



**[6450-01-P]**

**DEPARTMENT OF ENERGY**

Exports of U.S.-origin highly enriched uranium for medical isotope production:

Certification of Insufficient Supplies of Non-Highly Enriched Uranium (HEU)-based Molybdenum-99 for United States domestic demand

**AGENCY:** National Nuclear Security Administration, Department of Energy.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Energy, in accordance with the American Medical Isotopes Production Act of 2012 (AMIPA), issued a certification that there is an insufficient global supply of molybdenum-99 (Mo-99) produced without the use of HEU available to satisfy the domestic U.S. 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. This certification is effective for no more than two years from the effective date of January 2, 2020.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information may be sent to: Joan Dix, Deputy Director, Office of Conversion, [Mo99@nnsa.doe.gov](mailto:Mo99@nnsa.doe.gov), 202-586-2695

**SUPPLEMENTARY INFORMATION:**

**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. 112-239)), 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 inserted 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.

The law provides that the ban on HEU exports would become effective seven years after enactment of AMIPA only if the Secretary of Energy jointly certifies, 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. The law further provides that the Secretary of Energy can extend the deadline for the joint certification if the Secretary certifies 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.

In preparation for a Secretarial certification regarding the sufficiency of supply of non-HEU based Mo-99, the Department of Energy (DOE) published a notice and request for public comment in the *Federal Register* (84 FR 65378) on November 27, 2019 to collect input from the public on the state of the Mo-99 supply. DOE accepted comments, data, and information through December 27, 2019.

Based on these submissions, along with other publicly available healthcare data, and in coordination with the Department of Health and Human Services' Food and Drug

Administration, the Secretary of Energy has certified that there is insufficient global supply of non-HEU-based Mo-99 to meet U.S. market needs and that the export of U.S.-origin HEU is the most effective temporary means to increase the supply of Mo-99 to the U.S. market. While the statute provides that the resulting delay in the effective date of the HEU export licensing ban can be for up to six years, the Secretary's certification is effective for a period of no more than two years, following the certification's effective date of January 2, 2020. DOE will conduct periodic reviews of the domestic U.S. and global Mo-99 market and will work toward a certification to Congress, regarding the sufficiency of supply as soon as the statutory conditions are satisfied.

**CERTIFICATION:**

I hereby certify, pursuant to 42 U.S.C. § 2160d(d), that there is an insufficient global supply of molybdenum-99 produced without the use of highly enriched uranium available to satisfy the domestic U.S. market and that the export of U.S.-origin highly enriched uranium for the purposes of medical isotope production is the most effective temporary means to increase the supply of molybdenum-99 to the domestic U.S. market. This certification shall be effective on January 2, 2020, for a period of no more than two years from the effective date.

**Dan Brouillette**

**JAN – 2 2020**

**Dated: January 10, 2020.**

**For the Department of Energy.**

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**Brent K. Park,**

**Deputy Administrator, Defense Nuclear Nonproliferation.**

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