

State of Molybdenum-99 Production and Utilization and Progress toward Eliminating Use of Highly Enriched Uranium

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Vice-Chair of The Academies Committee

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2015 Mo-99 Topical Meeting

The National Academies of

SCIENCES • ENGINEERING • MEDICINE

TOPICS TO ADDRESS

- Study background
- Study task
- Committee membership
- Study schedule
- Information gathering process
- Contact information

THE ACADEMIES' STUDY BACKGROUND

Study mandated by U.S. Congress in American Medical Isotopes Production Act of 2012 (2012 Act)

Policy Goals

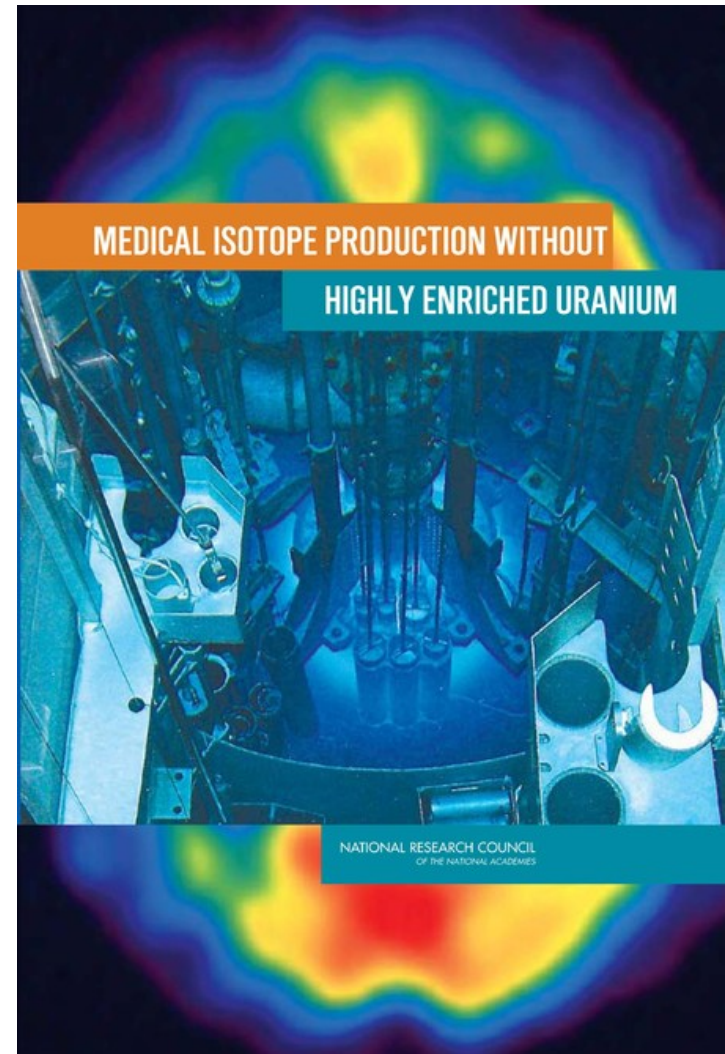
- Eliminate, to the extent feasible, use of HEU in civilian applications.
- Promote U.S.-based production of Mo-99 without the use of HEU.

Study sponsored by the U.S. Department of Energy–
National Nuclear Security Administration

Some provisions of the 2012 Act were suggested to Congress in a 2009 Academies report.

The 2009 Academies study was carried out under another congressional mandate (contained in the Energy Policy Act of 2005) to examine the technical and economic feasibility of producing medical isotopes without HEU.

The study report concluded that production of medical isotopes without HEU was economically and technically feasible.



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STUDY TASK

1. A list of facilities that produce molybdenum-99 for medical use, including an indication of whether these facilities utilize highly enriched uranium.
2. A review of international production of molybdenum-99 over the previous 5 years, including whether any new production was brought online; whether any facilities halted production unexpectedly; and whether any facilities used for production were decommissioned or otherwise permanently removed from service.
3. An assessment of progress made in the previous 5 years toward establishing domestic production of molybdenum-99 for medical use, including the extent to which other medical isotopes that have been produced with molybdenum-99, such as iodine-131 and xenon-133, are being used for medical purposes.

4. The adequacy of molybdenum-99 supplies to meet future domestic medical needs, particularly in 2016 and beyond.
5. An assessment of the progress made by the Department of Energy and others to eliminate worldwide use of highly enriched uranium in reactor targets and medical isotope production facilities. This assessment should identify key remaining obstacles for eliminating highly enriched uranium from reactor targets and medical isotope production facilities and recommend steps that could be taken to overcome the identified obstacles.

NSAC Mo-99 SUBCOMMITTEE VS ACADEMIES COMMITTEE TASKS

- NSAC's Mo-99 subcommittee task is to review the DOE/NNSA domestic Mo-99 program and make recommendations to improve the program
- The Academies committee has a broader task to examine
 - Overall domestic medical isotope production efforts
 - Adequacy of medical isotope supply, and
 - Progress toward eliminating HEU use from medical isotope production

COMMITTEE MEMBERSHIP

S. James Adelstein, *Chair*

Harvard Medical School

Thomas J. Ruth, *Vice-Chair*

TRIUMF

Lin-Wen Hu

Massachusetts Institute of Technology

Joseph C. Hung

Mayo Clinic

Robert T. Jubin

Oak Ridge National Laboratory

Emmett B. Keeler

Pardee RAND Graduate School

Gerald L. Kulcinski

University of Wisconsin-Madison

Jason S. Lewis

Memorial Sloan-Kettering Cancer Center

Kathryn A. Morton

University of Utah Health Care

Eugene J. Peterson

Los Alamos National Laboratory

Tor Raubenheimer

SLAC National Accelerator Laboratory

Henry D. Royal

Washington University School of Medicine

Felicia L. Taw

Los Alamos National Laboratory

CHAIR	VICE-CHAIR	
<ul style="list-style-type: none"> • S. James Adelstein 	<ul style="list-style-type: none"> • Thomas J. Ruth 	
ACCELERATOR DESIGN AND OPERATION	RADIOISOTOPE PRODUCTION	CHEMISTRY (RADIOPHARMACEUTICAL)
<ul style="list-style-type: none"> • Tor Raubenheimer • Thomas J. Ruth 	<ul style="list-style-type: none"> • Jason S. Lewis • Eugene J. Peterson • Thomas J. Ruth 	<ul style="list-style-type: none"> • Joseph C. Hung • Jason S. Lewis • Thomas J. Ruth
CHEMISTRY (NUCLEAR)	WASTE PROCESSING AND MANAGEMENT	NUCLEAR MEDICINE PRACTICE
<ul style="list-style-type: none"> • Robert T. Jubin • Felicia L. Taw 	<ul style="list-style-type: none"> • Robert T. Jubin • Felicia L. Taw 	<ul style="list-style-type: none"> • S. James Adelstein • Kathryn A. Morton • Henry D. Royal
MEDICAL ECONOMICS	NUCLEAR ENGINEERING	RADIOPHARMACY OPERATIONS
<ul style="list-style-type: none"> • Emmett B. Keeler 	<ul style="list-style-type: none"> • Lin-Wen Hu • Gerald L. Kulcinski 	<ul style="list-style-type: none"> • Joseph C. Hung • Jason S. Lewis

THE ACADEMIES' STUDY SCHEDULE

- Committee meetings
 - #1: February, 2015, Washington, DC
 - #2: May, 2015, Chicago, IL
 - #3: August, 2015, Washington, DC
 - #4: November, 2015, Washington, DC
 - #5: February, 2016, Irvine, CA
- Final report released to the U.S. Department of Energy, Congress, and public: June 2016

INFORMATION GATHERING PROCESS

- Invited briefings
- Letter requests for information
- Site visits
- Public comments (verbal and/or written)

INVITED BRIEFINGS (UP TO NOW)

Potential domestic producers

- **NorthStar Medical Technologies**
- **SHINE Medical Technologies**
- **Northwest Medical Isotopes**
- **General Atomics/Nordion**

Topics addressed

- Technology for producing Mo-99
- Current status of technology development and implementation efforts
- Current status of regulatory approval efforts
- Remaining technical and regulatory challenges
- Timeline and approaches for bringing Mo-99 to market
- Economic and logistical challenges for bringing Mo-99 to market

Generator Manufacturers

- **Lantheus Medical Imaging**
- **Mallinckrodt Pharmaceuticals**

Topics addressed

- Progress with HEU to LEU conversion efforts
- Technical, regulatory, and market challenges to conversion
- Timeline for commercial production of LEU-based Mo-99
- Economic, regulatory, and logistical challenges for bringing LEU-based Mo-99 to market

National Laboratories

- **Argonne National Laboratory**
- **Oak Ridge National Laboratory**
- **Los Alamos National Laboratory**
- **Y-12 National Security Complex**
- **Savannah River National Laboratory**

Topics addressed

- Type of assistance and to which commercial entities
- Progress with completion of projects and timelines
- Technical challenges related to the projects

Regulatory Agencies

- **Department of Energy** on uranium lease and take-back program
- **Food and Drug Administration** on the agency's role in Mo-99 production and utilization
- **Nuclear Regulatory Commission** on licensing activities related to molybdenum-99 production
- **Centers for Medicare and Medicaid Services** on Tc-99m payment economics

International Organizations

- **Nuclear Energy Agency, Organization for Economic Co-operation and Development** on economics of global radioisotope production
- **Euratom Supply Agency** on EU observatory on the supply of medical radioisotopes

SITE VISITS

Domestic

- University of Missouri Research Reactor Center ✓
- Argonne National Laboratory ✓
- Cardinal Health nuclear pharmacy ✓
- Lantheus Medical Imaging

International

- Russia ✓
- S. Africa
- Australia
- Canada
- Europe

To learn about:

- (1) Current capabilities and future plans for producing Mo-99/Tc-99m
- (2) Progress and challenges for eliminating HEU use in production targets.

QUESTIONS, COMMENTS, OR SUGGESTIONS?

Please contact us:

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Phone: 202-334-3066

If you would like to be added on the study listserv and receive updates, send us an email at Mo99@nas.edu