NNSA's Mo-99 Program:

Accelerating Reliable, Non-HEU Mo-99 Production Capabilities in the United States

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National Nuclear Security Administration
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Presentation Overview

- Overview of NNSA Mo-99 Program
- Program Budgets
- American Medical Isotopes Production Act (AMIPA) Requirements
- Domestic Technology Neutral Program
- National Laboratory Program
- Sunset Provision to End HEU Exports for Medical Isotope Production
- Uranium Lease and Take-Back Program
- Public Participation, Reports and Public Meeting Strategy

The NNSA Program

The NNSA Goal

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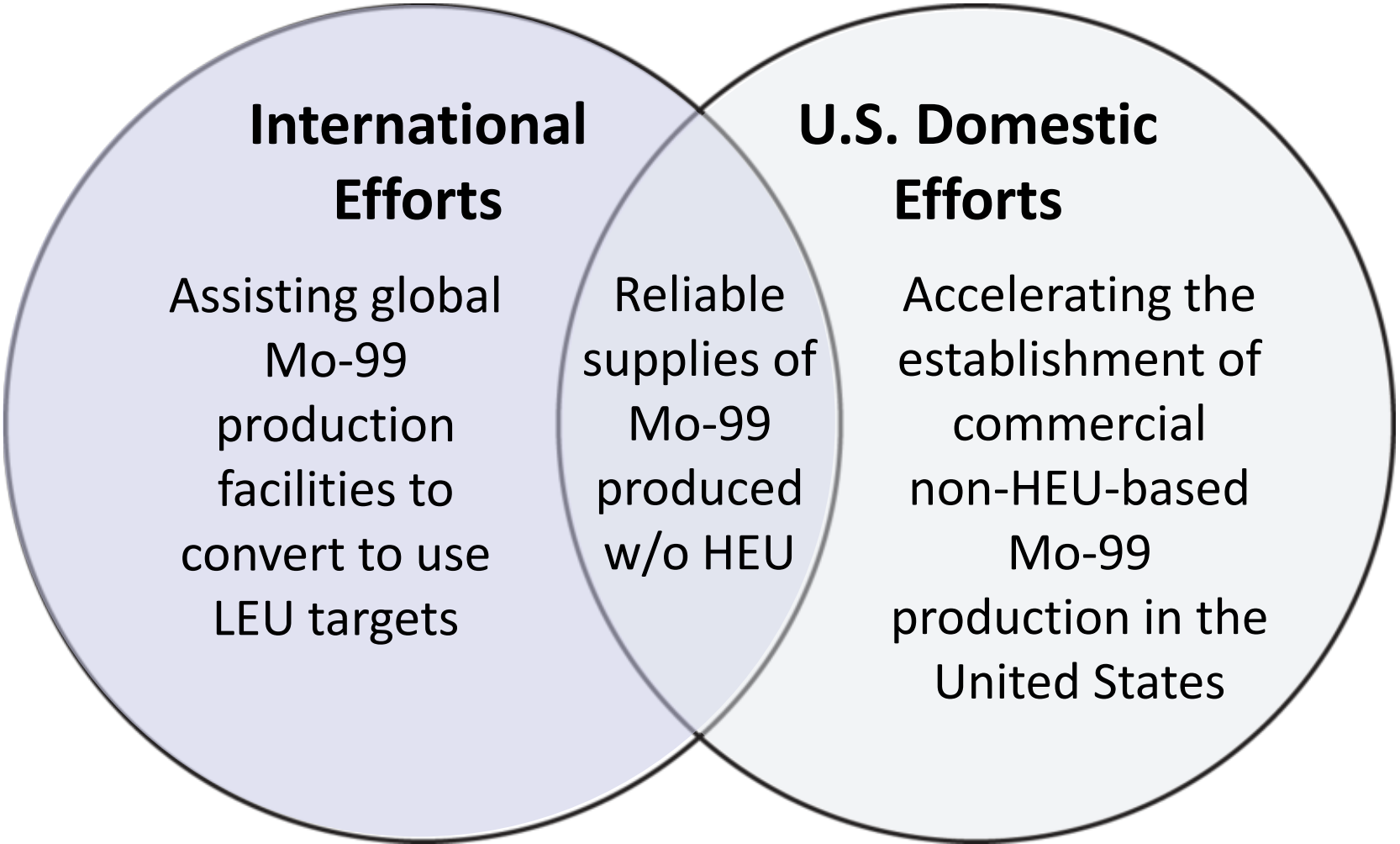
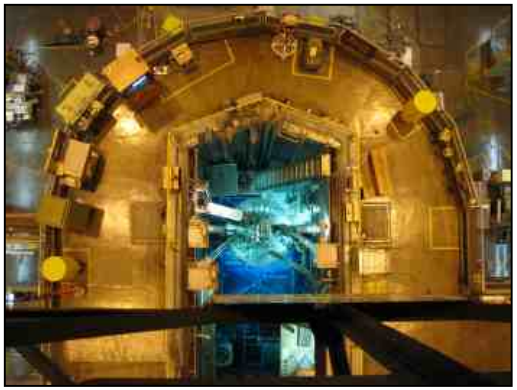
Goal: HEU Minimization with Mo-99



The Issue

- Molybdenum-99 (Mo-99) is the parent isotope of Tc-99m, a radioisotope used in approximately 40,000 medical diagnostic tests per day in the United States
- 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 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



SAFARI-1 Reactor (South Africa)

Example of a Tc-99m Generator
(Image courtesy of Lantheus Medical Imaging, Inc.)

Domestic Program Guided by AMIPA

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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

Mo-99 Program Budget

- In Fiscal Year 2019, Congress appropriated $35 million
  - $15 million for national laboratory and contractor technical support
  - $20 million to add to the new competitively awarded cooperative agreements

- Fiscal year 2020
  - President's request included $10 million for national laboratory and contractor support
  - House mark includes:
    - $5 million for national laboratory and contractor support
    - $35 million for a new funding opportunity announcement for additional cooperative agreements
  - Awaiting Fiscal Year 2020 Appropriations Bill for final guidance

Domestic Technology Neutral Program:
Cooperative Agreements

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- Issued a Funding Opportunity Announcement in July 2018 for new cooperative agreements
  - Four U.S. companies competitively awarded new cooperative agreements
    - ➢NorthStar Medical Radioisotopes, Beloit, WI
      - Neutron capture technology
    - ➢SHINE Medical Technologies, LLC, Janesville, WI
      - Accelerator-driven LEU solution target technology
    - ➢Northwest Medical Isotopes, LLC, Corvallis, OR
      - LEU particle target technology
    - ➢Niowave, Inc., Lansing, MI
      - Accelerator coupled to a subcritical uranium assembly technology

- Each new cooperative agreement award:
  - Specifies $30 million in total scope of work
  - Requires 50/50 industry cost-sharing
  - Has period of performance of 3 years

- Period of performance of NorthStar Medical Radioisotopes' existing cooperative agreement for its accelerator technology was extended until December 2021

Domestic Technology Neutral Program:
National Laboratory Support

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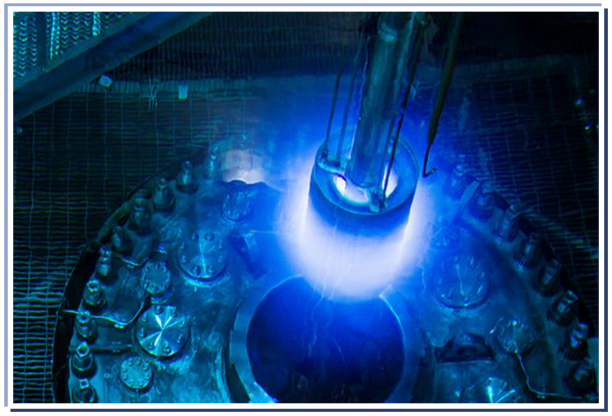
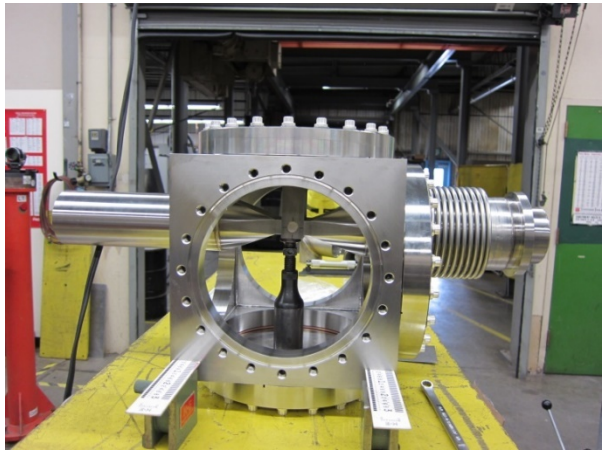
NNSA ensures the expertise of the U.S. National Laboratories are available to:

- Support technical development of the Mo-99 cooperative agreement technical pathways as well as other potential technologies
- Ensure the expertise and equipment at the national laboratories are available to support the acceleration of commercial projects using non-HEU technologies
- All work packages are funded by NNSA outside of the cooperative agreement funding and results are available in the public-domain



High Flux Isotope Reactor (HFIR) (ORNL)



Target assembly for eMo-100 accelerator production (LANL)

Electron Linear Accelerator Facility (ANL)

National Laboratory Support

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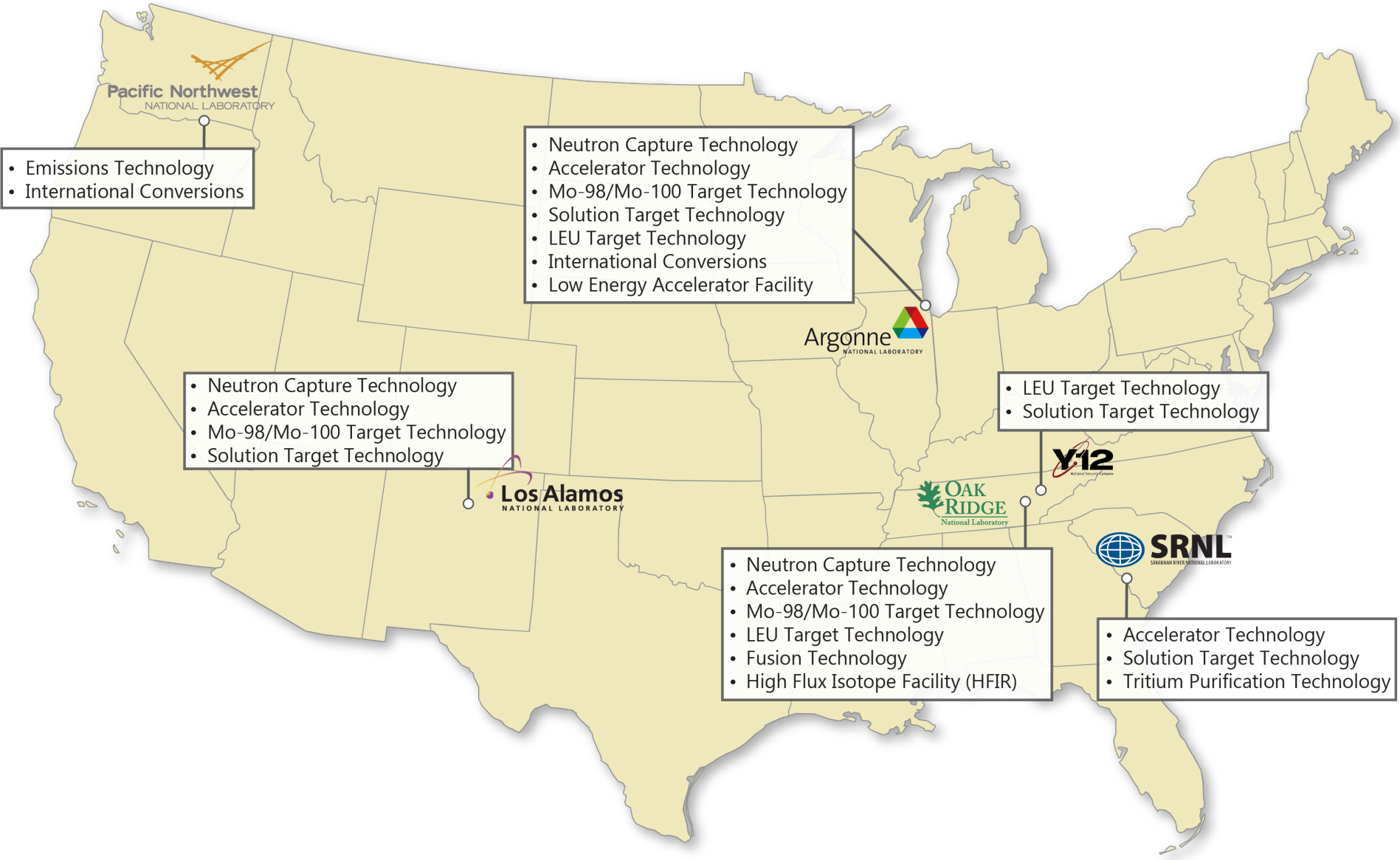
- Since 2012, NNSA has provided over $100 million in non-proprietary technical support at the national laboratories to 10 companies to accelerate the development of a diverse set of Mo-99 production technologies

- Currently, NNSA is providing non-proprietary laboratory support to assist in development of Mo-99 production technologies at:
  - NorthStar Medical Radioisotopes
  - SHINE Medical Technologies
  - Northwest Medical Isotopes
  - Niowave
  - BWX Technologies
  - Coqui Radiopharmaceuticals
  - Global Medical Isotopes Systems
  - Magneto-Intertial Fusion Technologies
  - Eden Radioisotopes
  - Flibe Energy

NNSA and National Labs



Sunset Provision to End HEU Exports for Medical Isotope Production

- The American Medical Isotope 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

- DOE/NNSA is working closely with the Department of Health and Human Services and DOE's Isotope Production Office to review the market supplies of Mo-99 and other medical isotopes in order to make a determination on whether to enact the ban in January 2020, or whether to extend the ban, in accordance with AMIPA

Uranium Lease and Take-Back Program

HQ Management	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 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

Public Participation and Reports

- Public meetings
  - Annual Mo-99 topical meetings or symposiums
  - Annual Mo-99 Stakeholder meeting
- Public Reports
  - Annual Report to Congress
  - National Academy of Sciences Report
- Annual oversight by the Nuclear Science Advisory Committee (NSAC)

Public Meeting Strategy

- Annual U.S. Stakeholder Meeting
  - One day workshop focused on U.S. Mo-99 industry and U.S. supply issues

- International Mo-99 Symposium
  - All plans are tentative pending receipt of final DOE approvals
  - Week of April 26, 2020
  - Intercontinental Hotel, Czech Republic
  - Meeting in cooperation with the IAEA
  - Build global awareness of U.S. and international industry capabilities, foster discussions on ways to address Mo-99 supply issues, and reinforce the viability of, and options for, non-HEU produced Mo-99
  - Three day symposium will focus on relevant global Mo-99 topics and issues
  - Optional tours of relevant Mo-99 related facilities (LVR-15 proposed)

Public Reports

- Report to Congress
  - Required within 1 year after enactment of AMIPA, and annually thereafter for 5 years
- Report covering Mo-99 activities in calendar year 2018
  - Signed in April 2019
  - Final annual Report to Congress required by AMIPA
- National Academy of Sciences Report
  - Published in 2016
  - https://www.nap.edu/catalog/23563/molybdenum-99-for-medical-imaging

Oversight

- Use the NSAC to conduct annual reviews of the progress made in achieving program goals and make recommendations to improve program effectiveness
- Charged by DOE's Office of Science
- Held annually in the Washington, DC area as a public meeting in the December timeframe
- NSAC report regarding 2018 program activities published and posted on April 17, 2019
  - https://science.energy.gov/np/nsac/
  - Included two recommendations:
    1) NNSA must encourage cooperative agreement partners and others interested in the ULTB program to engage with them early on, so plans including take-back can be developed in a timely fashion;
    2) NNSA must develop a waste take-back process document to formalize the commitment to this process, including a model timeline and an estimate of costs under a set of well-defined scenario templates, to formalize communications with potential users. This must be presented to the subcommittee in advance of the next meeting.

Inter-Agency Coordination

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Accomplishing the NNSA mission requires cooperation with other governmental agencies, including:

Office of Science and Technology Policy

Nuclear Regulatory Commission

Food and Drug Administration

Centers for Medicaid and Medicare Services

State Department

THANK YOU FOR YOUR ATTENTION!

QUESTIONS

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