



# DOE/NNSA Support for Mo-99 Production without the use of HEU



### **Discussion Overview**



- Overview of Mo-99
- Mo-99 Program objectives
- Current status of international Mo-99 production
- Domestic Mo-99 Program Update
- Overview of U.S. national laboratory support
- Update on ULTB
- HEU Export Ban
- Public participation & meetings

### Molybdenum-99 (Mo-99) Overview

- Molybdenum-99 (Mo-99) is the parent isotope of technetium-99m (Tc-99m), a radioisotope used in approximately 40,000 medical diagnostic tests per day in the United States to:
  - Diagnose heart disease
  - Treat cancer
  - Study organ structure and function
- Mo-99 has a short half life (66 hours) and cannot be stockpiled
- U.S. demand is approximately 50% of the world market
- There are four major global producers of Mo-99, all outside the United States
- Historically, much of the global Mo-99 supply was produced using highly enriched uranium (HEU)
- Shortages of Mo-99 in 2009 and 2010 due to the unexpected shut down of two major production facilities highlighted the need for new, non-HEU-based Mo-99 production in the United States





**Example of a Tc-99m Generator** 

(image courtesy of Lantheus Medical Imagine, Inc.)







### **Goal: HEU Minimization with Mo-99**



Assisting global Mo-99 production facilities to convert to use LEU targets Reliable supplies of Mo-99 produced w/o HEU

### U.S. Domestic Efforts

Accelerating the establishment of commercial non-HEU-based Mo-99 production in the United States

### **Status of International Mo-99 Production**





\*ANSTO (Australia) has always produced Mo-99 with LEU targets

American Medical Isotopes Production Act (AMIPA)



# The American Medical Isotopes Production Act of 2012

## Domestic Technology Neutral Program

Uranium Lease & Takeback Program (ULTB)

## Public Participation & Reports

Sunset Provision to End HEU Exports for Medical Isotope Production

# Domestic Technology Neutral Program:

**Cooperative Agreements** 



- Since 2012, DOE/NNSA has competitively awarded \$160M to industry partners to establish a domestic Mo-99 production capability.
- In 2018, NorthStar Medical Radioisotopes began producing and distributing non-HEUbased Mo-99 to U.S. customers, the first domestic production in nearly 30 years
- In July 2020, NNSA released a Funding Opportunity Announcement
  - Focus on commercial deployment rather than technology development
  - Total funding that will be awarded under this FOA is \$85M
- In March 2021, DOE/NNSA selected U.S. companies to negotiate competitively awarded new cooperative agreements.
- Each new cooperative agreement award:
  - Was reviewed on the basis that commercial scale production of 1,500 curies per week (Ci/week) would occur by December 31, 2023, with a subsequent ramp up to 3,000 Ci/week
  - Requires 50/50 industry cost-sharing
  - Funding amounts are variable not an even distribution between awards
- Additional details will be available when the awards are finalized in late Summer

#### **Domestic Technology Neutral Program:** *National Laboratory Support*



NNSA ensures the expertise and equipment of the U.S. National Laboratories is available to:

- Support development of Mo-99 cooperative agreement technical pathways, as well as other potential technologies
- All work packages are funded by NNSA outside of the cooperative agreement funding- results are non-proprietary and are made available in the public-domain



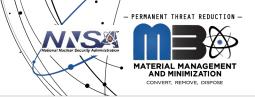
High Flux Isotope Reactor (HFIR) (ORNL)



Target assembly for eMo-100 accelerator production (LANL)

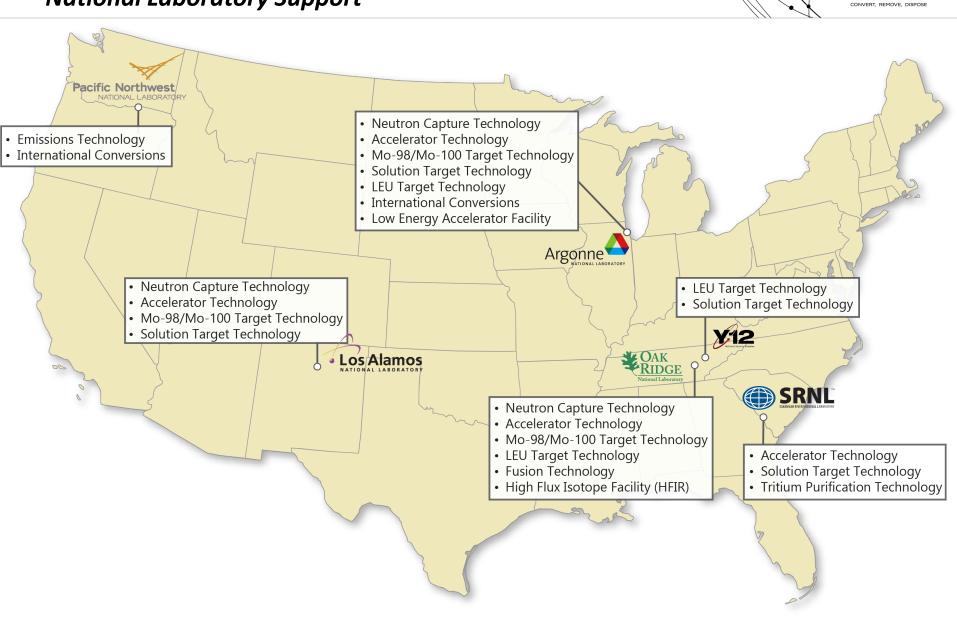
Electron Linear Accelerator Facility (ANL)

#### Domestic Technology Neutral Program: National Laboratory Support



- Since 2012, NNSA has provided over \$150 million in non-proprietary technical support at the national laboratories to 9 companies to support the development of a diverse set of Mo-99 production technologies
- During FY2020 and FY2021, NNSA provided non-proprietary laboratory support to assist in development of Mo-99 production technologies at:
  - Eden Radioisotopes
  - Coqui Radiopharmaceuticals
  - Niowave
  - NorthStar Medical Radioisotopes
  - Northwest Medical Isotopes
  - SHINE Medical Technologies
- The Program will continue to provide non-proprietary laboratory support to interested commercial entities.
- The FY2022 work packages will be developed shortly and are created in cooperation with the interested commercial entity

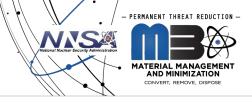
#### **Domestic Technology Neutral Program:** *National Laboratory Support*



- PERMANENT THREAT REDUCTION -

AND MINIMIZATIO

NISA



Management	NNSA's Office of Conversion is the Programmatic lead for ULTB
Make LEU Available	NNSA Production Office (NPO) at Y-12 leases LEU required for domestic Mo-99 production
Spent Fuel & Waste Management	DOE's Office of Environmental Management (EM) manages the Take-Back program for the disposition of spent nuclear fuel and radioactive waste without a commercial disposal path
Costs	Contracts are negotiated to ensure U.S. government recovers costs of chosen waste disposal path





- The American Medical Isotopes Production Act (AMIPA) contains a sunset provision to end the export of HEU from the United States for use in medical isotope production on January 2, 2020.
- In January 2020 the Secretary of Energy certified to Congress that there is an insufficient supply of Mo-99 produced without the use of HEU available to meet U.S. patient needs
  - Resulted in an extension to the period of time that the Nuclear Regulatory Commission (NRC) may issue HEU export licenses for medical isotope production
  - Extension is effective for no more than two years (until January 2022)
- DOE/NNSA is working with the Department of Health and Human Services to recommend a decision before January 2022 on whether the continued authority to export HEU for medical isotope production is necessary.

### Public Participation and Reports in 2020 and 2021



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#### Public meetings

- Public meetings on hold in 2020 and 2021 due to COVID-19
- If travel remains unavailable in 2021, NNSA will consider a virtual Annual Mo-99 Stakeholder meeting
- The International Mo-99 Symposium in Prague, Czechia was postponed. NNSA is currently evaluating how to proceed.
- Virtual public updates are provided as possible:
  Conferences (NRC's RIC, SNMMI, WOSMIP), CORAR
- Nuclear Science Advisory Committee (NSAC)
  - Annual oversight by Mo-99 Subcommittee May 2021