U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration

Defense Nuclear Nonproliferation

Global Threat Reduction Initiative

National Nuclear Security Administration

Defense Nuclear Nonproliferation

GTRI's Support for non-HEU-Based Mo-99 Production

December 19, 2013

The NSAC Charge

Public Participation and Review [Sec. 3173 (a) (4)] of the American Medical Isotopes Production Act of 2012

The Act requires two forms of public participation and review:

1. Develop and update the program plan through annual public workshops
2. Use the Nuclear Science Advisory Committee (NSAC) to conduct annual reviews of the program
   - NSAC review in coordination with DOE's Office of Science, Office of Nuclear Physics

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  - Requires the Secretary of Energy to establish a technology-neutral program to provide assistance to commercial entities to accelerate production of Mo-99 in the United States without the use of HEU

  - Requires annual public participation and review

  - Requires development assistance for fuels, targets, and processes

  - Establishes a Uranium Lease and Take Back program

  - Requires DOE and NRC to coordinate environmental reviews where practicable

  - Provides a cutoff in exports of HEU for isotope production in 7 years, with possibility for extension in the event of a supply shortage

  - Requires a number of reports to be submitted to Congress

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GTRI Mission & Program Goals

Mission

Reduce and protect vulnerable nuclear and radiological material located at civilian sites worldwide.

Goals

1. Convert
2. Remove
3. Protect

Convert

Convert research reactors and isotope production facilities from the use of highly enriched uranium (HEU) to low enriched uranium (LEU)

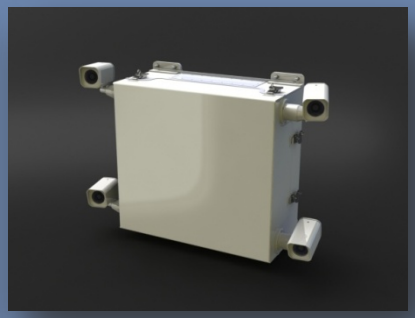
These efforts result in permanent threat reduction by minimizing and, to the extent possible, eliminating the need for HEU in civilian applications – each reactor converted or shut down eliminates a source of bomb material.

Remove

Remove and dispose of excess nuclear and radiological materials.

These efforts result in permanent threat reduction by eliminating bomb material at civilian sites – each kilogram or curie of this dangerous material that is removed reduces the risk of a terrorist bomb.

Protect



Protect high priority nuclear and radiological materials from theft and sabotage

These efforts result in threat reduction by improving security on the bomb material remaining at civilian sites – each vulnerable building that is protected reduces the risk until a permanent threat reduction solution can be implemented.

GTRI's Mo-99 Objective and Strategy

Objective: Accelerate the establishment of reliable supplies of the medical isotope molybdenum-99 produced without highly enriched uranium

GTRI's strategy seeks to address weaknesses in the current Mo-99 supply chain:

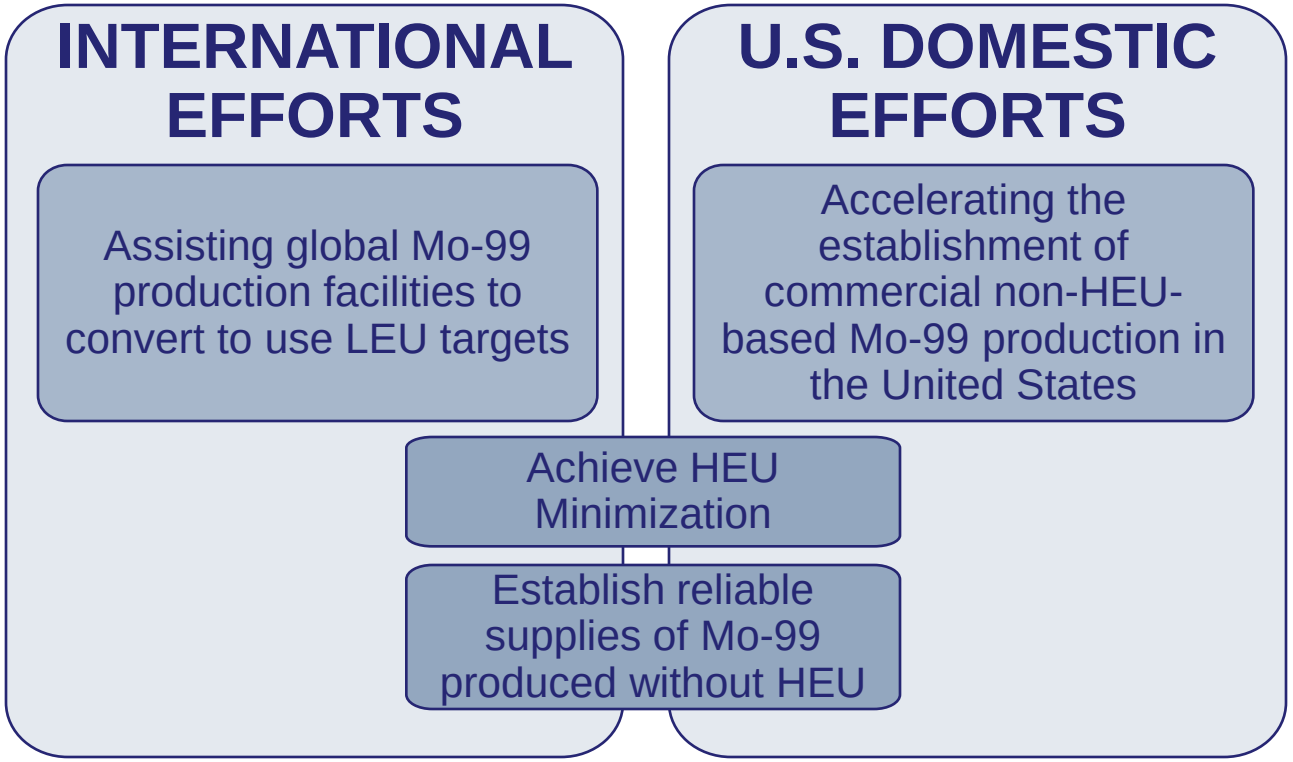
- The current supply chain uses HEU to produce Mo-99
- Most Mo-99 production in today's marketplace is subsidized by foreign governments
- The current supply chain does not always have enough reserve capacity to ensure a reliable supply when one or more producers are out of operation
- The current supply chain is primarily dependent on aging facilities
- The current supply chain relies on one technology to produce Mo-99

A long-term, reliable supply of Mo-99 requires that global production of Mo-99 transition to a full-cost recovery, non-HEU-based industry

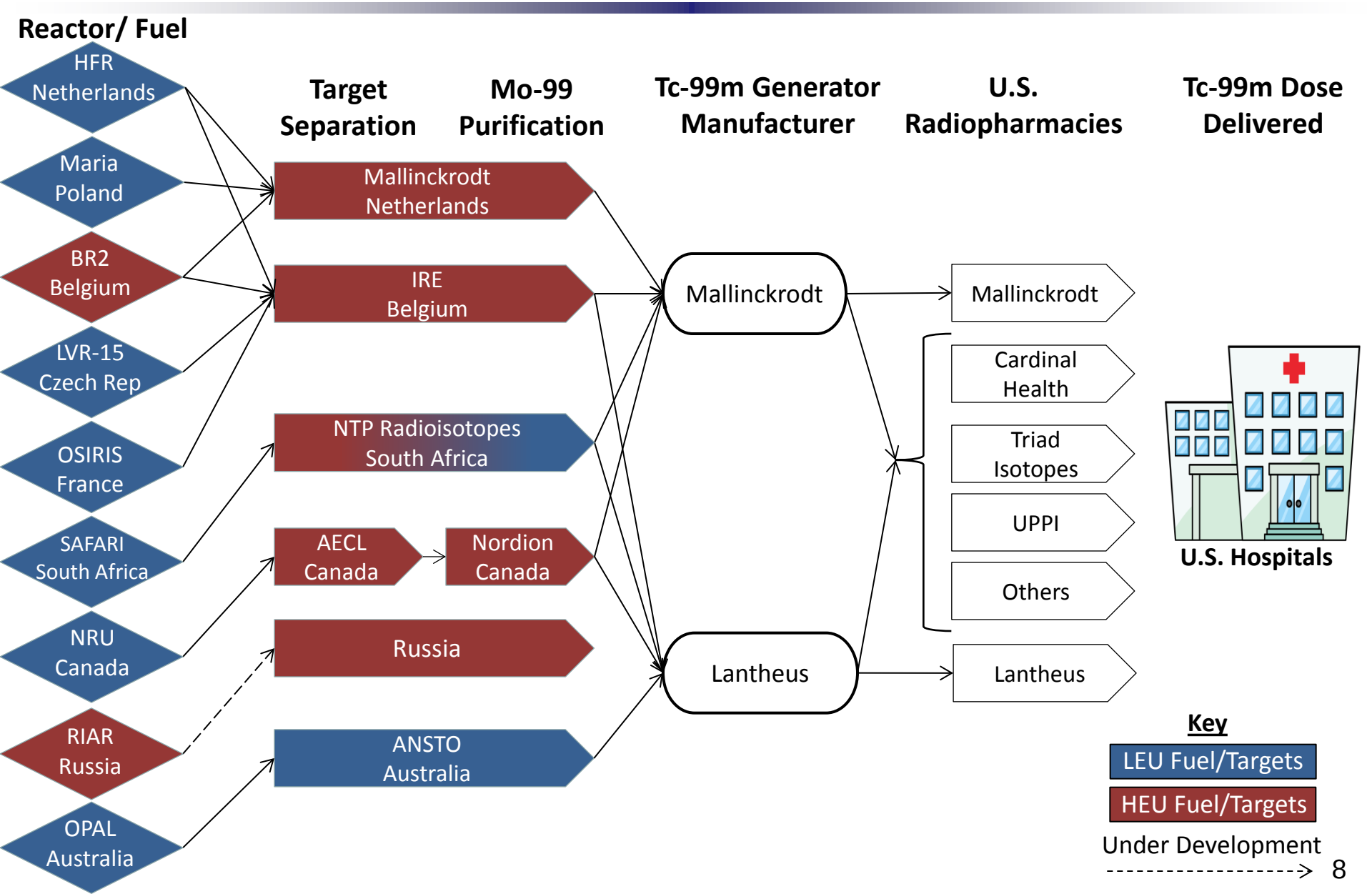
GTRI's Mo-99 Objective and Strategy

International & U.S. Domestic Approaches

- Under its long-standing HEU minimization mission, GTRI provides assistance to research reactors and isotope production facilities to convert from the use of HEU to LEU.
- GTRI's mission includes accelerating the establishment of a reliable U.S. domestic supply of Mo-99 produced without the use of HEU.



Current U.S. Mo-99 Supply Matrix



GTRI's Strategy for Reliable Non-HEU-Based Mo-99 Supply

Global Mo-99 Market – Major Producers

HEU | Non-HEU

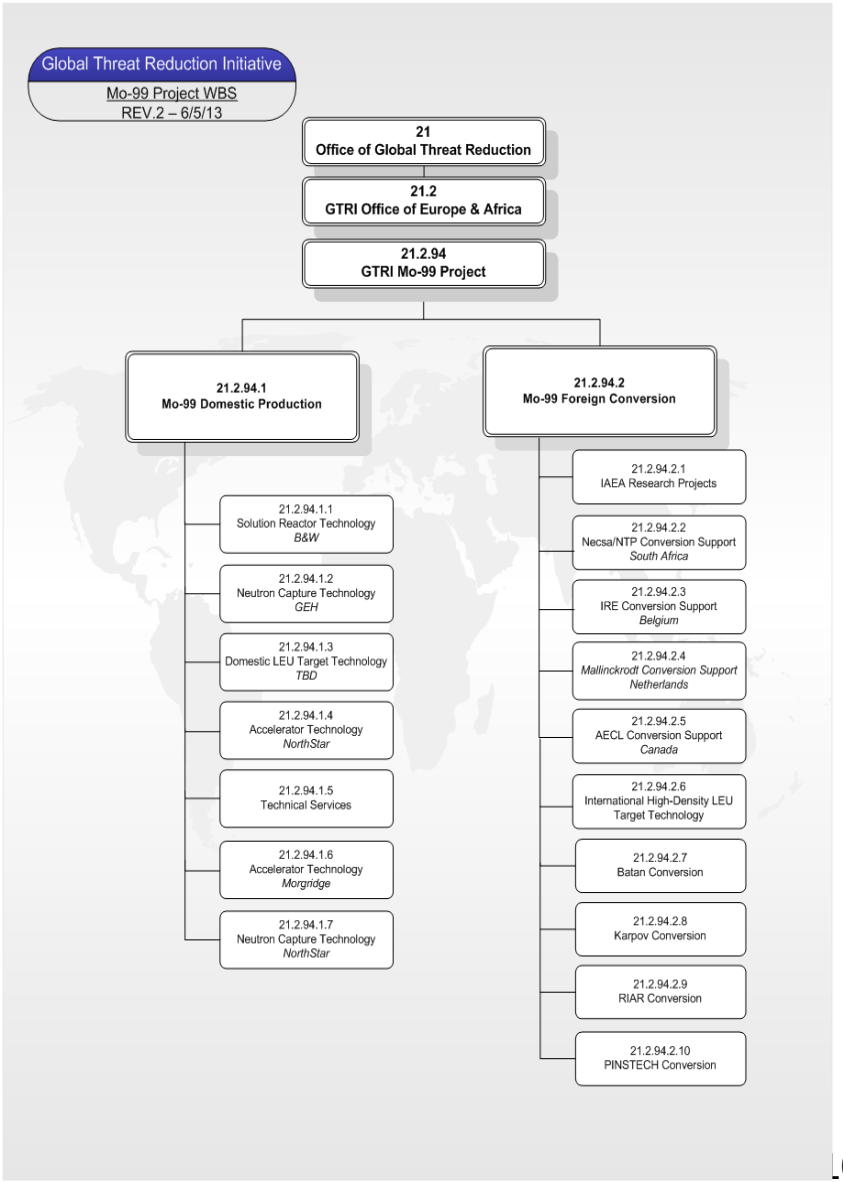
ANSTO (Australia)	NTP Radioisotopes (South Africa)	Mallinckrodt (Netherlands)	IRE (Belgium)	AECL-Nordion (Canada)
ANSTO (Australia)	NTP Radioisotopes (South Africa)	Mallinckrodt (Netherlands)	IRE (Belgium)	AECL-Nordion (Canada)
ANSTO (Australia)	NTP Radioisotopes (South Africa)	Mallinckrodt (Netherlands)	IRE (Belgium)	2016

U.S. Domestic Mo-99 Projects

GTRI's Mo-99 Program
Project Execution and Implementation

- In 2010 GTRI received the Project Management Institute's Distinguished Project Award for the G2 Project Management System

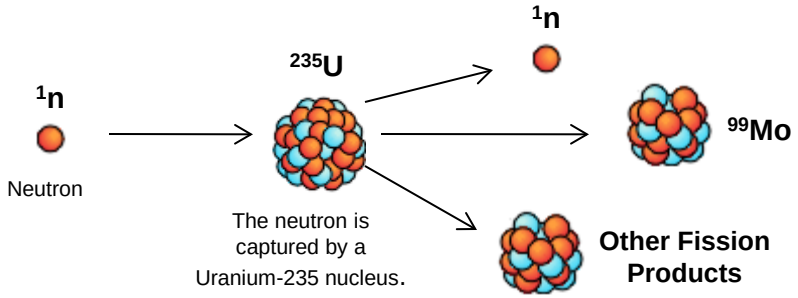
- In 2010 GTRI received the American Nuclear Society's Operation and Power Division Meritorious Performance in Operations Award



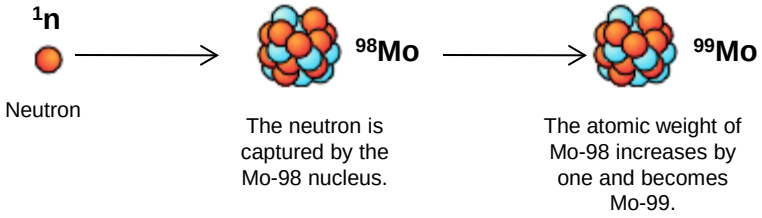
GTRI and U.S. Domestic Mo-99

Implementing a Technology-Neutral Program

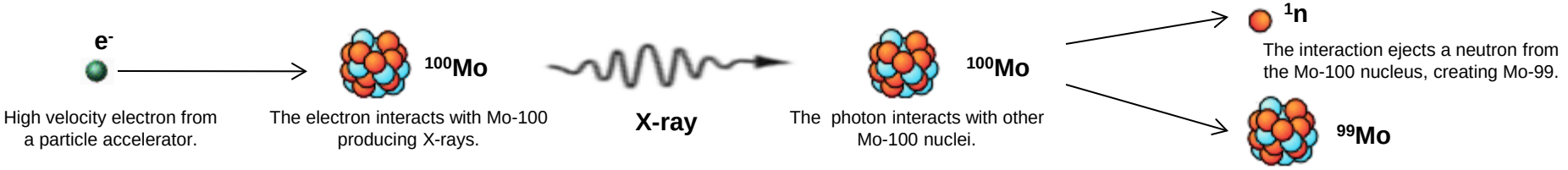
LEU Fission Based: ^{235}U (n,f)



Neutron Capture:(n,γ)



Accelerator Based: (γ,n)



GTRI and U.S. Domestic Mo-99
Cooperative Agreement Partners

Objective: To accelerate existing commercial projects to meet at least 100% of the U.S. demand of Mo-99 produced without HEU.

NorthStar Medical Radioisotopes, LLC

- NNSA has partnered with NorthStar Medical Radioisotopes to pursue accelerator and neutron capture technologies.

Morgridge Institute for Research/SHINE Medical Technologies

- NNSA has partnered with Morgridge Institute for Research to pursue accelerator with LEU fission technology in cooperation with SHINE Medical Technologies.

Babcock and Wilcox (B&W):

- NNSA has partnered with Babcock and Wilcox (B&W) to pursue LEU solution reactor technology.

General Electric-Hitachi (GEH):

- NNSA has partnered with General Electric-Hitachi to pursue neutron capture technology. *On February 7, 2012, GEH announced its business decision to suspend progress on the project indefinitely due to market conditions.*

Consistent with section 988 of the 2005 Energy Policy Act, each cooperative agreement is awarded under a 50% - 50% cost-share arrangement. The cooperative agreements are currently limited to $25M each.

Programmatic Risks

- **Market Risks**
  - Continued government subsidization of Mo-99 producers
  - Loss of commercial partners due to poor economic conditions
  - Continued HEU-based Mo-99 production
  - Unknown cost of GTCC/HLW disposal
- **Technical Risks**
  - Novel technology challenges
  - Patent issues preventing further technology development
- **Regulatory Risks**
  - Licensing from NRC, FDA, and NEPA
- **Contracting Risks**
  - Lack of contracts with a generator manufacturers due to slow customer uptake
- **Policy Risks**
  - Loss of high-level government support

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Public Participation and Review

Public Workshops on Mo-99

- 2013 OSTP Mo-99 Stakeholders Meetings – *Interagency Working Group, Mallinckrodt, Lantheus, CORAR, HPS, AAPM, ASTRO, ACR, SNMMI, NANP, ASNC, AHA, NAS, U.S. Radiopharmacies & Health Care Industry, Future U.S Mo-99 Producers*

  Washington, DC
  February 25, 2013
  June 20, 2013
  December 11, 2013

- 2013 Mo-99 Topical Meeting
  April 1-4, 2013 – Chicago

- 2014 Mo-99 Topical Meeting
  Proposed Location: Washington, DC
  Proposed Dates: June 24-27, 2014

- Request for Public Comment
  December 10, 2013 to January 11, 2014

Public Participation and Review

Other Program Reviews and Sources of Input:

- 2009 National Academies Study – "Medical Isotope Production Without Highly Enriched Uranium"
- 2012 Inspector General (IG) Audit of the Mo-99 Domestic Projects
- Semi-Annual Independent Technical Reviews of the Mo-99 Domestic Cooperative Agreement Partners

Upcoming Program Reviews:

- Nuclear Science Advisory Committee (NSAC) Mo-99 Program Review
- National Academies Study required by the AMIPA
- 2013 Report to Congress

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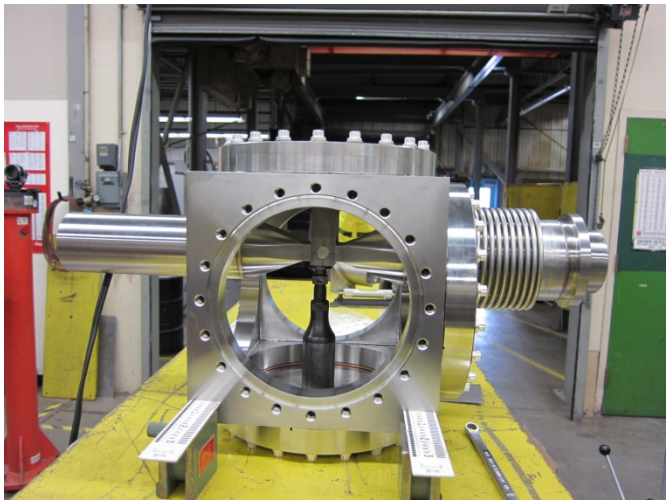
U.S. National Laboratories Support to Mo-99 Production

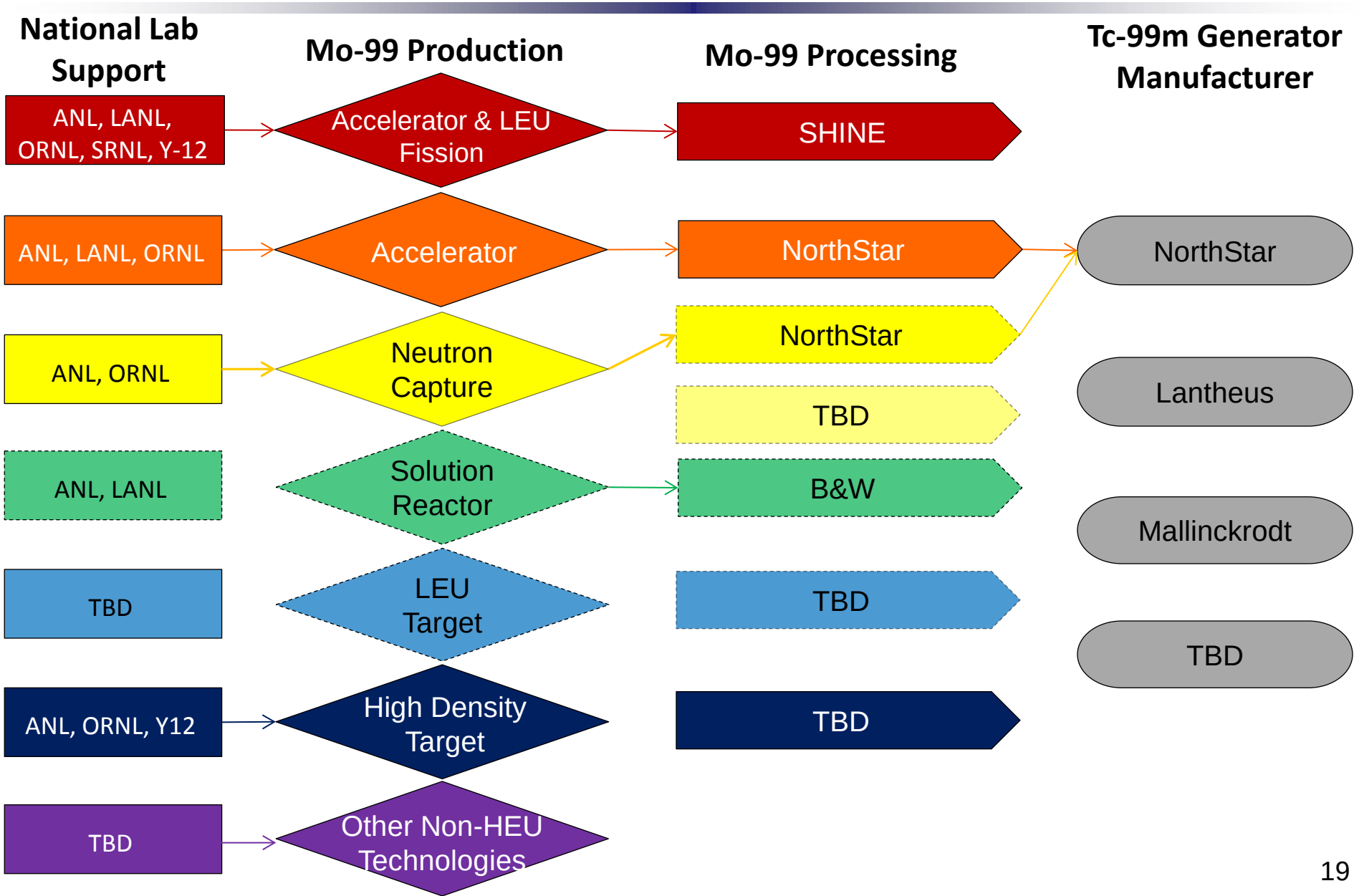
GTRI makes the expertise of the U.S. National Laboratories available to:

- Support technical development of each of the Mo-99 technical pathways
- Ensure the expertise at the national laboratories is available to support the acceleration of commercial projects using non-HEU technologies

All work packages funded by NNSA outside the cooperative agreement are open-sourced, non-proprietary, non-critical-path activities.



National Laboratory Technical Support for Mo99 Production



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Uranium Lease and Take-Back Program & NEPA Requirements

Uranium Lease and Take-Back Program

- Section 3173(e) of the FY13 NDAA directs DOE to establish the program by 2016 (not later than three years after the date of enactment on January 2, 2013).

- DOE has set up an Intra-agency Working Group to ensure the development of this program is comprehensive and efficient.

- The lease contracts established under the program will be implemented under full-cost recovery principles. The exact costs have not yet been determined at this time.

National Environmental Policy Act Requirements for Mo-99

- DOE and the Nuclear Regulatory Commission will coordinate, where possible, the execution of environmental reviews to minimize and/or eliminate the duplication of efforts.

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GTRI & International Mo-99

Assisting Conversion from HEU Targets to LEU Targets

- **Four-party joint statement at the 2012 Nuclear Security Summit on the minimization of HEU and the reliable supply of medical radioisotopes**

  "…Belgium, the Netherlands, and France, in cooperation with the United States, reaffirm their determination to support conversion of European production industries to non-HEU-based processes by 2015….."

- **GTRI offers support to international Mo-99 producers to convert Mo-99 production from HEU targets to LEU targets**

  South Africa

  GTRI has provided NTP Radioisotopes in South Africa up to $25M in support to convert Mo-99 production from HEU targets to LEU targets by the end of 2015, and to address the HEU in Mo-99 waste residue.

  In June 2010 South Africa successfully achieved the first large-scale production of Mo-99 using LEU targets, and the first shipment of FDA-approved Mo-99 produced with LEU targets was received in the United States in December 2010.

  Belgium

  GTRI has contributed $6.8M towards the conversion of the IRE isotope production facility in Belgium from HEU targets to LEU targets for completion by the end of 2015.

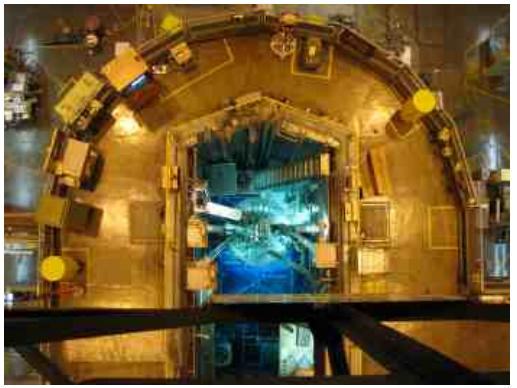
  The Netherlands

  The Netherlands has committed to conversion of its Mo-99 production facility by the end of 2015. On December 11, 2013, Mallinckrodt announced that technical difficulties are putting the date to conversion at risk.

  Canada

  The NRU reactor in Canada is expected to cease isotope production in 2016.

Nuclear Security Summit
Seoul 2012



SAFARI-1 Reactor (South Africa)

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DOE Reports to Congress

- Annual DOE Secretarial Reports to Congress
  - Names of recipients of DOE support for domestic Mo-99 production
  - Amount of DOE funding committed to each project
  - Milestones expected to be reached for each project for the year
  - How each project is expected to support increased Mo-99 production
  - The findings of the evaluation of projects
  - The use of DOE funds used for the projects
  - A description of actions taken to implement the Uranium Lease and Take-Back Program

- National Academy of Sciences Report required by the AMIPA
  - Lists all global Mo-99 facilities and whether they use HEU
  - Reviews international Mo-99 production over the past 5 years
  - Assesses progress made over the past 5 years toward establishing domestic Mo-99 production
  - Assesses DOE progress to eliminate HEU in research reactors and isotope production facilities.

Other USG Initiatives

In addition to the American Medical Isotopes Production Act, there are other USG efforts to help achieve the objective to Accelerate the establishment of reliable supplies of the medical isotope molybdenum-99 produced without HEU, including:

- White House Fact Sheet on Mo-99
- Participating in various domestic and international working groups
- Mo-99 stakeholder outreach
- Ensuring the implementation of OECD-NEA policy recommendations in the United States

U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration
Defense Nuclear Nonproliferation

U.S. Government Public Statement

Encouraging Reliable Supplies of Molydenum-99 Produced without Highly Enriched Uranium

- **Calling upon the Mo-99 industry to voluntarily establish a unique product code or similar identifying markers for Mo-99-based radiopharmaceutical products that are produced without the use of HEU;**
  In January 2013, the U.S. Mo-99 industry began to uniquely identify, or “label”, Mo-99-based radiopharmaceuticals that are produced without HEU.

- **Preferentially procuring, through certain U.S. government entities, Mo-99-based products produced without the use of HEU, whenever they are available, and in a manner consistent with U.S. obligations under international trade agreements;**
  On April 15, 2013, the Veterans Health Administration (VHA) issued a policy that encourages VHA hospitals to preferentially procure non-HEU based Mo-99. VHA is currently working to issue a policy statement to preferentially procure Mo-99-based radiopharmaceutical products produced without HEU.

- **Examining potential health-insurance payment options that might promote a sustainable non-HEU supply of Mo-99;**
  On January 1, 2013, the U.S. Centers for Medicaid and Medicare (CMS) issued a new rule that offers a $10 premium payment to any medical procedure that uses Mo-99-based radiopharmaceutical products produced without HEU.

- **Taking steps to further reduce exports of HEU that will be used for medical isotope production when sufficient supplies of non-HEU-produced Mo-99 are available to the global marketplace;**
  Exports of HEU for medical isotope production are made on an annual basis and exports of HEU will be reduced as sufficient supplies of non-HEU-based Mo-99 become available.

- **Continuing to encourage domestic commercial entities in their efforts to produce Mo-99 without HEU during the transition of the Mo-99 industry to full-cost-recovery, and directing those resources to the projects with the greatest demonstrated progress; and**
  We intend to continue to support our domestic commercial partners to produce Mo-99 without the use of HEU in the United States.

- **Continuing to provide support to international producers to assist in the conversion of Mo-99 production facilities from HEU to LEU.**
  Consistent with our long-standing HEU minimization mission and international commitments, we intend to continue to provide support to convert the existing Mo-99 producers to LEU targets.

Working Groups on Mo-99

GTRI's Mo-99 Program is working to accelerate the establishment of a reliable supply of the medical isotope Mo-99 produced without highly enriched uranium (HEU).

International Coordination on Mo-99 Supply and Resolving Economic Issues

Organization for Economic Cooperation and Development – Nuclear Energy Agency (OECD-NEA)

- High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR)

International Technical Development Cooperation

IAEA Coordinated Research Projects and Consultancy Groups on Mo-99:

- Peaceful Uses Initiative on Supporting the Global Deployment of Mo-99 Production Capacity for Nuclear Medicine Applications Without the Use of HEU (est. 2013)
- Conversion Planning for Mo-99 Production from HEU to LEU (est. 2010)
- Current and Novel, Non-HEU-Based Isotope Production and Supply Technologies for Mo-99 and Tc-99 (est. 2010)
- Feasibility Evaluation of the Use of Low Enriched Uranium Fuelled Homogeneous Aqueous Solution Nuclear Reactors for the Production of Short Lived Fission Product Isotopes (est. 2010)
- Progress with the Production of Molybdenum-99 using Neutron Activation (est. 2010)
- Small-Scale Indigenous Production Using LEU Targets or Neutron Activation (est. 2005)

Encouraging the use of non-HEU-based Mo-99 in the United States

U.S. Interagency Working Group (est. 2009) - OSTP, OMB, DOE-NA, DOE-SC, DOE-NE, DOE-EM, FDA, HHS/CMS, DOS, DHS, NRC, DOT, NIH, VA

- Hosted by the Office of Science and Technology Policy of the Executive Office of the President

Other Stakeholder Coordination and Outreach

- GTRI hosts the annual Mo-99 Topical Meeting
- GTRI participates in annual Society of Nuclear Medicine and Molecular Imaging meeting, American Nuclear Society meeting, and other conferences
- GTRI participates, by invitation, in the EU Observatory Working Group on Mo-99

OECD-NEA

OECD-NEA High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR)

- The HLG-MR was established in 2009 in response to Mo-99 shortages due to the unscheduled outages of two major supply chain facilities.
- 15 member countries, plus IAEA and European Supply Agency
- The HLG-MR convenes in two-year mandates
  - 2009-2011: First mandate, Chaired by Canada
  - 2011-2013: Second mandate, Chaired by U.S.
  - 2013-2015: Third mandate, Chair TBD
- The HLG-MR identified weaknesses in the supply chain that led to the shortages, and developed six policy principles to promote the transition of the global production of Mo-99 to a full-cost-recovery, non-HEU-based industry

OECD-NEA Six Principles

Six principles intended to strengthen the security of the global Mo-99 supply:

1. All reactor operators and host governments should ensure that full operating costs, including capital replacement costs, are included in the price of irradiated uranium targets for ^{99}Mo production.

2. Reserve capacity should be sourced and paid for by the supply chain. A common approach should be used to determine the amount of reserve capacity required and the price of reserve capacity options.

3. Recognizing and encouraging the role of the market, governments should remove all ^{99}Mo-related subsidies to reactors, require reactors to implement full-cost pricing methodology and not interfere in normal market operations as the resulting price impacts are felt in the supply chain. This should occur over a period of two to three years to allow for the market to adjust to the new pricing paradigm.

4. Governments should provide support to processors to facilitate the conversion of the processing facility to LEU.

5. International collaboration through a policy and information sharing forum should be continued, recognising the importance of a global harmonised approach to addressing security of supply and the value to international consensus in encouraging domestic action.

6. An International Expert Panel should be developed that would evaluate the ^{99}Mo/^{99m}Tc supply chain every two years. The review would assess whether reactors were implementing full-cost pricing and other harmonised policy approaches agreed to by the HLG-MR. The Panel would also review the co-ordination of operating schedules to ensure that no market abuse was occurring.