



For Immediate Release

SHINE files application with federal regulators to produce medical isotopes in short supply

JANESVILLE, WI, July 22, 2019 – SHINE Medical Technologies LLC today announced that the company has filed an application with the U.S. Nuclear Regulatory Commission to produce medical isotopes, including molybdenum-99 (Mo-99), iodine-131 and xenon-133, at its production facility in Janesville, WI. SHINE broke ground on the facility in May of this year.

SHINE's facility will be the first of its kind in the world, utilizing the company's patented technology to produce Mo-99 and other isotopes used in more than 40 million medical imaging procedures every year.

"Completing our NRC operating license application signals the transition of our efforts to establish a secure global supply of medical isotopes from the design and engineering phase to the construction and delivery phase," said Greg Piefer, founder and CEO of SHINE. "This required an extraordinary effort by our world-class team, including more than 150,000 person-hours of work. Time and time again, they have stepped up and delivered high-quality products, demonstrating SHINE's commitment to supplying lifesaving medical tracers and therapeutics to an underserved and growing global market."



The SHINE NRC operating license application team witness the signing of the application submission letter on July 16, 2019. Front row: SHINE Director of Process Engineering Tracy Radel, Director of Licensing Jeff Bartelme, VP of Regulatory Affairs and Quality Jim Costedio and COO Steve Miltenberger.



There are only four major facilities in the world that produce one of the most important isotopes, Mo-99, despite its widespread use in heart stress tests, cancer staging and other medical applications. Chronic global shortages of Mo-99 routinely and significantly affect the diagnosis and treatment of patients around the world.

“SHINE’s fusion-fission technology enables us to produce Mo-99 more safely, cleanly and efficiently than conventional reactor-based technologies,” Piefer said. “The completion of this milestone should signal to the market that SHINE is on track to help end isotope shortages once the Janesville production facility, capable of producing more than one-third of global demand for Mo-99, is online.”

“The best way to secure the future is to create it and the submission of our NRC application is the latest example of SHINE creating an exciting, productive future,” said Jim Costedio, SHINE’s vice president of regulatory affairs and quality. “SHINE’s application represents years of tireless work by a team that included not just our regulatory and engineering groups, but outstanding people from across the company. We look forward to working with the NRC staff during the review of our application.”

About Medical Isotopes

Medical isotopes are radioisotopes that are used in the diagnosis and treatment of disease. Molybdenum-99 (Mo-99) is a radioisotope that decays into the diagnostic imaging agent technetium 99m (Tc-99m). The workhorse of nuclear medicine, Tc-99m is used in more than 40 million medical imaging procedures each year, primarily in stress tests to diagnose heart disease and to stage cases of cancer. SHINE was founded to deploy a safe, cost-effective and environmentally friendly technology to produce a variety of medical isotopes, including Mo-99. Roughly one percent of all Mo-99 in the world decays every hour, meaning it must be produced continuously. Current production is limited to only a handful of government-owned nuclear research reactors, the majority of which are overseas.

About SHINE Medical Technologies LLC

Founded in 2010, SHINE is a development-stage company working to become a manufacturer of radioisotopes for nuclear medicine. The SHINE system uses a [patented, proprietary manufacturing process](#) that offers major advantages over existing and proposed production technologies. It does not require a nuclear reactor, uses less electricity, generates less waste and is compatible with the nation’s existing supply chain for Mo-99. In 2014, SHINE announced the execution of Mo-99 supply agreements with [GE Healthcare](#) and [Lantheus Medical Imaging](#). In 2015, with the help of Argonne National Laboratory, GE Healthcare demonstrated that SHINE Mo-99 can act as a drop-in replacement for reactor-based Mo-99. In 2016, SHINE received regulatory approval from the



Nuclear Regulatory Commission to construct its production facility. The company began construction of the facility in the spring of 2019. Learn more at <https://shinemed.com>.

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