

SNMMI POSITION STATEMENT
DIAGNOSTIC IMAGING – CRITICAL TESTS AT RISK

Technetium-99m is ideally suited for many medical imaging tests because it produces high quality images with minimal radiation exposure to patients. As a result, it is used in approximately 50,000 diagnostic medical procedures every day in the United States. However, it has a relatively short half-life (6 h) and is produced on an as-needed basis by the Mo-99/Tc-99m generator. The Mo-99/Tc-99m generator has a useful life of approximately 7 d, and therefore it must be replaced on a weekly basis. Although the U.S. consumes approximately one-half of the world's supply of Mo-99, at the present time the domestic supply of Mo-99 is minimal. The minimal US supply of Mo-99 combined with aging production facilities has resulted in frequent shortages of Mo-99 in North America and around the world despite efforts to develop a sustainable robust supply chain. This is a significant concern because any disruptions in production place patients at great risk of not getting much-needed "standard of care" diagnostic tests.

Previous shortages have led to extraordinary efforts by Mo-99 producers, Mo-99 processors, and generator manufacturers to improve the reliability of Mo-99 production. This improvement in reliability has come about through the combined efforts of many stakeholders including producers, regulatory agencies, industry groups, and professional associations, including SNMMI. Efforts to date have included the construction of new processing facilities, the addition of new reactors to the supply chain, sharing scheduled maintenance dates to minimize production gaps, and holding target slots in reserve in case there is an unanticipated need for additional production capacity. While these developments have improved the security of the Mo-99 supply, more needs to be accomplished, especially in the area of domestic supply.

Complicating these efforts has been the additional challenge of converting the targets that are used by the production reactors from highly enriched uranium (HEU) targets to low enriched uranium (LEU). The goal of this conversion is to eliminate the nuclear security risks associated with the use of HEU around the world. Despite the time consuming and costly aspects of this challenge, full conversion to LEU production is nearly complete.

The goal of the American Medical Isotope Production Act of 2011 was to develop new Mo-99 production facilities within the US. However, despite assistance from the DOE, there have been significant delays in developing significant domestic sources of Mo-99. These delays are the result of many factors including overly optimistic estimates of when and how much Mo-99 could be produced, technology and regulatory issues, problems with market acceptance, and problems raising sufficient capital to move past the proof-of-concept stage. As a result, of the three US companies originally involved with the DOE cooperative agreements to produce Mo-99, only two are still active.

Thus, despite considerable effort, we still find ourselves in the position of having an insufficient supply of Mo-99 when there are disruptions in the world-wide supply chain. And there is still no major producer of Mo-99 in the US.

Therefore, the SNMMI continues to support additional funding to develop new technologies for Mo-99 production. It also recommends continued support for development of additional Mo-99 supply using proven technologies to ensure the financial and operational sustainability of the Mo-99 supply chain and to ensure the safety and well-being of patients who require Tc-99m imaging procedures.