[6450-01-P]

DEPARTMENT OF ENERGY

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; Request for Public Comment

AGENCY: National Nuclear Security Administration, Department of Energy.

ACTION: Notice; request for public comment.

SUMMARY: The U.S. Department of Energy (DOE), in accordance with the American Medical Isotope Production Act of 2012 (AMIPA), is preparing for a Secretarial certification regarding the sufficiency of supply of non-HEU based molybdenum-99 (Mo-99). DOE will collect input from the public as part of its certification development process and consider this information as part of its analysis to determine the state of Mo-99 supply to meet U.S. patient needs.

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

ADDRESSES: Interested persons may submit comments by any of the following methods.

1. Email: *joan.dix@nnsa.doe.gov*;

2. Postal Mail:

Joan Dix, Deputy Director, Office of Conversion
Department of Energy,
National Nuclear Security Administration
1000 Independence Avenue, SW
Washington, DC 20585

Instructions: All submissions received must include the agency name for this request for public comment. No facsimiles (faxes) will be accepted. Due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, DOE encourages responders to submit comments electronically to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Requests for additional information may be sent to:

Joan Dix, Deputy Director, Office of Conversion

joan.dix@nnsa.doe.gov

202-586-2695

SUPPLEMENTARY INFORMATION:

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I. Authority and Background

The American Medical Isotopes Production Act of 2012 (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 highly enriched uranium (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.

The law 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 regarding the sufficiency of Mo-99 supply, or, to unilaterally certify that there is insufficient 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 enactment of the export license ban for up to six years.

In accordance with AMIPA and to ensure public review and comments the development of the certification is being announced in the *Federal Register*.

The U.S. medical community depends on a reliable supply of the radioisotope Mo-99 for nuclear medical diagnostic and therapeutic procedures. Approximately 80 percent of all of these procedures depend on the use of technetium-99m (Tc-99m), a decay product of Mo-99. Tc-99m is used in approximately 40,000 diagnostic and therapeutic nuclear medicine procedures every day in the United States. Its primary uses include diagnosing heart disease, treating cancer, and 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 was produced using targets fabricated with proliferation sensitive HEU.

II. Issues on Which DOE Seeks Comment and Information

This request for public comment seeks information from interested parties on the status of Mo-99 supplies for U.S. patients. For all comments, DOE requests that interested parties 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 public comment on 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) Have there been shortages of Mo-99 in the United States? If so, how severe, how often, and how did shortages impact patient care?

4) What has caused shortages of Mo-99 in the United States?

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?

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?

Although comments are particularly welcome on the issues discussed above, DOE also requests comments on other topics that commenters consider significant in preparing for the Secretarial certification.

III. Submission of Comments

DOE will accept comments, data, and information in response to this notice on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Any information that may be confidential and exempt by law from public disclosure should be submitted as described in section IV of this document, Confidential Business Information.

IV. Confidential Business Information

Pursuant to 10 CFR 1004.11, any person submitting information he or she believes to be confidential and exempt by law from public disclosure should submit via email or postal mail 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.

Dated: November 20, 2019.

For the Department of Energy.

Brent K. Park,
Deputy Administrator, Defense Nuclear Nonproliferation.

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