Testimony of

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THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

Senate Committee on Energy and Natural Resources

Hearing on the

H.R. 3276, the American Medical Isotopes Production Act of 2009

December 3, 2009

Good morning Chairman Bingaman and members of the committee, my name is Kevin Crowley, and I am the director of the National Research Council's Nuclear and Radiation Studies Board.[1] I also directed the National Research Council study entitled *Medical Isotope Production without Highly Enriched Uranium*, which is the subject of my testimony today. This report was completed in late 2008 and released to the public in January 2009.

My testimony will address the following three topics: the origin of our medical isotopes study; study charges and principal report findings; and comments on H.R. 3276 in light of those findings.

STUDY ORIGIN

The mandate for this National Research Council study came from Section 630 of the Energy Policy Act of 2005 (Public Law 109-58). Section 630 directed the Secretary of Energy to enter into an arrangement with the National Academy of Sciences for a study on the elimination of highly enriched uranium (HEU[2]) from reactor fuel, reactor targets, and medical isotope production facilities. Our study focused on the production and use of molybdenum 99 because its decay product, technetium 99m, is used in over two-thirds of all diagnostic medical isotope procedures in the United States. Our report concluded that the production of molybdenum 99 in quantities sufficient to meet current healthcare needs would ensure that other reactor-produced medical isotopes (such as iodine and xenon) would also be available in sufficient quantities.

The congressional mandate for our study arose because of a conflict between the Energy Policy Act of 1992, which created increasing pressure to phase out U.S. exports of HEU for reactor fuels and targets, and the Energy Policy Act of 2005, which sought to increase the reliability of medical isotope supply by lifting the requirements of the 1992

[1] The National Research Council is the operating arm of the National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine of the National Academies, chartered by Congress in 1863 to advise the government on matters of science and technology. The Nuclear and Radiation Studies Board is responsible for oversight of National Research Council studies on safety and security of nuclear materials and waste.

[2] HEU is defined as uranium enriched in the isotope uranium 235 to levels greater than or equal to 20 percent. The United States supplies most of the HEU that is used to produce medical isotopes worldwide.

Act for HEU exports to Belgium, Canada, France, Germany, and the Netherlands for medical isotope production.

STUDY CHARGES AND PRINCIPAL FINDINGS

Our study had five charges, the first four of which were specified in the 2005 Act; the last charge was negotiated with the study sponsor, the National Nuclear Security Administration, to assist it in achieving its mandate to minimize HEU use in civilian applications. The study charges and some principal findings are summarized below.

Charge 1: Determine the feasibility of procuring supplies of medical isotopes from commercial sources that do not use HEU. We found that, at the present time, there are not sufficient quantities of medical isotopes produced without HEU to meet U.S. domestic needs. However, we also found no technical reason that adequate quantities could not be produced using low enriched uranium (LEU[3]) targets. Our report noted that Argentina and Australia are now producing molybdenum 99 with LEU targets. These countries are producing primarily for domestic and regional needs, but they are exploring opportunities to become global suppliers.

Charge 2: Determine the current and projected demand and availability of medical isotopes in regular current domestic use. We found that the U.S. demand for molybdenum 99 is about 5,000-7,000 6-day curies per week,[4] which is about half of the global demand for this isotope. We also found that domestic demand for this isotope is likely to grow at rates of 3-5 percent per year over the next 5 years, and that growth will likely continue over the longer term as the U.S. population ages. The global demand for this isotope could grow even more rapidly in the years ahead as nuclear medicine technologies find more widespread application, especially in developing countries. Robust international growth could impact future domestic molybdenum 99 supply, availability, and price because the United States does not produce this isotope for medical use.

[3] LEU is uranium enriched in the isotope uranium 235 to less than 20 percent.
[4] A 6-day curie is a measure of the quantity of molybdenum 99 present 6 days after it leaves a producer's facility. Time calibration is necessary because the quantity of molybdenum 99 decreases by about 1 percent per hour as a result of radioactive decay.

Global molybdenum 99 production is insufficient to meet current demand owing to the recent shutdowns of two reactors: The NRU Reactor in Canada and HFR in the Netherlands. These reactors are 52 and 48 years old, respectively, and are likely nearing the ends of their operating lifetimes. The supply disruptions arising from these reactor shutdowns are impacting the availability of molybdenum 99 for medical use and the continuity of patient care in the United States and elsewhere. Supply reliability is likely to continue to be a serious problem for the United States until new supply capacity is brought online.

Charge 3: Determine the progress being made by the Department of Energy and others to eliminate all use of HEU in reactor fuel, reactor targets, and medical isotope production facilities. The U.S. Department of Energy (DOE) is leading the Global Threat Reduction Initiative (GTRI), which is working to convert reactor fuel and targets from HEU to LEU. Our report found that DOE has made substantial progress in converting reactor fuel and targets through the GTRI. We recommended that DOE determine the feasibility of converting 78 HEU-fueled research and test reactors that are currently out of scope of the GTRI program, and also that DOE increase its focus on eliminating the HEU wastes that result from medical isotope production.

Our report notes that molybdenum 99 producers have been slow to adopt the LEU-based production processes that have been developed by DOE and others. This is likely because producers have no good business reason for converting to LEU-based production: they would realize little or no direct revenue benefit from conversion, as conversion would not enhance product quality, nor would it reduce the production costs. In fact, we saw no evidence during our study that large-scale producers were doing the necessary research and development work to support conversion to LEU-based production.

Charge 4: Determine the potential cost differential in medical isotope production in reactors and target processing facilities if the products were derived from production systems that do not involve fuels and targets with HEU. We found that the anticipated average cost increase to convert to the production of medical isotopes without the use of HEU would likely be less than 10 percent for most current large-scale

producers given a sufficiently long amortization period. This finding was based on a conservative present value cost analysis at three steps in the molybdenum 99/technetium 99m supply chain: production of molybdenum 99, production of technetium generators, and delivery of technetium 99m doses. In fact, we concluded that a 10 percent increase in price at any of these three points in the supply chain would result in a trivial (< 1 percent) increase in the price of a typical medical isotope procedure.

Charge 5: Identify additional steps that could be taken by DOE and medical isotope producers to improve the feasibility of conversion to LEU-based isotope production processes. We identified additional steps that could be taken by DOE and others to improve the feasibility of conversion of medical isotope production. We specifically suggested that:

- Producers should commit to conversion and announce a best-effort schedule for eliminating HEU-based production.
- DOE should make the considerable technical expertise of the national laboratory system available to assist producers with conversion-related research and development.
- The Department of State should intensify the diplomatic pressure on countries that still use HEU to induce them to convert.
- The Food and Drug Administration (FDA) should work with industry and technical experts to ensure that there is a common understanding of likely FDA requirements for obtaining regulatory approvals for the medical use of LEU-based molybdenum 99/technetium 99m.
- The U.S. Congress should provide clear and consistent policy directions concerning conversion to LEU-based molybdenum 99 production; consider a gradual phaseout of HEU exports for medical isotope production; and consider incentives to motivate conversion and the development of domestic sources of molybdenum 99 production.

Notable progress has been made in implementing these suggestions since our report was published: DOE has offered technical assistance to medical isotope producers; the FDA acted promptly to approve the domestic sale of radiopharmaceuticals containing technetium 99m from Australia and South Africa; Mallinckrodt and Babcock and Wilcox have announced a partnership to produce molybdenum 99 using an LEU solution reactor; and the South African producer NTP recently announced that it would convert its medical isotope production process to LEU targets.

COMMENTS ON H.R. 3276

The American Medical Isotopes Production Act of 2009 is responsive to many of the findings from our report. Notably, the legislation seeks to address the chronic supply reliability problem by providing incentives for the development of domestic supplies of molybdenum 99 for medical use. Development of a domestic supply of molybdenum 99 could help alleviate current global shortages and insulate the United States from future supply disruptions. It could also help to ensure the continued availability of this workhorse isotope to meet future domestic demand if, as expected, the global demand for this isotope continues to grow.

The legislation sends a clear policy signal of Congress' intention to phase out HEU for medical isotope production; this signal could provide a powerful near-term incentive for conversion. The legislation's proposed phase-out period of 7 years, with an additional 4 years if needed, is largely consistent with our report's suggested phase-out period of 7-10 years. We judged that 7-10 years would be sufficient for producers to make an orderly conversion to LEU-based production. This judgment was based on previous experiences with conversion and our understanding of regulatory processes.

The legislation's authorization of appropriations to develop a domestic supply capacity for medical isotope production is consistent with our report's suggestion that Congress provide temporary financial incentives for conversion to LEU-based production and development of domestic supplies. Our report notes that "because current supplies of Mo-99 are produced in reactors built largely at government expense, private companies

that can provide new domestic supplies of [molybdenum 99] might not choose to compete without government assistance."

The uranium lease and take back provision in the legislation was not specifically identified as an incentive in our report. However, it could serve to promote domestic production by allowing producers to sidestep the regulatory uncertainties associated with waste classification and disposition.

Finally, the legislation would empower the Secretary of Energy to provide assistance for the development of fuels, targets, and processes for domestic production of molybdenum 99. This is consistent with our report's suggestion that the Department of Energy make the technical expertise of the DOE national laboratory system available to assist producers with conversion-related research and development.

This concludes my testimony to the committee. I would be pleased to answer your questions.