

NIOWAVE
Accelerating the Fight Against Cancer



Niowave's Domestic Production of Mo-99 and other Fission Products without a Nuclear Reactor

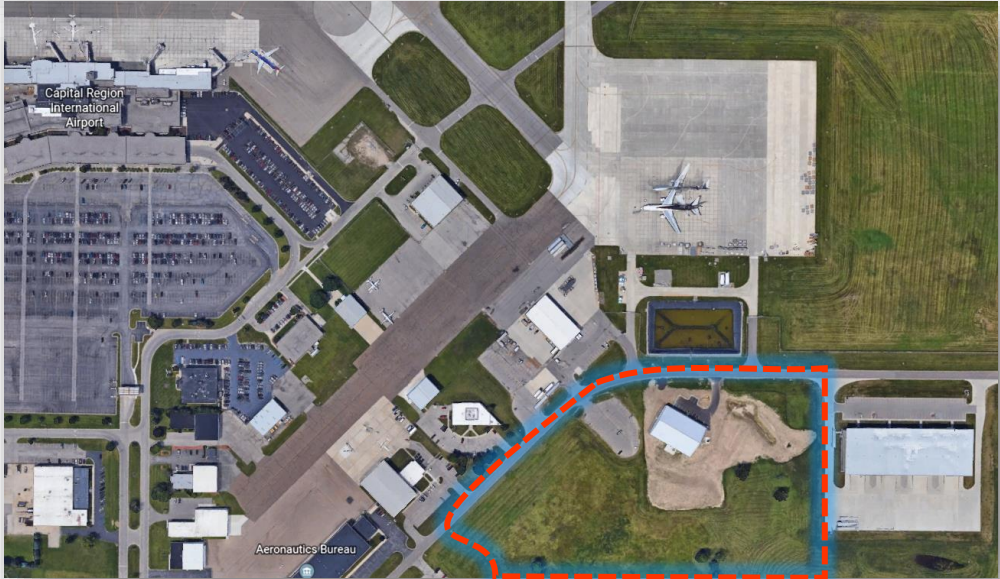
NRC Pre-Application Meeting
Radiation Protection, Material Control & Accounting, Physical Protection
September 21, 2022

Open Session

Outline

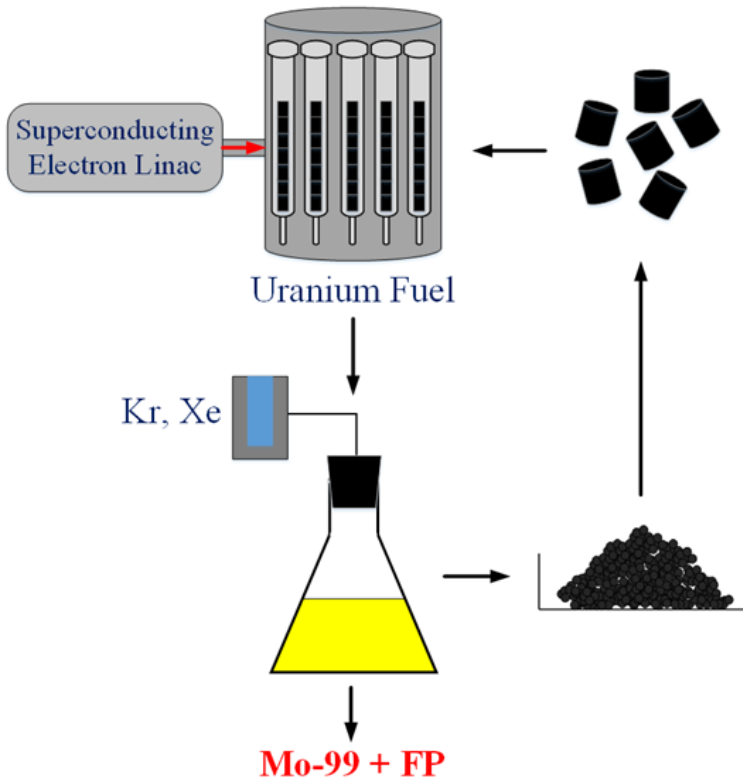
- Intro
- Radiation Protection
- Materials Controls & Accounting
- Physical Protection
- Licensing and Building Path

Facilities (Lansing, Michigan)

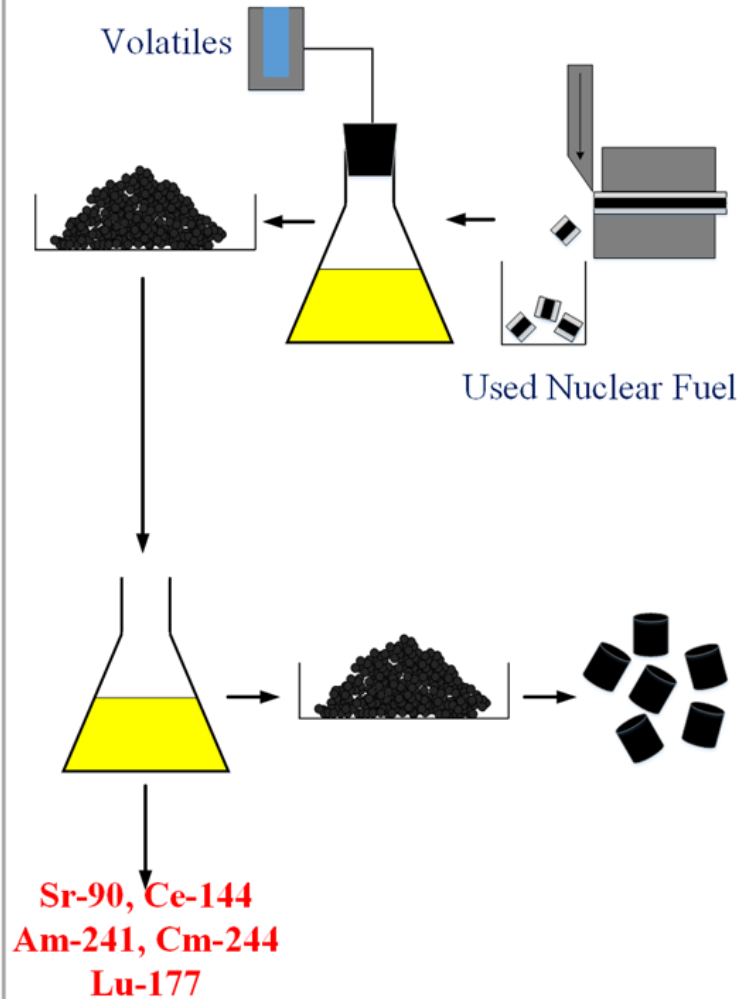


Isotope Program Overview

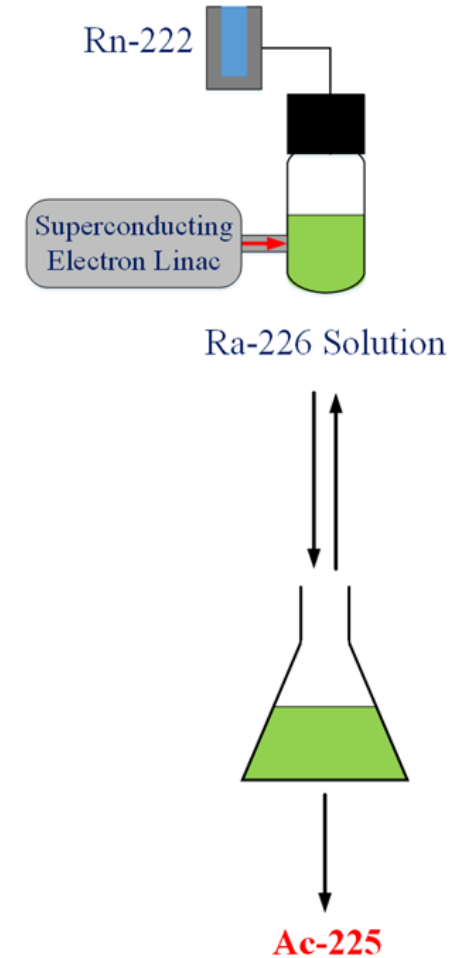
Mo-99 Program



Reactor Program



Ac-225 Program



Regulatory Agencies

- State of Michigan
 - 40 MeV, 100 kW superconducting electron linac
- Department of Transportation (DOT)
 - HAZMAT & DOT compliant program
- Nuclear Regulatory Commission (NRC)
 - Current licenses through Region III (Chicago)
 - NSIR Office (DC)
- Food and Drug Administration (FDA)

NRC Licensing Achievements

- ✓ License to process NU
 - Close-loop uranium cycle
 - Extract and purify fission products
- ✓ Irradiate subcritical assembly of LEU and NU
- ✓ License to process radium
 - Isolate and handle radon and radium
 - Irradiate to produce Ac-225
- ✓ License to process Sr-90
 - Extract Y-90 from Sr-90
- ✓ Emergency Plan, Part 30.32(i)
 - Reviewed and Recommended by NRC Nuclear Security and Incident Response
- ✓ Category 2 Byproduct Security, Part 37
 - Partnering with the Office of Radiological Security





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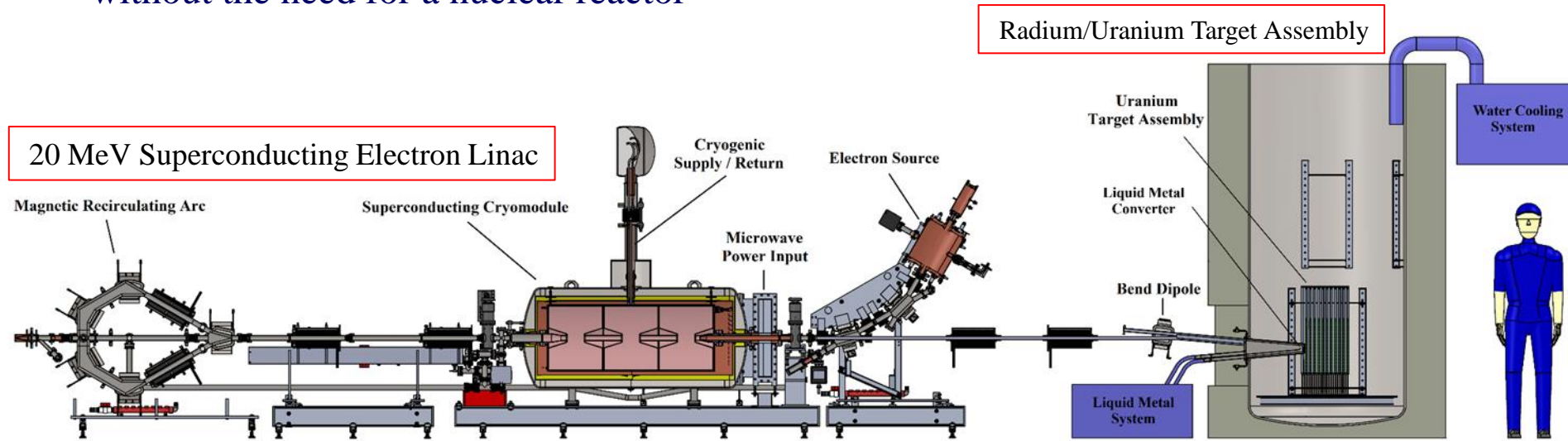
Mo-99 Commercial Facility



Therapeutic α and β Emitters

Niowave manufactures radioisotopes from radium and uranium using a superconducting electron linear accelerator without the need for a nuclear reactor

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Radium (Ra-226) α emitters

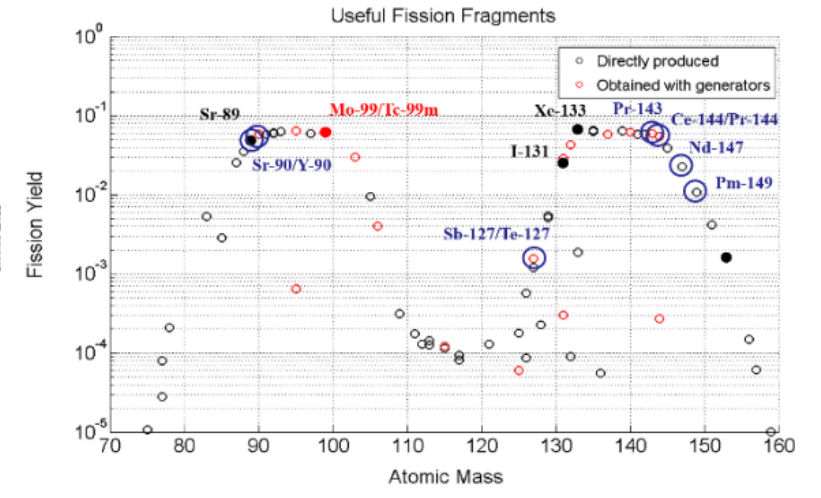
$e^- \rightarrow \gamma + \text{Ra-226} \rightarrow \text{Ra-225} + n \rightarrow \text{Ac-225}$

Ac-225	10 d
Rn-222	3.8 d
Po-210	138 d
Bi-210	5.0 d
Bi-213	46 m
Bi-214	20 m
Pb-214	27 m

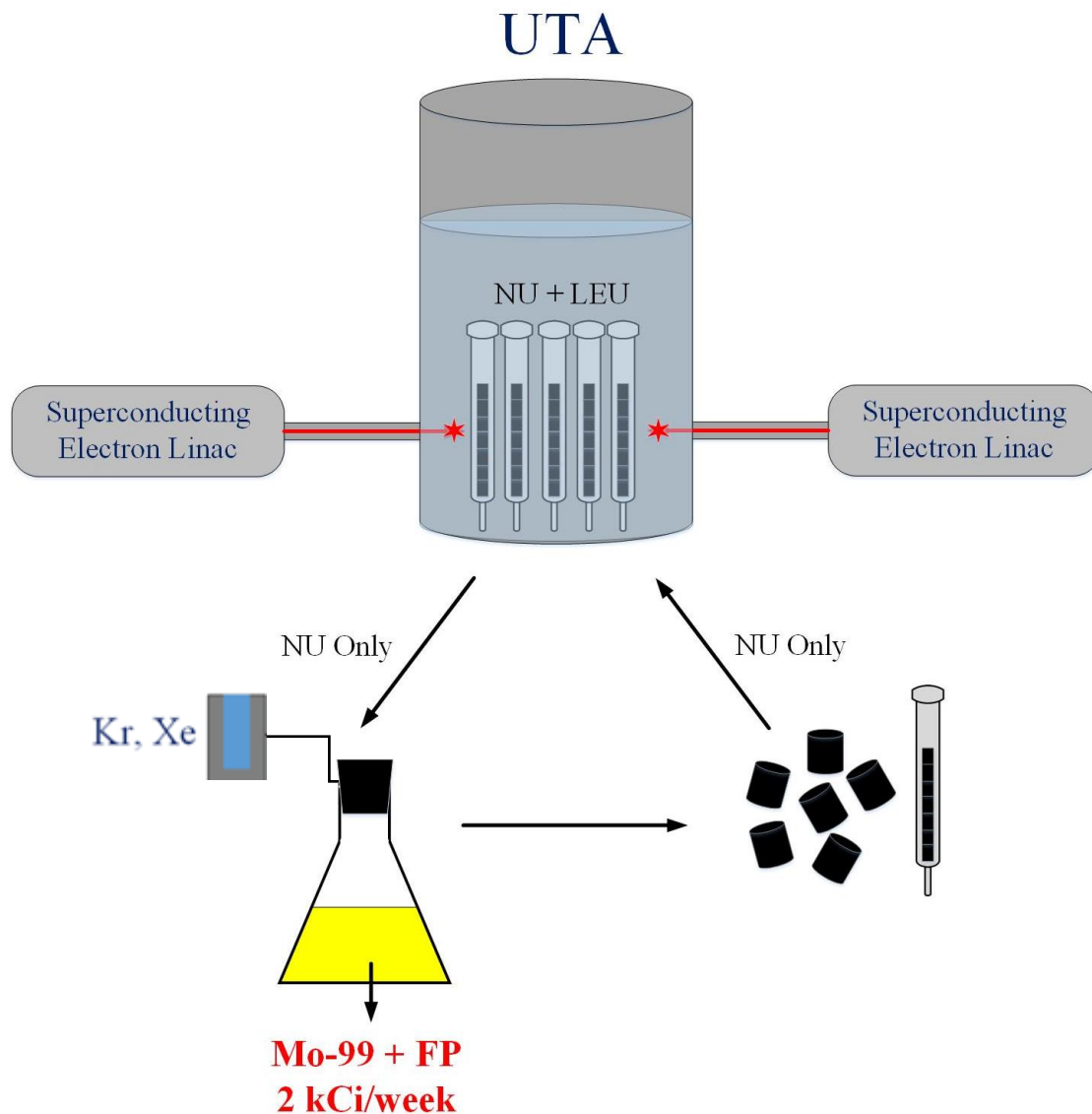
Uranium (U-235/238) β emitters

$e^- \rightarrow \gamma + \text{U-238/235} \rightarrow \text{Mo-99} + n \rightarrow \text{Xe-137}$

Mo-99 \rightarrow Tc-99m	I-131
Sb-127 \rightarrow Te-127	Xe-133
Ba-140 \rightarrow La-140	Sr-89
Ce-143 \rightarrow Pr-143	Y-91
Sr-90 \rightarrow Y-90	Ce-141
Ce-144 \rightarrow Pr-144	Nd-147
	Pm-149



Mo-99 Commercial System Overview



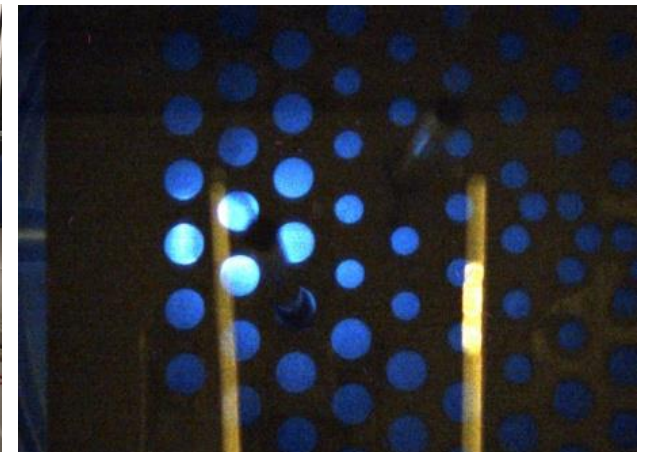
Accelerator Driven Neutron Source (x2)	
Electron Beam Power	200 kW = 40 MeV x 5 mA
Neutron Source Intensity	$\sim 10^{15}$ n/s

Uranium Target Assembly	
k_{eff}	≤ 0.95
LEU Target Mass	XX kgU
NU Target Mass	60 kgU
LEU Fission Power	280 kW
NU Fission Power	50 kW
Mo-99 Activity Produced	13 kCi/week EOB

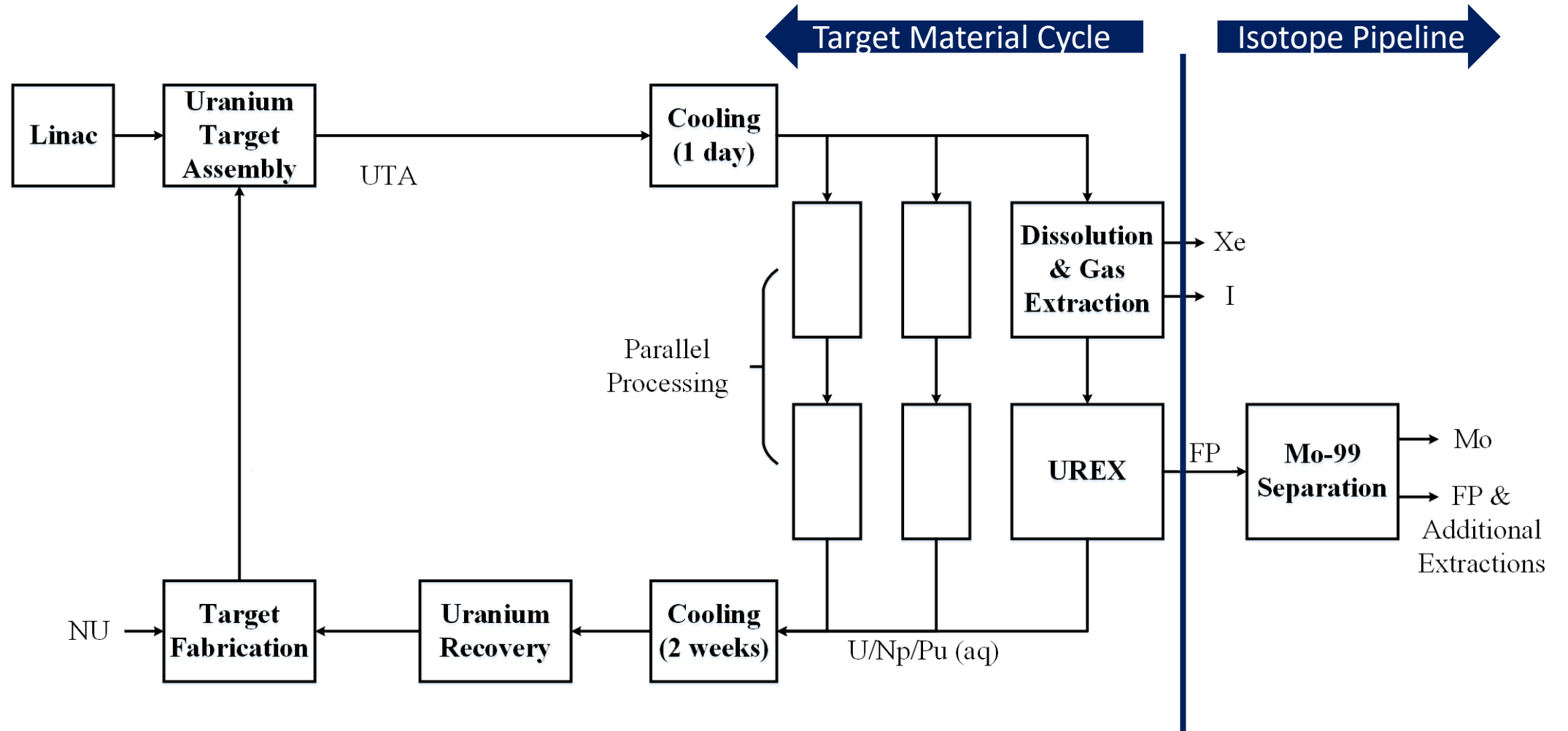
Uranium Cycle & Isotope Pipeline	
NU processed	60 kgU/week
LEU processed	None
Mo-99 Activity Extracted & Shipped	2 kCi/week EOB (5% US Demand)
Other Isotopes	Various

Accelerator Systems in Operation

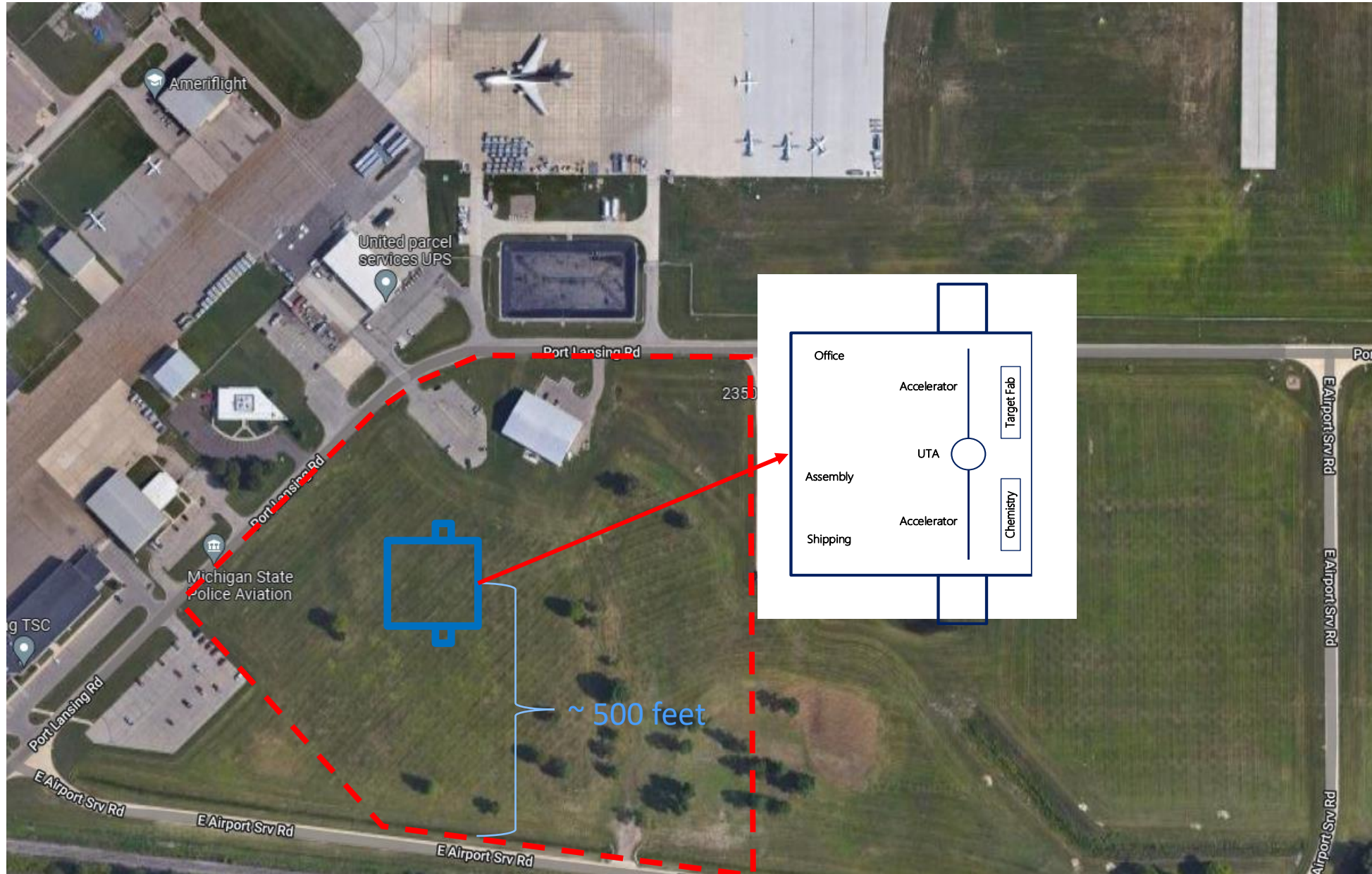
- All key systems in operation at lower powers and energies
 - Recirculating beamline
 - Beam diagnostics
 - Electron Source
- Licensed by Michigan to 40 MeV, 100 kW
 - Machine interlocks meet state requirements
 - Demonstrate shielding plan at each step up in power and energy



Closed Loop Uranium Cycle



Mo-99 Commercial Facility Overview





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Radiation Protection



Commitment to Radiation Safety

Niowave is committed to radiation safety and the ALARA principle.

- Niowave designs systems to keep radiation workers doing routine operations below 10% of the NRC limits.
- Niowave enforces a threshold for halting radiation work for any workers above 50% of NRC limits.
- Niowave has established a Radiation Safety Committee to review the radiation safety program and support constant improvements.
- Radioactive handling is approved through a Radiological Work Permit
 - AU approval required
 - Specific training for each job is listed and required
 - Dose estimates are included

Radiation Safety Training [1]

The current radiation safety training program given to all new employees and annual refresher for all employees covers the following topics:

- Radiation Safety Regulations
- Radiation basics
- Activity basics
- Biological Effects of Radiation
- Dose and effective dose
- ALARA Principle
- Times, distance, and shielding
- Monitoring
- Records and Reports
- Safety Procedures
- Accelerator-Produced Radioactivity
- Security
- Emergencies Procedures and Contact List
- Niowave Postings

A passing grade of 80% is required for radiation workers and 70% for non-radiation workers.



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Material Control & Accounting



Biannual Inventory

- An inventory of all radioactive material will be performed biannually, at an interval not to exceed 6 months.
- Radionuclides, quantities, manufacturer's name, model numbers, and the date of inventory
- All the materials will be visually inspected and the log entry for each piece of radioactive material confirmed. If a discrepancy is found, the RSO will investigate it and report if necessary.
- Records of inventories will be maintained for 3 years

Secure RAM and Constant Control

Two-layer security for all RAM

- Locked doors (buildings, labs, etc.)
- Locked equipment (drums, manifolds, etc.)
- Controlled key access to material and rooms for only those trained to the areas

Niowave has developed written procedures for licensed material accountability and control to ensure that:

- License possession limits are not exceeded
- Licensed material is secured from unauthorized access or removal
- Licensed material is maintained under constant surveillance and control
- Records of extraction, transfer, and disposal of licensed material are maintained





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Physical Protection



Access Authorization Program

- Trustworthy and Reliable
- Background investigations
- Criminal history checks
- Personal information protection



Security Program

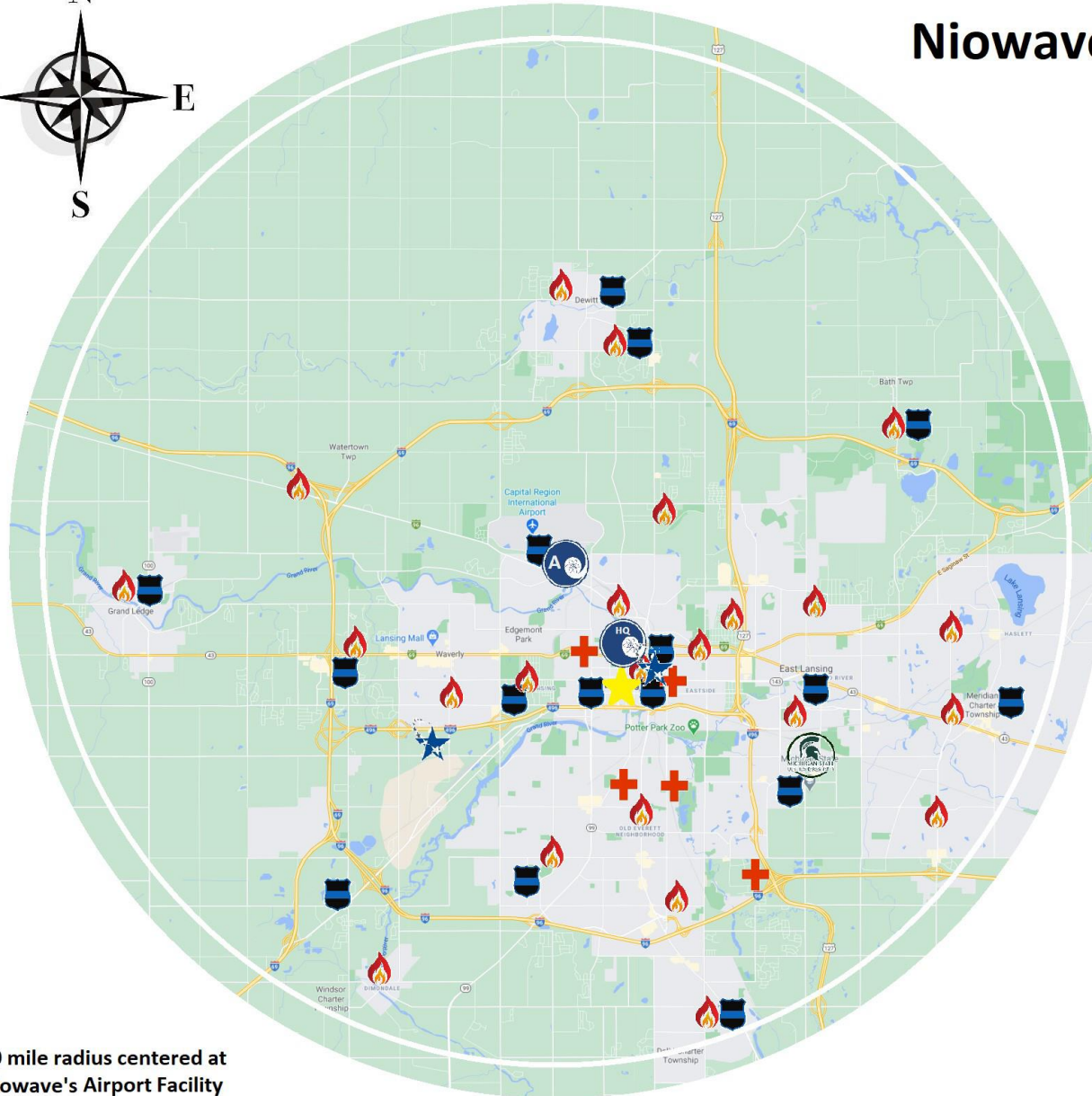
- Management structure
- LLEA coordination
 - Lansing Police
 - Lansing Fire (HAZMAT)
- Security zones
- Interlock systems
- Transportation security
- Security information protection



Niowave passed inspection for readiness to implement a Part 37 Security Program by NRC Region III in 2021



Niowave Airport Facility Emergency Map



- Niowave Airport Facility
- Niowave Head Quarters
- Police Station
- Fire Station
- Hospital
- Capital Building
- Michigan State University
- Lansing Community College

10 mile radius centered at
Niowave's Airport Facility



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Next Steps



Scaling Up to Commercial-Scale

- ✓ Scaled up from existing system
- ✓ Remain less than strategic significance of SNM (less than Cat III SNM)
- ✓ Remain Cat 2 Byproduct Material
- ✓ Process NU only
- ✓ Same linac controls and State license
- ✓ Same Security
 - Expand existing Emergency Plan
 - NEPA Categorical Exclusion Determination
 - Perform an ISA and prepare an ISA Summary



Next Steps

- Continue design development for Commercial Facility
- Move forward with leasing land
- Start building during review
- Apply ISA methodology to all nodes
- Prepare ISA Summary and supporting documents
- Prepare license application following NUREG-1520 (informed, as appropriate by the ISG to NUREG-1537)



Next Meetings

- Organization & Administration, ISA Commitments, Management Measures
- General Information, Environmental Protection, Decommissioning
- Determination for NEPA Categorical Exclusion
- ISA: Fire Safety, Aircraft, Emergency Management
- ISA: Chemical Process Safety
- ISA: Nuclear Criticality Safety
- Follow-up Meeting (if required)
- License Submission (Spring 2023)



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Thank You