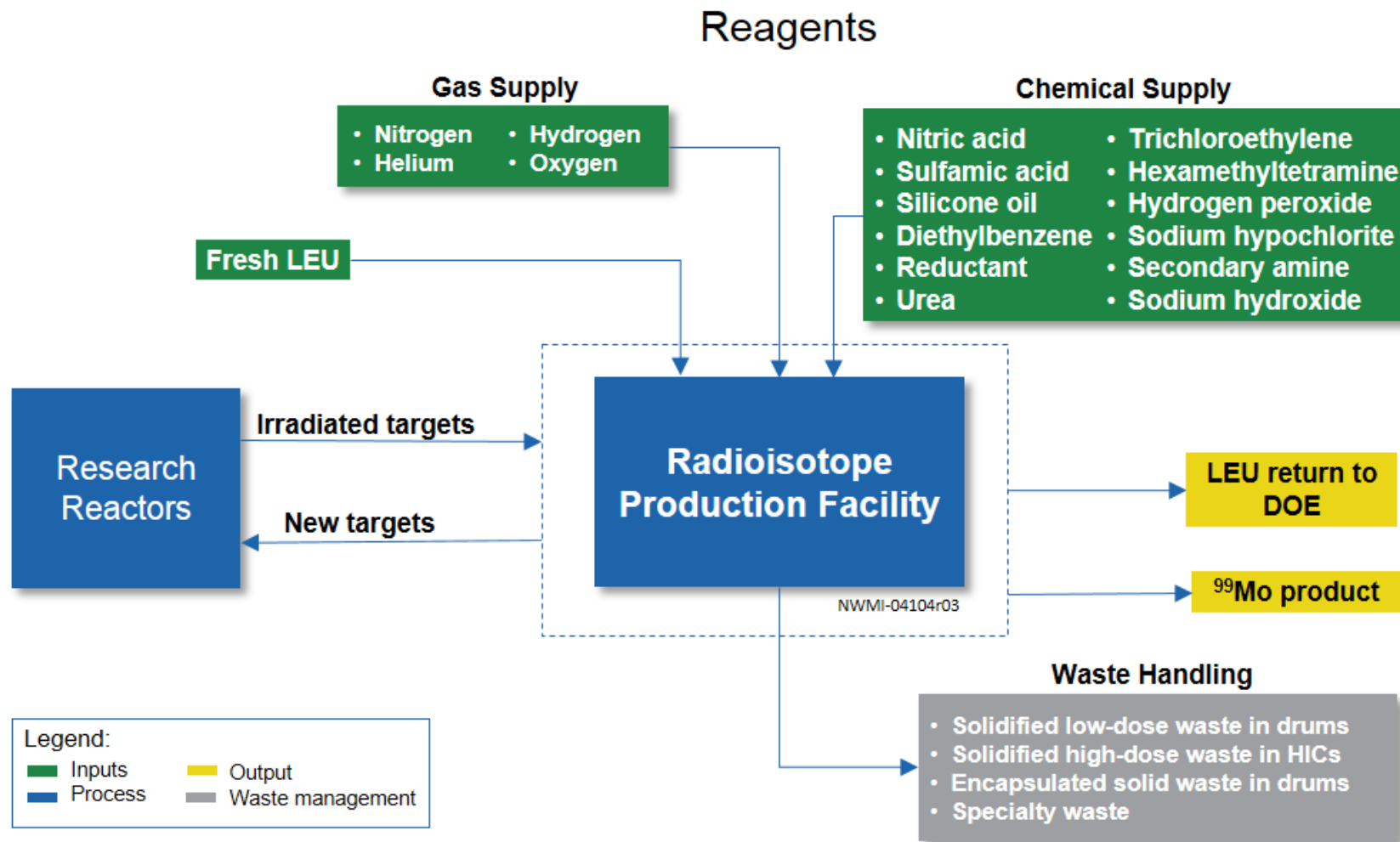
- Provides an integrated system of features that protects workers from high-dose radiation generated during facility operations
- Will withstand seismic and other concurrent loads, while maintaining containment and shielding during a design basis event
- Primary function is to reduce radiation dose rates 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

Exhibit NWMI-004-R



RPF Description

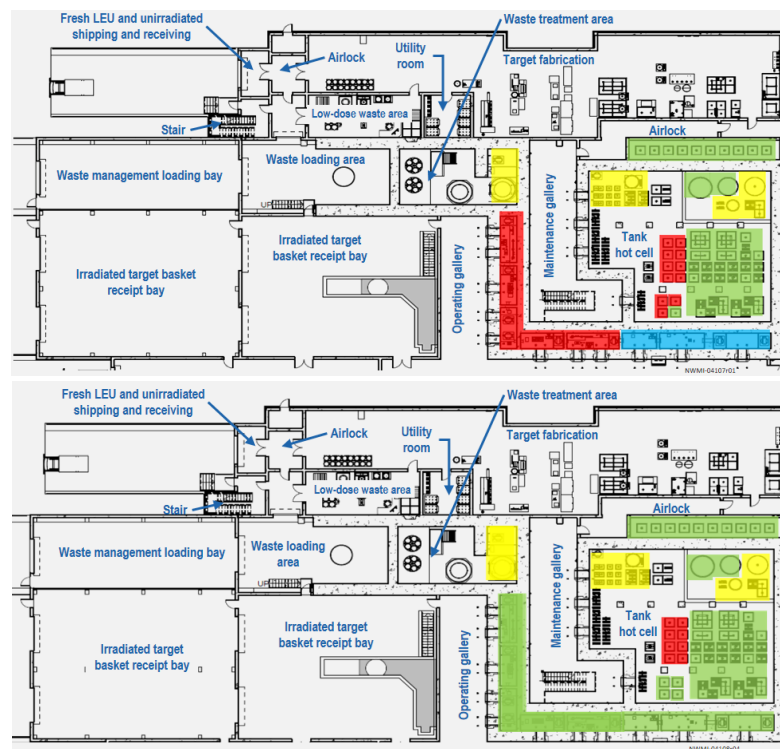
- First level footprint ~52,000 square feet (ft²)
 - Target fabrication area
 - Hot cell processing area (dissolution, ⁹⁹Mo, and ²³⁵U recovery)
 - Waste management, laboratory, and utility areas
- Basement ~2,000 ft² (tank hot cell, decay vault)
- Second level ~17,000 ft² (utility, ventilation, offgas equipment)
- Waste Management Building ~1,200 ft²
- Administration Building (outside secured RPF area) ~10,000 ft²
- 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

Exhibit NWMI-004-R

- 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



< 40 hr EOI

Legend

Red	>100K Ci
Yellow	>50K Ci
Blue	>10K Ci
Green	<10K Ci

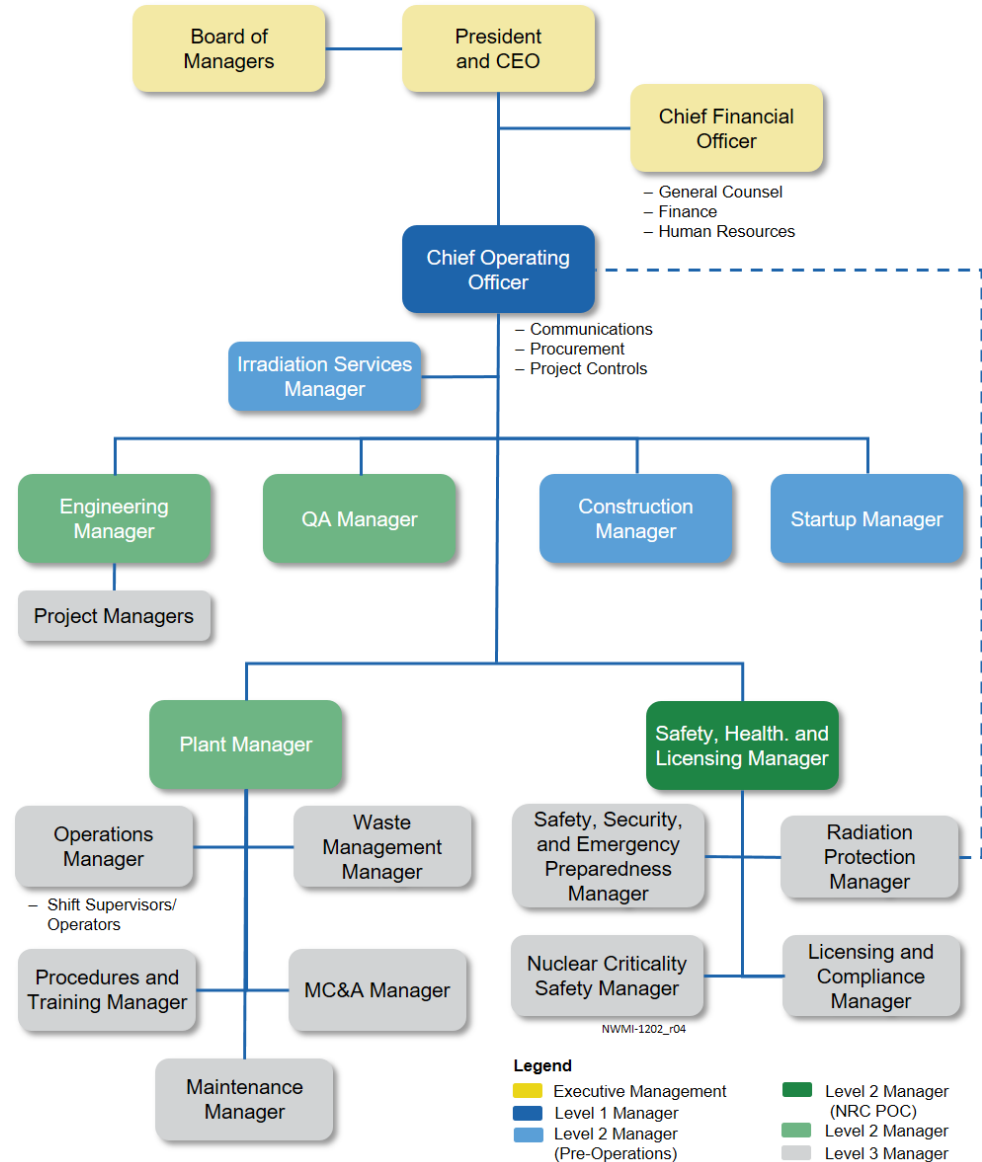
> 40 hr EOI

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}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?

Exhibit NWMI-004-R

