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SENATE

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AMERICAN MEDICAL ISOTOPES PRODUCTION ACT

MAY 18, 2011.—Ordered to be printed

Mr. BINGAMAN, from the Committee on Energy and Natural Resources, submitted the following

R E P O R T

[To accompany S. 99]

The Committee on Energy and Natural Resources, to which was referred the bill (S. 99) 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, having considered the same, reports favorably thereon with an amendment and recommends that the bill, as amended, do pass.

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “American Medical Isotopes Production Act of 2011”.

SEC. 2. DEFINITIONS.

In this Act:

- (1) DEPARTMENT.—The term “Department” means the Department of Energy.
- (2) HIGHLY ENRICHED URANIUM.—The term “highly enriched uranium” means uranium enriched to 20 percent or greater in the isotope U-235.
- (3) LOW ENRICHED URANIUM.—The term “low enriched uranium” means uranium enriched to less than 20 percent in the isotope U-235.
- (4) SECRETARY.—The term “Secretary” means the Secretary of Energy.

SEC. 3. IMPROVING THE RELIABILITY OF DOMESTIC MEDICAL ISOTOPE SUPPLY.

(a) MEDICAL ISOTOPE DEVELOPMENT PROJECTS.—

- (1) IN GENERAL.—The Secretary 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 molybdenum-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 in the United States fueled with highly enriched uranium shall not be disqualified from the program if the Secretary 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 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.
- (5) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to the Secretary for carrying out the program under paragraph (1) \$143,000,000 for the period encompassing fiscal years 2011 through 2014.
- (b) **DEVELOPMENT ASSISTANCE.**—The Secretary 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.**—
- (1) **IN GENERAL.**—The Secretary shall establish a program to make low-enriched uranium available, through lease contracts, for irradiation for the production of molybdenum-99 for medical uses.
 - (2) **TITLE.**—The lease contracts shall provide for the producers of the molybdenum-99 to take title to and be responsible for the molybdenum-99 created by the irradiation, processing, or purification of uranium leased under this section.
 - (3) **DUTIES.**—
 - (A) **SECRETARY.**—The lease contracts shall require the Secretary—
 - (i) to retain responsibility for the final disposition of spent nuclear fuel created by the irradiation, processing, or purification of uranium leased under this section for the production of medical isotopes; and
 - (ii) to take title to and be responsible for the final disposition of radioactive waste created by the irradiation, processing, or purification of uranium leased under this section for which the Secretary determines the producer does not have access to a disposal path.
 - (B) **PRODUCER.**—The producer of the spent nuclear fuel and radioactive waste shall accurately characterize, appropriately package, and transport the spent nuclear fuel and radioactive waste prior to acceptance by the Department.
 - (4) **COMPENSATION.**—
 - (A) **IN GENERAL.**—Subject to subparagraph (B), the lease contracts shall 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—
 - (i) the final disposition of spent nuclear fuel and radioactive waste for which the Department is responsible under paragraph (3); and
 - (ii) other costs associated with carrying out the uranium lease and take-back program authorized by this subsection.
 - (B) **DISCOUNT RATE.**—The discount rate used to determine the net present value of costs described in subparagraph (A)(ii) shall be not greater than the average interest rate on marketable Treasury securities.
 - (5) **AUTHORIZED USE OF FUNDS.**—The Secretary may obligate and expend funds received under leases entered into under this subsection, which shall remain available until expended, for the purpose of carrying out the activities au-

thorized by this Act, including activities related to the final disposition of spent nuclear fuel and radioactive waste for which the Department is responsible under paragraph (3).

(6) EXCHANGE OF URANIUM FOR SERVICES.—The Secretary shall not barter or otherwise sell or transfer uranium in any form in exchange for—

(A) services related to the final disposition of the spent nuclear fuel and radioactive waste for which the Department is responsible under paragraph (3); or

(B) any other services associated with carrying out the uranium lease and take-back program authorized by this subsection.

(d) COORDINATION OF ENVIRONMENTAL REVIEWS.—The Department and the Nuclear Regulatory Commission shall ensure to the maximum extent practicable that environmental reviews for the production of the medical isotopes shall complement and not duplicate each review.

(e) OPERATIONAL DATE.—The Secretary shall establish a program as described in subsection (c)(3) not later than 3 years after the date of enactment of this Act.

(f) RADIOACTIVE WASTE.—Notwithstanding section 2 of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10101), radioactive material resulting from the production of medical isotopes that has been permanently removed from a reactor or subcritical assembly and for which there is no further use shall be considered low-level radioactive waste if the material is acceptable under Federal requirements for disposal as low-level radioactive waste.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary \$5,000,000 for the establishment of a program for the final disposition of spent nuclear fuel and radioactive waste for which the Department is responsible under subsection (c).

SEC. 4. EXPORTS.

Section 134 of the Atomic Energy Act of 1954 (42 U.S.C. 2160d) is amended by striking subsection c. and inserting the following:

“c. Effective 7 years after the date of enactment of the American Medical Isotopes Production Act of 2011, 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.

“d. The period referred to in subsection b. may be extended for no more than 6 years if, no earlier than 6 years after the date of enactment of the American Medical Isotopes Production Act of 2011, 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.

“e. 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.

“f. 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 enacts a Joint Resolution approving the temporary suspension of the restriction of export licenses.

“g. 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 medical 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 or therapeutic procedures or for research and development.”.

SEC. 5. 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 used as fuel or targets in a nuclear research or test reactor, 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. 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:

“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 medical 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 or 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 at the end of the items relating to chapter 10 of title I:

“Sec. 112. Domestic medical isotope production.”.

SEC. 7. ANNUAL DEPARTMENT REPORTS.

(a) **IN GENERAL.**—Not later than 1 year after the date of enactment of this Act, and annually thereafter for 5 years, the Secretary shall report to Congress on Department actions to support the production in the United States, without the use of highly enriched uranium, of molybdenum-99 for medical uses.

(b) **CONTENTS.**—The reports shall include the following:

- (1) For medical isotope development projects—

- (A) the names of any recipients of Department support under section 3;
 - (B) the amount of Department 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); and
 - (F) the ultimate use of any Department funds used to support projects under section 3.
- (2) A description of actions taken in the previous year by the Secretary to ensure the safe disposition of spent nuclear fuel and radioactive waste for which the Department is responsible under section 3(c).

SEC. 8. NATIONAL ACADEMY OF SCIENCES REPORT.

(a) **IN GENERAL.**—The Secretary shall enter into an arrangement with the National Academy of Sciences to conduct a study of the state of molybdenum-99 production and utilization, to be provided to Congress not later than 5 years after the date of enactment of this Act.

(b) **CONTENTS.**—The 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 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 and others to eliminate all worldwide use of highly enriched uranium in reactor fuel, reactor targets, and medical isotope production facilities.

SEC. 9. BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go-Act of 2010, shall be determined by reference to the latest statement titled “Budgetary Effects of PAYGO Legislation” for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

PURPOSE

The purpose of S. 99 is to promote the domestic production of molybdenum-99 for medical isotope production and to condition and phase out the export of highly enriched uranium for the production of medical isotopes.

BACKGROUND AND NEED

Molybdenum-99 and its decay product, technetium-99m, are the workhorses of nuclear medicine. Currently, molybdenum-99 is produced by irradiating a uranium-235 target in a nuclear reactor, which causes the uranium-235 atoms to split into molybdenum-99 and other fission products. Molybdenum-99 is then chemically separated from the other fission products, collected in small cylinders known as technetium generators, and shipped to radiopharmacies and hospitals.

Molybdenum-99 is unstable. Half of any given amount decays in about 66 hours, producing technetium-99m. Technetium-99m is recovered from the generator and used in medical diagnostic imaging of the brain, kidney, heart, bone, liver, and lung. Technetium-99m,

like molybdenum-99 is unstable; half of any given amount decays in about 6 hours. A technetium generator only lasts about 6 days.

The production of molybdenum-99 and technetium-99m are extremely important to the detection and treatment of disease. Technetium-99m is used in two-thirds of the 16 million nuclear medical procedures performed in the United States each year, which amounts to about 41,000 uses per day. Because of their short “half-lives,” neither molybdenum-99 nor technetium-99m can be stockpiled. They must be produced on an ongoing and reliable basis to ensure constant availability for necessary medical procedures.

The United States consumes approximately half of the world’s supply of molybdenum-99, but since 1989 has had no domestic source of supply. Between 95 and 98 percent of the world’s molybdenum-99 is produced by four companies in Canada, Belgium, the Netherlands, and South Africa. The United States is dependent on two of these companies: MDS Nordion, which is based in Canada, historically supplies about 60 percent of our needs; and Malinckrodt, which is based in the Netherlands and supplies the rest.

Because the United States is 100 percent dependent upon foreign sources for these medical isotopes, any delay in their production could cause a shortage of molybdenum-99 and technetium-99m. For example, the Canadian reactor that produces molybdenum-99 was shut down between May 2009 and the fall of 2010. The Netherlands reactor was also shut down for repairs between February and the fall of 2010. The result of the outage of these two aging reactors was that there were days during the summer of 2010 when U.S. patients could not receive technetium-99m, thus forgoing important diagnostic procedures. These reactors are expected to shut down in 2016, thus exacerbating the shortage of technetium-99m to U.S. patients for the foreseeable future.

In addition to the current supply concerns, molybdenum-99 production has long posed nuclear proliferation concerns. All four of the companies that are responsible for 95 to 98 percent of the world’s production use highly enriched uranium targets to produce molybdenum-99. The United States is the world’s primary supplier of the highly enriched uranium used for molybdenum-99 production. Highly enriched uranium, if obtained by terrorists or a rogue state, could be used to produce a nuclear weapon.

As a result of the nuclear proliferation concern, the Energy Policy Act of 1992 amended the Atomic Energy Act of 1954 to restrict the export of highly enriched uranium. The Energy Policy Act of 2005 subsequently relaxed this restriction to permit exports to certain countries to continue for medical isotope production. In addition, the Energy Policy Act of 2005 asked the National Academy of Sciences to determine if it is feasible to obtain medical isotopes from sources using low enriched uranium targets.

The National Academy of Sciences published its report, *Medical Isotope Production Without Highly Enriched Uranium*, in January 2009. The Academy found that although, at present, sufficient quantities of medical isotopes to meet our domestic needs cannot be produced without highly enriched uranium, there is no technical reason that adequate quantities could not be produced using low enriched uranium targets. It noted that Argentina and Australia are already producing molybdenum-99 with low enriched uranium targets, though in relatively small quantities sufficient only to

meet their regional needs. It also found that use of highly enriched uranium targets could be phased out and replaced by low enriched uranium targets in 7 to 10 years. This conclusion was further bolstered by the November 2009 Report of the Export Review Panel to Canada's Minister of Natural Resources, which recommended that any new reactor-based source of molybdenum-99 use low enriched uranium.

S. 99 is needed to help facilitate the development of a stable domestic supply of molybdenum-99, as well as the conversion of medical isotope production from the use of highly enriched to low enriched uranium both by directing the Secretary of Energy to establish a technology neutral program to support the production of molybdenum-99 without the use of highly enriched uranium and by phasing out the export of highly enriched uranium.

LEGISLATIVE HISTORY

S. 99 was introduced by Senator Bingaman on January 25, 2011. Senator Murkowski was an original cosponsor. As introduced, S. 99 was identical to H.R. 3276, as reported by the Committee on Energy and Natural Resources, in the 111th Congress. H.R. 3276 was introduced by Representative Markey on July 21, 2009, was reported by the Committee on Energy and Commerce on November 4, 2009 (H. Rept. 111-328), and passed the House on November 5, 2009 by a vote of 400 to 17.

The Committee on Energy and Natural Resources held a hearing on H.R. 3276 on December 3, 2009 (S. Hrg. 111-314), and ordered it favorably reported, with amendments, on December 16, 2009. (S. Rept. 111-120.)

The Committee held a hearing on S. 99 on February 1, 2011 (S. Hrg. 112-4), and ordered it favorably reported, with an amendment in the nature of a substitute, on April 12, 2011.

COMMITTEE RECOMMENDATION

The Senate Committee on Energy and Natural Resources, in open business session on April 12, 2011, by a voice vote of a quorum present recommends that the Senate pass S. 99, if amended as described herein.

COMMITTEE AMENDMENTS

During its consideration of S. 99, the Committee adopted an amendment in the nature of a substitute. The amendment makes a number of changes in the bill as introduced.

New definitions for the terms "Department" and "Secretary" are added to the definition section, which is moved to the beginning of the bill and redesignated "section 2" instead of "section 8."

The exemption in section 3(a)(3) (formerly section 2(a)(3)), which permits existing reactors fueled with highly enriched uranium to participate in the development program, is restricted to reactors in the United States.

The uranium lease and take-back program in section 3(c) (formerly section 4(c)) is clarified by providing that the producers will take title to the molybdenum-99, the Secretary will take title to the spent nuclear fuel and radioactive wastes for which the producers do not have access to a disposal path, and the producers will char-

acterize, package, and transport the spent nuclear fuel and radioactive waste prior to acceptance by the Department. Former section 4(c) is further modified to require producers to compensate the Department for costs associated with the lease and take-back program (in the new section 3(c)(4)), to authorize the Secretary to spend funds received under the leases to carry out the program, including the disposal of radioactive waste for which the Department is responsible under the lease contracts (in section 3(c)(5)), and to clarify the restrictions on exchanging of uranium for services (in section 3(c)(6)).

New subsections are added to require the Department and the Nuclear Regulatory Commission to coordinate environmental reviews for medical isotope production (section 3(d)), to require the Secretary to make the program to take back spent nuclear fuel and radioactive wastes operational within 3 years of the date of enactment (section 3(e)), to allow radioactive material resulting from the production of medical isotopes for which there is no further use to be treated as low-level radioactive waste if it meets federal requirements for disposal as low-level radioactive waste (section 3(f)), and to authorize appropriation of \$5 million to establish the program to take back spent nuclear fuel and radioactive waste.

Section 4 (formerly section 3) is modified to strike only section 134c. (and not section 134b.) of the Atomic Energy Act of 1954.

Section 5 (formerly section 4) is modified to require the Nuclear Regulatory Commission to report on the exports of highly enriched uranium used as fuel or isotope targets, rather than on all highly enriched uranium exports.

SECTION-BY-SECTION ANALYSIS

Section 1 provides a short title.

Section 2 defines terms used throughout the Act.

Section 3(a)(1) directs the Secretary of Energy (the Secretary) to establish a technology-neutral, cost-shared program to evaluate and support projects for the production of molybdenum-99 for medical uses without the use of highly enriched uranium.

Subsection (a)(2) provides criteria for evaluating projects.

Subsection (a)(3) permits existing U.S. reactors fueled with highly enriched uranium to participate in the program under specified conditions.

Subsection (a)(4) requires the Secretary to develop and update a program plan through public workshops, and to use the Nuclear Science Advisory Committee to review program progress.

Subsection (a)(5) authorizes \$143 million to be appropriated to the Secretary for fiscal years 2011 through 2014 to carry out the program.

Subsection (b) directs the Secretary to establish a program to provide assistance for the development of fuels, targets, and processes for production of molybdenum-99 without the use of highly enriched uranium, and for commercial operations using such fuels, targets, and processes.

Subsection (c)(1) directs the Secretary to establish a program to supply, through lease contracts, low enriched uranium for use in the production of molybdenum-99 for medical uses.

Subsection (c)(2) requires that the lease contracts provide for the producers of molybdenum-99 to take title to and be responsible for the molybdenum-99 derived from the low enriched uranium.

Subsection (c)(3)(A) requires the Secretary to be responsible for the final disposition of the spent nuclear fuel from the lease contracts and to take title to and be responsible for the waste created through the irradiation, processing, or purification of the low enriched uranium from the lease contracts for which the Secretary determines that the producer of the molybdenum-99 does not have a commercially available disposal path.

Subsection (c)(3)(B) requires the producer of the molybdenum-99 to accurately characterize, appropriately package, and transport the spent nuclear fuel and radioactive waste (for which there is no commercial disposal path) prior to acceptance by the Department.

Subsection (c)(4)(A) requires the lease contracts to provide for compensation to be paid to the Department in cash for the low-enriched uranium leased under the contracts, the final disposal of the spent fuel and radioactive waste, and other costs of carrying out the program. It further provides that the compensation for the leased uranium be in amounts equal to prevailing market rates for the sale of comparable uranium products, and that the compensation for final disposition and other costs be in amounts equal to the net present value of the cost to the Federal Government. Subparagraph (B) provides that the discount rate used to determine the net present value shall not be greater than the average interest rate on marketable Treasury securities. To be cost neutral, these securities should correspond to the period for final disposal of spent nuclear fuel and radioactive waste.

Subsection (c)(5) authorizes the Secretary to obligate and expend funds received under the lease contracts without fiscal year limitation for activities in the Act, including those associated with final disposition of the spent nuclear fuel and radioactive waste.

Subsection (c)(6) prohibits the use of bartering uranium for services of any kind associated with the lease contracts and final disposition of spent nuclear fuel and radioactive waste.

Subsection (d) directs that the Department of Energy and the Nuclear Regulatory Commission, shall to the greatest extent practicable ensure that environmental reviews complement and not duplicate each other through the use of cooperating agencies or other regulatory mechanisms.

Subsection (e) requires that the Secretary establish the lease contract program, including the ability to take spent nuclear fuel and radioactive waste under the lease contracts not later than 3 years after date of enactment.

Subsection (f) allows radioactive material resulting from the production of medical isotopes to be classified as low-level radioactive waste if it meets federal requirements for disposal as low-level radioactive waste.

Subsection (g) authorizes the appropriation of \$5,000,000 to start up the program to take back the spent nuclear fuel and radioactive waste under subsection (c).

Section 4 amends section 134 of the Atomic Energy Act of 1954, 42 U.S.C. 2160d, by striking subsection (c), and by adding 5 new subsections designated (c) through (f). New subsection (c) prohibits the Nuclear Regulatory Commission from issuing a license for the

export of highly enriched uranium for medical isotope production effective 7 years after the date of enactment.

New Atomic Energy Act section 134d. permits the 7-year period in subsection (c) to be extended for up to 6 additional years if the Secretary certifies that there is insufficient global supply of molybdenum-99 produced without the use of highly enriched uranium to satisfy the domestic market and that the export of highly enriched uranium is the most effective temporary means to increase the domestic supply of molybdenum-99.

New section 134e. requires public notice and comment on the certification.

New section 134f. provides for the suspension, for up to 12 months, of the prohibition on the export licensing of highly enriched uranium after it has become effective if there is a critical shortage of molybdenum-99, the Secretary certifies that the export of highly enriched uranium is the only effective temporary means to increase the supply, and Congress enacts a joint resolution approving the temporary suspension.

New section 134g. defines terms used in section 134 of the Atomic Energy Act of 1954.

Section 5 requires the Chairman of the Nuclear Regulatory Commission to submit to Congress a report on the current disposition of previous exports of highly enriched uranium used as targets of fuel in a nuclear research or test reactor.

Section 6 adds a new section 112 to the Atomic Energy Act of 1954 to authorize the Nuclear Regulatory Commission to license the use in the United States of highly enriched uranium as a target for medical isotope production only if, in addition to other requirements of the Atomic Energy Act, the Commission determines that no low enriched uranium target can be used in the reactor, and the recipient has provided assurances that if a low enriched uranium target can be used, it will be, and the Secretary certifies that the United States Government is actively supporting the development of low enriched uranium targets for the reactor.

Section 7 requires the Secretary to report to Congress one year after the date of enactment of S. 99, and annually for the ensuing 5 years, on actions to support the production of molybdenum-99 for medical uses without the use of highly enriched uranium.

Section 8 requires the National Academy of Sciences to study the state of molybdenum-99 production and use not later than 5 years after the date of enactment of S. 99.

Section 9 provides that the Chairman of the Budget Senate Committee shall determine and submit to the Congressional Record the budgetary affects of this Act under the "Pay-As-You-Go-Act of 2010".

COST AND BUDGETARY CONSIDERATIONS

The following estimate of costs of this measure has been provided by the Congressional Budget Office.

S. 99—American Medical Isotopes Production Act of 2011

Summary: S. 99 would authorize funding to support projects to produce molybdenum-99, a radioactive isotope used in certain medical procedures. Assuming appropriation of the authorized amounts, CBO estimates that implementing S. 99 would cost \$150

million over the 2011–2016 period. CBO also estimates that enacting the legislation would affect direct spending; therefore, pay-as-you-go procedures apply. CBO estimates, however, that the net impact on direct spending would be negligible in any given year. Enacting S. 99 would not affect revenues.

S. 99 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 99 is shown in the following table. The costs of this legislation fall within budget function 270 (energy).

	By fiscal year, in millions of dollars—					
	2012	2013	2014	2015	2016	2012–2016
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	150	0	0	0	0	150
Estimated Outlays	43	38	30	24	15	150

Basis of estimate: For this estimate, CBO assumes that S. 99 will be enacted near the end of fiscal year 2011 and that authorized amounts will be provided near the start of 2012.

CBO estimates that implementing S. 99 would require appropriations totaling \$150 million for a program to support projects to produce molybdenum-99, a radioactive isotope produced from uranium, for use in certain medical procedures. In addition, the bill would direct the Secretary of Energy to make low-enriched uranium (LEU) available through lease contracts to producers of molybdenum-99. Such lease contracts would provide for the Secretary to retain financial responsibility for certain waste generated by the irradiation, processing, or purification of LEU.

CBO estimates that implementing S. 99 would increase discretionary spending by \$150 million over the 2012–2016 period. We also estimate that leasing LEU would have a negligible net impact on direct spending.

Spending Subject to Appropriation

S. 99 would specifically authorize appropriations totaling \$143 million to provide direct financial support for projects to produce molybdenum-99 and \$5 million to establish a program to dispose of certain waste resulting from federal leases of LEU. In addition, CBO estimates that completing various studies, reports, and regulatory activities under the bill would require appropriations totaling \$2 million over the 2012–2016 period. Assuming appropriation of the authorized and estimated amounts, CBO estimates that spending would total \$150 million over the 2012–2016 period. That estimate is based on information from the Department of Energy (DOE) about the types of molybdenum-99 projects that might be supported under S. 99 and takes into account historical spending patterns for similar activities.

Under S. 99, the federal government would be responsible for disposing of certain types of waste generated by molybdenum-99 producers who lease LEU from DOE. Spending related to waste generated under such leases would be subject to the availability of appropriated funds. Based on information from DOE about the volume of LEU that the agency anticipates would be leased under S.

99, CBO expects that resulting quantities of waste would be small. While waste disposal costs would be incurred over many years and could reach significant levels over time, CBO estimates that any increased costs over the 2012–2016 period would not exceed the \$5 million specifically authorized to be appropriated under the bill.

Direct Spending

S. 99 would direct the Secretary to lease LEU to producers of molybdenum-99. Under current law, CBO estimates that sales of the material that would be leased under the bill would otherwise generate offsetting receipts (a credit against direct spending) totaling about \$1 million annually. Because S. 99 would require that lessees pay fees equivalent to the prevailing market rates for the sale of comparable uranium products, CBO estimates that any differences in receipts generated under the bill would be negligible in any given year.

The bill also would require that the Secretary charge LEU lessees a fee to offset the net present value of DOE's anticipated costs to dispose of certain types of waste generated from leased LEU. Under the bill DOE could spend those fees, without further appropriation, for activities related to waste disposal. Based on information from DOE about the range of potential costs the agency might face to dispose of waste pursuant to LEU leases, CBO estimates that any net change in direct spending resulting from the collection and spending of such fees would be negligible in any given year.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. CBO estimates that enacting S. 99 would have a negligible net impact on direct spending in any given year, and would not have any impact on revenues.

Intergovernmental and private-sector impact: S. 99 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal Costs: Megan Carroll; Impact on State, Local, and Tribal Governments: Ryan Miller; Impact on the Private Sector: Amy Petz.

Estimate approved by: Theresa Gullo, Deputy Assistant Director for Budget Analysis.

REGULATORY IMPACT EVALUATION

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes the following evaluation of the regulatory impact which would be incurred in carrying out S. 99.

The bill is not a regulatory measure in the sense of imposing Government established standards or significant economic responsibilities on private individuals and businesses.

No personal information would be collected in administering the program. Therefore, there would be no impact on personal privacy.

Little, if any, additional paperwork would result from the enactment of S. 99.

CONGRESSIONALLY DIRECTED SPENDING

S. 99, as reported, does not contain congressionally directed spending items, limited tax benefits, or limited tariff benefits as defined in rule XLIV of the Standing Rules of the Senate.

EXECUTIVE COMMUNICATIONS

The testimony of the National Nuclear Security Administration at the Committee's hearing on S. 99 on February 1, 2011, follows:

DR. PARRISH STAPLES, DIRECTOR, OFFICE OF EUROPEAN AND AFRICAN THREAT REDUCTION, GLOBAL THREAT REDUCTION INITIATIVE, DEFENSE NUCLEAR NONPROLIFERATION, NATIONAL NUCLEAR SECURITY ADMINISTRATION, DEPARTMENT OF ENERGY

Chairman Bingaman, Ranking Member Murkowski, and Committee Members, thank you for the opportunity to testify about the National Nuclear Security Administration's (NNSA's) support for accelerating development of a domestic commercial supply of Molybdenum-99 (Mo-99) without using highly enriched uranium (HEU). This effort is part of our larger global nonproliferation program to minimize and, where possible, eliminate the use of HEU in civilian nuclear applications, including in the production of medical radioisotopes. My testimony will update you on testimony provided to this committee in December 2009 about (1) the nonproliferation and medical benefits of S.99, the *American Medical Isotopes Production Act of 2011*; (2) the NNSA's progress to accelerate the establishment of a non-HEU based domestic commercial supply of Mo-99; and (3) changing global market conditions that could undermine our efforts for a reliable domestic production of non-HEU-based Mo-99.

Mo-99 is the parent isotope of Technetium-99m, which is used in approximately 50,000 diagnostic medical procedures every day in the United States. It has a very short half life and therefore must be produced on a continuous basis to meet the needs of the medical community. Any interruptions in production can place patients at risk if diagnostic tests cannot be performed.

Currently, the United States depends entirely on foreign producers for all of its Mo-99. Of the major international suppliers of commercial Mo-99, Canada, the Netherlands, and Belgium use HEU targets to produce this vital medical isotope. Only South Africa, which partnered with NNSA to convert its HEU reactor to low enriched uranium (LEU) fuel, has begun LEU-based Mo-99 production.

Mo-99 production processes based on HEU utilize nuclear material enriched to the same degree as nuclear material used to produce nuclear weapons and improvised nuclear devices. World leaders at the 2010 Nuclear Security Summit and other fora underscored the need to minimize and, where possible, eliminate the use of HEU due to the grave threats posed by excess nuclear materials and the possible acquisition of such materials by terrorists or rogue

states. New technical advances in Mo-99 production processes, many of which have been supported by the U.S. Department of Energy and NNSA working closely with industry and our national laboratories, are demonstrating that HEU is no longer required. S. 99, the *American Medical Isotopes Production Act of 2011* will encourage Mo-99 suppliers worldwide not to use HEU and to develop a reliable supply of Mo-99 for the U.S. medical community. Provisions of this legislation, in particular Section 5, are aligned with the NNSA's nonproliferation mission to assist in the conversion of research reactors and isotope production facilities worldwide from the use of HEU to LEU, and to establish a reliable supply of Mo-99 produced without the use of HEU in the United States.

Furthermore, the HEU-free, U.S.-based Mo-99 production encouraged by the *American Medical Isotopes Production Act of 2011* would serve as an example for eliminating HEU in the global medical isotope business. The proposed legislation will promote the reliable supply of Mo-99 to hospitals throughout our country and will ultimately ensure the level of patient care that our citizens require in a way that is consistent with our nuclear nonproliferation goals.

As has been the case in 2009–2010, global Mo-99 shortages can occur with any change in the production schedules of the major producers. Unforeseen shutdowns due to technical problems or scheduled maintenance of the aging reactors currently producing Mo-99 can threaten the fragile supply chain for the much needed medical isotopes. Under the leadership of the Office of Science and Technology Policy of the Executive Office of the President, an Interagency working group, which includes NNSA and other Department of Energy offices, is pursuing the following actions: (1) investigating options to focus on near-term efforts to increase the supply to the U.S. during periods when the major suppliers will be out of operation; (2) coordinating efforts to maximize the success of the commercial sector to develop new longer-term production capabilities for the U.S. medical community; and (3) working with representatives of the medical community to ensure communication about the timing of scheduled maintenance to more efficiently manage use of available Mo-99 supplies.

NNSA frequently meets with the existing major global Mo-99 producers as part of its nuclear nonproliferation agenda to promote the development of a long-term reliable supply of Mo-99 using LEU. NNSA's programs can also assist other countries with conversion, where possible. For example, with NNSA's support, the South African Nuclear Energy Corporation (Necsa) became the first major supplier to produce large-scale quantities of LEU-based Mo-99, and completed its first shipment of FDA-approved, LEU-based Mo-99 to the United States in December 2010. Necsa's achievement to produce large-scale quantities of LEU-based Mo-99 is an important nonproliferation advance as it demonstrates the technical viability of pro-

ducing Mo-99 consistent with international commitments to minimize and eliminate the use of HEU in isotope production. With appropriate Congressional support, the long-term goal of steady state production from LEU could be achieved globally, and could thus provide a complementary, consistent supply of the medical isotope to health care providers.

The 2009 National Academies report confirmed that production of Mo-99 is both technically and economically feasible, and as a result, NNSA is demonstrating the feasibility of non-HEU based Mo-99 production by working with four commercial entities to develop technology pathways to produce adequate quantities of Mo-99 for the United States. These include: LEU solution reactor technology; neutron capture technology; and accelerator technology. The strategy is to move away from reliance on a sole technology and a limited number of facilities, as is the case with the global Mo-99 market today. The goal is for each technology to be commercially successful, and therefore NNSA's approach is technology neutral. NNSA also makes available to these commercial partners the technical expertise of the U.S. national laboratories gained from their many years of work to develop non-HEU based Mo-99 production technologies. We share the goals of this bill and look forward to working with you to ensure the accomplishment of nuclear threat reduction activities and the development of a reliable supply of medical isotopes to the public, while ensuring greater Presidential flexibility.

Despite the good progress, challenges remain that could obstruct the successful and accelerated establishment of a domestic supply of Mo-99. First, the major global producers have been and continue to be heavily subsidized by their governments. Such subsidies put at risk the economic viability of U.S. companies starting up high-tech, capital intensive businesses to produce non-HEU based Mo-99. A 2010 independent economic study by the Organization for Economic Cooperation and Development's Nuclear Energy Agency entitled "An Economic Study of the Molybdenum-99 Supply Chain", underscores this issue by citing that long-term subsidies have damaged industry's attempts to enter the global Mo-99 market. To provide a level playing field for U.S. companies, meet nonproliferation goals, and build a non-HEU based industry for Mo99, there must be a concerted global commitment that all new or expanded long-term Mo-99 production be undertaken without HEU. Very importantly, we must achieve full cost recovery across the entire global commercial industry. Any foreign government subsidy of HEU-based production puts the objectives of this legislation at risk.

We have significant concerns about the scope, costs, and other implications of Section 2(c), the "Uranium Lease and Take Back" provision. In addition, the proposed program could risk lengthening the timeframe to Mo-99 production if the schedule of implementing the proposed "Uranium Lease and Take Back" subprogram were to have any link-

age to the expected production schedule of the commercial projects to produce Mo-99.

NNSA will use its existing, well-established program management and procurement oversight tools to ensure that the innovative non-HEU based technologies it supports are developed on schedule and that cost-shared funds are properly applied so that Mo-99 is delivered to the U.S. market on time and within anticipated costs. NNSA will also coordinate closely with the Nuclear Regulatory Commission and the Food and Drug Administration on regulatory issues associated with the commercial use of new technology.

To summarize, the Department of Energy and NNSA believe that, overall, this legislation will be helpful in providing public visibility to critical nonproliferation goals and to equally critical medical needs. With clear commitment and sustained support, we can secure our citizens' health needs as well as their national security. I thank Senator Bingaman, Ranking Member Murkowski, and Members of the Committee for your continued leadership in supporting this legislation and we look forward to working with you to address any issues raised here today. I appreciate the opportunity to testify and am ready to answer your questions.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by the bill S. 99, as ordered reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

ATOMIC ENERGY ACT OF 1954

AN ACT To amend the Atomic Energy Act of 1946, as amended, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Atomic Energy Act of 1946, as amended, is amended to read as follows:

ATOMIC ENERGY ACT OF 1954

TITLE I—ATOMIC ENERGY

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CHAPTER 10. ATOMIC ENERGY LICENSES

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Sec. 110. Exclusions.
 Sec. 112. Domestic medical isotope production.

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TITLE I—ATOMIC ENERGY

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CHAPTER 10. ATOMIC ENERGY LICENSES

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SEC. 111. a. The Nuclear Regulatory Commission is authorized to license the distribution of special nuclear material, source material, and byproduct material by the Department of Energy pursuant to section 54, 64, and 82 of this Act, respectively, in accordance with the same procedures established by law for the export licensing of such material by any person: *Provided*, That nothing in this section shall require the licensing of the distribution of byproduct material by the Department of Energy under section 82 of this Act.

b. The Department of Energy shall not distribute any special nuclear material or source material under section 54 or 64 of this Act other than under an export license issued by the Nuclear Regulatory Commission until (1) the Department has obtained the concurrence of the Department of State and has consulted with the Nuclear Regulatory Commission and the Department of Defense under mutually agreed procedures which shall be established within not more than ninety days after the date of enactment of this provision and (2) the Department finds based on a reasonable judgment of the assurances provided and the information available to the United States Government, that the criteria in section 127 of this Act or their equivalent and any applicable criteria in subsection 128 are met, and that the proposed distribution would not be inimical to the common defense and security.

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;*

(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.*

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CHAPTER 11. INTERNATIONAL ACTIVITIES

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SEC. 134. FURTHER RESTRICTIONS ON EXPORTS.—

a. **IN GENERAL.**—Except as provided in subsection b., the Commission may issue a license for the export of highly enriched uranium to be used as a fuel or target in a nuclear research or test reactor only if, in addition to any other requirements of this Act, the Commission determines that—

(1) there is no alternative nuclear reactor fuel or target enriched in the isotope 235 to a lesser percent than the proposed export, that can be used in that reactor;

(2) the proposed recipient of that uranium has provided assurances that, whenever an alternative nuclear reactor fuel or target can be used in that reactor, it will use that alternative in lieu of highly enriched uranium; and

(3) the United States Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.

b. MEDICAL ISOTOPE PRODUCTION.—

(1) **DEFINITIONS.**—In this subsection:

(A) **HIGHLY ENRICHED URANIUM.**—The term "highly enriched uranium" means uranium enriched to include concentration of U-235 above 20 percent.

(B) **MEDICAL ISOTOPE.**—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.

(C) **RADIOPHARMACEUTICAL.**—The term "radiopharmaceutical" means a radioactive isotope that—

(i) contains byproduct material combined with chemical or biological material; and

(ii) is designed to accumulate temporarily in a part of the body for therapeutic purposes or for enabling the production of a useful image for use in a diagnosis of a medical condition.

(D) **RECIPIENT COUNTRY.**—The term "recipient country" means Canada, Belgium, France, Germany, and the Netherlands.

(2) LICENSES.—The Commission may issue a license authorizing the export (including shipment to and use at intermediate and ultimate consignees specified in the license) to a recipient country of highly enriched uranium for medical isotope production if, in addition to any other requirements of this Act (except subsection a.), the Commission determines that—

(A) a recipient country that supplies an assurance letter to the United States Government in connection with the consideration by the Commission of the export license application has informed the United States Government that any intermediate consignees and the ultimate consignee specified in the application are required to use the highly enriched uranium solely to produce medical isotopes; and

(B) the highly enriched uranium for medical isotope production will be irradiated only in a reactor in a recipient country that—

(i) uses an alternative nuclear reactor fuel; or

(ii) is the subject of an agreement with the United States Government to convert to an alternative nuclear reactor fuel when alternative nuclear reactor fuel can be used in the reactor.

(3) REVIEW OF PHYSICAL PROTECTION REQUIREMENTS.—

(A) IN GENERAL.—The Commission shall review the adequacy of physical protection requirements that, as of the date of an application under paragraph (2), are applicable to the transportation and storage of highly enriched uranium for medical isotope production or control of residual material after irradiation and extraction of medical isotopes.

(B) IMPOSITION OF ADDITIONAL REQUIREMENTS.—If the Commission determines that additional physical protection requirements are necessary (including a limit on the quantity of highly enriched uranium that may be contained in a single shipment), the Commission shall impose such requirements as license conditions or through other appropriate means.

(4) FIRST REPORT TO CONGRESS.—

(A) NAS STUDY.—The Secretary shall enter into an arrangement with the National Academy of Sciences to conduct a study to determine—

(i) the feasibility of procuring supplies of medical isotopes from commercial sources that do not use highly enriched uranium;

(ii) the current and projected demand and availability of medical isotopes in regular current domestic use;

(iii) the progress that is being made by the Department of Energy and others to eliminate all use of highly enriched uranium in reactor fuel, reactor targets, and medical isotope production facilities; and

(iv) the potential cost differential in medical isotope production in the reactors and target processing facilities if the products were derived from production systems that do not involve fuels and targets with highly enriched uranium.

(B) FEASIBILITY.—For the purpose of this subsection, the use of low enriched uranium to produce medical isotopes shall be determined to be feasible if—

(i) low enriched uranium targets have been developed and demonstrated for use in the reactors and target processing facilities that produce significant quantities of medical isotopes to serve United States needs for such isotopes;

(ii) sufficient quantities of medical isotopes are available from low enriched uranium targets and fuel to meet United States domestic needs; and

(iii) the average anticipated total cost increase from production of medical isotopes in such facilities without use of highly enriched uranium is less than 10 percent.

(C) REPORT BY THE SECRETARY.—Not later than 5 years after the date of enactment of the Energy Policy Act of 2005, the Secretary shall submit to Congress a report that—

(i) contains the findings of the National Academy of Sciences made in the study under subparagraph (A); and

(ii) discloses the existence of any commitments from commercial producers to provide domestic requirements for medical isotopes without use of highly enriched uranium consistent with the feasibility criteria described in subparagraph (B) not later than the date that is 4 years after the date of submission of the report.

(5) SECOND REPORT TO CONGRESS.—If the study of the National Academy of Sciences determines under paragraph (4)(A)(i) that the procurement of supplies of medical isotopes from commercial sources that do not use highly enriched uranium is feasible, but the Secretary is unable to report the existence of commitments under paragraph (4)(C)(ii), not later than the date that is 6 years after the date of enactment of the Energy Policy Act of 2005, the Secretary shall submit to Congress a report that describes options for developing domestic supplies of medical isotopes in quantities that are adequate to meet domestic demand without the use of highly enriched uranium consistent with the cost increase described in paragraph (4)(B)(iii).

(6) CERTIFICATION.—At such time as commercial facilities that do not use highly enriched uranium are capable of meeting domestic requirements for medical isotopes, within the cost increase described in paragraph (4)(B)(iii) and without impairing the reliable supply of medical isotopes for domestic utilization, the Secretary shall submit to Congress a certification to that effect.

(7) SUNSET PROVISION.—After the Secretary submits a certification under paragraph (6), the Commission shall, by rule, terminate its review of export license applications under this subsection.

[c. 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; and

[(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.]

c. Effective 7 years after the date of enactment of the American Medical Isotopes Production Act of 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.

d. The period referred to in subsection b. may be extended for no more than 6 years if, no earlier than 6 years after the date of enactment of the American Medical Isotopes Production Act of 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.

e. 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.

f. 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 enacts a Joint Resolution approving the temporary suspension of the restriction of export licenses.

g. 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.

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