NAS Report Warns of U.S. Radioisotope Shortages

The National Academies of Sciences, Engineering, and Medicine (NAS) on September 12 released a congressionally mandated report on the status of the current and future supply of ^{99}Mo and ^{99m}Tc and on progress made in eliminating highly enriched uranium (HEU) from ^{99}Mo production. Although the current supply of ^{99}Mo and ^{99m}Tc is sufficient to meet U.S. and global demands, the report warned that changes to the supply chain late in 2016 could lead to severe shortages and result in interruptions in nuclear medicine practice.

Nearly 95% of the world's supply of ^{99}Mo is produced by irradiating targets in 7 research reactors located in Australia, Canada, European countries, and South Africa. The isotope has not been commercially produced in the United States since the late 1980s. The NAS report, titled *Molybdenum-99 for Medical Imaging,* found that the supply of ^{99}Mo will be reduced substantially when Canada's National Research Universal reactor, built at Chalk River in 1957, stops production in fall 2016. Canada will then become a "supplier of last resort," producing ^{99}Mo only in the event of severe global shortages, until its reactor shuts down permanently at the end of March 2018.

The committee that conducted the study and wrote the report predicted a substantial likelihood of severe ^{99}Mo and ^{99m}Tc shortages after October 2016, "should any of the other current suppliers fail, and lasting at least until other global suppliers complete their planned capacity expansions, currently scheduled for 2017." The committee recommended that the U.S. government continue to work with the Canadian government to ensure that an executable and well-communicated plan is in place to restart the supply of ^{99}Mo from Canada between October 2016 and March 2018, if needed. "Current efforts to increase the supply of ^{99}Mo by expansion of existing overseas production and initiation of domestic production by methods not requiring HEU are important to ensure future availability," said NAS committee chair S. James Adelstein, MD, PhD, Paul C. Cabot Distinguished Professor of Medical Biophysics at Harvard Medical School (Boston, MA). "Although there are plans from both existing international suppliers and potential domestic suppliers to fill the expected supply gap from Canada, the committee is concerned that any delays in bringing additional supplies of ^{99}Mo to the market would increase the risks of substantial shortages."

The United States currently consumes about half of the ^{99}Mo produced worldwide. However, demand has been declining for at least a decade and decreased by about 25% between 2009–2010 and 2014–2015. The committee noted that domestic demand is unlikely to increase significantly over the next 5 years, but international demand and competition for output could increase, primarily because of higher utilization in Asian markets.

The report indicated that the American Medical Isotopes Production Act of 2012 and financial support from the U.S. Department of Energy (DOE) National Nuclear Security Administration have stimulated private sector efforts to establish U.S. domestic production of ^{99}Mo for medical use. However, no domestic commercial production will be established before Canada stops regular production of the isotope. The report also noted that potential domestic suppliers face technical, financial, regulatory, and market penetration challenges. The market challenges will likely increase after current global ^{99}Mo suppliers expand production.

NAS reported that 4 of 5 global ^{99}Mo suppliers have committed to converting from HEU to low-enriched uranium (LEU) reactor targets and are making "uneven progress" toward that goal. Conversion could be completed by the end of 2019 if current schedules are met. The Russian Federation has indicated its intention to become a global ^{99}Mo supplier. Its current ^{99}Mo production uses HEU targets, and no commitment or schedule has been announced to convert to LEU. The report cautioned that continued sale of ^{99}Mo produced with HEU targets to international markets could disrupt progress toward full market adoption of ^{99}Mo from non-HEU sources. The committee recommended that the U.S. government, through the U.S. Department of State, the U.S. DOE National Nuclear Security Administration, and the U.S. scientific and technical communities, engage with the Russian government to clarify a schedule for converting ^{99}Mo production from HEU to LEU targets.

The report also raised concern about the large quantities of waste containing HEU that have accumulated from several decades of ^{99}Mo production and will continue to exist at multiple locations. The U.S. government is working with global suppliers and their governments to examine options for downblending or returning this material to the United States. The NAS committee recommended that the U.S. government work with global molybdenum suppliers and their regulators to reduce the proliferation hazard from processing waste from medical isotope production containing HEU of U.S. origin and that it develop a global inventory of this waste.

SNMMI President Sally W. Schwarz, MS, RPh, BCNP, a professor of radiology at Washington University School of Medicine (St. Louis, MO). agreed in general with the report's assessments and also noted in a related SNMMI press release: "Development of these new, non-HEU production methods is costly, even when shared with governments. It will take time and incremental changes to reach a balance point of fair reimbursement for increased costs for all members of the supply chain, including ^{99}Mo producers, generator manufacturers, nuclear pharmacies, hospitals, and patients." Despite concerns about immediate shortages, Schwarz expressed optimism about future radioisotope supplies: "The innovative, safer production methods and facilities that will be coming online over the next few years will certainly help ensure a safe, reliable supply of ^{99}Mo."

Full copies of the NAS report are available at www.nap.edu.

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