6450-01-

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Supply of Molybdenum-99 (Mo-99) Produced Without the Use of Highly Enriched Uranium (HEU)

AGENCY: National Nuclear Security Administration (NNSA), Department of Energy (DOE).

ACTION: Request for information (RFI).

SUMMARY: DOE, in accordance with Section 3174 of the American Medical Isotopes Production Act of 2012 (AMIPA), is preparing for a Secretarial certification regarding the sufficiency of supply of non-HEU based Mo-99. DOE is seeking public input as part of its certification development process and analysis to determine the sufficiency of Mo-99 supply to meet U.S. patient needs.

DATES: DOE will accept comments, data, and information in response to this RFI on or before [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***].

ADDRESSES: Interested persons may submit comments via e-mail to the Office of Conversion at *OfficeofConversion@nnsa.doe.gov.*

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing coronavirus (COVID–19) pandemic. DOE is currently accepting only electronic submissions at this time.

If a commenter finds that this change poses an undue hardship, please contact the Office of Conversion at *OfficeofConversion@nnsa.doe.gov* to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier. No facsimiles (faxes) will be accepted.

Instructions: All submissions received must include the agency name and title for this RFI in Microsoft Word or PDF file format and avoid the use of special characters or any form of encryption.

FOR FURTHER INFORMATION CONTACT: Requests for additional information may be sent to Max Postman in the Office of Conversion at 240-246-5564, *Max.Postman@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Authority and Background

The U.S. medical community depends on a reliable supply of the radioisotope Mo-99 for nuclear medical diagnostic procedures. Approximately 80 percent of these procedures depend on the use of technetium-99m (Tc-99m), a decay product of Mo-99. Tc-99m is used in over 40,000 medical procedures every day in the United States. Its primary uses include diagnosing heart disease and cancer, as well as studying organ structure and function. Historically, the United States has not had the capability to produce Mo-99 domestically and, until 2018, imported 100 percent of its supply from international producers, some of which supply was produced using targets fabricated with proliferation-sensitive HEU.

AMIPA (Subtitle F, Title XXXI of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-139)), enacted on January 2, 2013, amended Section 134 of the Atomic Energy Act of 1954 (42 U.S.C. 2160d) by striking subsection c. and

inserting language that prohibits the Nuclear Regulatory Commission (NRC) from issuing a license for the export of HEU from the United States for the purposes of medical isotope production, effective seven years after enactment of AMIPA, subject to a certification regarding the sufficiency of Mo-99 supply in the United States.

Section 3174 of AMIPA requires the Secretary of Energy to either jointly certify, with the Secretary of Health and Human Services, that there is a sufficient supply of Mo-99 produced without the use of HEU available to meet U.S. patient needs, and that it is not necessary to export U.S.-origin HEU for the purposes of medical isotope production in order to meet U.S. patient needs, or, to unilaterally certify that there is insufficient global supply of Mo-99 produced without the use of HEU available to satisfy the domestic market, and that the export of U.S.-origin HEU for the purposes of medical isotope production is the most effective temporary means to increase the supply of Mo-99 to the domestic U.S. market, thereby delaying the effective date of the export license ban for up to six years.

DOE published a *Federal Register* notice (84 FR 65378) on November 27, 2019 requesting public comment on the status of Mo-99 supplies for U.S. patients in preparation for a Secretarial certification regarding the sufficiency of supply of non-HEU based Mo-99. The Secretary of Energy certified on January 2, 2020, that, at the time, there was an insufficient global supply of Mo-99 produced without the use of HEU and that the export of U.S.-origin HEU for the purposes of medical isotope production was the most effective temporary means to increase the supply of Mo-99 to the domestic U.S. market. This certification was published in the *Federal Register* on January 21, 2020 (85 FR 3362). This certification was effective for no more than two years from the effective date of January 2, 2020. The *Federal Register* notice stated that DOE would conduct periodic reviews of the domestic U.S. and global Mo-99 markets and would work toward

a certification to Congress regarding the sufficiency of supply as soon as the statutory conditions are satisfied.

DOE must issue a new certification on or before January 2, 2022. In accordance with AMIPA and to ensure public review and comments, the development of the certification is being announced in the *Federal Register*.

II. Issues on Which DOE Seeks Comment and Information

DOE is seeking information from interested parties on the status of Mo-99 supplies for U.S. patients. DOE requests that commenters fully explain any assumptions that underlie their reasoning. DOE also requests that commenters provide underlying data or other information sufficient to allow DOE to review and verify any of the assumptions, calculations, or views expressed by the commenters. DOE specifically invites responses to the following questions:

(1) Do current supplies of Mo-99 meet U.S. patient demand?

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

(3) 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?

(4) How would extending the period that the NRC may issue HEU export licenses for medical isotope production impact the supply of Mo-99 in the United States?

(5) How would enacting a ban on the export of HEU for medical isotope production impact the supply of Mo-99 in the United States?

In addition, DOE welcomes information on other topics that interested parties consider significant in preparing for the Secretarial certification.

Confidential Business Information: According to 10 CFR 1004.11, any person submitting information he or she believes to be confidential and exempt from public disclosure should submit via email two well-marked copies: One copy of the document marked "confidential" including all the information believed to be confidential, and one copy of the document marked "non-confidential" with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Signing Authority

This document of the Department of Energy was signed on September 29, 2021, by Kasia Mendelsohn, Acting Deputy Administrator for Defense Nuclear Nonproliferation, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the *Federal Register*.

Signed in Washington, DC, on September 30, 2021.

Treena V. Garrett,

Federal Register Liaison Officer,

U.S. Department of Energy.

[FR Doc. 2021-21634 Filed: 10/4/2021 8:45 am; Publication Date: 10/5/2021]