

October 12, 2016

Dear Nuclear Medicine Professional:

In recent weeks there have been numerous articles published which cast doubt on the future supply of our industry's primary isotopes, molybdenum-99 (Mo-99) and technetium-99m (Tc-99m). The majority of these headlines have been linked to the transition of the National Research Universal (NRU) reactor in Canada away from routine production of medical isotopes, including Mo-99, or to the length of time the current research reactors around the world have been serving our industry. Unfortunately, these publications have caused many healthcare professionals and other stakeholders to believe our industry is destined for significant isotope supply shortages in the coming months. Given the important role Mallinckrodt occupies in the supply chain for Mo-99, Tc-99m and other medical isotopes, I am writing to you today, as a member of the nuclear medicine community, to share a more positive and detailed perspective about our supply outlook. I will also highlight the significant steps that Mallinckrodt and others have been taking in recent years – and continue to take – to ensure reliable access to the vital radiopharmaceutical products on which pharmacists, technologists, physicians and, most importantly, patients depend.

Simply put, Mallinckrodt does not anticipate that our industry is at increased risk for isotope supply shortages when the NRU reactor ceases routine production of Mo-99 at the end of this month. We have been in the medical isotopes production and distribution business for over 50 years on two continents, serving the needs of tens of millions of patients each year across more than 50 countries. We are a global leader in the production of Mo-99, routinely producing it four days per week since the 1990s, and we are a global leader in the production of Tc-99m generators. Mallinckrodt is deeply rooted in this industry and we have forged partnerships with the key stakeholders at every link in the supply chain. Examples of these partnerships include the U.S. Department of Energy that provides the enriched uranium for our targets; the research reactors that irradiate those targets; the providers that handle the waste from our Mo-99 and Tc-99m generator production processes; the numerous regulatory authorities in multiple countries that oversee each step of the manufacturing process; and the clinicians who use these isotopes to diagnose and treat their patients. We are passionate about this industry and have an expansive view of the global medical isotope supply chain. The news that the NRU will cease producing Mo-99 is several years old and we have not used Mo-99 from the NRU as a routine part of our production for roughly an equivalent period. Over time, Mallinckrodt has taken steps to increase its Mo-99 production capacity with the following costly investments to fortify our ability to reliably meet our customers' needs:

- Modifying our target rigs in reactors to increase our irradiation capacity
- Enhancing our ability to transport irradiated targets
- Increasing the number of irradiated targets we can process during a single Mo-99 production run to further augment our capacity
- Adding a fifth Mo-99 production day to increase our capacity by 20%
- Contracting for extra target irradiation positions with our reactor partners (known as Outage Reserve Capacity) to allow for irradiation of additional targets for unexpected surges in Mo-99 needs

- Maintaining diversity of supply by contracting with three reactors for the irradiation of targets and retaining long-standing supply agreements with other Mo-99 processors

These are vital supply-related accomplishments. In addition, it has also been important to comply with the U.S. government mandate to transition from the use of high-enriched uranium (HEU) to low-enriched uranium (LEU) for Mo-99 production and support global non-proliferation efforts. To that end, Mallinckrodt has invested significant resources to the scientific and technological modifications that will be necessary to complete this conversion and operate without the use of HEU in the coming years. At this time, we expect to fully convert our production process to LEU-derived Mo-99 by the end of 2017.

It's important to acknowledge that other Mo-99 suppliers are also dedicated to reliability and have been taking similar steps to make sure patients around the world continue to have access to the medical isotopes on which our modality depends. These suppliers have also long been aware of the NRU schedule and have been working diligently to increase their Mo-99 production capacity. Even though we produce the majority of our own Mo-99, as noted we also maintain supply agreements with, and purchase from, these providers as part of our supply diversity strategy.

Although the age of the reactor fleet could be considered a concern, these reactor operators adhere to a strict maintenance schedule, and throughout different periods of time many systems have been updated and replaced. The Polish Maria reactor, which Mallinckrodt uses for the irradiation of targets for Mo-99 production, underwent extensive renovations in every operating system in 1993. The BR2 reactor in Belgium, another reactor Mallinckrodt utilizes, just finished a major replacement of a key operating system. And the High Flux Reactor (HFR) in the Netherlands has undergone several recent upgrades. All of these upgrades have improved the performance of these reactors and lengthened their lifetimes. In addition, the FRM II reactor in Germany is expected to begin irradiating targets in the next two years, and the new Jules Horowitz reactor in France is nearing completion and expected to start irradiating targets in 2021.

Let us not forget the significant value that the nuclear medicine modality offers for patients. Because of your devotion as a healthcare provider, our long history as a dedicated supplier and the unique characteristics of radiopharmaceuticals, nuclear medicine is a very cost-effective and essential tool for the diagnosis and treatment of disease around the world. With our continued collaboration across the industry, we can all help to ensure nuclear medicines' vital role in healthcare is maintained. I would invite you to reach out directly to me or anyone of the sales and marketing professionals at Mallinckrodt. We are here to help and would welcome the opportunity to discuss how we can continue to work together to keep nuclear medicine strong and reliable.

Sincerely,



Dan Bague
Vice President and General Manager
Global Nuclear Imaging