SNMMI Comments to the Department of Energy: Current $^{99}$Mo Supply vs. Demand

On November 27, 2019, the Department of Energy submitted a request for public comment on Exports of U.S-Origin Highly Enriched Uranium for Medical Isotope Production: Sufficient or Insufficient Supplies of Non-HEU-based Molybdenum-99 for United States Domestic Demand. The comment period ended on December 27, 2019.

The six key questions, along with the SNMMI’s responses, are below.

1. **Do current supplies of Mo-99 meet U.S. patient demand?**
   Most of the time, they do, 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 regard 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 of Mo-99. These issues were related to interruptions in the international supply chain.

   For example, in July 2018, NTP Radioisotopes in South Africa reported issues with their Mo-99 production, while from July 16–20, the OPAL reactor in Australia was shut down for scheduled maintenance. This combination of events resulted in a significant decrease in Mo-99 availability. In October 2018, NTP experienced continued production issues, which resulted in a significant Mo-99 shortage during the first half of November. The NTP facility was not able to resume service for several months, and this coincided with a technical issue with the High-Flux Reactor (HFR) in the Netherlands, presenting additional Mo-99 production challenges. More recently, the ANSTO production facility, which processes Mo-99 produced in the OPAL reactor, was shut down because of a plumbing issue in their facility, and it has still not resumed full-scale operation.

2. **Do current supplies of non-HEU based Mo-99 meet U.S. patient demand?**
   Not all the time, as demonstrated by previous and ongoing shortages due to issues at the ANSTO, NTP, and HFR facilities. The supply of non-HEU Mo-99 needs to be significantly more robust before we feel confident that the supply is reliable enough to meet day-to-day patient-care needs.

3. **Have there been shortages of Mo-99 in the United States? If so, how severe, how often, and how did shortages impact patient care?**
   Yes. As described in Section 1, there have been at least three times within the past two years where the Mo-99 supply was insufficient. This resulted in limited-to-no availability of Mo-99/Tc-99m generators in several parts of the country. As stated in question 1, unexpected technical issues created challenges achieving a reliable supply of Mo-99. Although these shortages were not experienced throughout the entire country, they still resulted in the rescheduling or cancellation of many critical patient examinations or the substitution with a procedure that is less accurate than the nuclear medicine examination.

4. **What has caused shortages of Mo-99 in the United States?**
   At the present time, a very small fraction (<10%) of the Mo-99 used in the United States is produced in the United States. The United States is therefore dependent on a worldwide network of reactors, where the Mo-99 is produced, and production facilities, where it is extracted from the irradiated targets. While the supply is adequate when all these facilities are producing Mo-99 as planned, the unplanned shutdown of any of these reactors or production facilities causes worldwide ripples in the
availability of Mo-99/Tc-99m generators and thus the availability of Tc-99m for clinical use. As we have experienced throughout the past 10 or more years, since the shutdown of the Chalk River reactors in Canada, these unplanned shutdowns happen on a regular—although unpredictable—basis.

5. 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?

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 U.S. that are developing alternative (non-HEU) production methods under NNSA-sponsored development programs to develop an adequate and reliable U.S. 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 toward this goal. While these are encouraging developments, the amount of Mo-99 that currently is being produced in the U.S. remains extremely small compared to demand.

6. How would enacting a ban on the export of HEU for medical isotope production impact the supply of Mo-99 to the United States?

Enacting a ban on the export of HEU for medical isotope production will exacerbate the existing problem of sporadic shortages of Mo-99 by removing one of the major production sites (HFR) from the supply chain.