November 4, 2021

Kasia Mendelsohn  
Acting Deputy Administrator for Defense Nuclear Nonproliferation  
Office of Conversion  
Department of Energy, National Nuclear Security Administration  
1000 Independence Avenue, SW  
Washington, DC 20585

Re: Supply of Molybdenum-99 (Mo-99) Produced Without the Use of Highly Enriched Uranium (HEU); 86 FR 54961 Notice

Dear Ms. Mendelsohn:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI)\(^1\) appreciates the opportunity to comment on the open Federal Register Notice addressing the supply of the radioisotope Molybdenum-99 (Mo-99) for nuclear medicine diagnostic and therapeutic procedures.

For more than 50 years, SNMMI members have developed—and continue to advance—innovations in medical imaging and radionuclide therapy leading to improved noninvasive diagnosis, management, and treatment of diseases, with benefit to numerous generations of patients. Over 20,000,000 Americans each year are diagnosed and/or treated using nuclear medicine and molecular imaging. These vital tests and treatments are used in the treatment of cancer, heart disease and many other conditions. Molybdenum-99 is the parent radioisotope of technetium-99m (Tc-99m), which is used in approximately 50,000 diagnostic medical procedures every day in the United States. Technetium-99m is an ideal radioisotope for many medical imaging tests, providing high-quality results with the minimal radiation exposure to patients.

Although the large majority of nuclear medicine procedures rely on Tc-99m (and Mo-99), it is important to note that the sporadic shortages of medical radioisotopes are not only a problem for Mo-99, but also include iodine-131 (I-131), which among other applications is used for the diagnosis and treatment of

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\(^1\) SNMMI has more than 15,000 members, including physicians, technologists, scientists, physicists, chemists and pharmacists, all participating in the field of nuclear medicine and molecular imaging. These members set the standard for nuclear medicine practice by creating clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging and nuclear medicine therapy research and practice.
cancer in children, and xenon-133, which is used to evaluate lung function. Both radioisotopes, like Mo-99, are produced by irradiation of HEU or LEU.

1) **Do current supplies of Mo-99 meet U.S. patient demand? Do current supplies of non-HEU based Mo-99 meet U.S. patient demand?**

Most of the time the supply meets demand, but shortages still occur. Through its website, emails and social media SNMMI maintains close ties with its members throughout the country and assesses any issues encountered by its membership with regards to the nuclear medicine service being provided to our patients.

On multiple occasions over the past several years, members throughout the United States reported limited supplies of Tc-99m for clinical imaging because of disruptions in the production and transportation of Mo-99. These issues were related to interruptions in international supply chain.

At the present time, our members and those of our industry partner, the Council on Radionuclides and Radiopharmaceuticals (CORAR), report that the supplies of Mo-99 and Xe-133 are sufficient to meet US patient needs. Therefore, SNMMI believes that AMIPA’s\(^2\) goal, to end HEU-based Mo-99 production, has largely been achieved.

2) **Since the publication of DOE’s November 27, 2019 Federal Register notice requesting public comment on the status of Mo-99 supplies for U.S. patients (84 FR 65378) have there been shortages of Mo-99 in the United States? If so, how severe, how often, and how did shortages impact patient care? What caused such shortages?**

In 2020, because of the COVID-19 pandemic, international commercial airline flights were sharply reduced in the spring and summer, and the industry had to use dedicated charters for transportation. SNMMI petitioned the State Department and US embassy in the Netherlands to urge KLM to resume carrying radioactive material. Also in the spring of 2020, the nuclear regulator in Australia gave the go-ahead to ANSTO to resume Mo-99 production. Overall, there were some delays with flights from Europe to the US, but those delays had little effect on the patient access as the number of nuclear medicine procedures performed during this period also experienced a substantial decline.

3) **How would extending the period that the NRC may issue HEU export licenses for medical isotope production impact the supply of Mo-99 to the United States? How would enacting a ban on the export of HEU for medical isotope production impact the supply of Mo-99 to the United States?**

Extending the period of time that the NRC can issue HEU export licenses will allow more time for those facilities that have not completed the transition from HEU to LEU production to complete this transition while ensuring a more stable supply of Mo-99 during the transition period. It will also allow time for those companies in the US that are developing alternative (non-HEU) production methods to prepare for the end of HEU-based production.

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\(^2\) Pub. L. 112-139.
production methods under NNSA-sponsored development programs to develop an adequate and reliable US Mo-99 supply. One company is already providing Mo-99/Tc-99m generators using domestically produced non-HEU Mo-99, and another company has made significant progress towards this goal. While these are encouraging developments, the amount of Mo-99 that is currently being produced in the US remains extremely small compared to demand.

CORAR has informed us that one major European processor continues to transition I-131 production from HEU to LEU. It is estimated, through reports in the public domain, that this conversion will be completed no later than the end of CY 2022. However, this conversion timeline does not take into account the availability of LEU-sourced I-131 that meets FDA regulatory requirements. A shortage of I-131 will affect both routine clinical care, such as radiiodine therapy for thyroid cancer, but also clinical trials including those that depend on I-131 for the preparation of I-131-mIBG, which is used to treat neuroblastoma, a malignancy that primarily is in children. Therefore, in order to avert patient access issues caused by a shortage of FDA-approved I-131, SNMMI encourages DOE to work with stakeholders to investigate and ensure the supply of I-131 meeting US demand.

The Society appreciates the opportunity to provide feedback to the DOE on the supply of Mo-99. SNMMI is ready to discuss any of its comments with the DOE. In this regard, please contact Julia Bellinger, Director, Health Policy and Regulatory Affairs, at jbellinger@snmmi.org.

Sincerely,

Richard Wahl, MD
President, SNMMI