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H. R. 3276

[Report No. 111–120]

IN THE SENATE OF THE UNITED STATES

NOVEMBER 6, 2009

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JANUARY 28, 2010

Reported by Mr. BINGAMAN, with amendments

[Omit the part struck through and insert the part printed in italic]

AN ACT

To promote the production of molybdenum-99 in the United States for medical isotope production, and to condition and phase out the export of highly enriched uranium for the production of medical isotopes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''American Medical Isotopes Production Act of ~~2009~~*2010*''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Molybdenum-99 is a critical medical isotope whose decay product technecium-99m is used in approximately two-thirds of all diagnostic medical isotope procedures in the United States, or 16 million medical procedures annually, including for the detection of cancer, heart disease, and thyroid disease, investigating the operation of the brain and kidney, imaging stress fractures, and tracking cancer stages.

(2) Molybdenum-99 has a half-life of 66 hours, and decays at a rate of approximately one percent per hour after production. As such, molybdenum-99 cannot be stockpiled. Instead, molybdenum-99 production must be scheduled to meet the projected demand and any interruption of the supply chain from production, to processing, packaging, distribution, and use can disrupt patient care.

(3) There are no facilities within the United States that are dedicated to the production of molybdenum-99 for medical uses. The United States must import molybdenum-99 from foreign production facilities, and is dependent upon the continued operation of these foreign facilities for millions of critical medical procedures annually.

(4) Most reactors in the world which produce molybdenum-99 utilize highly enriched uranium, which can also be used in the construction of nuclear weapons. In January 2009, the National Academy of Sciences encouraged molybdenum-99 producers to convert from highly enriched uranium to low enriched uranium, and found that there are ''no technical reasons that adequate quantities cannot be produced from LEU targets in the future'' and that ''a 7-10 year phase-out period would likely allow enough time for all current HEU-based producers to convert''.

(5) The 51-year-old National Research Universal reactor in Canada, which is responsible for producing approximately sixty percent of United States demand for molybdenum-99 under normal conditions, was shut down unexpectedly May 14, 2009, after the discovery of a leak of radioactive water. It is unclear whether the National Research Universal reactor will be able to resume production of molybdenum-99.

(6) The United States currently faces an acute shortage of molybdenum-99 and its decay product technetium-99m due to technical problems which

have seriously interrupted operations of foreign nuclear reactors producing molybdenum-99.

(7) As a result of the critical shortage of molybdenum-99, patient care in the United States is suffering. Medical procedures requiring technetium-99 are being rationed or delayed, and alternative treatments which are less effective, more costly, and may result in increased radiation doses to patients are being substituted in lieu of technetium-99.

(8) The radioactive isotope molybdenum-99 and its decay product technetium-99m are critical to the health care of Americans, and the continued availability of these isotopes, in a reliable and affordable manner, is in the interest of the United States.

(9) The United States should move expeditiously to ensure that an adequate and reliable supply of molybdenum-99 can be produced in the United States, without the use of highly enriched uranium.

(10) Other important medical isotopes, including iodine-131 and xenon-133, can be produced as byproducts of the molybdenum-99 fission production process. In January 2009, the National Academy of Sciences concluded that these important medical isotopes "will be sufficiently available if Mo-99 is avail-

able''. The coproduction of medically useful isotopes such as iodine-131 and xenon-133 is an important benefit of establishing molybdenum-99 production in the United States without the use of highly enriched uranium, and these coproduced isotopes should also be available for necessary medical uses.

(11) The United States should accelerate its efforts to convert nuclear reactors worldwide away from the use of highly enriched uranium, which can be used in nuclear weapons, to low enriched uranium. Converting nuclear reactors away from the use of highly enriched uranium is a critically important element of United States efforts to prevent nuclear terrorism, and supports the goal announced in Prague by President Barack Obama on April 5, 2009, to create ''a new international effort to secure all vulnerable nuclear material around the world within four years''.

(12) The United States is engaged in an effort to convert civilian nuclear test and research reactors from highly enriched uranium fuel to low enriched uranium fuel through the Global Threat Reduction Initiative. As of September 2009, this program has successfully converted 17 reactors in the United States to low enriched uranium fuel, some of which

~~are capable of producing molybdenum-99 for medical uses.~~

SEC. ~~3.~~*2.* IMPROVING THE RELIABILITY OF DOMESTIC MEDICAL ISOTOPE SUPPLY.

(a) MEDICAL ISOTOPE DEVELOPMENT PROJECTS.—

(1) IN GENERAL.—The Secretary of Energy ~~shall establish a program to evaluate and support projects for the production in the United States, without the use of highly enriched uranium, of significant quantities of molybdenum-99 for medical uses.~~ *shall establish a technology-neutral program—*

(A) to evaluate and support projects for the production in the United States, without the use of highly enriched uranium, of significant quantities of molybdenum-99 for medical uses;

(B) to be carried out in cooperation with non-Federal entities; and

(C) the costs of which shall be shared in accordance with section 988 of the Energy Policy Act of 2005 (42 U.S.C. 16352).

(2) CRITERIA.—Projects shall be judged against the following primary criteria:

(A) The length of time necessary for the proposed project to begin production of molyb-

denum-99 for medical uses within the United States.

(B) The capability of the proposed project to produce a significant percentage of United States demand for molybdenum-99 for medical uses.

(C) The cost of the proposed project.

(3) EXEMPTION.—An existing reactor fueled with highly enriched uranium shall not be disqualified from the program if the Secretary of Energy determines that—

(A) there is no alternative nuclear reactor fuel, enriched in the isotope U-235 to less than 20 percent, that can be used in that reactor;

(B) the reactor operator has provided assurances that, whenever an alternative nuclear reactor fuel, enriched in the isotope U-235 to less than 20 percent, can be used in that reactor, it will use that alternative in lieu of highly enriched uranium; and

(C) the reactor operator has provided a current report on the status of its efforts to convert the reactor to an alternative nuclear reactor fuel enriched in the isotope U-235 to less

than 20 percent, and an anticipated schedule for completion of conversion.

(4) PUBLIC PARTICIPATION AND REVIEW.—The Secretary of Energy shall—

(A) develop a program plan and annually update the program plan through public workshops; and

(B) use the Nuclear Science Advisory Committee to conduct annual reviews of the progress made in achieving the program goals.

~~(4)~~*(5)* AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Energy for carrying out the program under paragraph (1) $163,000,000 for the period encompassing fiscal years 2010 through 2014.

(b) DEVELOPMENT ASSISTANCE.—The Secretary of Energy shall establish a program to provide assistance for—

(1) the development of fuels, targets, and processes for domestic molybdenum-99 production that do not use highly enriched uranium; and

(2) commercial operations using the fuels, targets, and processes described in paragraph (1).

(c) URANIUM LEASE AND TAKE BACK.—The Secretary of Energy shall establish a program to make low

enriched uranium available, through lease contracts, for irradiation for the production of molybdenum-99 for medical uses. The lease contracts shall provide for the Secretary to retain responsibility for the final disposition of radioactive waste created by the irradiation, processing, or purification of leased uranium. The lease contracts shall also provide for compensation in cash amounts equivalent to prevailing market rates for the sale of comparable uranium products and for compensation in cash amounts equivalent to the net present value of the cost to the Federal Government for the final disposition of such radioactive waste, provided that the discount rate used to determine the net present value of such costs shall be no greater than the average interest rate on marketable Treasury securities. The Secretary shall not barter or otherwise sell or transfer uranium in any form in exchange for services related to final disposition of the radioactive waste from such leased uranium.

SEC. 4.*3.* EXPORTS.

Section 134 of the Atomic Energy Act of 1954 (42 U.S.C. ~~2160d(b)~~*2160d*) is amended by striking subsections b. and c. and inserting in lieu thereof the following:

''b. Effective 7 years after the date of enactment of the American Medical Isotopes Production Act of ~~2009~~*2010*, the Commission may not issue a license for the

export of highly enriched uranium from the United States for the purposes of medical isotope production.

''c. The period referred to in subsection b. may be extended for no more than ~~four~~ *6* years if, no earlier than 6 years after the date of enactment of the American Medical Isotopes Production Act of ~~2009~~*2010*, the Secretary of Energy certifies to the Committee on Energy and Commerce of the House of Representatives and the Committee on Energy and Natural Resources of the Senate that—

''(1) there is insufficient global supply of molybdenum-99 produced without the use of highly enriched uranium available to satisfy the domestic United States market; and

''(2) the export of United States-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 United States market.

''d. To ensure public review and comment, the development of the certification described in subsection c. shall be carried out through announcement in the Federal Register.

''~~d.~~*e.* At any time after the restriction of export licenses provided for in subsection b. becomes effective, if there is a critical shortage in the supply of molybdenum-99 available to satisfy the domestic United States medical

isotope needs, the restriction of export licenses may be suspended for a period of no more than 12 months, if—

''(1) the Secretary of Energy certifies to the Congress that the export of United States-origin highly enriched uranium for the purposes of medical isotope production is the only effective temporary means to increase the supply of molybdenum-99 necessary to meet United States medical isotope needs during that period; and

''(2) the Congress ~~passes~~*enacts* a Joint Resolution approving the temporary suspension of the restriction of export licenses.

''~~e.~~*f.* As used in this section—

''(1) the term 'alternative nuclear reactor fuel or target' means a nuclear reactor fuel or target which is enriched to less than 20 percent in the isotope U-235;

''(2) the term 'highly enriched uranium' means uranium enriched to 20 percent or more in the isotope U-235;

''(3) a fuel or target 'can be used' in a nuclear research or test reactor if—

''(A) the fuel or target has been qualified by the Reduced Enrichment Research and Test

Reactor Program of the Department of Energy; and

''(B) use of the fuel or target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor; and

''(4) the term 'medical isotope' includes molybdenum-99, iodine-131, xenon-133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.''.

SEC. ~~5.~~*4.* REPORT ON DISPOSITION OF EXPORTS.

Not later than 1 year after the date of the enactment of this Act, the Chairman of the Nuclear Regulatory Commission, after consulting with other relevant agencies, shall submit to the Congress a report detailing the current disposition of previous United States exports of highly enriched uranium, including—

(1) their location;

(2) whether they are irradiated;

(3) whether they have been used for the purpose stated in their export license;

(4) whether they have been used for an alternative purpose and, if so, whether such alternative purpose has been explicitly approved by the Commission;

(5) the year of export, and reimportation, if applicable;

(6) their current physical and chemical forms; and

(7) whether they are being stored in a manner which adequately protects against theft and unauthorized access.

SEC. 6.5. DOMESTIC MEDICAL ISOTOPE PRODUCTION.

(a) IN GENERAL.—Chapter 10 of the Atomic Energy Act of 1954 (42 U.S.C. 2131 et seq.) is amended by adding at the end the following new section:

''SEC. 112. DOMESTIC MEDICAL ISOTOPE PRODUCTION. a. The Commission may issue a license, or grant an amendment to an existing license, for the use in the United States of highly enriched uranium as a target for medical isotope production in a nuclear reactor, only if, in addition to any other requirement of this Act—

''(1) the Commission determines that—

''(A) there is no alternative medical isotope production target, enriched in the isotope U-

235 to less than 20 percent, that can be used in that reactor; and

''(B) the proposed recipient of the medical isotope production target has provided assurances that, whenever an alternative medical isotope production target can be used in that reactor, it will use that alternative in lieu of highly enriched uranium; and

''(2) the Secretary of Energy has certified that the United States Government is actively supporting the development of an alternative medical isotope production target that can be used in that reactor.

''b. As used in this section—

''(1) the term 'alternative medical isotope production target' means a nuclear reactor target which is enriched to less than 20 percent of the isotope U-235;

''(2) a target 'can be used' in a nuclear research or test reactor if—

''(A) the target has been qualified by the Reduced Enrichment Research and Test Reactor Program of the Department of Energy; and

''(B) use of the target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the

reactor without a large percentage increase in the total cost of operating the reactor;

''(3) the term 'highly enriched uranium' means uranium enriched to 20 percent or more in the isotope U-235; and

''(4) the term 'medical isotope' includes molybdenum-99, iodine-131, xenon-133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic procedures or for research and development.''.

(b) TABLE OF CONTENTS.—The table of contents for the Atomic Energy Act of 1954 is amended by inserting the following new item ~~after the item relating to section 111.~~ *at the end of the items relating to chapter 10 of title I:*

''Sec. 112. Domestic medical isotope production.''.

SEC. ~~7.~~*6.* ANNUAL DEPARTMENT OF ENERGY REPORTS.

The Secretary of Energy shall report to Congress no later than one year after the date of enactment of this Act, and annually thereafter for 5 years, on Department of Energy actions to support the production in the United States, without the use of highly enriched uranium, of molybdenum-99 for medical uses. These reports shall include the following:

(1) For medical isotope development projects—

(A) the names of any recipients of Department of Energy support under ~~section 3~~ *section 2* of this Act;

(B) the amount of Department of Energy funding committed to each project;

(C) the milestones expected to be reached for each project during the year for which support is provided;

(D) how each project is expected to support the increased production of molybdenum-99 for medical uses;

(E) the findings of the evaluation of projects under section ~~3(a)(2)~~ *2(a)(2)* of this Act; and

(F) the ultimate use of any Department of Energy funds used to support projects under ~~section 3~~ *section 2* of this Act.

(2) A description of actions taken in the previous year by the Secretary of Energy to ensure the safe disposition of radioactive waste from used molybdenum-99 targets.

SEC. ~~8~~*7*. NATIONAL ACADEMY OF SCIENCES REPORT.

The Secretary of Energy shall enter into an arrangement with the National Academy of Sciences to conduct a study of the state of molybdenum-99 production and uti-

lization, to be provided to the Congress not later than 5 years after the date of enactment of this Act. This report shall include the following:

(1) For molybdenum-99 production—

(A) a list of all facilities in the world producing molybdenum-99 for medical uses, including an indication of whether these facilities use highly enriched uranium in any way;

(B) a review of international production of molybdenum-99 over the previous 5 years, including—

(i) whether any new production was brought online;

(ii) whether any facilities halted production unexpectedly; and

(iii) whether any facilities used for production were decommissioned or otherwise permanently removed from service; and

(C) an assessment of progress made in the previous 5 years toward establishing domestic production of molybdenum-99 for medical uses, including the extent to which other medical isotopes ~~coproduced~~*that have been produced* with

molybdenum-99, such as iodine-131 and xenon-133, are being used for medical purposes.

(2) An assessment of the progress made by the Department of Energy and others to eliminate all worldwide use of highly enriched uranium in reactor fuel, reactor targets, and medical isotope production facilities.

SEC. ~~9.~~*8.* DEFINITIONS.

In this Act the following definitions apply:

(1) HIGHLY ENRICHED URANIUM.—The term ''highly enriched uranium'' means uranium enriched to 20 percent or greater in the isotope U-235.

(2) LOW ENRICHED URANIUM.—The term ''low enriched uranium'' means uranium enriched to less than 20 percent in the isotope U-235.

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