Improving Radionuclide Availability

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In 2009, the unexpected shutdown of the National Research Universal (NRU) reactor at Chalk River in Canada led to a worldwide shortage of ^{99}Mo from which nuclear medicine has yet to completely recover. Recently, however, there has been significant progress in the production of both ^{99}Mo and other radionuclides that are essential to the practice of nuclear medicine. SNMMI is committed to supporting improvements in the radionuclide supply chain so that nuclear medicine practitioners and patients are not faced with similar shortages in the future.

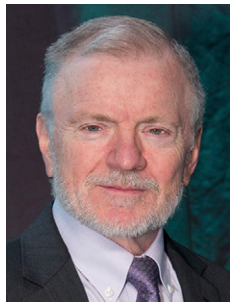
Although the ^{99}Mo/^{99m}Tc generator was developed in the late 1950s, it was not until 1970, when the "instant kit" was developed, that there was a rapid expansion in the development of new ^{99m}Tc radiopharmaceuticals. The development of new ^{99m}Tc radiopharmaceuticals was so successful that more than 80% of all nuclear medicine procedures are now performed with ^{99m}Tc—more than 15 million studies per year in the United States. The continued use of these radiopharmaceuticals depends on reliable sources of ^{99}Mo for production of the ^{99}Mo/^{99m}Tc generators that supply the ^{99m}Tc. However, while the United States consumes approximately 50% of all ^{99}Mo produced worldwide, the ^{99}Mo used here is produced primarily at facilities located outside the country.

The absence of domestic ^{99}Mo production became a significant problem during the 2000s, with several unwelcome developments. The most dramatic was the 9/11 terrorist attacks, which raised significant concern about terrorists gaining access to the highly enriched uranium (HEU) used to produce ^{99}Mo. The second was the 2009 NRU reactor shutdown, which lasted more than a year and caused a worldwide shortage of ^{99}Mo.

These issues led the U.S. Congress to pass the American Medical Isotope Production Act (AMIPA) in 2013. This legislation mandated that the U.S. eliminate the exportation of HEU for medical isotope production by 2020 and provided $100 million to support the development of domestic production of ^{99}Mo. It also required that this effort be "technology neutral"; in other words, it was up to applicants to develop innovative ways to make ^{99}Mo without using HEU.

Since 2013, American companies have made considerable progress in developing a reliable domestic supply of ^{99}Mo that does not rely on HEU, in some cases with the support of AMIPA and in some cases without. Companies supported by AMIPA include:

- NorthStar Medical Radioisotopes (Beloit, WI), which introduced its RadioGenix generator in 2018 and continues to improve their ^{99}Mo production process;
- SHINE Medical Technologies (Janesville, WI), which is using a deuterium–tritium (DT) generator as a neutron source with a low-enriched uranium (LEU) solution target. The company has demonstrated that their ^{99}Mo is compatible with existing generator designs and expects to bring its ^{99}Mo to the market in late 2021;



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- Niowave (Lansing, MI), which is using an electron linac as a neutron source, also with an LEU solution target, and expects to be in production in 2024 or 2025; and
- Northwest Medical Isotopes (Corvallis, OR), which is using LEU targets in existing reactors, such as the University of Missouri MU Research Reactor (Columbia) and plans to enter the market in 2023.

One company not supported by AMIPA that has made considerable progress is BWX Technologies (Lynchburg, VA), which is using the Ontario Power Generation reactors to irradiate novel ^{98}Mo targets and produce high specific activity ^{99}Mo. BWX Technologies has developed a new generator that is approximately the same size as existing generators and can produce ^{99m}Tc that is compatible with existing kits.

SNMMI has been working closely with U.S. government agencies, particularly the Department of Energy, as well as industry and other stakeholders in the United States and internationally, and will continue to do so until there is a reliable domestic supply of ^{99}Mo. During the COVID-19 pandemic, SNMMI worked with government and industry to alleviate transportation problems caused by the sharp decrease in international flights. Moving forward, SNMMI will continue to keep its members informed on new developments in the status of ^{99}Mo production and availability.

Beyond the ^{99}Mo/^{99m}Tc generator, innovation in radionuclide production extends in many other directions. One example is the development of a cyclotron method for production of ^{68}Ga that circumvents the shortage of ^{68}Ge used in the ^{68}Ge/^{68}Ga generator while possibly also reducing costs. A second example is development of alternative production methods for ^{225}Ac to supplement the limited supply of ^{225}Ac available from the Oak Ridge National Laboratory (TN) ^{229}Th generator. These innovations are enhancing the supply of radionuclides essential to nuclear medicine, providing the foundation the profession needs to grow and advance.