

NIOWAVE
Accelerating the Fight Against Cancer



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

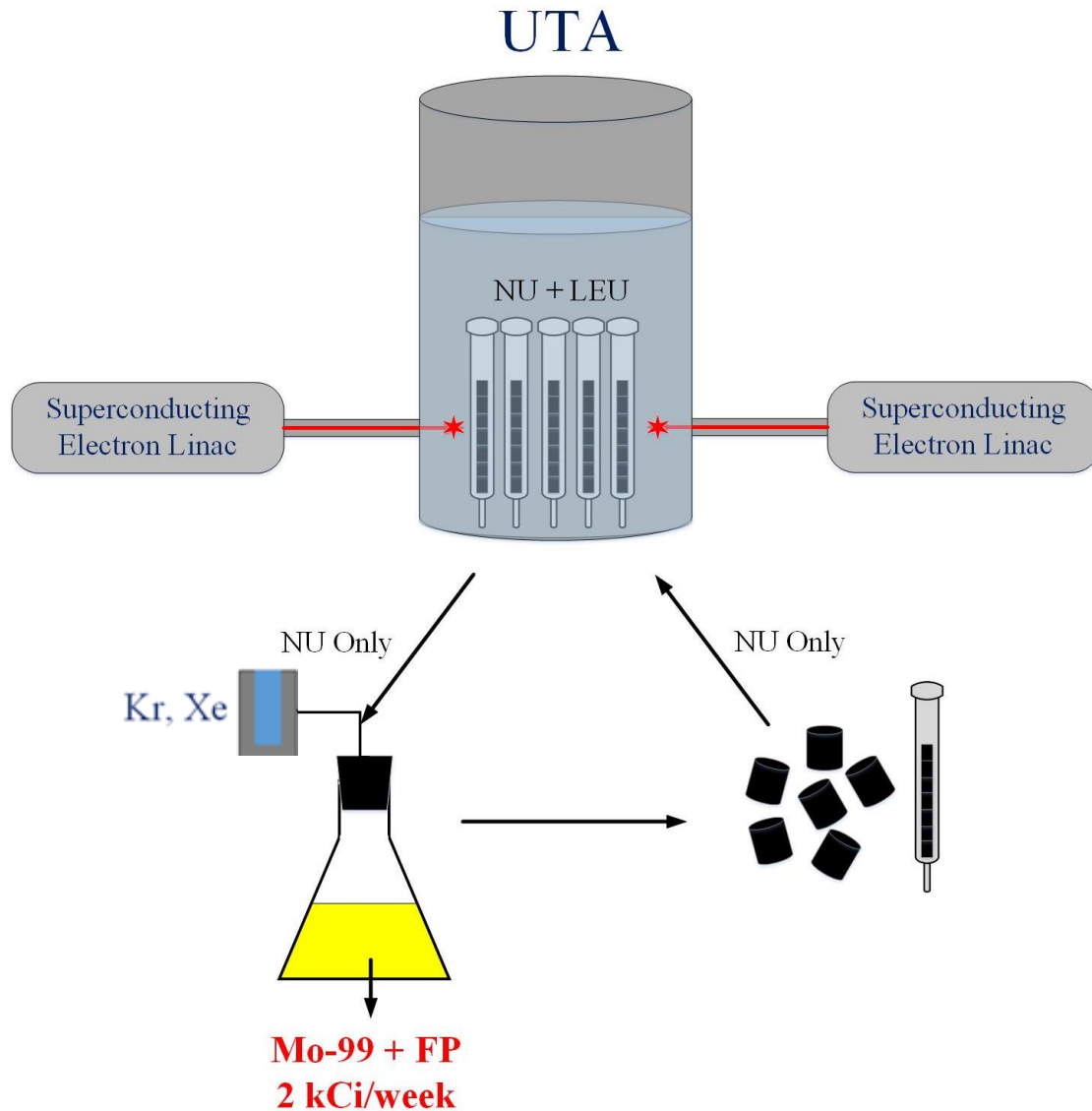
NRC Pre-Application Meeting
Design
August 3, 2022

Open Session

Outline

- Conceptual Design
- Licensing Status
- Leveraged Experience
- Location
- Next Steps

Mo-99 Commercial Facility



Uranium Target Assembly (UTA)	
k_{eff}	≤ 0.95
LEU Fuel Mass	XX kgU
NU Target Mass	54 kgU
LEU Fission Power	~250 kW
NU Fission Power	50 kW
Mo-99 Activity Produced	2 kCi/week (5% US Demand)

Lead-Bismuth Eutectic (LBE) Neutron Source (2 per UTA)	
Electron Energy	40 MeV
Accelerator Power	200 kW
T_{max} LBE	500 °C
V_{max} LBE	2 m/s
Neutron Source Intensity	$\sim 2.0 \times 10^{15}$ n/s



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



Leveraged Experience [1]

- ✓ National Lab and University Partners
- ✓ MSU Facility for Rare Isotope Beams (FRIB)
 - Submitted an Environmental Report to DOE
 - DOE published an Environmental Assessment
- ✓ Construction Partner
 - Christman Constructors, Inc.
- ✓ Niowave Regulatory Experience
 - NSIR Recommended Emergency Plan
 - Cat 2 Byproduct Security Plan
 - State of Michigan License
 - DOT and IATA Trained
 - NRC Region III SNM materials license

Leveraged Experience [2]

✓ Niowave's FDA-Compliant Quality System

- Process Failure Mode and Effects Analysis (PFMEA)
- Management Measures (toward compliance with 70.61)
- Document Control

✓ Niowave IT Department

- Cyber Security
- Redundant Data Recovery
- Controls

National Lab & University Partners

ANL – UREX, Mo-99 Chemistry

LANL – LBE Target

ORNL – Neutronics and Shielding Calculations

PNNL – Dissolution & Gas Extraction

SRNL – UREX

Y-12 – Uranium Recovery and LEU

UNLV – UREX, Mo-99 Chemistry, Other Isotopes

MSU – Other Isotopes, Radiopharmaceuticals



Construction Partner



Christman Constructors, Inc. (CCI) was awarded the cast-in-place concrete, carpentry and general trades work for the Facility for Rare Isotope Beams (FRIB), a new nuclear science facility at Michigan State University.

The project included:

- 42,000 cubic yards of concrete
- The use of high density 250 P.C.F. concrete
- Largest monolithic wall pour, 48' tall, 7' wide, and 650 cubic yards



Quality System

- Implemented 21 CFR 820 / ISO 13485 Quality System
 - 200+ Documents released and trained
 - ISO 13485 certified
- Passed multiple customer & certified body audits with zero findings within the last year
- FDA qualified supplier of Y-90 for clinical use





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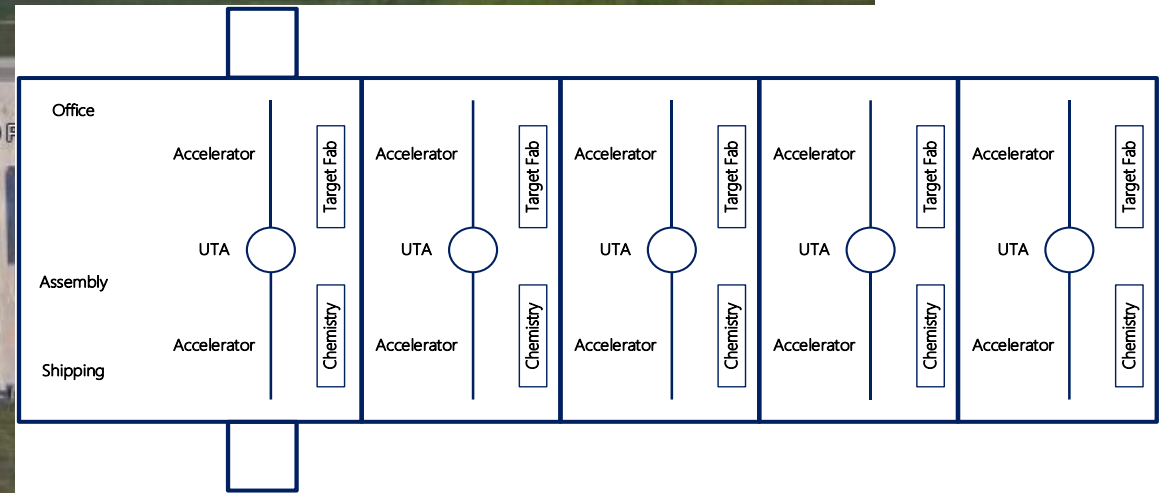
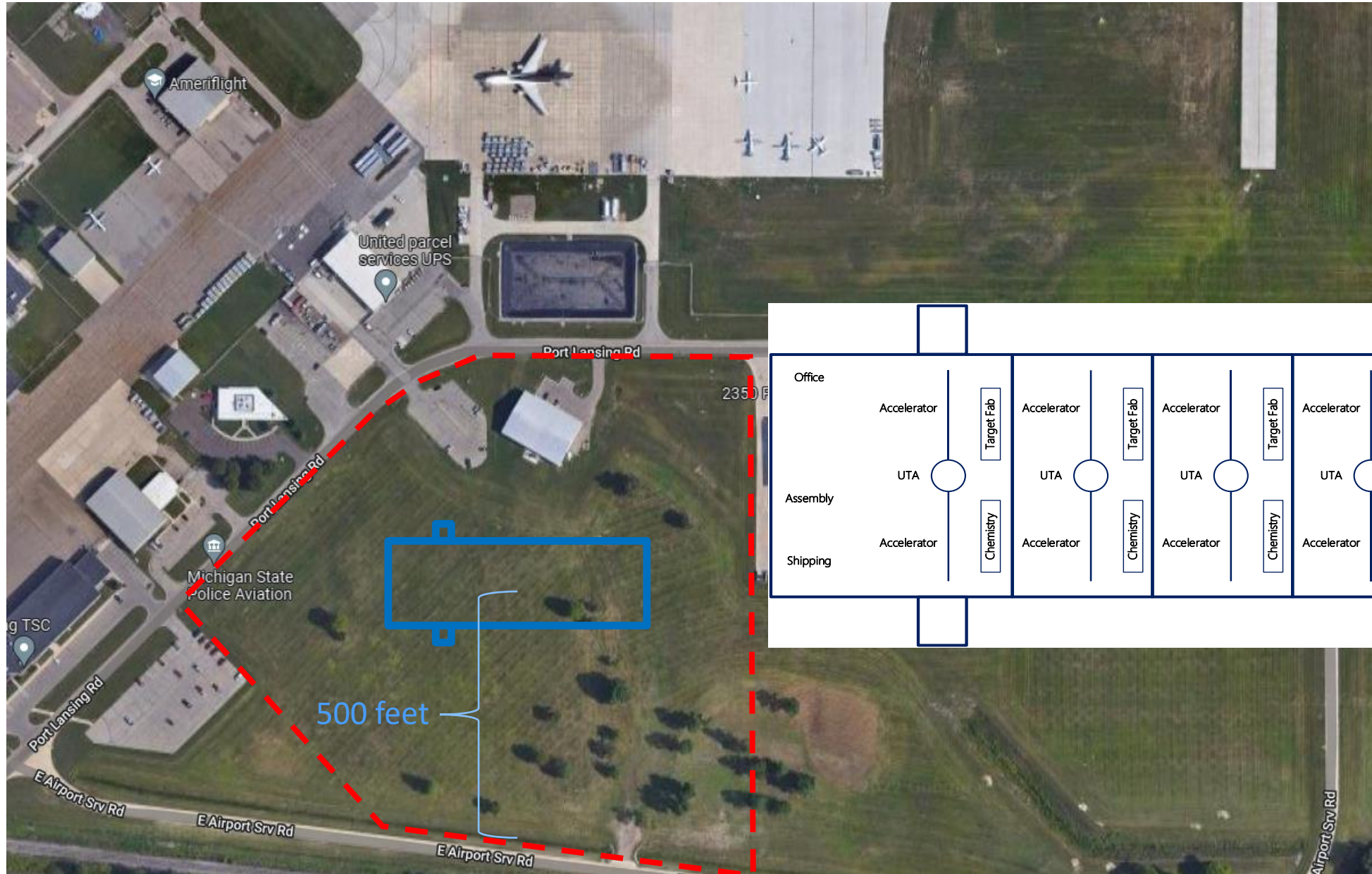
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Mo-99 Commercial Facility



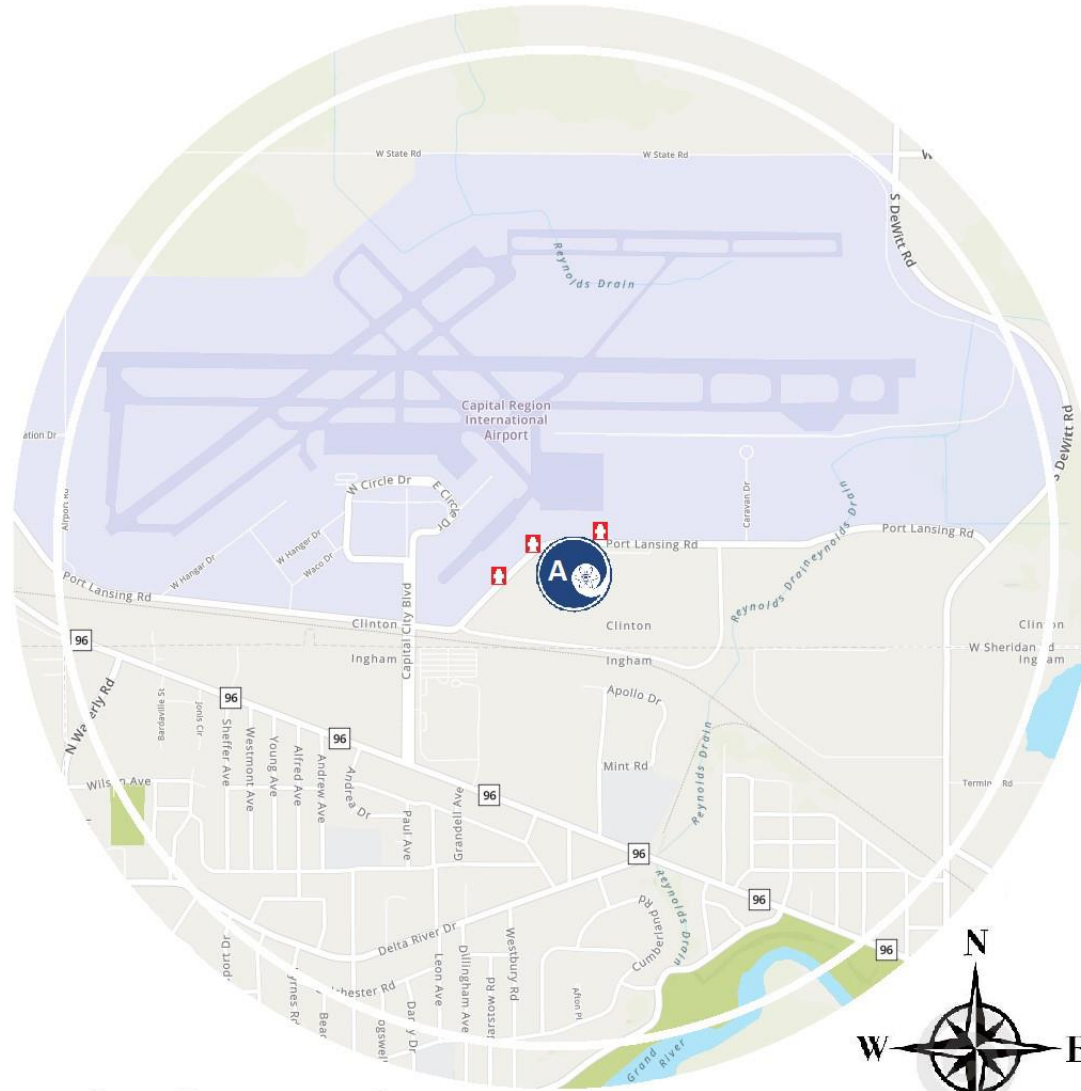
Mo-99 Commercial Facility

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Airport Location

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Facilities not
in flight path

**1 mile radius centered at
Niowave's Airport Facility**

 **Fire Hydrant**



Next Steps

- Continue design development for commercial facility
- Move forward with leasing land
- Start building during review (if NEPA Cat Ex)
- Perform hazard and consequence analyses
- Prepare ISA summary and supporting documentation
- Prepare a license application following NUREG-1520 (informed, as appropriate by the ISG to NUREG-1537)

Next Meetings

- NEPA Categorical Exclusion Determination
- Security, Structural, Fire Safety, Emergency Management
- Management Measures QA, Cyber security, MCA, DFP
- Mechanical, Human Factors, Instrumentation & Controls
- Neutronics, Thermal Hydraulics, Shielding
- Radiochem, Waste
- ISA, Rad Protection, Crit Safety



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Thank You