

NIOWAVE'S DOMESTIC PRODUCTION OF MO-99 AND OTHER FISSION PRODUCTS WITHOUT A NUCLEAR REACTOR

NRC PUBLIC MEETING
NOVEMBER 9TH, 2021

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OUTLINE (PUBLIC MEETING)

- Niowave Background
- Radioisotope program overview
- Reactor Program
- Ac-225 Program
- Mo-99 Program
 - Accelerator
 - Uranium Target Assembly
 - Radiochemistry
 - Phase 2 status

NIOWAVE BACKGROUND

COMPANY HISTORY



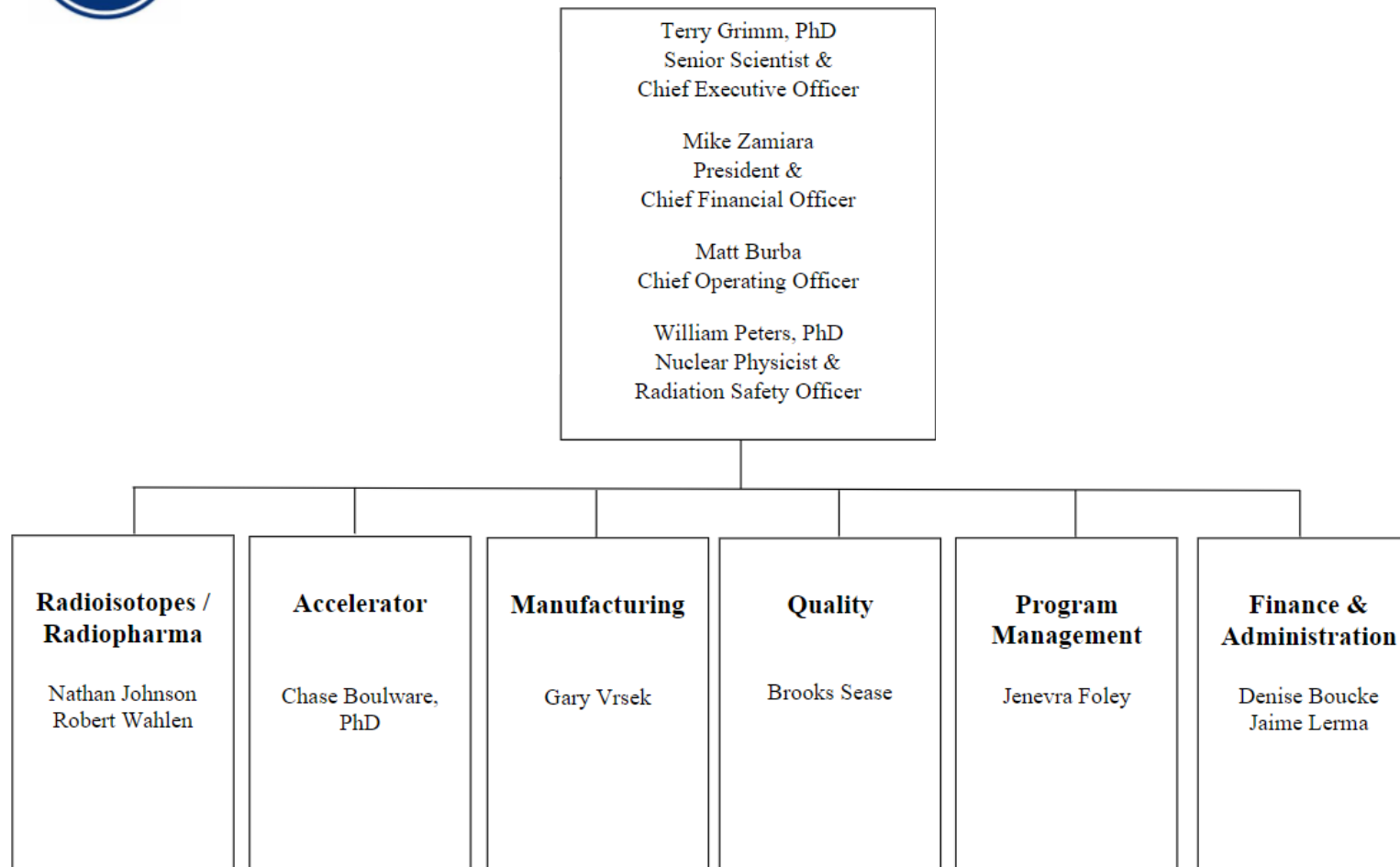
In 2005, founder Dr. Terry Grimm spread his entrepreneurial wings to develop commercial applications for the accelerator technology he had been developing in DOE labs for 20 years. In the last 15 years, Niowave has been awarded \$100M+ of contracts to develop its technology, culminating in selection for a \$30M award to provide a domestic supply of Mo-99 in the US.



ORG CHART

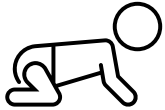


Niowave Organizational Chart



NIOWAVE
Accelerating Your Particles

PATH TO VERTICAL INTEGRATION



\$1.1B

CRAWL: RADIOISOTOPES

- Sell radioisotopes as raw material to OEMs and CDMOs for production of a drug
 - Examples: Mo-99, Y-90, Ac-225
- Starting Q3 2021
- Sales will be by activity level (i.e. mCi), pricing will decrease as volumes go up
 - \$1000s/kCi for > kCi/wk demand
 - \$1000s/Ci for >100 Ci/wk
 - \$1000s/mCi for <1 Ci/wk



\$3.8B

WALK: RADIOLABELED ISOTOPES

- Bind targeting molecule to the radioisotopes we produce, package doses and distribute as CDMO
 - Optimized supply chain length by combining all manufacturing steps
 - Newly launched products or ones with complex supply chains are best value
 - Examples: Ac-225, Lu-177 + PSMA
- Some contracting in 2021, full support available in 2022
- Sales will be by dose, will likely be tied to reimbursement payment from the hospital



\$6.9B

RUN: RADIOPHARMACEUTICALS

- Launch a new cancer-fighting drug to the market with industry and financial partners
 - MSU (trastuzumab)
 - Ac-225
- Development projects start in 2021; full drug development over 3-5 years
- Requires significant capital to fund FDA clinical trials
- Uniquely positioned to supply a variety of isotopes to multiple research centers

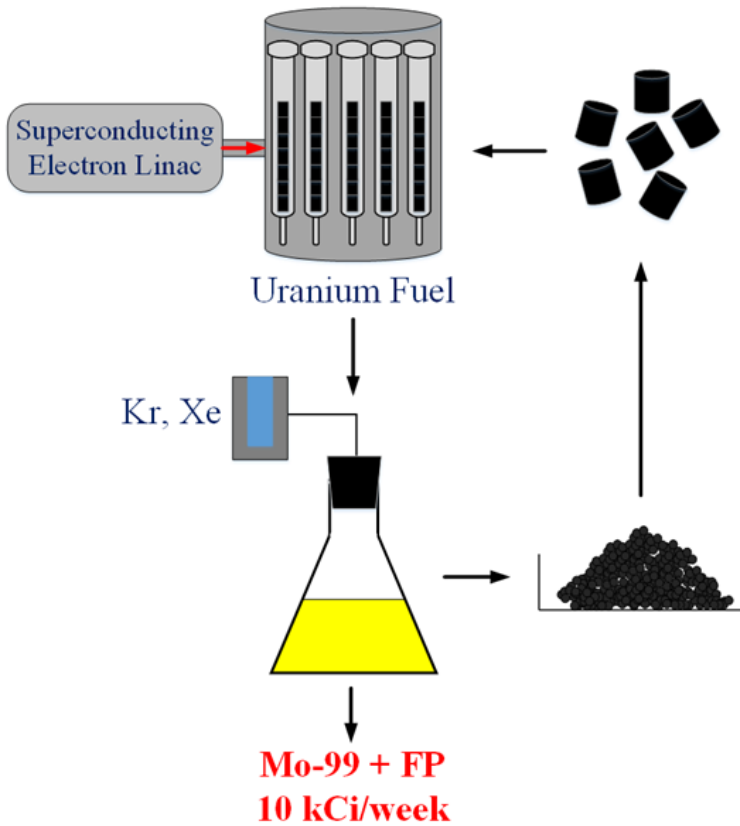


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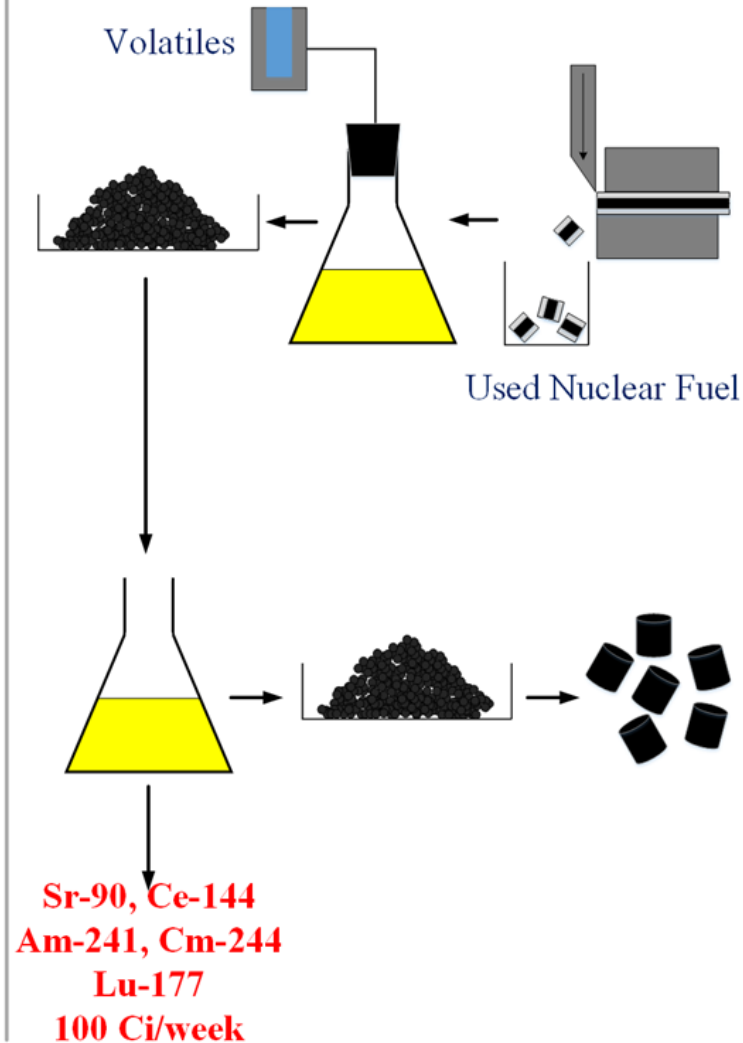
RADIOISOTOPE PROGRAMS

ISOTOPE PROGRAM OVERVIEW

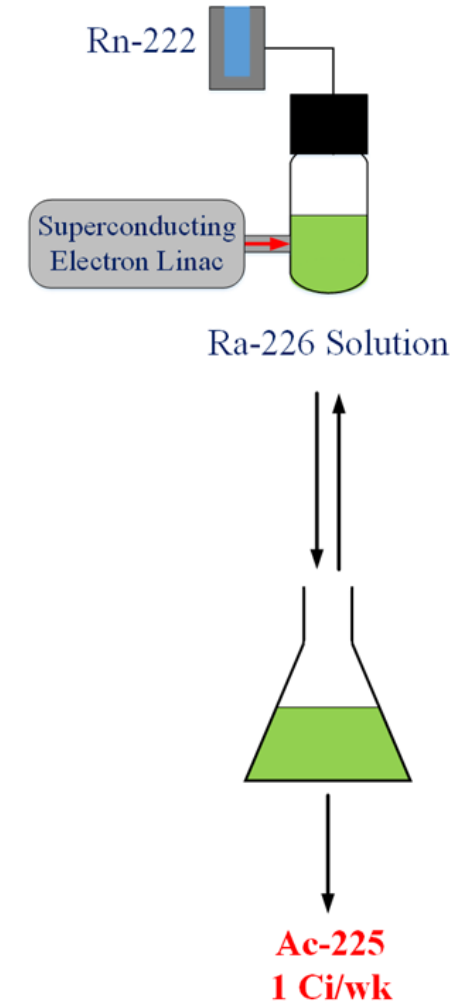
Mo-99 Program



Reactor Program



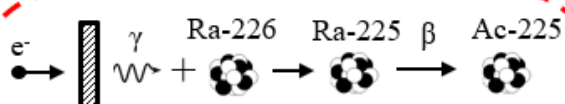
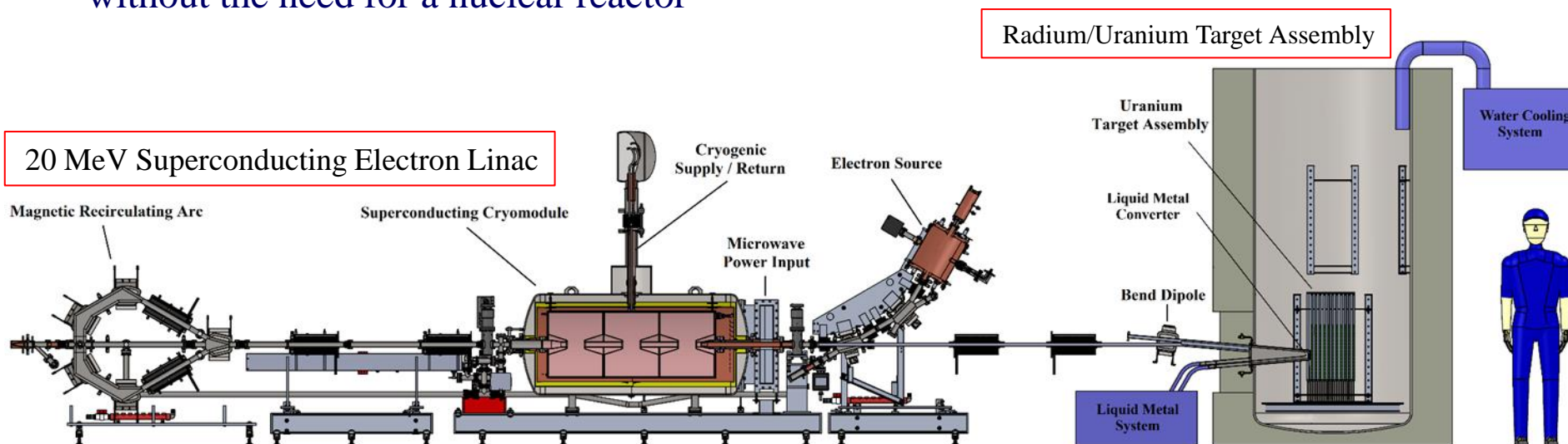
Ac-225 Program



THERAPEUTIC α & β EMITTERS

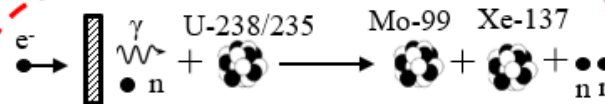
Niowave manufactures radioisotopes from radium and uranium using a superconducting electron linear accelerator without the need for a nuclear reactor

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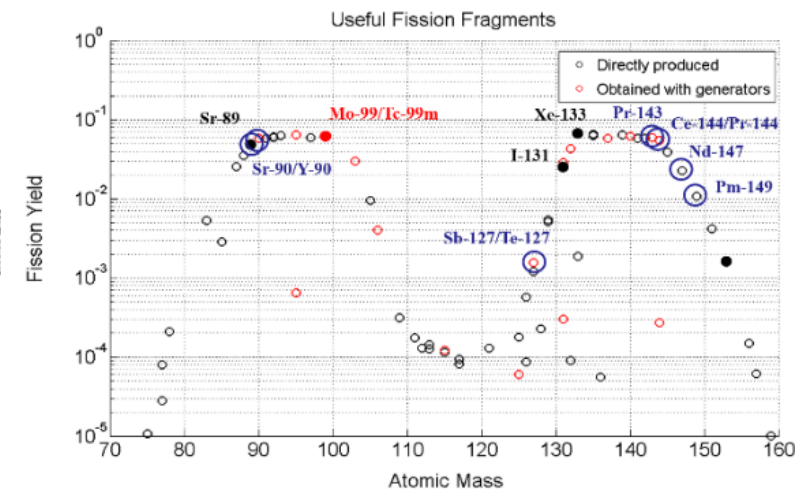
Radium
(Ra-226)
 α emitters

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

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





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Accelerating Your Particles

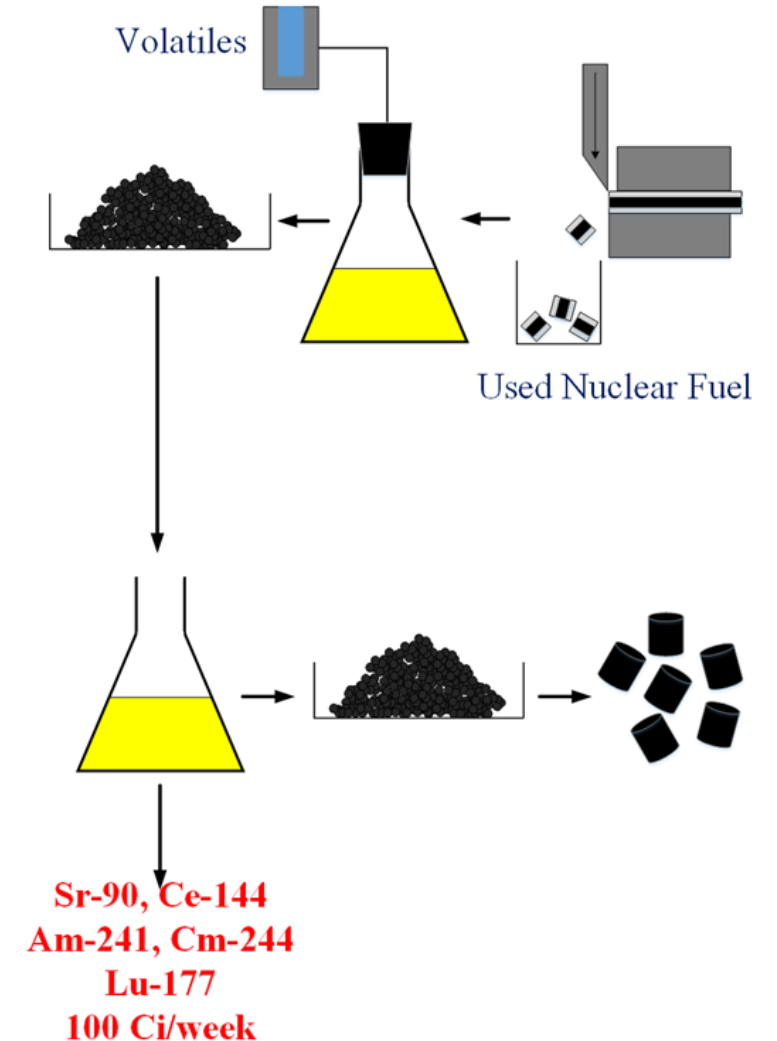
REACTOR PROGRAM

REACTOR* PROGRAM

*someone else's reactor

- Sr-90
 - Recovered from used fuel
 - Extract and purify Y-90
 - Niowave's first commercial isotope
 - ISO-13485 registered (FDA)
- Lu-177
 - Generated from Yb pellets
 - Loaded into research reactors
 - Extracted and purified at Niowave
 - Supply a growing market

Reactor Program



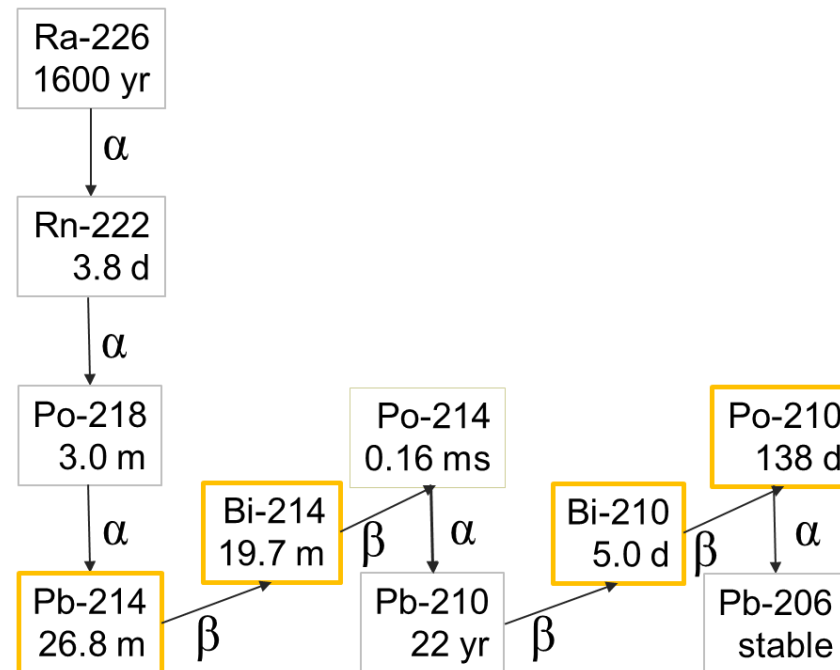


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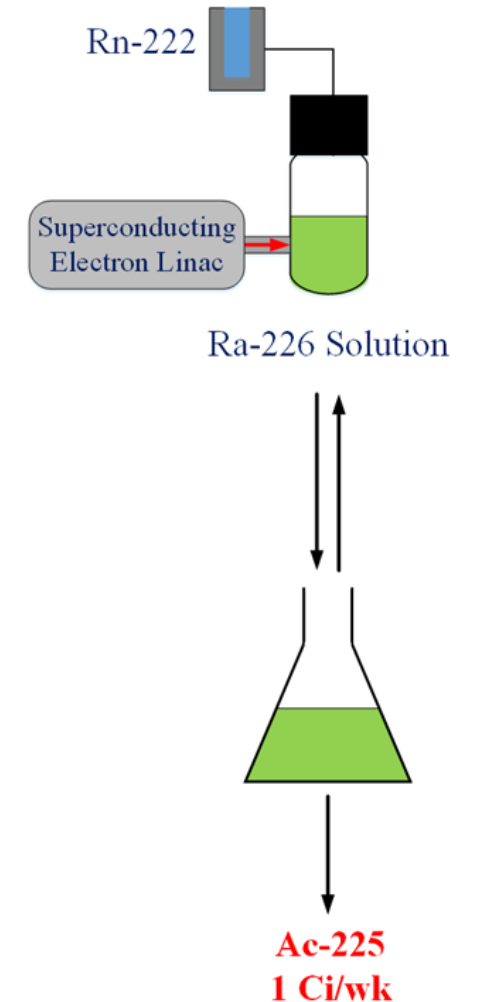
AC-225 PROGRAM

AC-225 PROGRAM

- Linac used to produce Ac-225 from radium target material
- Natural decay products also extracted



Ac-225 Program





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MO-99 PROGRAM

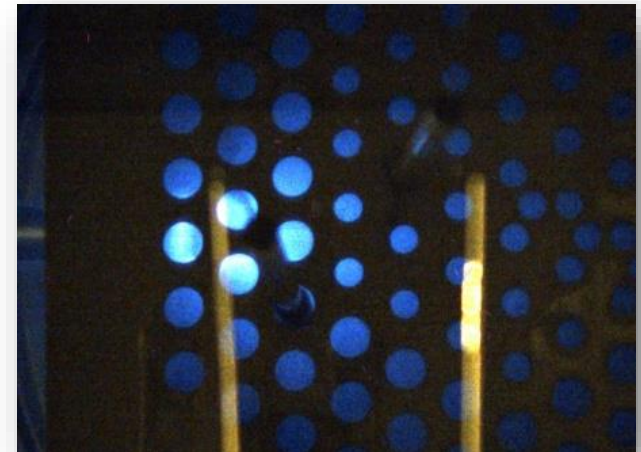
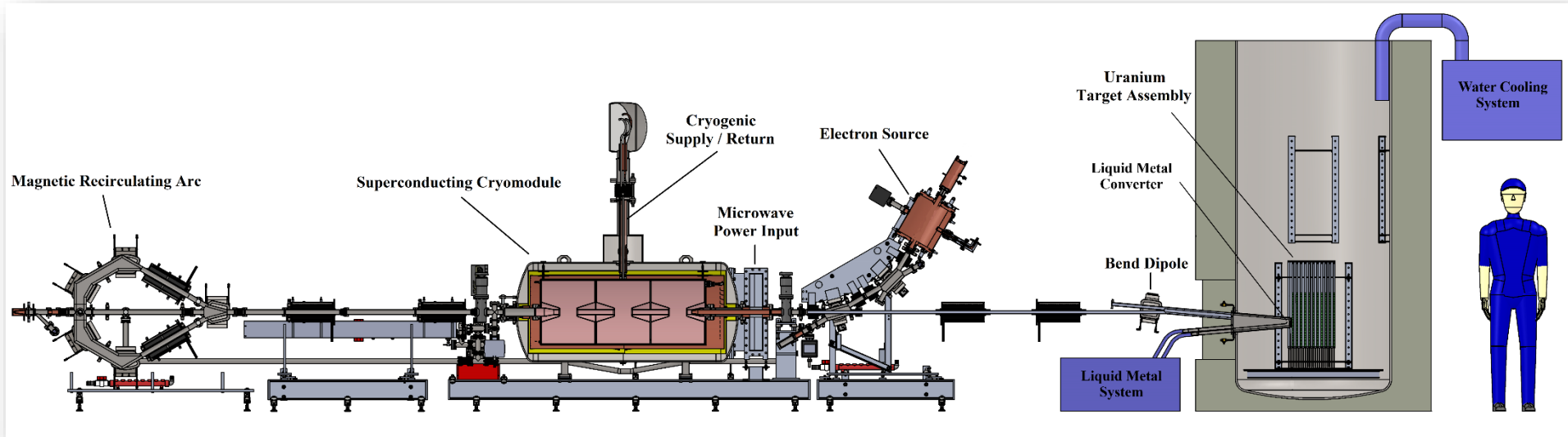
SCALING UP TO COMMERCIAL SCALE



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ACCELERATOR

ACCELERATOR TECHNOLOGY



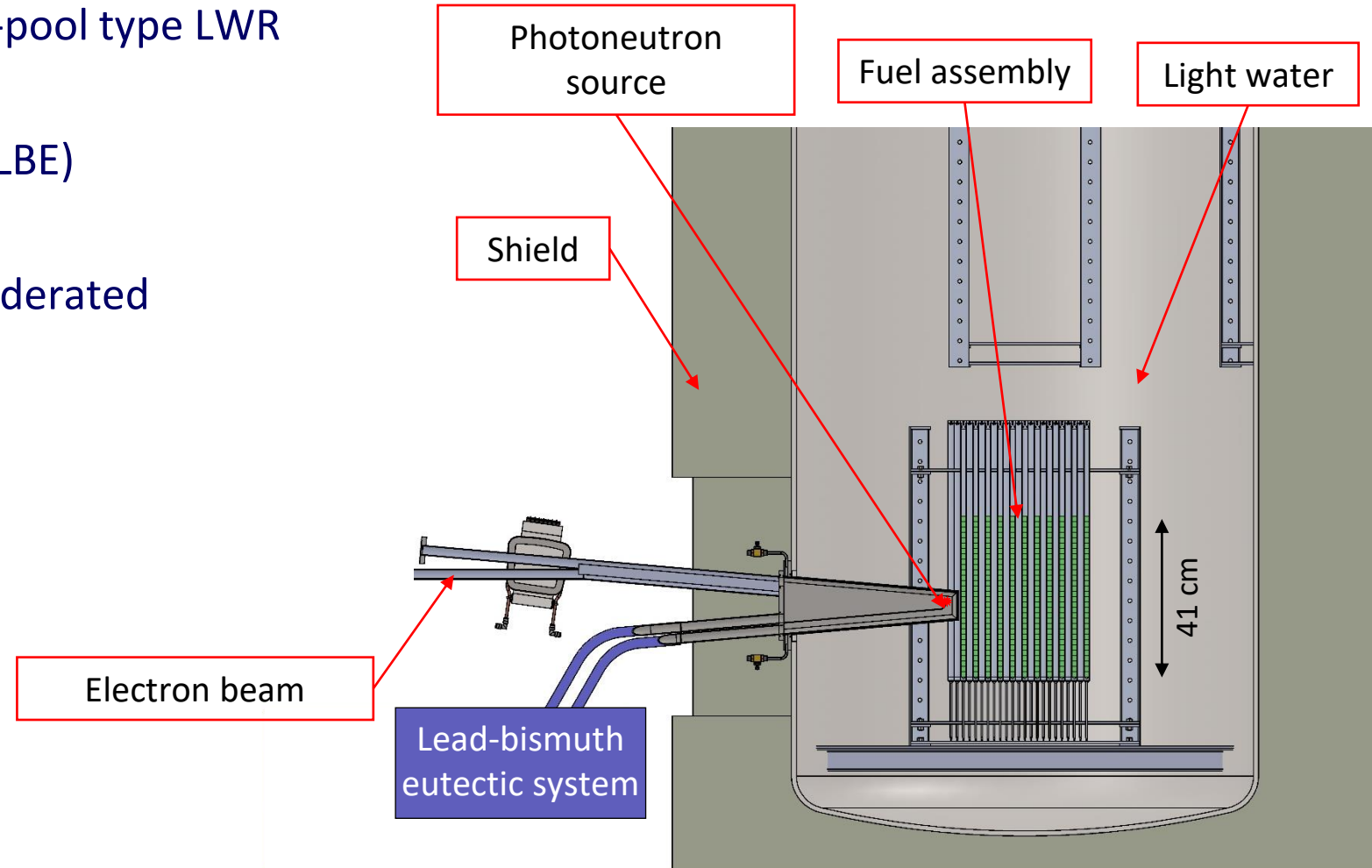


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URANIUM TARGET ASSEMBLY

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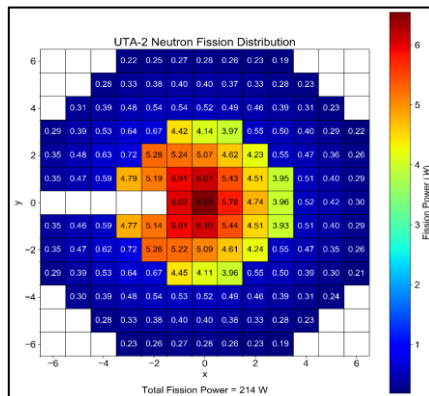
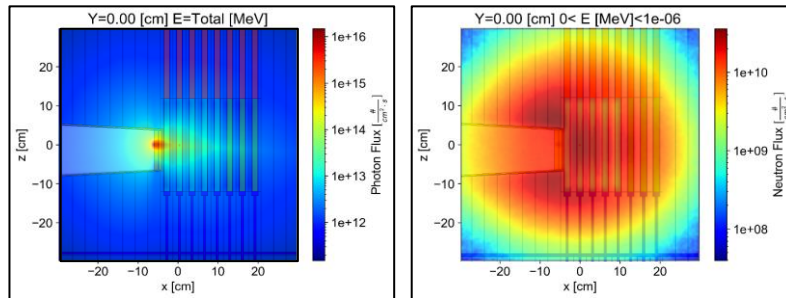
- The Uranium Target Assembly (UTA) is a subcritical assembly, open-pool type LWR
 - Electron linac driven
 - Photoneutron source (LBE)
 - Uranium oxide fuel
 - Light water cooled, moderated



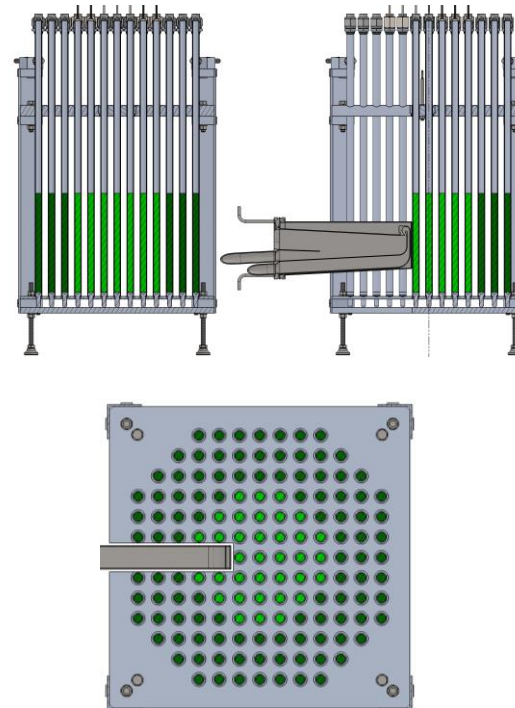
UTA-2, PILOT SCALE

- 230 W fission power, 20 MeV / 10 kW electron beam
- 4.5 kgU LEU, 15 kgU NU
- Neutronics and shielding design complete in collaboration with ORNL
- Mechanical design and construction underway.

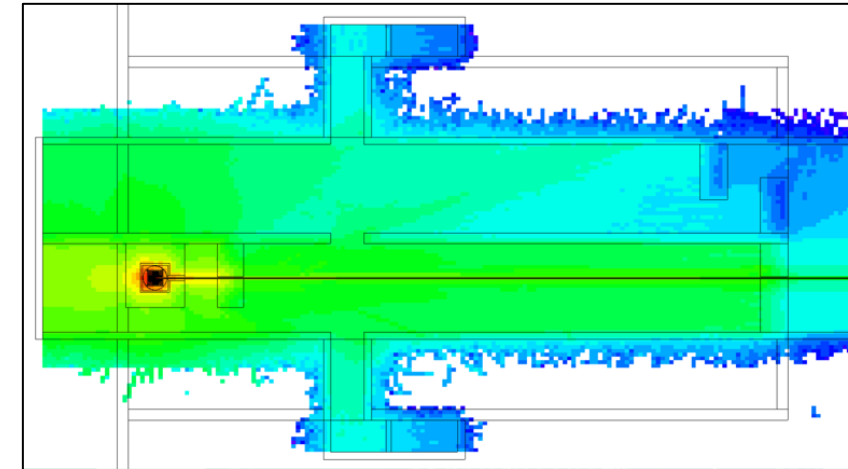
Neutronics Design



Mechanical Design



Shielding Simulations

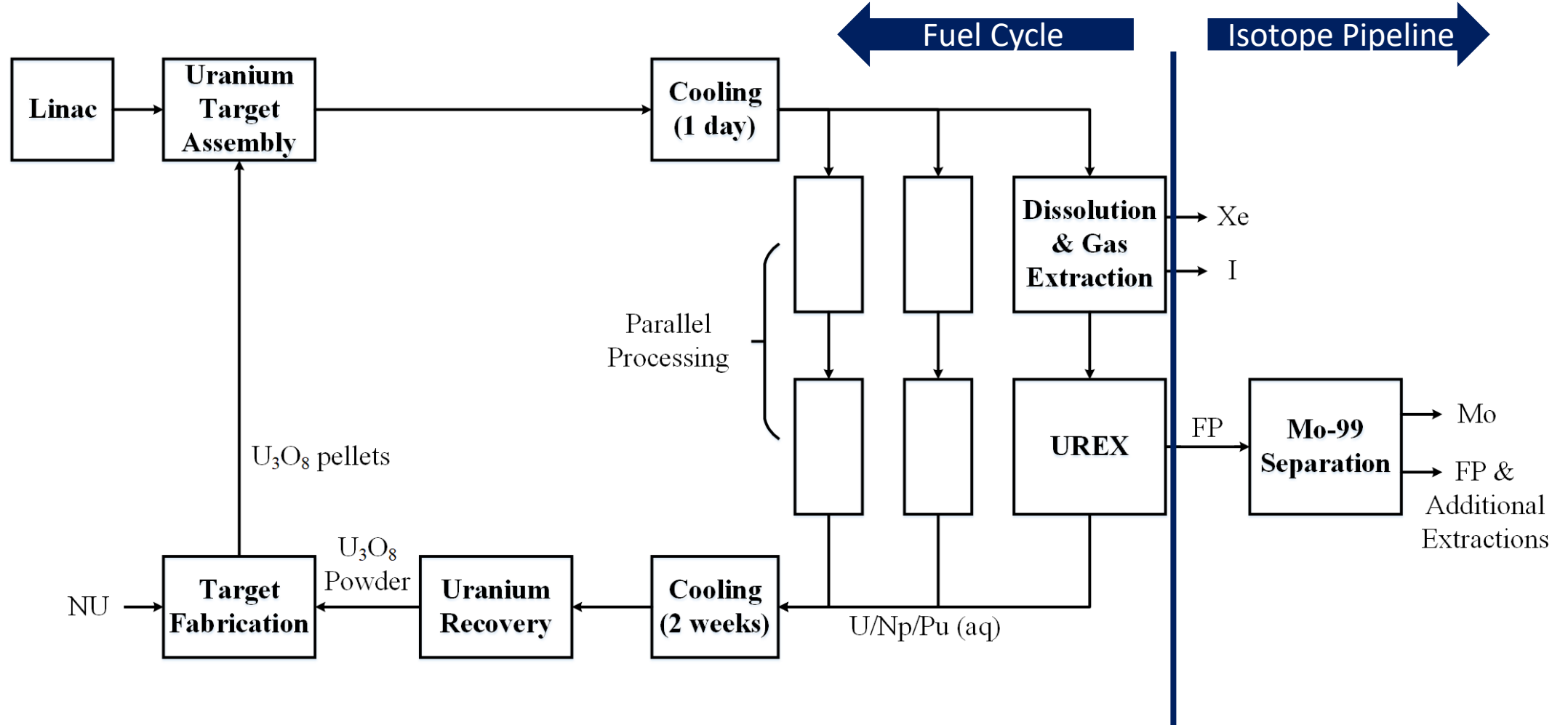




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RADIOCHEMISTRY

CLOSED-LOOP FUEL CYCLE



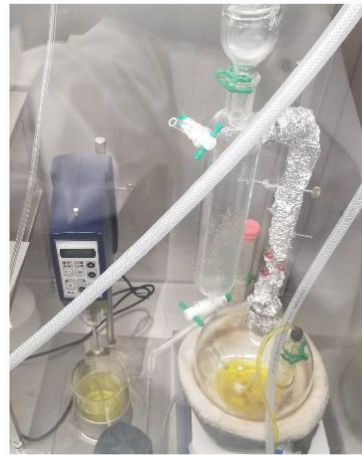
Dissolution, Xenon & Iodine Extraction



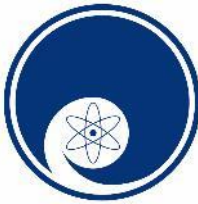
UREX



Uranium Recovery



Target Fabrication

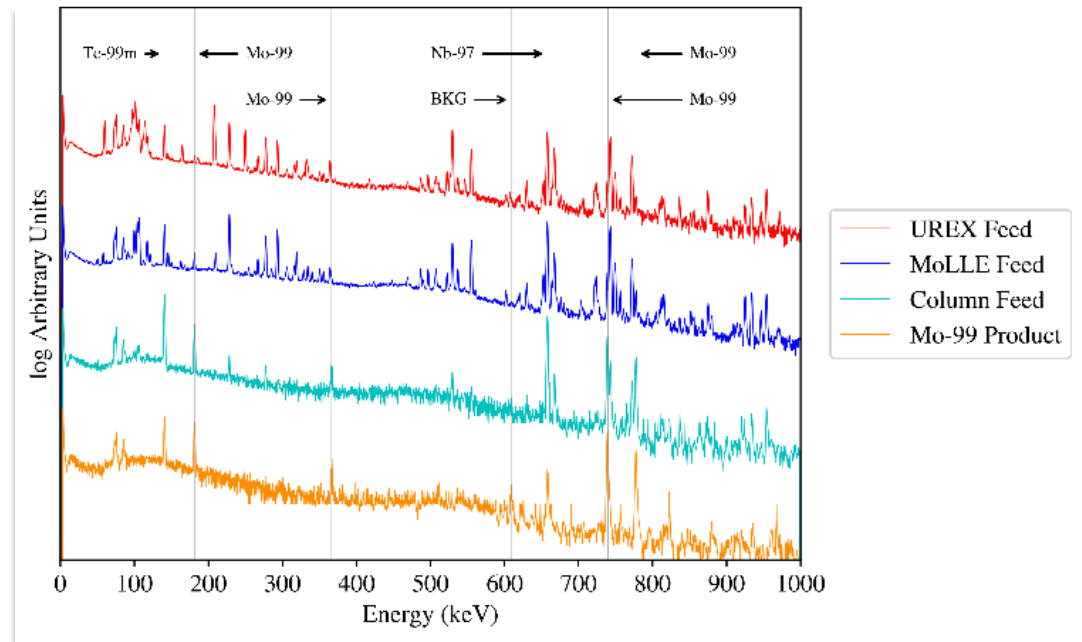


NIOMAVE
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MO-99 CHEMISTRY

Mo-99 Separation Chemistry:

- Mo-99 extracted using a novel liquid-liquid extraction technique.



M. Alex Brown, et.al., "Recovery of High Specific Activity Molybdenum-99 from Accelerator-Induced Fission on Low-Enriched Uranium for Technetium-99m Generators." *Scientific Reports*

NATIONAL LAB & UNIVERSITY PARTNERS

Argonne – UREX, Mo-99 Chemistry

LANL – LBE Target

ORNL – Target Fabrication

PNNL – Dissolution & Gas Extraction

SRNL – UREX

Y-12 – Uranium Recovery

UNLV – UREX, Mo-99 Chemistry, Other Isotopes

MSU – Other Isotopes, Radiopharmaceuticals



STATUS REVIEW

- Reactor and Ac-225 programs
 - Commercial-scale already
 - Amendments to Airport Facility license to grow operations are under review
 - Licensed through NRC Region-III
- Mo-99
 - Phase-2 UTA (pilot scale) is tested and commissioning soon
 - Phase-2 radiochemistry has been demonstrated (complete loop)
 - Entire Phase-2 system is being installed at Airport Facility
 - Commercially viable (with other fission products)
 - Licensed through NRC Region-III

END OF PUBLIC PORTION

The remaining sections of this document contains Niowave Proprietary Data.
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