Domestic Non-Uranium-Based ^{99m}Tc Production System Approved

The U.S. Food and Drug Administration (FDA) and the Nuclear Regulatory Commission (NRC) on February 8 described new steps to ensure a stable and secure supply of ^{99m}Tc. The FDA announced approval of the RadioGenix system (NorthStar Medical Radioisotopes, LLC; Beloit, WI), described as a ^{99m}Tc generator used to produce sterile, nonpyrogenic ^{99m}Tc-sodium pertechnetate injection from the company's non-uranium-based ^{99}Mo. The FDA decision marks the launch of the first approved domestic source for production of ^{99}Mo in more than 25 years. The United States has had to rely on foreign producers for 100% of its ^{99}Mo supply, some of which includes highly enriched uranium (HEU) in production processes. Recent years have been marked with repeated world shortages resulting from accidents, planned and unplanned nuclear reactor shutdowns, and the closing of several major facilities. The most recent shortages resulted from unexpected events at reactors in South Africa and Australia.

"Every day, tens of thousands of people in the U.S. undergo a nuclear medical imaging procedure that depends on ^{99m}Tc," said Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research. "This radioisotope is vital to disease detection, yet health care professionals have faced challenges with adequate supply due to a complex supply chain that sometimes resulted in shortages. Today's approval has been the result of years of coordination across the FDA and with U.S. government organizations and marks the first domestic supply . . .in 30 years, which will help to ensure more reliable, clean, and secure access to this important imaging agent used in nuclear medicine."

"With the FDA's approval of the RadioGenix System, NorthStar can begin providing its customers with a reliable and environmentally friendly supply of the ^{99}Mo radioisotope for the United States," said George P. Messina, chair and CEO of NorthStar Medical Radioisotopes. ". . .we are extremely proud to pioneer domestic production of ^{99}Mo that is independent of uranium-based product. The approval by the FDA will reduce the U.S. health care system's reliance on fragile foreign supply of ^{99}Mo and the use of enriched uranium target material."

Messina credited the Department of Energy (DOE) National Nuclear Security Administration (NNSA) for 7 years of cooperation in developing the RadioGenix system and NorthStar's neutron capture process to produce ^{99}Mo without the use of uranium. In a separate press release the DOE/NNSA noted that the American Medical Isotopes Production Act of 2012 has directed the agencies to implement a technology-neutral program, in cooperation with non-federal entities, to support projects in the United States for production of ^{99}Mo without HEU for medical uses. In January the NNSA announced that its collaboration with Curium (St. Louis, MO) had resulted in complete conversion of that company's ^{99}Mo production from HEU to low-enriched uranium.

"The FDA's approval of NorthStar's technology to produce ^{99}Mo in the United States is a win–win for national security and health care," said Steven C. Erhart, DOE Acting Under Secretary for Nuclear Security and NNSA Administrator. "The domestic production of this critical medical isotope without HEU reduces global proliferation threats while also providing a more reliable supply to health care providers that need ^{99}Mo for diagnostic medical procedures every single day."

The approval did not require new clinical studies, because it relied on safety and efficacy information and data from an already FDA-approved ^{99m}Tc generator. The FDA decision specifically granted approval for the RadioGenix system "to produce ^{99m}Tc-sodium pertechnetate to be injected intravenously, instilled into the bladder or eye, or used with other FDA-approved imaging drugs to examine specific tissues and organs." The NRC will issue guidance for medical and commercial nuclear pharmacy users on license amendments needed to possess and use the RadioGenix system and will issue such licenses to enable medical use of the ^{99m}Tc produced by the system.

U.S. Food and Drug Administration
Nuclear Regulatory Commission
National Nuclear Security Administration
NorthStar Medical Radioisotopes, LLC