Ensuring a Safe, Reliable Supply of ^{99}Mo/^{99m}Tc

Sally W. Schwarz, MS, RPh, BCNP, FAPhA, SNMMI President

As my year as president of SNMMI gets underway, a continuing focus for nuclear medicine is development of a reliable, domestic supply of radioisotopes. ^{99m}Tc remains the most commonly used radioisotope worldwide—used in 20–40 million diagnostic procedures each year. Shortages of ^{99}Mo (the parent of ^{99m}Tc), resulting from reliance in recent years on aging reactors, have led to major efforts around the globe to ensure a reliable supply. Since the 2009 shortage of ^{99}Mo, there has been pessimism about meeting future needs for ^{99m}Tc. In addition, the Canadian National Research Universal reactor will cease routine ^{99}Mo production this year (but will serve as a backup until March 2018 should a significant unplanned shortage occur without an alternate supply). However, much progress has been made so far this decade, and we now have reason to be cautiously optimistic.

I am SNMMI's representative to the High-Level Group on the Security of Supply of Medical Radioisotopes, which was established in 2009 by the Nuclear Energy Agency, working with the International Atomic Energy Agency and the European Commission's Euratom Supply Agency. Including experts from around the globe, the group is working to ensure than an ongoing, reliable supply of ^{99}Mo will be available as needed for clinical use throughout the world. The most recent meeting was held this July in Paris, France.

The international response to the supply crisis has included developing new production methods that move away from the use of high-enriched ^{235}U (HEU). Long-time global suppliers, such as Mallinckrodt and Lantheus, have undertaken the difficult task of converting from HEU to low-enriched ^{235}U (LEU) targets and fuel, and complete conversion will be online in the next couple of years. The Australian Nuclear Science and Technology Organization began ^{99}Mo production with LEU several years ago.

In the United States, which accounts for half of world demand for ^{99}Mo, the U.S. Department of Energy National Nuclear Security Administration (DOE/NNSA) is providing matching funding opportunities for research and development of domestic ^{99}Mo production methods that do not use HEU. DOE/NNSA currently has 3 active cooperative agreement partners in this endeavor: NorthStar Medical Isotopes, LLC; SHINE Medical Technologies, Inc.; and General Atomics, which is working with Nordion and the Missouri University Research Reactor. All 3 companies are developing processes that use non-HEU technology. In addition, NorthStar is working on a second process involving a neutron capture production process. A number of other independently funded U.S. companies are also working on new methods of ^{99}Mo production. These new production methods and facilities will be coming online over the next 2–5 years and will certainly help ensure a safe, reliable supply of ^{99}Mo. This will be an ongoing process, because other existing aging reactors will need to be replaced during this same time.

Sally W. Schwarz, MS, RPh, BCNP

Economic factors are also part of the supply problem. 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.

I will keep you updated on this critical issue as we work toward a safe, reliable, and fairly priced supply of ^{99}Mo/^{99m}Tc, so that we are able provide our patients with high-quality, cost-effective care.