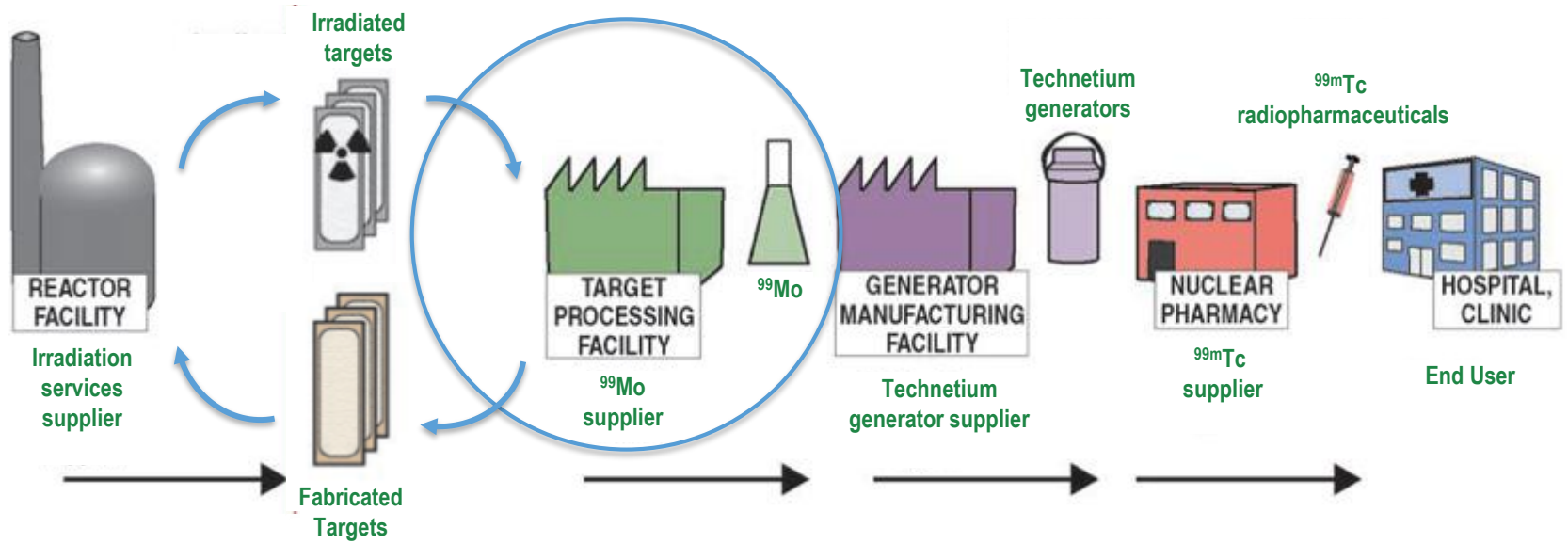
U.S. Nuclear Regulatory Commission
Commission Mandatory Meeting

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

NWMI Mission

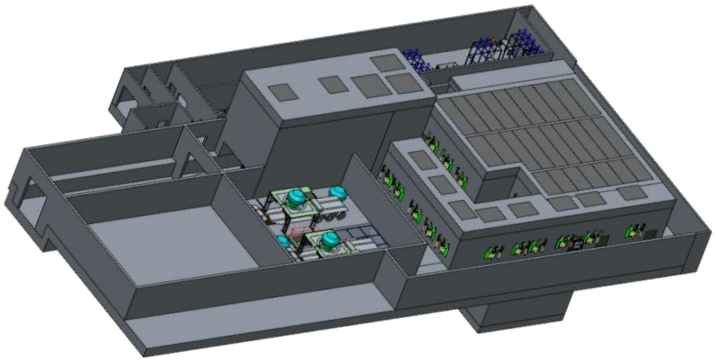
Assure a Domestic, Secure, and Reliable Supply of Molybdenum-99 (^{99}Mo)



- 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

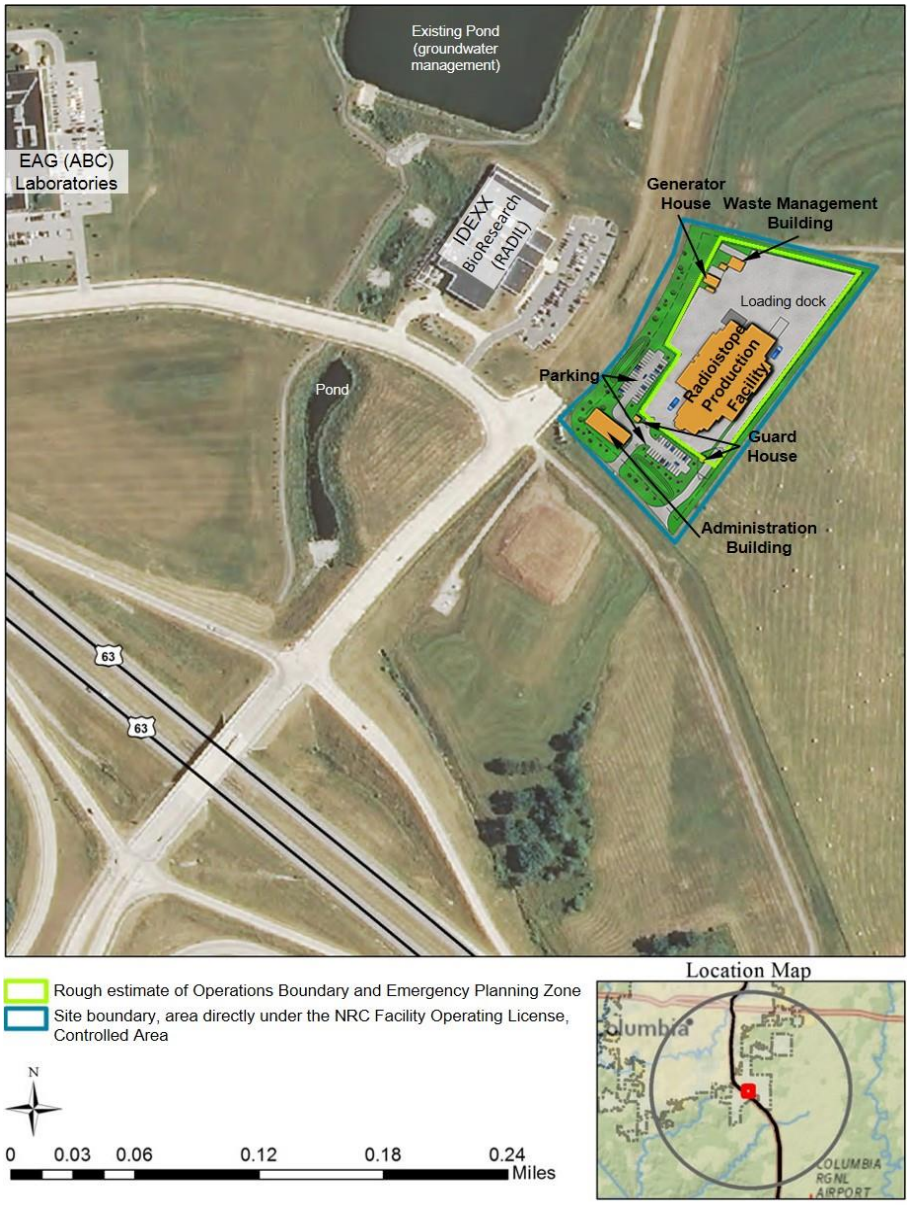
Primary Assumptions

- 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

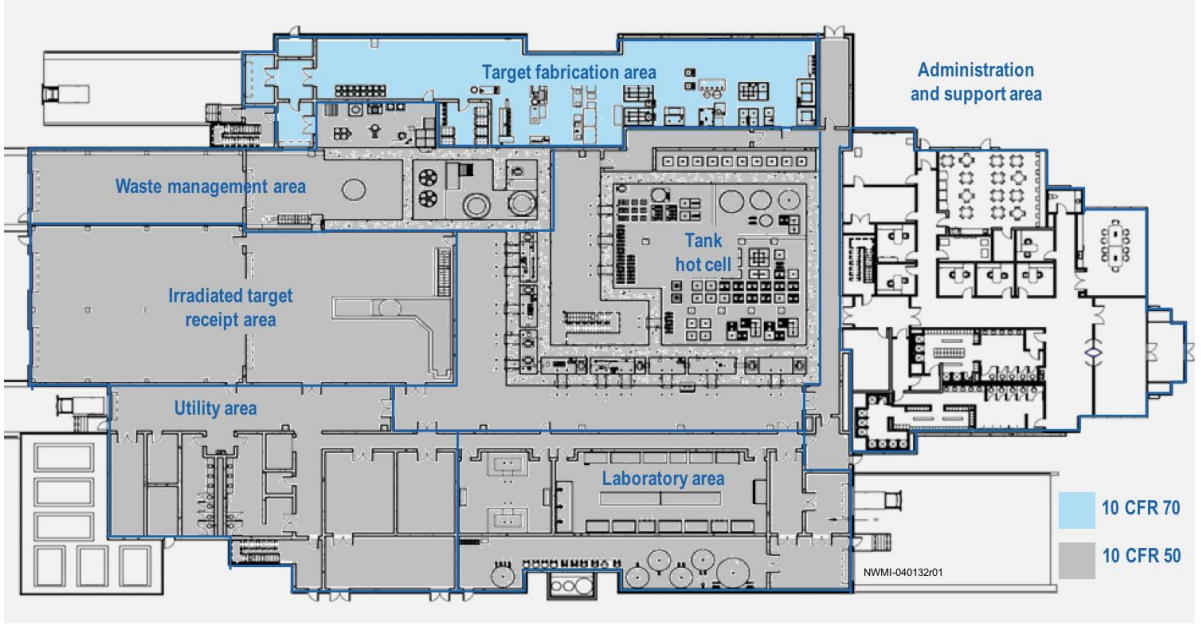


Licensing Approach

- ***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

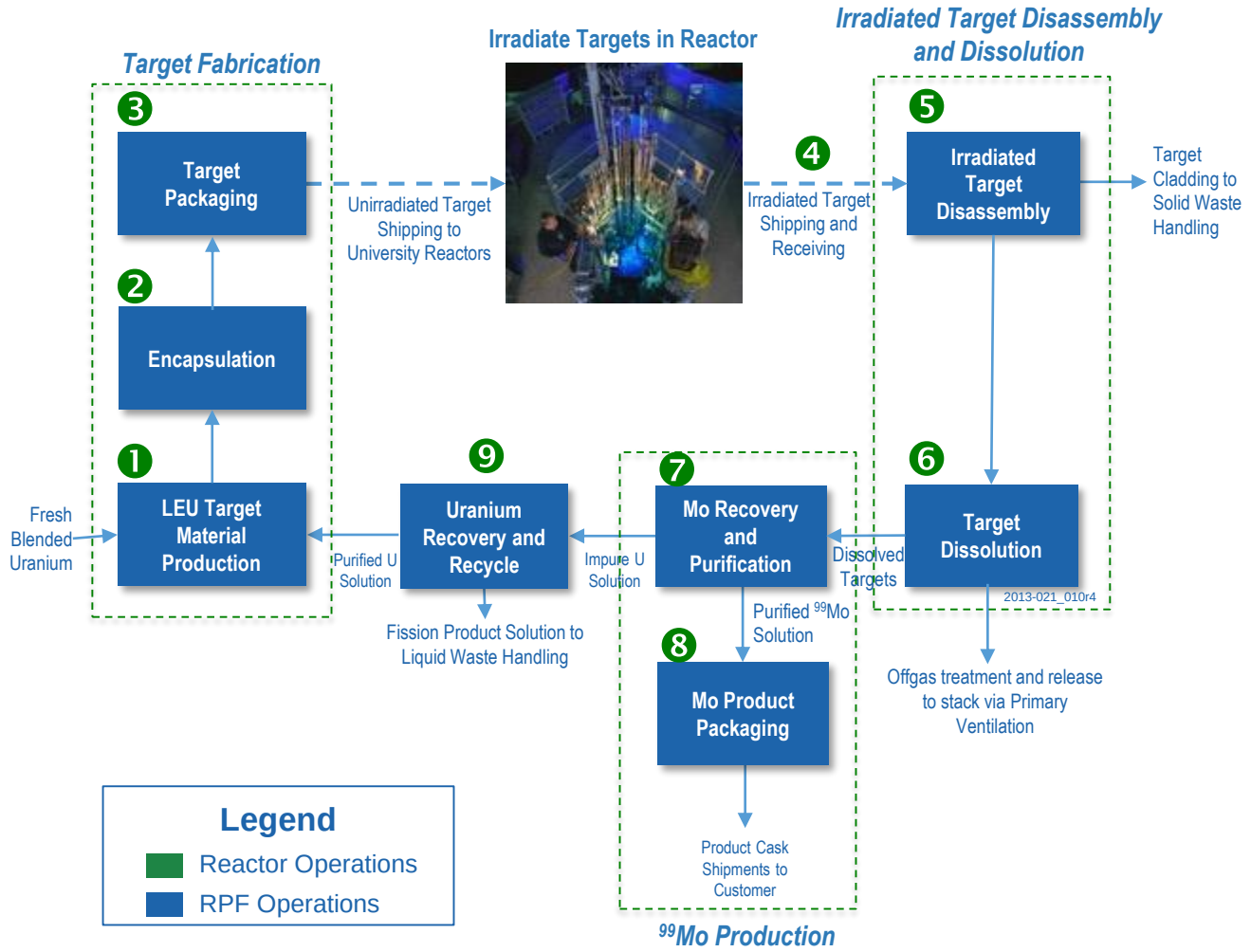
- Additional RPF operational activities are subject to other NRC regulations
  - 10 CFR 70, "Domestic Licensing of Special Nuclear Material," to receive, possess, use, and transfer special nuclear material
    - Receiving LEU from U.S. Department of Energy (DOE)
    - Producing LEU target materials and 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

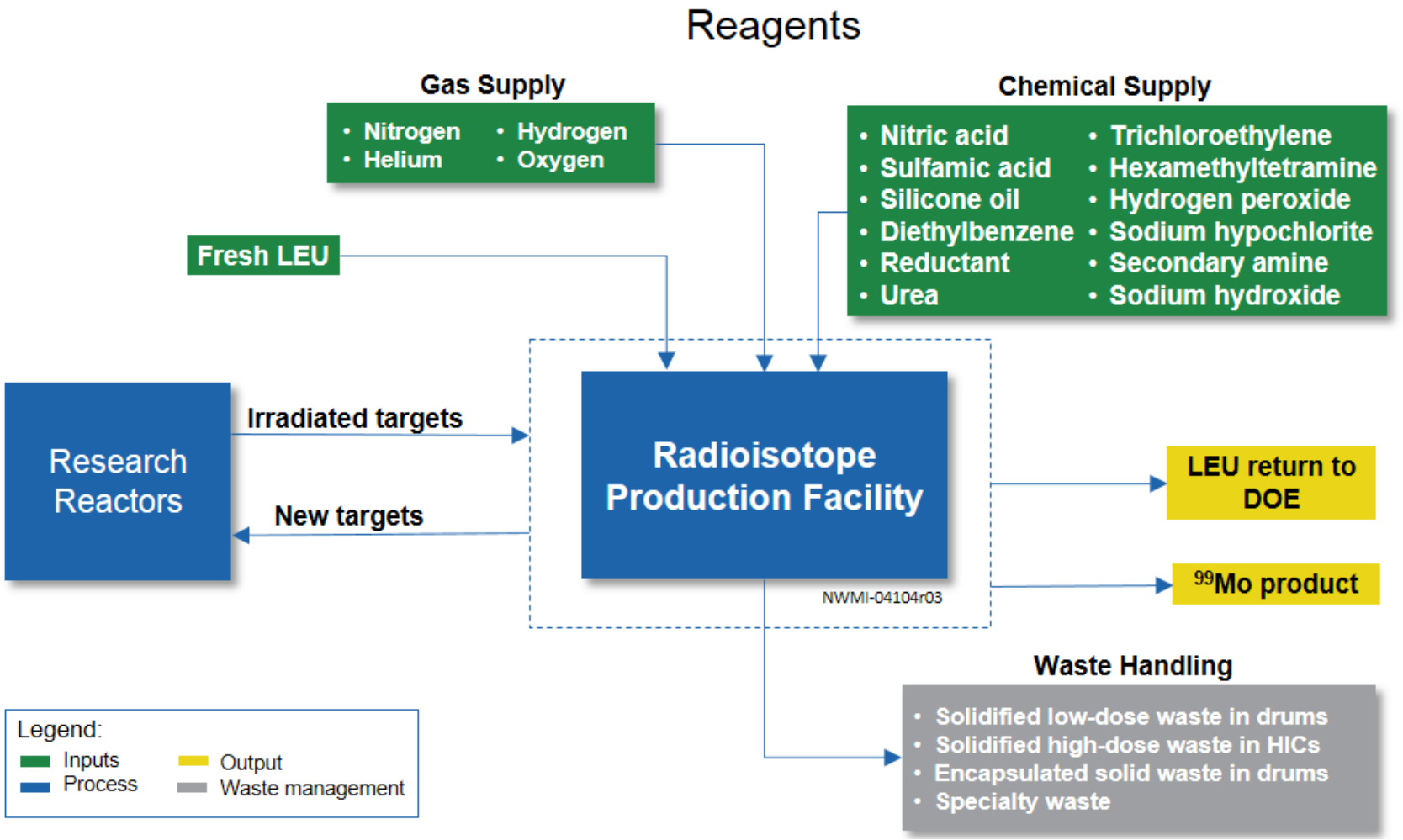


1. LEU target material is fabricated (both fresh LEU and recycled U)
2. LEU target material encapsulated using metal cladding → LEU target
3. LEU targets are packaged and shipped to university reactors for irradiation
4. After irradiation, targets are shipped back to RPF
5. Irradiated LEU targets disassembled
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

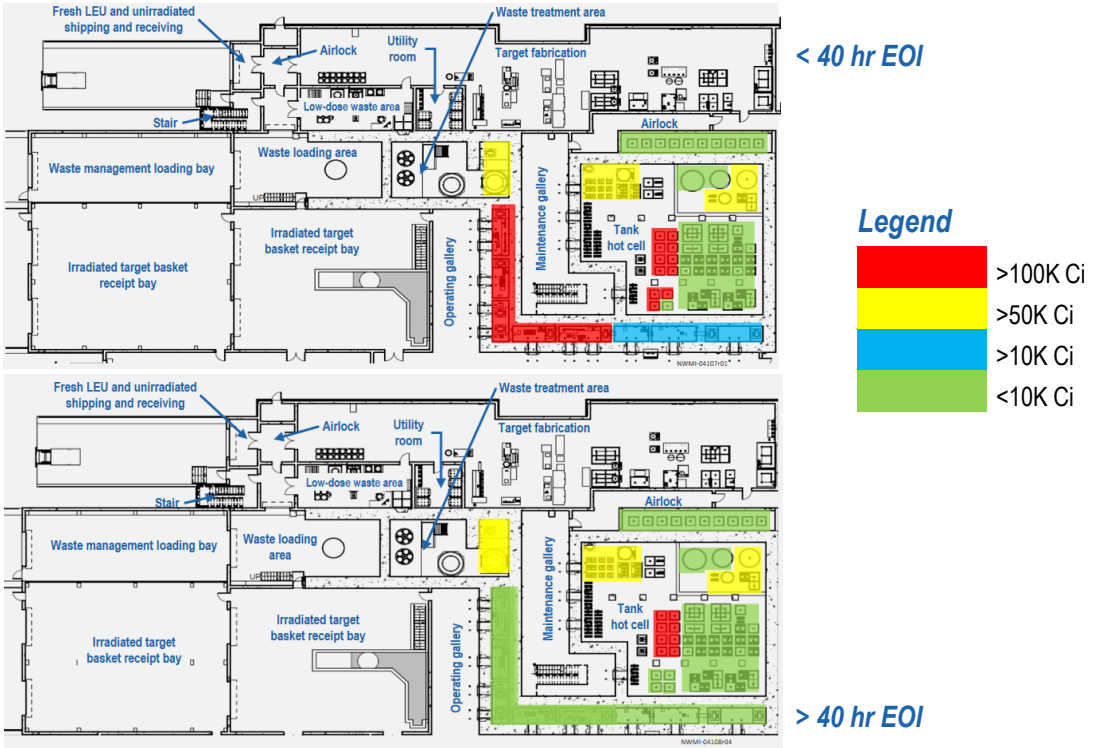


RPF Description

- 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

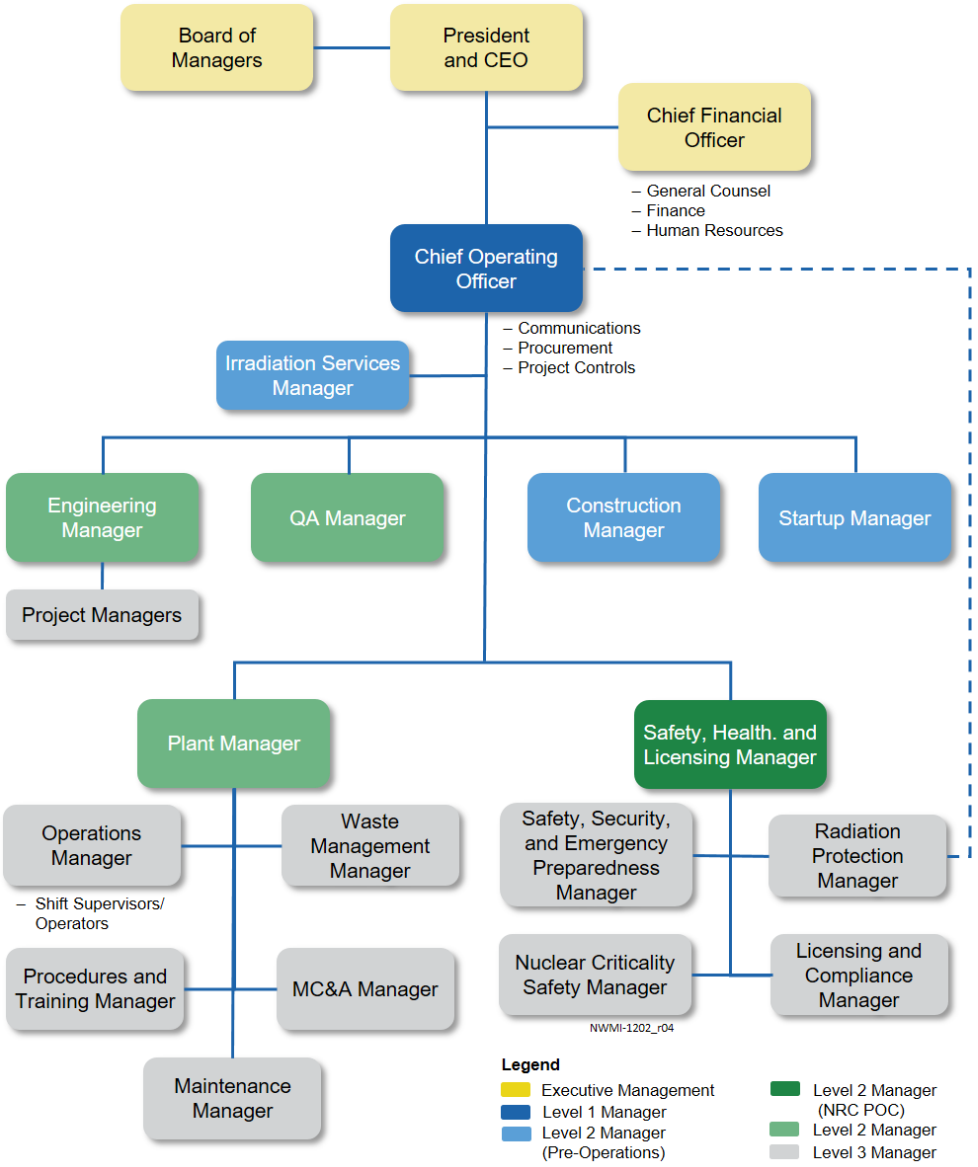


Transportation

- 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?