U.S. DEPARTMENT OF ENERGY

Defense Nuclear Nonproliferation

Global Threat Reduction Initiative

Efforts to Establish a Reliable Domestic Supply of Molybdenum-99

March 11, 2014

U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration

Defense Nuclear Nonproliferation

GTRI Program Goals

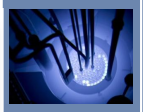
MISSION

[illegible]

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)

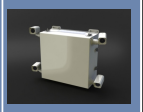
THESE EFFORTS RESULT IN PERMANENT THREAT REDUCTION BY MINIMIZING AND, TO THE EXTENT POSSIBLE, ELIMINATING THE NEED FOR HEU IN CIVILIAN APPLICATIONS – EACH REACTOR CONVERTED OR SHUT DOWN ELIMINATES A SOURCE OF BOMB MATERIAL.

REMOVE

REMOVE AND DISPOSE OF EXCESS NUCLEAR AND RADIOLOGICAL MATERIALS; AND

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.

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

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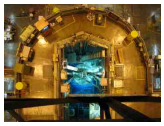
What is Mo-99?

- Molybdenum-99 (Mo-99) is the parent product of Tc-99m, a radioisotope used in approximately 50,000 medical diagnostic tests per day in the U.S. (over 18 million per year in the U.S.)
- Primary uses include detection of heart disease, cancer, study of organ structure and function, and other applications.
- Mo-99 has a short half life (66 hours) and cannot be stockpiled
- U.S. demand is approximately 50% of the world market
  - The historic global demand is ~12,000 6-day curies per week.
  - Since the 2009-2010 shortages, global demand has been ~10,000 6-day curies per week.
- Mo-99 is produced at only 5 processing facilities worldwide, in cooperation with 8 research reactor facilities
  - Processing facilities located in Canada (HEU), The Netherlands (HEU), Belgium (HEU), South Africa (HEU and LEU), and Australia (LEU)
  - Research reactors used for irradiation located in Canada, The Netherlands, Belgium, France, Poland, Czech Republic, South Africa, and Australia

Tc-99m generator and labeling kits



SAFARI-1 Reactor (South Africa)

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GTRI Supports International Commitments to Eliminate the use of HEU in Isotope Production

White House Public Statement – June 2012

The White House released a Fact Sheet announcing possible options to support the establishment of a reliable supply of molybdenum-99 produced without HEU.

Nuclear Security Summit – March 2012

"We encourage States to take measures to minimize the use of HEU, including through the conversion of reactors from highly enriched to low enriched uranium (LEU) fuel, where technically and economically feasible, taking into account the need for assured supplies of medical isotopes, and encourage States in a position to do so, by the end of 2013, to announce voluntary specific actions intended to minimize the use of HEU. We also encourage States to promote the use of LEU fuels and targets in commercial applications such as isotope production, and in this regard, welcome relevant international cooperation on high-density LEU fuel to support the conversion of research and test reactors."

Belgium-France-Netherlands-United States Joint Statement on the Minimization of HEU and the Reliable Supply of Medical Radioisotopes – March 2012

"…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, subject to regulatory approvals, to reach a sustainable medical isotope production for the benefit of patients in Europe, the United States and elsewhere. As a result, in the longer term, the use of HEU will be completely eliminated for medical isotopes that are produced in Belgium, France, and The Netherlands and used in those countries and in the United States."

Nuclear Security Summit– April 2010

"Participating States, as appropriate, will collaborate to research and develop new technologies that require neither highly enriched uranium fuels for reactor operation nor highly enriched uranium targets for producing medical or other isotopes, and will encourage the use of low enriched uranium and other proliferation-resistant technologies and fuels in various commercial applications such as isotope production;"

UN Security Council Resolution 1887 – September 2009

"Calls upon all States to manage responsibly and minimize to the greatest extent that is technically and economically feasible the use of highly enriched uranium for civilian purposes, including by working to convert research reactors and radioisotope production processes to the use of low enriched uranium fuels and targets;"

Obama-Medvedev Moscow Joint Statement – July 2009

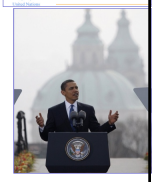
"…we declare an intent to broaden and deepen long-term cooperation to further increase the level of security of nuclear facilities around the world, including through minimization of the use of highly-enriched uranium in civilian applications and through consolidation and conversion of nuclear materials."

President Obama's Speech in Prague – April 2009

"Today, I am announcing a new international effort to secure all vulnerable nuclear material around the world within four years. We will set new standards, expand our cooperation with Russia, and pursue new partnerships to lock down these sensitive materials."

Nuclear Security Summit Seoul 2012

Security Council SC/9746



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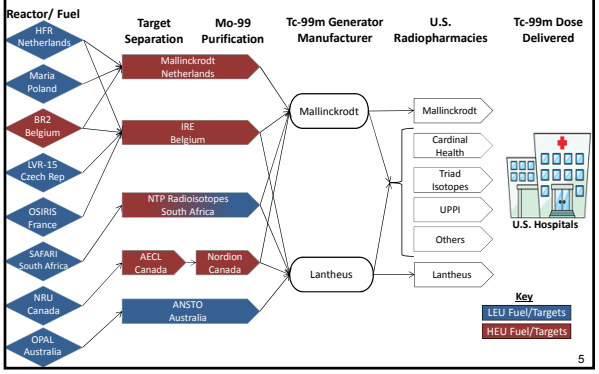
Current U.S. Mo-99 Supply Matrix



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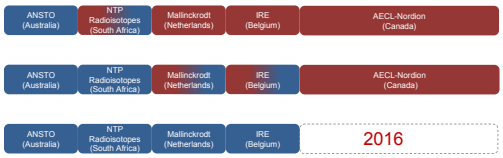
GTRI's Strategy for Reliable Non-HEU-Based Mo-99 Supply

Global Mo-99 Market – Major Producers

HEU | Non-HEU



U.S. Domestic Mo-99 Projects

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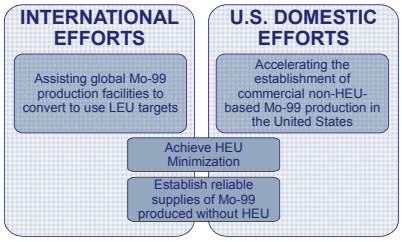
GTRI's Mo-99 Objective and Strategy
International & U.S. Domestic Approaches

- 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.



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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.

Each cooperative agreement is awarded under a 50% - 50% cost-share arrangement, consistent with the American Medical Isotopes Production Act and Section 988 of the Energy Policy Act of 2005. The cooperative agreements are currently limited to $25M each.

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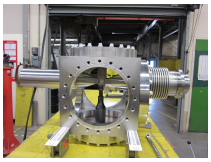
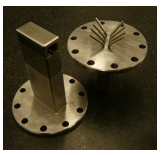
U.S. National Laboratories Support to Mo-99 Production

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.

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The American Medical Isotopes Production Act of 2012

- The Act was incorporated in the National Defense Authorization Act for Fiscal Year 2013 and enacted on January 2, 2013.
- Intended to help establish a reliable domestic supply of Mo-99 produced without the use of HEU and includes a number of short, medium, and long-term actions.
  - 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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White House Fact Sheet

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 January 3, 2014, the Department of Veteran's Affairs issued a policy memorandum that calls for Veterans Health Administration facilities to begin preferentially procuring non-HEU-based Mo-99/Tc-99m radiopharmaceutical products as they become commercially available.
- **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. This rule is now in its second year of implementation.
- **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**
  NNSA intends to continue to support its 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 long-standing HEU minimization and international commitments, NNSA intends to continue to provide support to convert existing Mo-99 producers to LEU targets.

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