

TechneLite® Generators Manufactured with LEU-based Mo-99

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ABSTRACT

Lantheus Medical Imaging, Inc. added TechneLite® (Tc-99m generator) manufactured using molybdenum-99 (Mo-99) produced from Low-Enriched Uranium (LEU) to its product portfolio in January 2013 as evidenced by the shipment of its' first "LEU TechneLite® generator". This "LEU generator" has been demonstrated to be equivalent in performance and use to the TechneLite® manufactured with Highly Enriched Uranium (HEU) sourced Mo-99. Tc-99m from the "LEU TechneLite®" meets all requirements of the USP. TechneLite® generator manufactured using a blend of HEU and LEU sourced Mo-99 was approved by the FDA in 2010, and such generators have been commercially available in the US since 2011.

Lantheus announced in 2012 additional access to LEU sourced Mo-99 from NTP Radioisotopes (South Africa). Currently, Lantheus receives Mo-99 from four major processors and seven associated reactors, and an increasing supply of Mo-99 from LEU targets from NTP as well as ANSTO (Australia) will be received over the next five years. Lantheus continues to receive HEU sourced Mo-99 from Nordion which supports the diverse Mo-99 supply chain. The "LEU TechneLite®" is manufactured in a dedicated manufacturing run and the generator has a unique product item number. NDC numbers have been established for the LEU generators and these will be reflected in the revised package insert. This helps the radiopharmacies and hospitals to file for the Centers for Medicare and Medicaid Services (CMS) incremental reimbursement provided for each Tc-99m diagnostic dose produced from non-HEU sourced Mo-99.

The progress Lantheus has made since the 2013 "LEU TechneLite®" product addition, the transition toward an all-LEU Mo-99 supply chain by the end of 2016, and a radiopharmacy's experience with implementation of the "LEU TechneLite® Generator" into their operations and product supply to their customers will be discussed.