Niowave's Domestic Production of Mo-99 from LEU without a Nuclear Reactor

Terry L. Grimm, Stephen S. Barnard, Chase H. Boulware,
Faisal Y. Odeh, Kristin A. Gore, Amanda K. Grimm,
Jerry L. Hollister, Mayir Mamtimin, and Valeriia N. Starovoitova
Niowave, Inc.
Lansing MI

September 2016
Presented at the Mo-99 Topical, St. Louis MO

NIOWAVE
Accelerating Your Particles

Outline

NIOWAVE
www.niowaveinc.com

- Superconducting Linacs and Their Applications
- Mo-99 Production from LEU
  - Intense Neutron Source
  - Uranium Targets
  - Radiochemistry
  - Uranium Recycling
- Business Plan
- Licensing (NRC and State of Michigan)
- Niowave Facilities

Why Superconducting?

NIOWAVE
www.niowaveinc.com

- 10^6 lower surface resistance than copper
  - Most RF power goes to electron beam
  - CW/continuous operation at relatively high accelerating gradients >10 MV/m

frequency

superconducting transition temperature

$$R_{BCS} \propto f^2 \exp\left(-\frac{T_c}{T}\right)$$

operating temperature

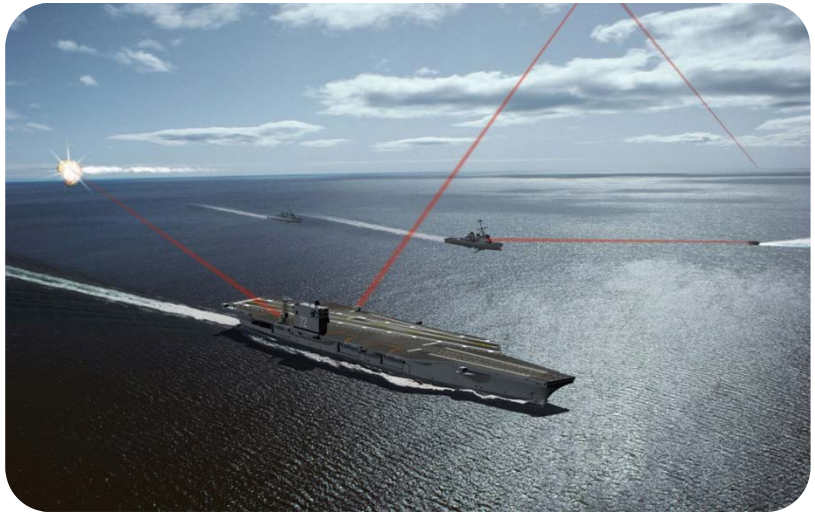
- For commercial electron linacs the minimum costs for a system occur around:
  - 300-350 MHz (multi-spoke structures)
  - 4.5 K (>1 atmosphere liquid helium)

Commercial Uses of Superconducting Electron Linacs

NIOWAVE
www.niowaveinc.com

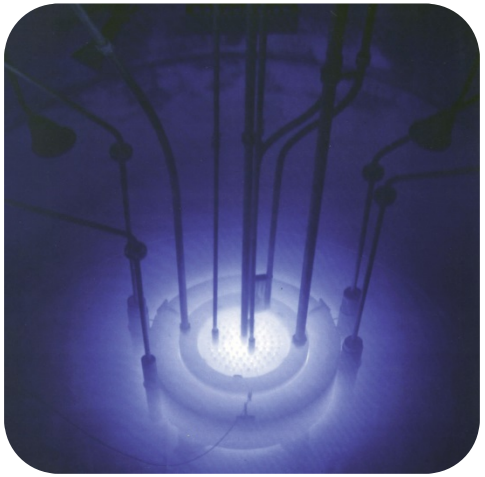
High Power X-Ray Sources

Radioisotope Production



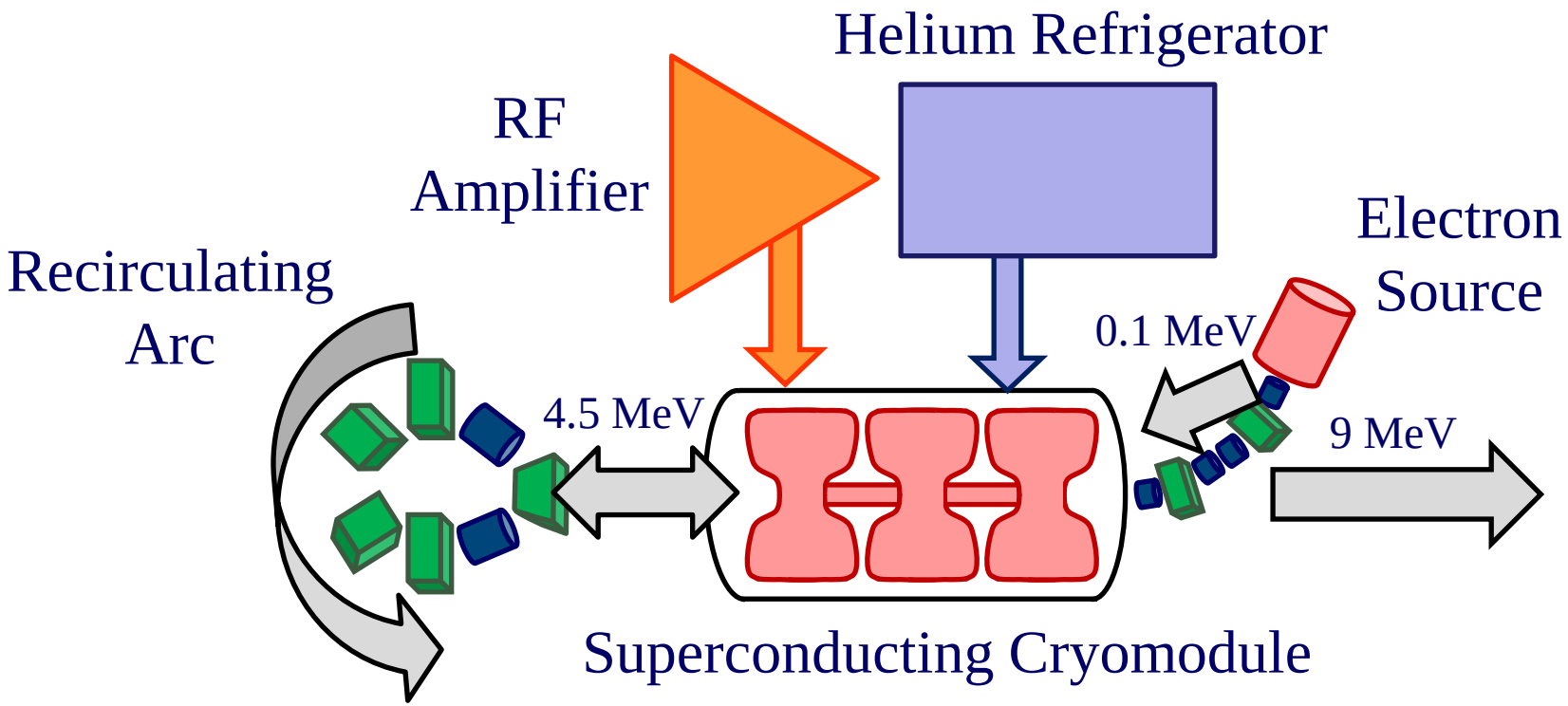
Free Electron Lasers

High Flux Neutron Sources



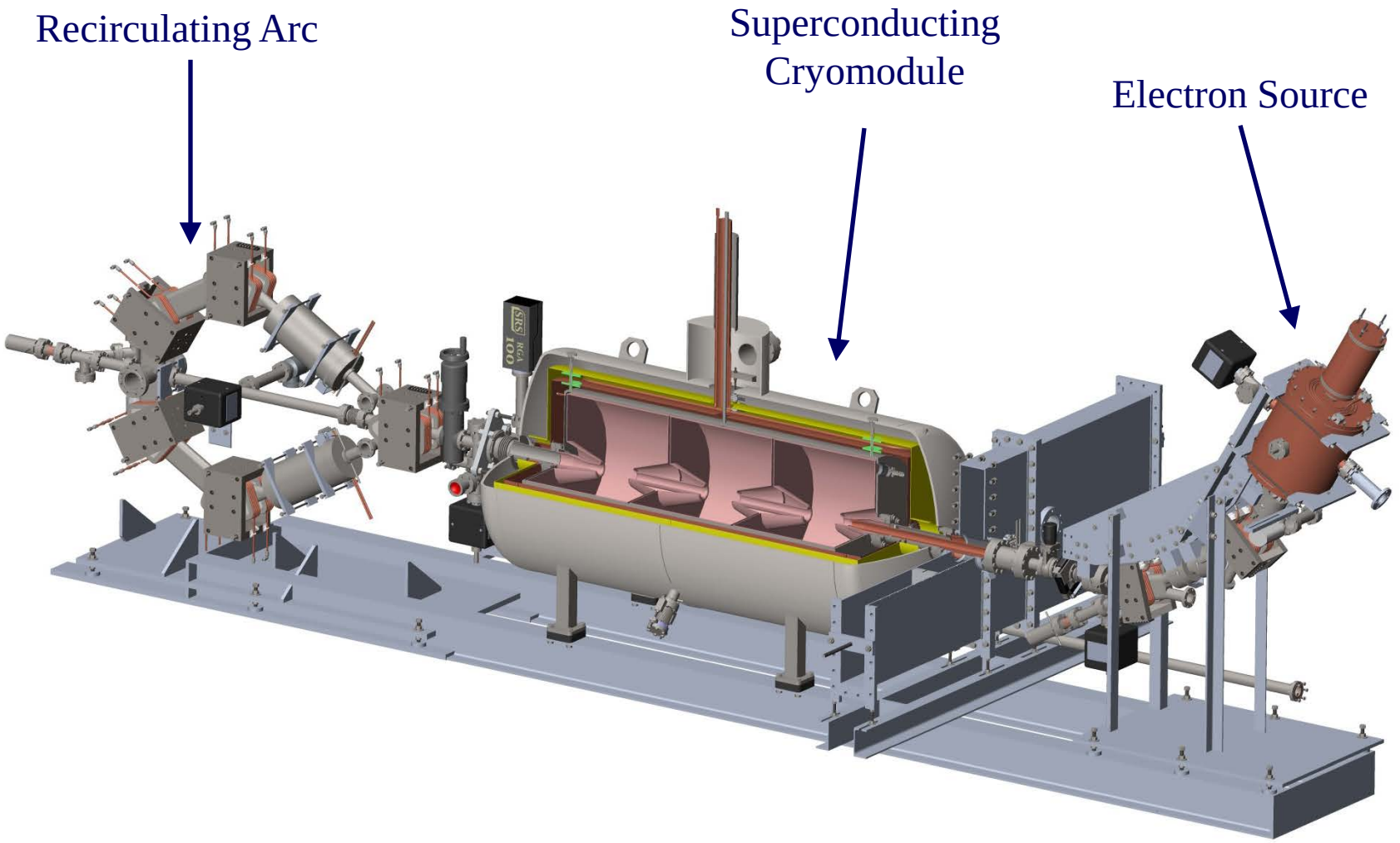
Superconducting Electron Linac [1]

NIOWAVE
www.niowaveinc.com

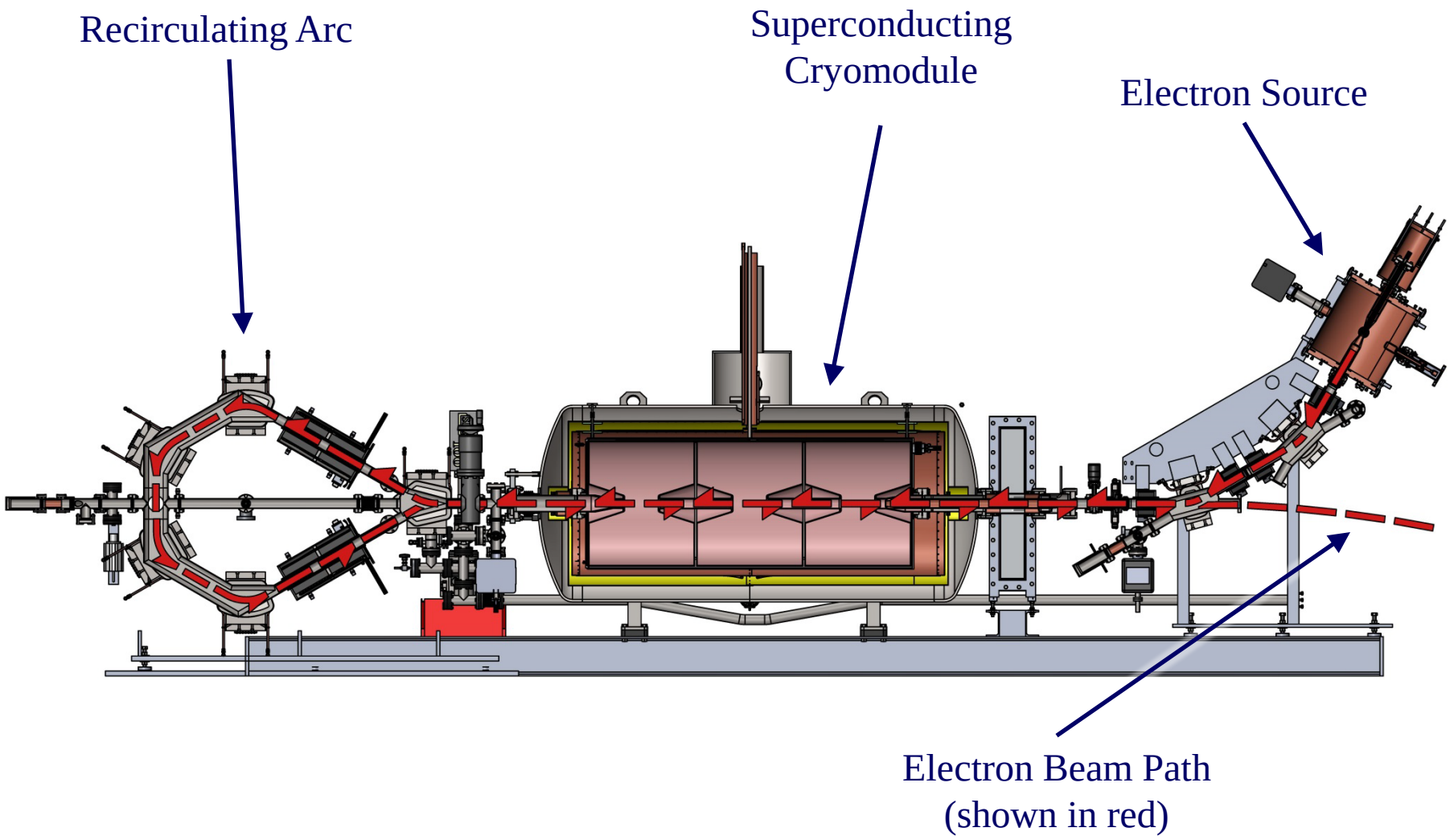


Energy	**Application**
< 9 MeV	Sterilization & Material Processing
9 MeV	Active Interrogation
> 9 MeV	Radioisotope Production

Superconducting Electron Linac [2]



Superconducting Electron Linac [3]



Turnkey Linac Subsystems [1]

NIOWAVE
www.niowaveinc.com

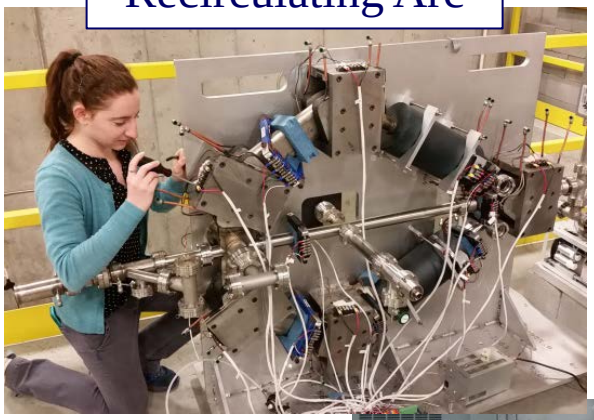
Superconducting cavities
in specialized geometries

Cryomodules

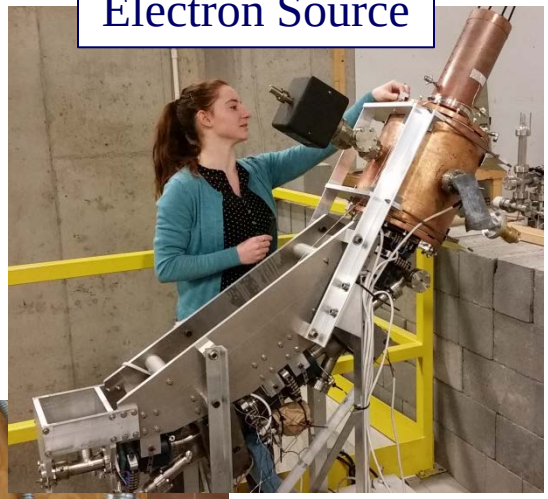
Turnkey Linac Subsystems [2]

NIOWAVE
www.niowaveinc.com

Recirculating Arc



Electron Source



Superconducting Cryomodule

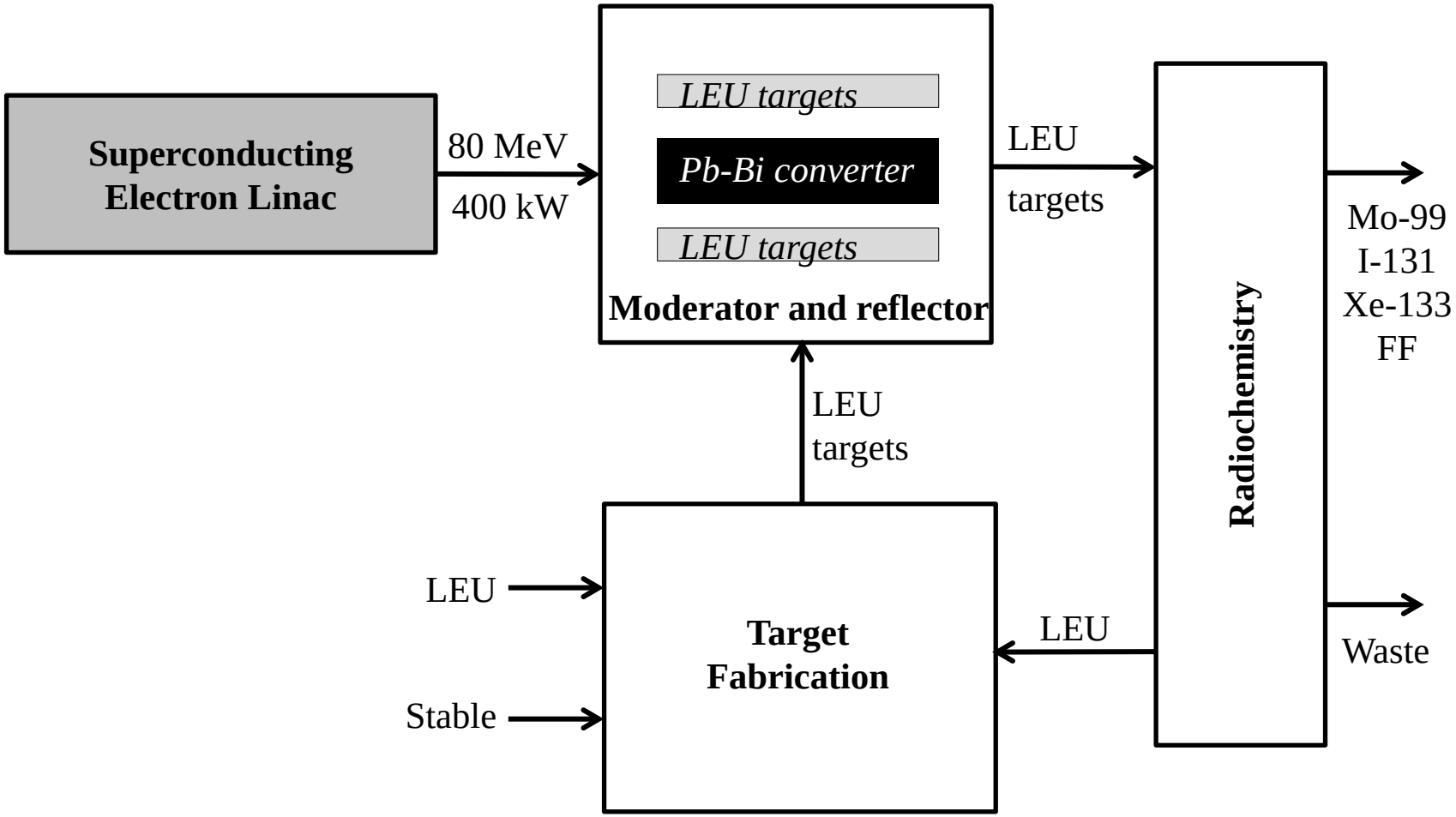
Turnkey Linac Subsystems [3]

NIOWAVE
www.niowaveinc.com

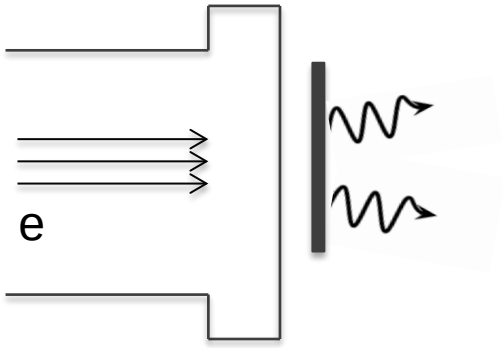
Solid-state and tetrode RF amplifiers (up to 60 kW)

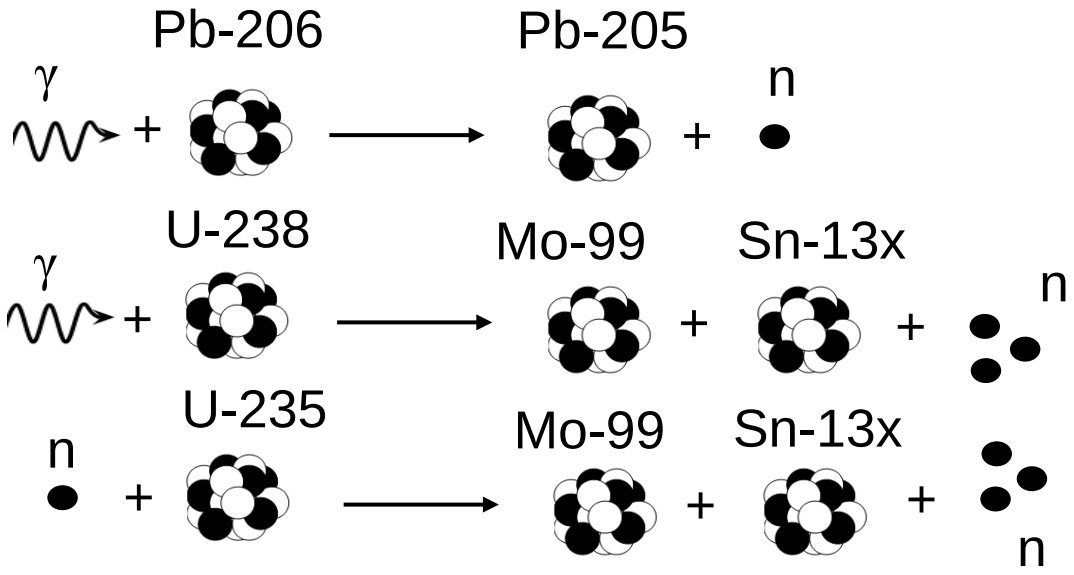
Commercial 4 K refrigerators (rugged piston-based systems, 100 W cryogenic capacity)

Conceptual Design



Intense Neutron Source [1]





Electrons are accelerated

Electrons break and produce photons

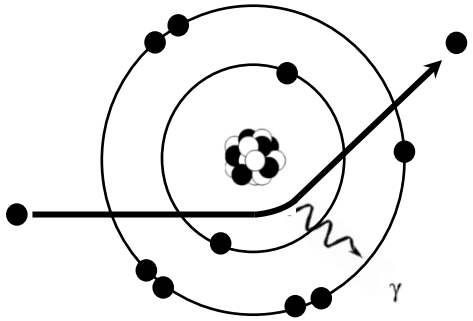
Neutrons are generated by:

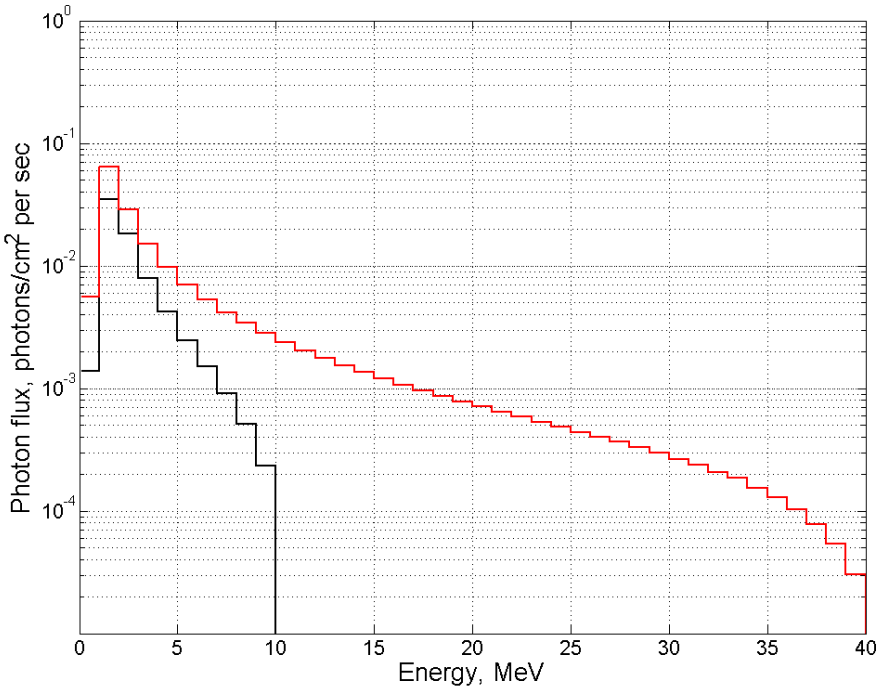
a) (γ, n) reactions
b) Photo-fissions
c) Neutron-induced fission

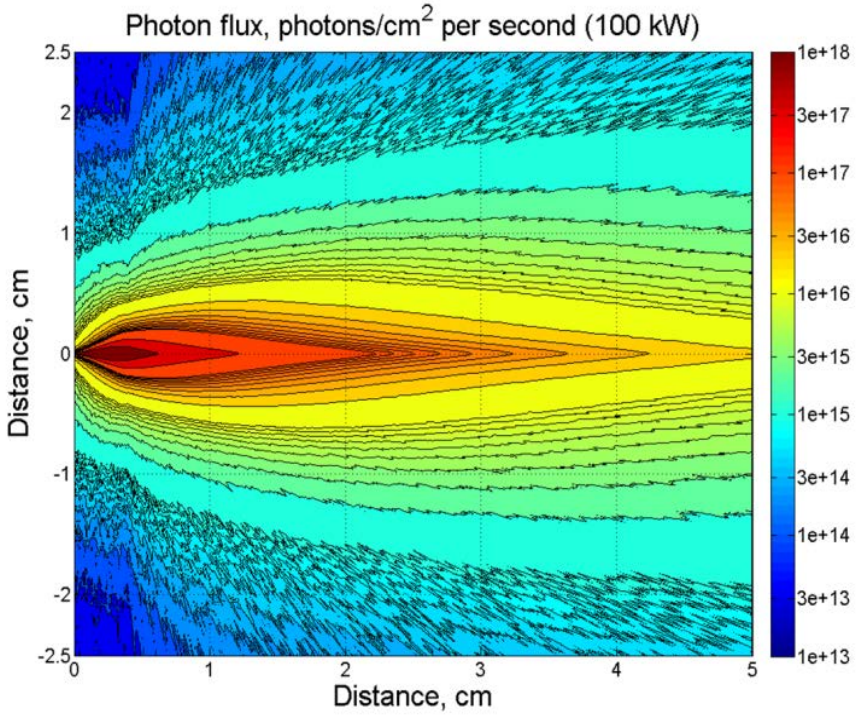
Intense Neutron Source [2]

NIOWAVE
www.niowaveinc.com

Breaking radiation (bremsstrahlung photons):





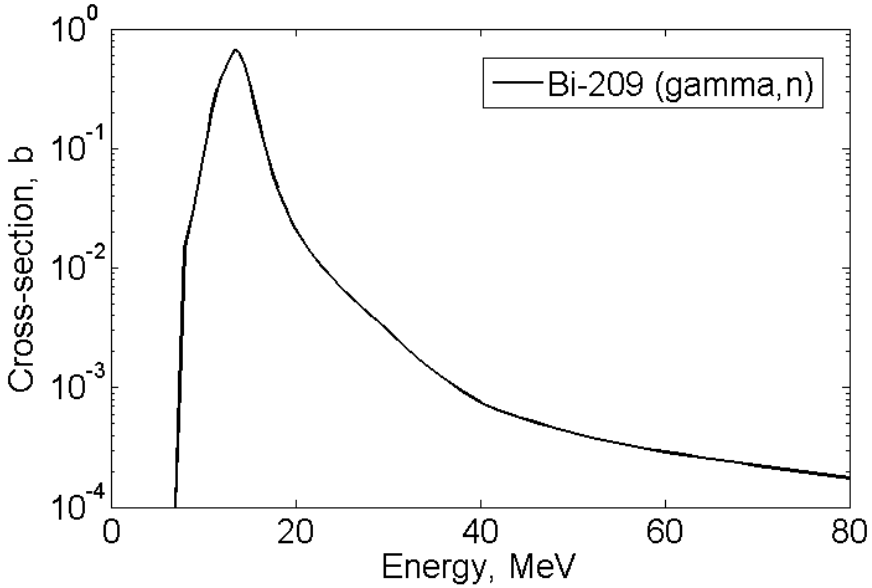


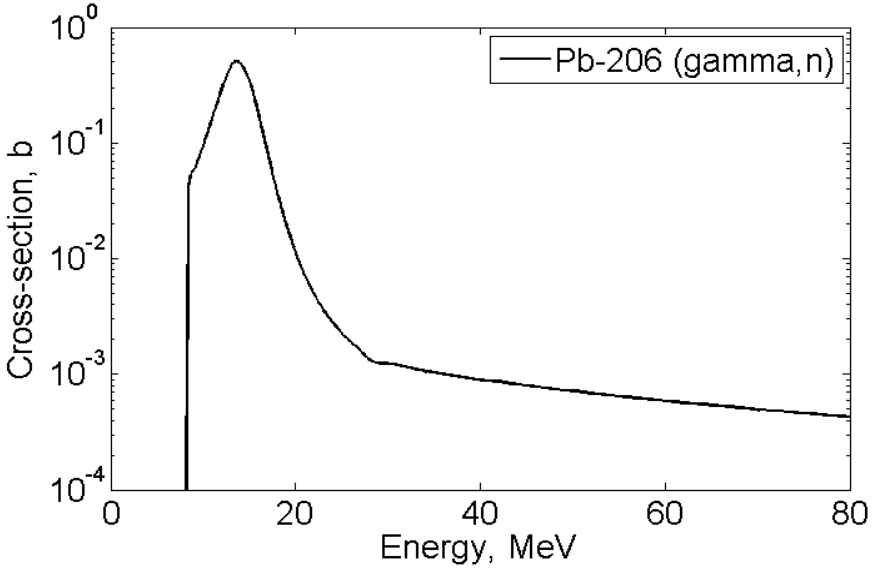
Intense Neutron Source [3]

NIOWAVE
www.niowaveinc.com

Lead-Bismuth Eutectic (PbBi):

- High conversion efficiency (Z=82,83)
- Low melting point (124°C)
- High boiling point
- (1670 °C)

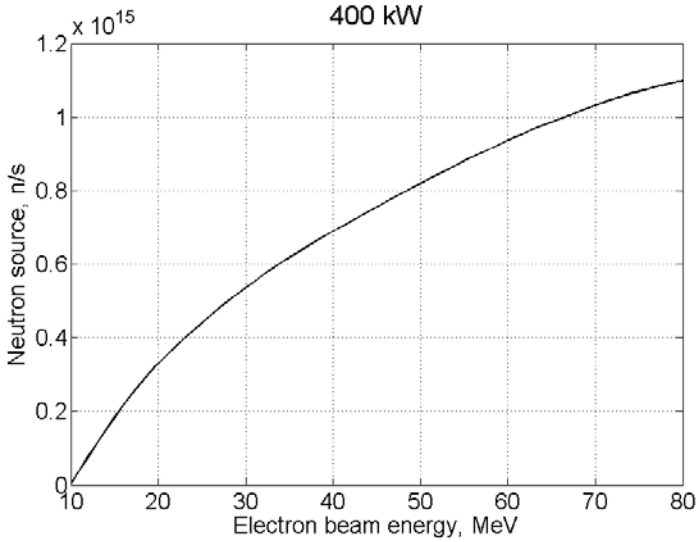


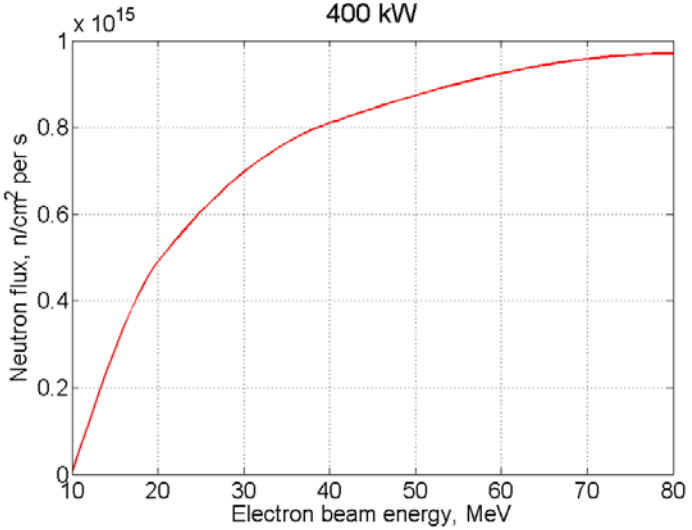


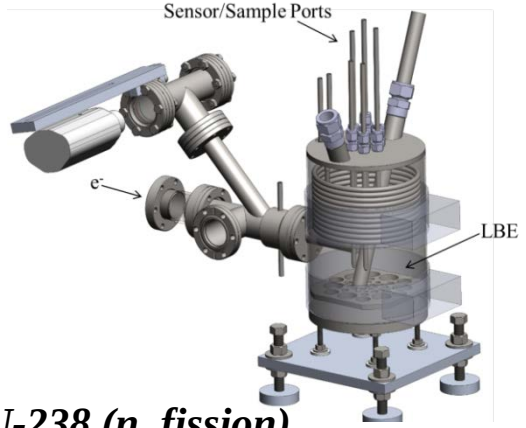
Intense Neutron Source [4]

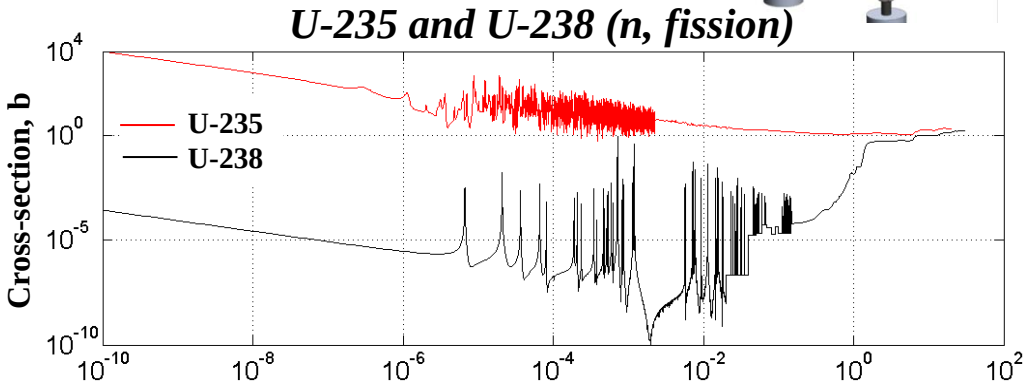
NIOWAVE
www.niowaveinc.com

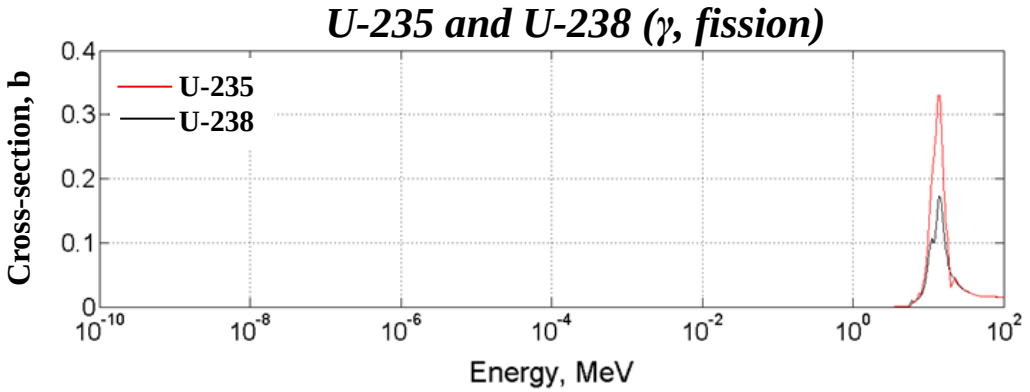
PbBi source intensity & flux:



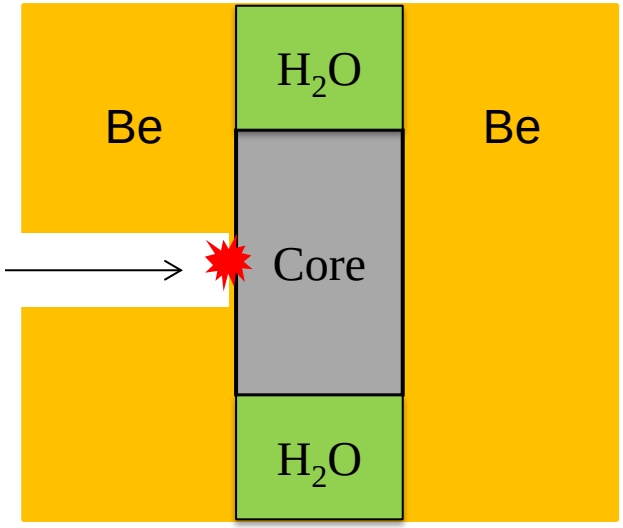


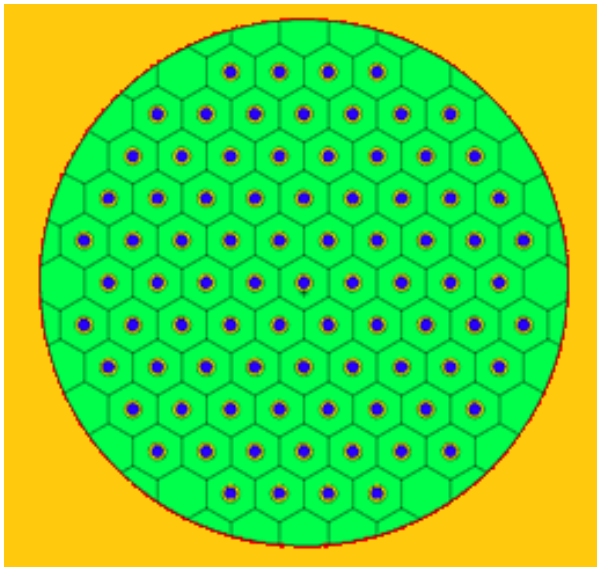






Uranium Targets [1]





LEU mass	< 10 kg
Mass of each rod	< 100 g
Number of rods	~ 90
E-beam power	80 MeV, 400 kW
Neutron source	~ 10^{15} n/s
Peak thermal neutron flux	~ 2x10^{13} n/cm^2*s
Fission power	266 kW
k-value	0.95
Time of irradiation	1 week
U-235 burnup	~ 0.02%
U-235 fissioned	~ 1.7 g/week
Mo-99 activity at the EOB	~ 9 kCi
Total FF activity at the EOB	~ 320 kCi
Total actinide activity at the EOB	~ 43 kCi

Uranium Targets [2]

NIOWAVE
www.niowaveinc.com

- Natural and LEU targets
  - Clad for containment of fission fragments
  - Metal and oxide
- LEU Acquisition
  - Y-12/NNSA
  - Commercial Suppliers

Uranium Targets [3]

NIOWAVE
www.niowaveinc.com

- E-beam: 80 MeV 400 kW
- k=0.95
- LEU core: <20%, <10 kg
- Irradiation: 1 week

Fission fragment	$T_{1/2}$(h)	Activity (kCi/week)	FF Activity Inventory (kCi)		
			EOB	24 hours	3 days
Mo-99	65.9	9.1	~320	~73	~38
I-131	192.5	2.4			
Xe-133	125.8	7.3			
Sr-91	9.6	10.5			
Sr-92	2.7	10.7			

Uranium Targets [4]

NIOWAVE
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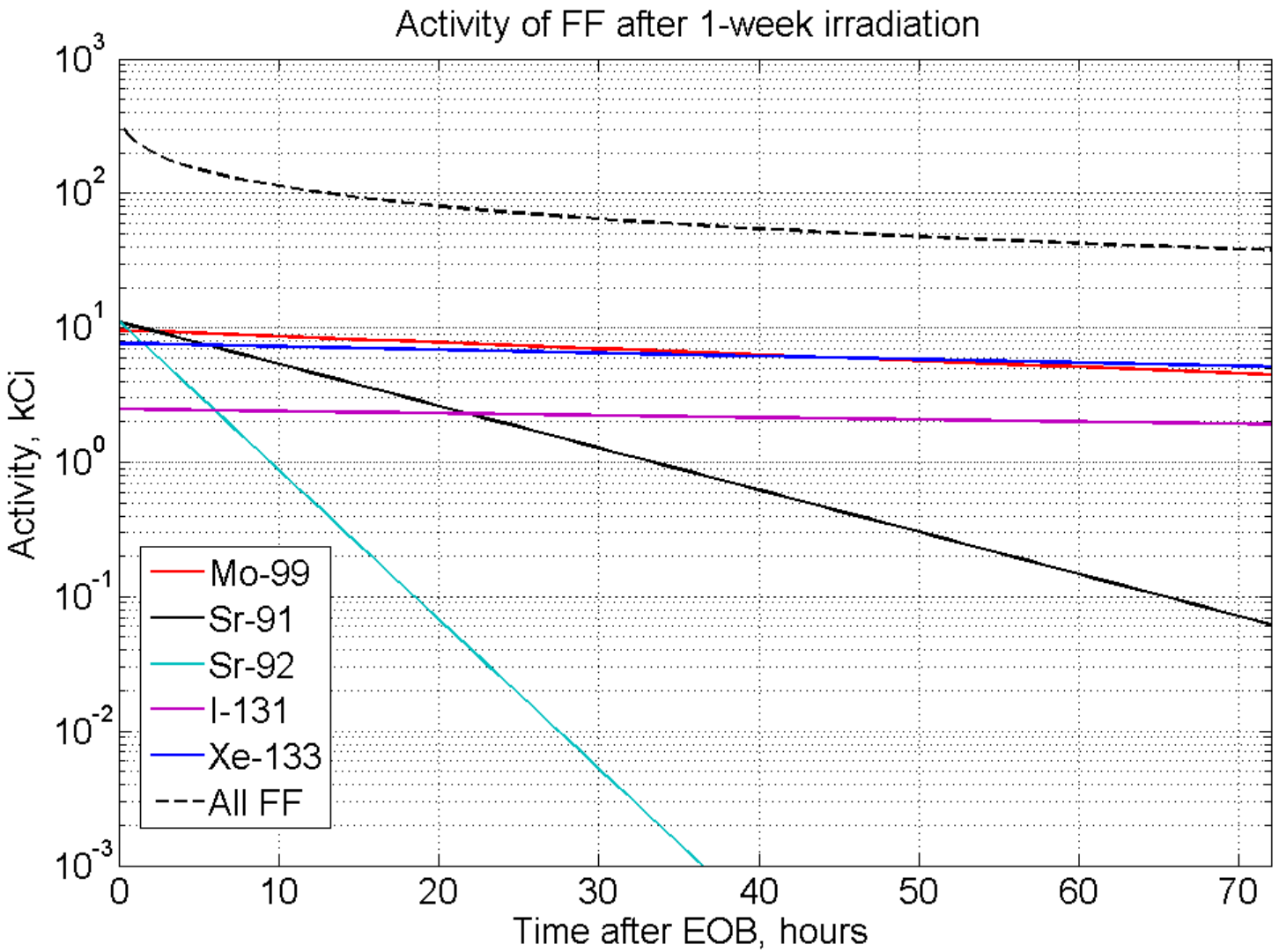


Radiochemistry [1]

NIOWAVE
www.niowaveinc.com

- Twelve rods will be processed daily
- Mass of each LEU rod – 99g
  - If the batch mass is less than 100 g of <20% LEU (<20 g U-235), then Part 30 Byproduct from accelerators applies
- Produce up to 9,000 Ci/wk (1,500 6-day Ci/wk)
- Extraction of Mo-99 and other isotopes using LEU modified Cintichem process
- Standard Tc-99m generators
  - Capable of using the existing supply chain

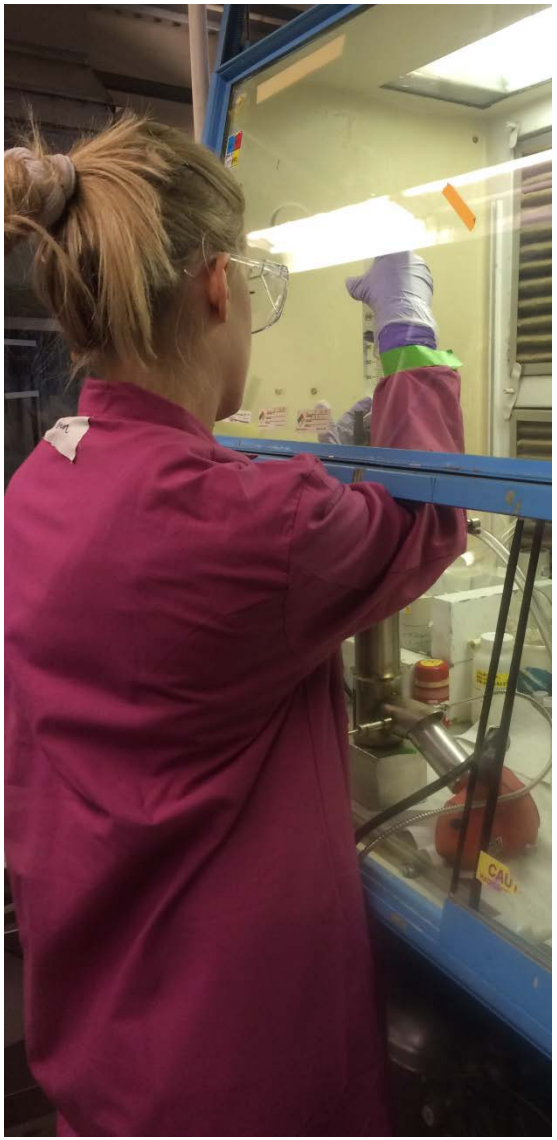
Radiochemistry [2]

NIOWAVE
www.niowaveinc.com

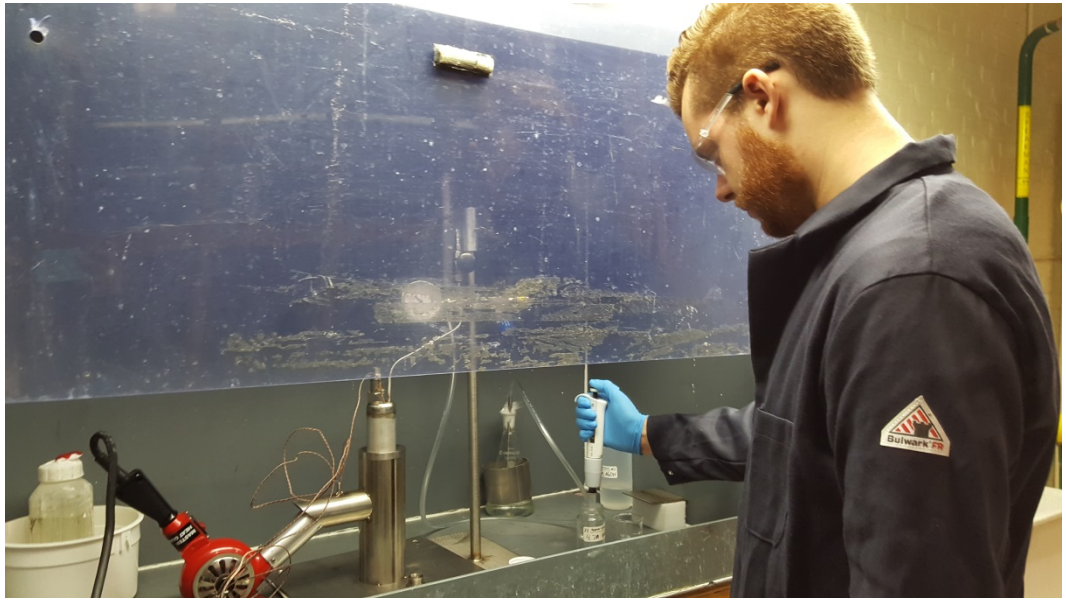
- Radiochemistry facility recently completed at Niowave
  - Niowave staff trained under ANL supervision

Radiochemistry [3]

NIOWAVE
www.niowaveinc.com



Radiochemistry [4]



Uranium Recycle

NIOWAVE
www.niowaveinc.com

- Extract uranium for reuse
  - LEU modified UREX process
- Waste will be solid
  - Class A-C
  - Shipped to LLW/HLW repositories

Business Plan [1]

NIOWAVE
www.niowaveinc.com

- Mo-99 by itself is NOT commercially viable
  - due to foreign subsidies of reactors and operations
- Other isotopes and radiopharmaceuticals have adequate profit margin for commercial viability
- Recycle of LEU further improves viability
- 10 year development plan to full scale production
  - Investment from other applications of the superconducting accelerator & partners
  - Could expedite with government support

Business Plan [2]

NIOWAVE
www.niowaveinc.com

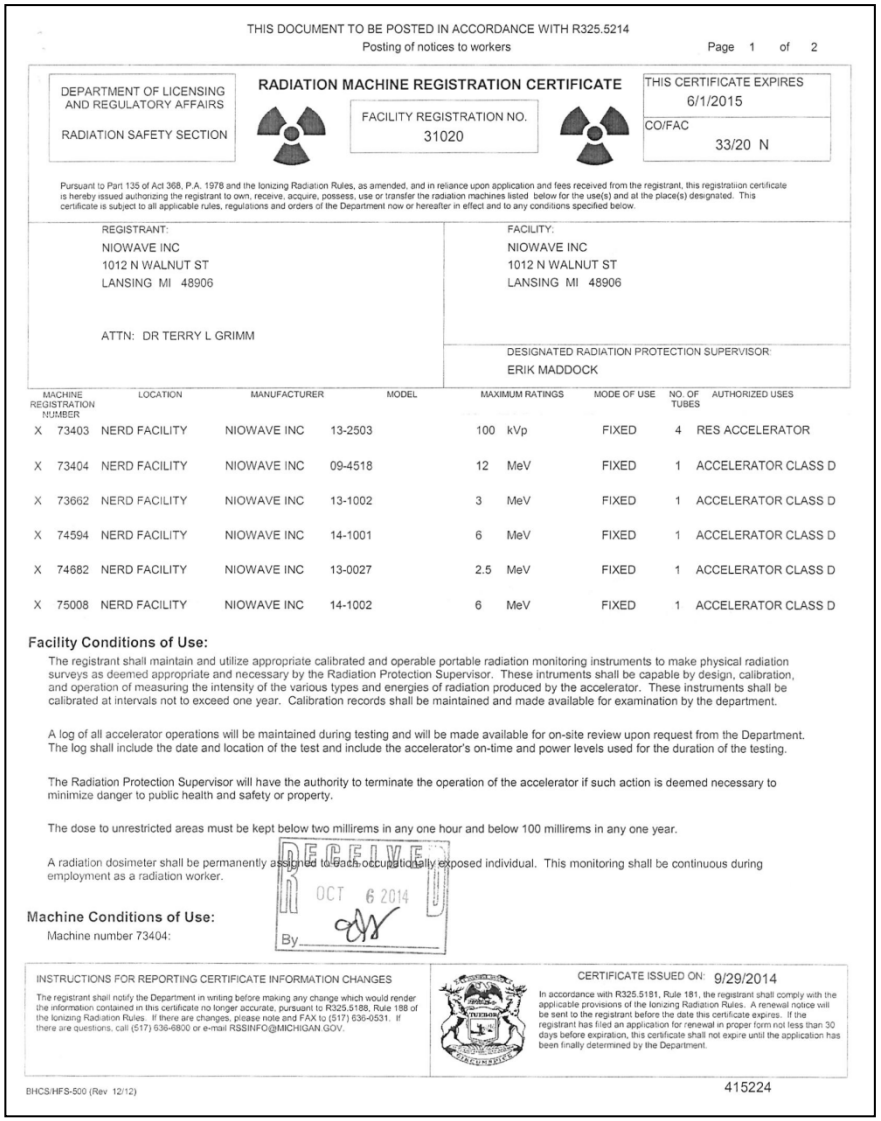
Projected revenue	CY2021	CY2026
Fraction of US Mo-99 market	5%	25%
Mo-99 revenue	7.5	37.5
Other isotopes	7.5	75
Other sources (n, x-ray, etc.)	10	20
TOTAL(M$)	**25**	**132.5**

* Presented to the National Academies Mo-99 Committee, Washington DC [Nov 2015]

Licenses Possessed [1]

NIOWAVE
www.niowaveinc.com

- State of Michigan:
  - Licensed to operate multiple electron linacs
    - Plan approved up to 40 MeV 100 kW
  - License number
    - PR-2013-0346



THIS DOCUMENT TO BE POSTED IN ACCORDANCE WITH R325.5214
Posting of notices to workers
Page 1 of 2

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
RADIATION SAFETY SECTION

RADIATION MACHINE REGISTRATION CERTIFICATE

FACILITY REGISTRATION NO. 31020

THIS CERTIFICATE EXPIRES 6/1/2015

CO/FAC 33/20 N

Pursuant to Part 135 of Act 368, P.A. 1978 and the Ionizing Radiation Rules, as amended, and in reliance upon application and fees received from the registrant, this registration certificate is hereby issued authorizing the registrant to own, receive, acquire, possess, use or transfer the radiation machines listed below for the use(s) and at the place(s) designated. This certificate is subject to all applicable rules, regulations and orders of the Department now or hereafter in effect and to any conditions specified below.

REGISTRANT:
NIOWAVE INC
1012 N WALNUT ST
LANSING MI 48906

ATTN: DR TERRY L GRIMM

FACILITY:
NIOWAVE INC
1012 N WALNUT ST
LANSING MI 48906

DESIGNATED RADIATION PROTECTION SUPERVISOR:
ERIK MADDOCK

	MACHINE REGISTRATION NUMBER	LOCATION	MANUFACTURER	MODEL	MAXIMUM RATINGS	MODE OF USE	NO. OF TUBES	AUTHORIZED USES
X	73403	NERD FACILITY	NIOWAVE INC	13-2503	100 kVp	FIXED	4	RES ACCELERATOR
X	73404	NERD FACILITY	NIOWAVE INC	09-4518	12 MeV	FIXED	1	ACCELERATOR CLASS D
X	73662	NERD FACILITY	NIOWAVE INC	13-1002	3 MeV	FIXED	1	ACCELERATOR CLASS D
X	74594	NERD FACILITY	NIOWAVE INC	14-1001	6 MeV	FIXED	1	ACCELERATOR CLASS D
X	74682	NERD FACILITY	NIOWAVE INC	13-0027	2.5 MeV	FIXED	1	ACCELERATOR CLASS D
X	75008	NERD FACILITY	NIOWAVE INC	14-1002	6 MeV	FIXED	1	ACCELERATOR CLASS D

Facility Conditions of Use:

The registrant shall maintain and utilize appropriate calibrated and operable portable radiation monitoring instruments to make physical radiation surveys as deemed appropriate and necessary by the Radiation Protection Supervisor. These intruments shall be capable by design, calibration, and operation of measuring the intensity of the various types and energies of radiation produced by the accelerator. These instruments shall be calibrated at intervals not to exceed one year. Calibration records shall be maintained and made available for examination by the department.

A log of all accelerator operations will be maintained during testing and will be made available for on-site review upon request from the Department. The log shall include the date and location of the test and include the accelerator's on-time and power levels used for the duration of the testing.

The Radiation Protection Supervisor will have the authority to terminate the operation of the accelerator if such action is deemed necessary to minimize danger to public health and safety or property.

The dose to unrestricted areas must be kept below two millirems in any one hour and below 100 millirems in any one year.

A radiation dosimeter shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

RECEIVED OCT 6 2014 By

Machine Conditions of Use:

Machine number 73404:

INSTRUCTIONS FOR REPORTING CERTIFICATE INFORMATION CHANGES

The registrant shall notify the Department in writing before making any change which would render the information contained in this certificate no longer accurate, pursuant to R325.5188, Rule 188 of the Ionizing Radiation Rules. If there are changes, please note and FAX to (517) 636-0531. If there are questions, call (517) 636-6800 or e-mail RSSINFO@MICHIGAN.GOV.

CERTIFICATE ISSUED ON: 9/29/2014

In accordance with R325.5181, Rule 181, the registrant shall comply with the applicable provisions of the Ionizing Radiation Rules. A renewal notice will be sent to the registrant before the date this certificate expires. If the registrant has filed an application for renewal in proper form not less than 30 days before expiration, this certificate shall not expire until the application has been finally determined by the Department.

BHCS/HFS-500 (Rev 12/12)

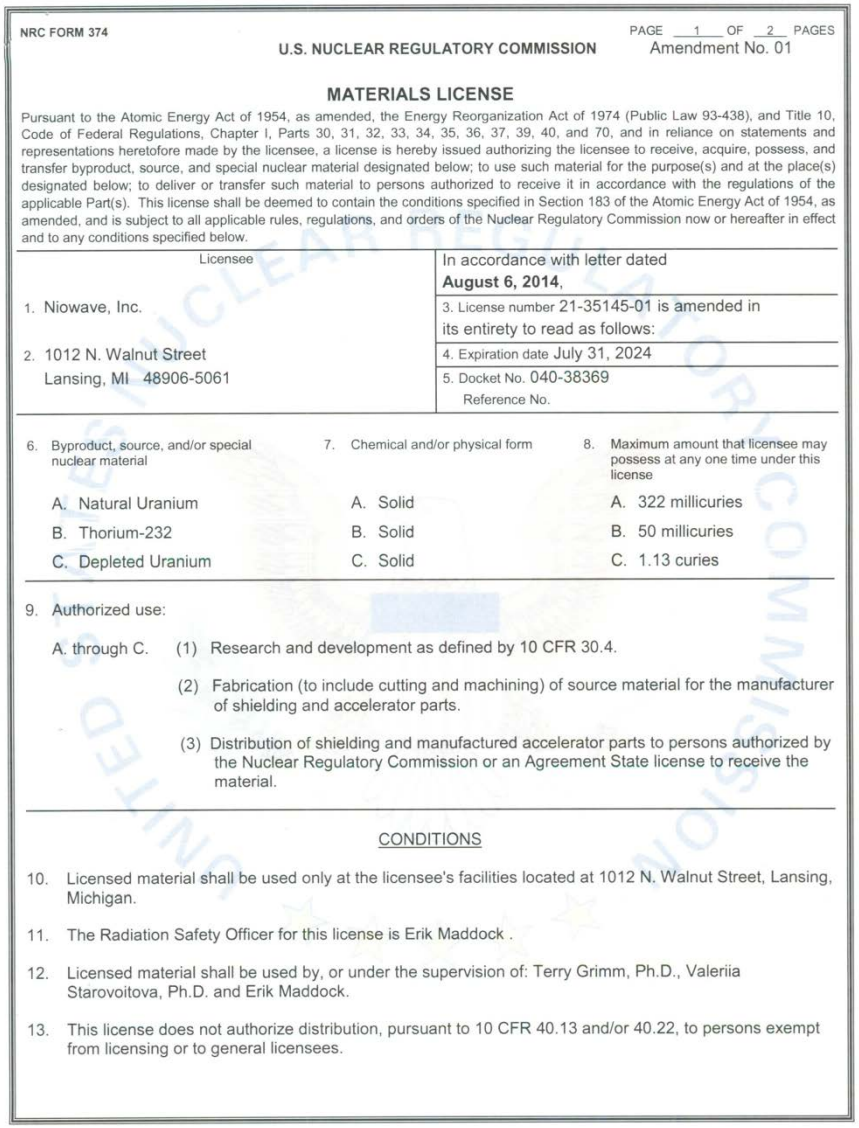
415224

Licenses Possessed [2]

NIOWAVE
www.niowaveinc.com

NRC: Source Material

- Licensed to possess, machine, and distribute DU, ^{nat}U, ^{232}Th
- License number 21-35145-01



NRC FORM 374 — PAGE 1 OF 2 PAGES

U.S. NUCLEAR REGULATORY COMMISSION — Amendment No. 01

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated **August 6, 2014**,
1. Niowave, Inc.	3. License number 21-35145-01 is amended in its entirety to read as follows:
2. 1012 N. Walnut Street Lansing, MI 48906-5061	4. Expiration date July 31, 2024
	5. Docket No. 040-38369 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Natural Uranium	A. Solid	A. 322 millicuries
B. Thorium-232	B. Solid	B. 50 millicuries
C. Depleted Uranium	C. Solid	C. 1.13 curies

9. Authorized use:

A. through C. (1) Research and development as defined by 10 CFR 30.4.

(2) Fabrication (to include cutting and machining) of source material for the manufacturer of shielding and accelerator parts.

(3) Distribution of shielding and manufactured accelerator parts to persons authorized by the Nuclear Regulatory Commission or an Agreement State license to receive the material.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1012 N. Walnut Street, Lansing, Michigan.

11. The Radiation Safety Officer for this license is Erik Maddock .

12. Licensed material shall be used by, or under the supervision of: Terry Grimm, Ph.D., Valeriia Starovoitova, Ph.D. and Erik Maddock.

13. This license does not authorize distribution, pursuant to 10 CFR 40.13 and/or 40.22, to persons exempt from licensing or to general licensees.

Licenses Possessed [3]

NIOWAVE
www.niowaveinc.com

NRC: LEU & Radioisotopes

- Licensed to produce, possess and transfer certain radioisotopes, as well as special nuclear material
- License number 21-35144-02

NRC FORM 374 PAGE 1 OF 3 PAGES

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Niowave, Inc.
2. 1012 North Walnut Street
   Lansing, MI 48906-5061

3. License number 21-35144-02
4. Expiration date March 31, 2025
5. Docket No. 030-38770
   Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Scandium-46	A. Solid	A. 1 millicurie
B. Scandium-47	B. Solid	B. 1 millicurie
C. Manganese-56	C. Solid	C. 1 millicurie
D. Zinc-65	D. Solid	D. 1 millicurie
E. Copper-67	E. Solid	E. 1 millicurie
F. Selenium-75	F. Solid	F. 1 millicurie
G. Yttrium-88	G. Solid	G. 1 millicurie
H. Strontium-89	H. Solid	H. 1 millicurie
I. Yttrium-90	I. Solid	I. 1 millicurie
J. Molybdenum-99	J. Solid	J. 1 millicurie
K. Holmium-166	K. Solid	K. 1 millicurie
L. Iridium-192	L. Solid	L. 1 millicurie
M. Gold-198	M. Solid	M. 1 millicurie
N. Uranium-234	N. Solid	N. 0.015 gram (93.7 microcuries)
O. Uranium-235	O. Solid	O. 2.3 grams (5 microcuries)
P. Uranium-238	P. Solid	P. 21 grams (7 microcuries)
Q. Any byproduct material with Atomic Numbers 1-83 with a half-life less than or equal to 120 days	Q. Incidentally activated products in solid form	Q. 15 millicuries total

Press Release - Oct 26, 2015

NIOWAVE
www.niowaveinc.com

- In September 2015 Niowave became the first domestic company in over 25 years to make Mo-99 from uranium
  - Without HEU or a nuclear reactor

"Today's announcement is a great example of the importance of public-private partnerships that help Michigan companies make new discoveries…"

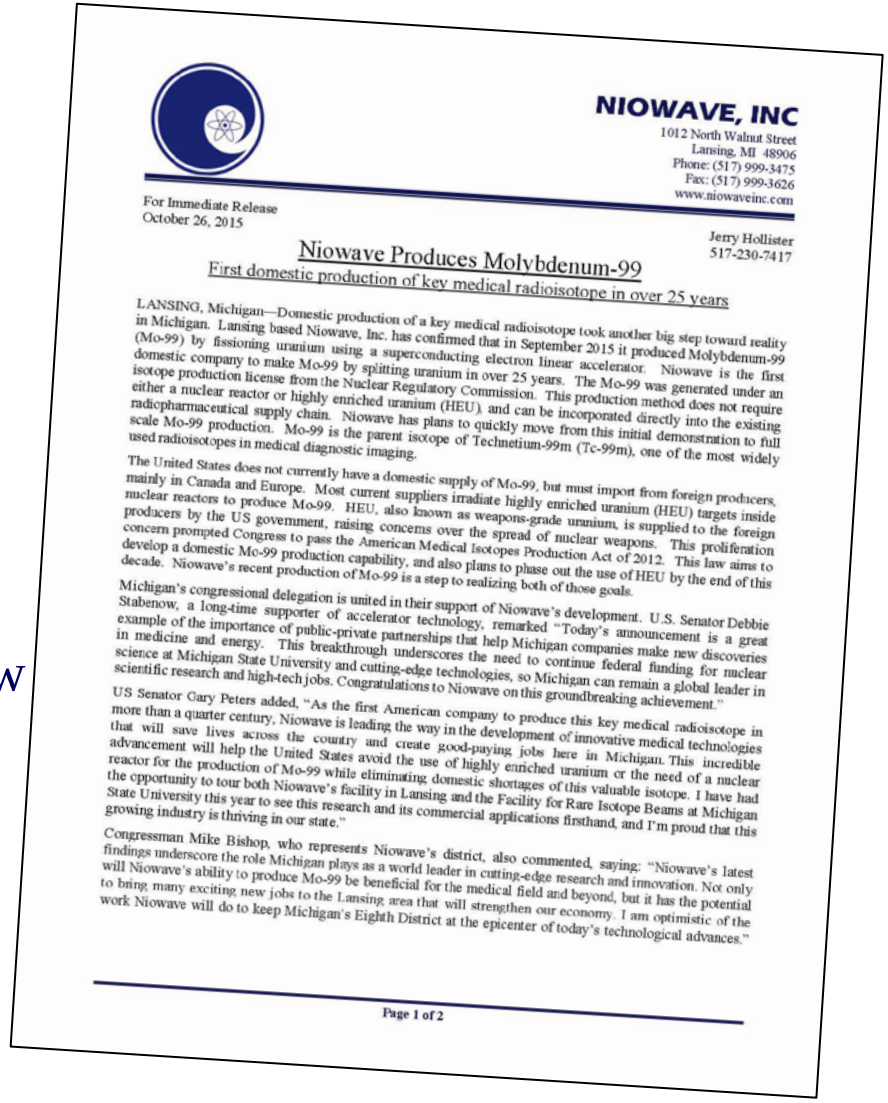
Senator Debbie Stabenow

"I have had the opportunity to tour Niowave… and am proud that this growing industry is thriving in our state."

Senator Gary Peters

"Niowave's latest findings underscore the role Michigan plays as a world leader in cutting-edge research and innovation."

Congressman Mike Bishop



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Niowave Produces Molybdenum-99

First domestic production of key medical radioisotope in over 25 years

LANSING, Michigan—Domestic production of a key medical radioisotope took another big step toward reality in Michigan. Lansing based Niowave, Inc. has confirmed that in September 2015 it produced Molybdenum-99 (Mo-99) by fissioning uranium using a superconducting electron linear accelerator. Niowave is the first domestic company to make Mo-99 by splitting uranium in over 25 years. The Mo-99 was generated under an isotope production license from the Nuclear Regulatory Commission. This production method does not require either a nuclear reactor or highly enriched uranium (HEU), and can be incorporated directly into the existing radiopharmaceutical supply chain. Niowave has plans to quickly move from this initial demonstration to full scale Mo-99 production. Mo-99 is the parent isotope of Technetium-99m (Tc-99m), one of the most widely used radioisotopes in medical diagnostic imaging.

The United States does not currently have a domestic supply of Mo-99, but must import from foreign producers, mainly in Canada and Europe. Most current suppliers irradiate highly enriched uranium (HEU) targets inside nuclear reactors to produce Mo-99. HEU, also known as weapons-grade uranium, is supplied to the foreign producers by the US government, raising concerns over the spread of nuclear weapons. This proliferation concern prompted Congress to pass the American Medical Isotopes Production Act of 2012. This law aims to develop a domestic Mo-99 production capability, and also plans to phase out the use of HEU by the end of this decade. Niowave's recent production of Mo-99 is a step to realizing both of those goals.

Michigan's congressional delegation is united in their support of Niowave's development. U.S. Senator Debbie Stabenow, a long-time supporter of accelerator technology, remarked "Today's announcement is a great example of the importance of public-private partnerships that help Michigan companies make new discoveries in medicine and energy. This breakthrough underscores the need to continue federal funding for nuclear science at Michigan State University and cutting-edge technologies, so Michigan can remain a global leader in scientific research and high-tech jobs. Congratulations to Niowave on this groundbreaking achievement."

US Senator Gary Peters added, "As the first American company to produce this key medical radioisotope in more than a quarter century, Niowave is leading the way in the development of innovative medical technologies that will save lives across the country and create good-paying jobs here in Michigan. This incredible advancement will help the United States avoid the use of highly enriched uranium or the need of a nuclear reactor for the production of Mo-99 while eliminating domestic shortages of this valuable isotope. I have had the opportunity to tour both Niowave's facility in Lansing and the Facility for Rare Isotope Beams at Michigan State University this year to see this research and its commercial applications firsthand, and I'm proud that this growing industry is thriving in our state."

Congressman Mike Bishop, who represents Niowave's district, also commented, saying: "Niowave's latest findings underscore the role Michigan plays as a world leader in cutting-edge research and innovation. Not only will Niowave's ability to produce Mo-99 be beneficial for the medical field and beyond, but it has the potential to bring many exciting new jobs to the Lansing area that will strengthen our economy. I am optimistic of the work Niowave will do to keep Michigan's Eighth District at the epicenter of today's technological advances."

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Licensing Plan

NIOWAVE
www.niowaveinc.com

- Existing NRC materials license
  - Limits quantity of LEU and radioisotopes, as well as form (solid, powder, liquid, gas)
  - Increase quantities and forms through amendments to existing license as technical and financial milestones are met
- Financial assurance required for license
  - Decommissioning plan and surety bond

Niowave Facilities

NIOWAVE
www.niowaveinc.com

75,000 square feet

- Engineering & design
- Machine shop
- Fabrication & welding
- Chemistry facility
- Class 100 Cleanroom

Test Facilities (2)

- Cryogenic test lab
- Two operating 100 W cryoplants
- 3 MW available at each location
- Licensed to operate up to 40 MeV and 100 kW

Lansing, Michigan Headquarters

Headquarters Test Facility

NIOWAVE
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The high-power test facility at Niowave headquarters allows parallel development on multiple superconducting linacs

- 3 MW electrical power available
- three below-grade trenches for source and cavity testing
- two shielded tunnels for beam operation up to 40 MeV, 100 kW

Niowave Airport Facility

NIOWAVE
www.niowaveinc.com

- Production & processing facility
  - Occupancy Jan 2015
  - 24/7 operation
  - Isotopes, x-rays, etc.
- Lansing International Airport
  - Foreign Trade Zone

Summary

NIOWAVE
www.niowaveinc.com

- Sept 2015 first domestic Mo-99 production at Niowave
- Sodium molybdate ($Na_2{}^{99}MoO_4$) available commercially
  - mCi quantities early 2017
  - Ci quantities late 2017
- Other isotopes available (same time frame)
  - I-131, Xe-133, FF, etc.