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111TH CONGRESS *2d Session* | SENATE | REPORT 111–120

AMERICAN MEDICAL ISOTOPES PRODUCTION ACT

JANUARY 28, 2010.—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 H.R. 3276]

The Committee on Energy and Natural Resources, to which was referred the Act (H.R. 3276) 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 amendments and recommends that the Act, as amended, do pass.

The amendments are as follows:

On page 2, line 3, strike "2009" and insert "2010".

Beginning on page 2, strike line 4 and all that follows through page 6, line 3.

On page 6, line 4, strike "**3**" and insert "**2**".

On page 6, strike lines 8 through 12 and insert the following:

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).

On page 7, between lines 17 and 18, insert the fol1owing:

(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.

On page 7, line 18, strike "(4)" and insert "(5)".
On page 9, line 1, strike "4" and insert "3".
On page 9, line 3, strike "2160d(b)" and insert "2160d".
On page 9, line 6, strike "2009" and insert "2010".
On page 9, line 11, strike "four" and insert "6".
On page 9, line 13, strike "2009" and insert "2010".
On page 9, after line 25, insert the following:
"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.
On page 10, line 1, strike "d." and insert "e.".
On page 10, line 14, strike "passes" and insert "enacts".
On page 10, line 17, strike "e." and insert "f.".
On page 11, line 18, strike "**5**" and insert "**4**".
On page 12, line 15, strike "**6**" and insert "**5**".
On page 14, lines 16 and 17, strike "after the item relating to section 111:" and insert "at the end of the items relating to chapter 10 of title I:".
On page 14, line 18, strike "**7**" and insert "**6**".
On page 15, line 3, strike "section 3" and insert "section 2".
On page 15, line 14, strike "3(a)(2)" and insert "2(a)(2)".
On page 15, line 17, strike "section 3" and insert "section 2".
On page 15, line 22, strike "**8**" and insert "**7**".
On page 16, line 24, strike "coproduced" and insert "that have been produced".
On page 17, line 8, strike "**9**" and insert "**8**".

PURPOSE

The purpose of H.R. 3276 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-99, are the workhorses of nuclear medicine. 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-99. Technetium-99 is recovered from the generator and used in medical diagnostic imaging of the brain, kidney, heart, bone, liver, and lung. Technetium-99, 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-99 are extremely important to the detection and treatment of disease. Technetium-99 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-99 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 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 based 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 and supplies 60 percent of our needs; and Mallinckrodt, which is based in the Netherlands and supplies the remaining 40 percent.

The United States currently faces a severe shortage of molybdenum-99 and technetium-99. The Canadian reactor that produces molybdenum-99 has been shut down since May 2009 and is not expected to be back in operation until the spring of 2010. The Netherlands reactor is also scheduled to be shut down for repairs for several months in early 2010.

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.

H.R. 3276 is needed to facilitate 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 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

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, and ordered it favorably reported, with amendments, on December 16, 2009.

COMMITTEE RECOMMENDATION

The Senate Committee on Energy and Natural Resources, in open business session on December 16, 2009, by a voice vote of a quorum present recommends that the Senate pass H.R. 3276, if amended as described herein.

COMMITTEE AMENDMENTS

During its consideration of H.R. 3276, the Committee adopted 19 numbered amendments and the staff made 6 technical or clerical corrections pursuant to rule 7(d) of the Rules of the Committee.

The first amendment updates the year in the short title.

The second strikes the findings; and the third makes a conforming change to a section number.

The fourth adds to the requirement that the Secretary of Energy establish a program to evaluate and support projects for the production of molybdenum-99 without the use of highly enriched uranium the additional requirements that the program be technology neutral, that it be carried out in cooperation with non-Federal entities, and that the costs be shared in accordance with section 988 of the Energy Policy Act of 2005.

The fifth requires the Secretary of Energy to develop a program plan and annually update it through public workshops, and to use the Nuclear Science Advisory Committee to conduct annual reviews of the progress made in achieving the program goals.

The eighth corrects a citation, and the sixth, seventh, ninth, and eleventh make conforming changes.

The tenth amendment lengthens the period of time by which the initial 7-year period during which the Nuclear Regulatory Commission may issue export licenses for highly enriched uranium for medical isotope production may be extended from 4 years to 6 years.

The twelfth amendment provides for public notice and comment on the certification needed to trigger an extension of the period of time during which the Nuclear Regulatory Commission may issue export licenses for highly enriched uranium.

The fourteenth and twenty-fourth amendments make technical clarifications, and the remaining amendments (numbered 13, 15 through 23, and 25) make conforming changes.

SECTION-BY-SECTION ANALYSIS

Section 1 provides a short title.

Section 2(a)(1) directs the Secretary of Energy (the Secretary) to establish a technology-neutral 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 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 $163 million to be appropriated to the Secretary for fiscal years 2010 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) directs the Secretary to establish a program to lease low enriched uranium for use in the production of molybdenum-99 for medical uses, and for taking back and disposing of radioactive waste created by the irradiation, processing, or purification of leased uranium.

Section 3 amends section 134 of the Atomic Energy Act of 1954, 42 U.S.C. 2160d, by striking subsection (b) (as added by section 630 of the Energy Policy Act of 2005) and subsection (c), and by adding 5 new subsections designated (b) through (f). New subsection (b) 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.

Subsection (c) permits the 7-year period in subsection (b) 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.

Subsection (d) requires public notice and comment on the certification.

Subsection (e) 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.

Subsection (f) defines terms used in section 134 of the Atomic Energy Act of 1954.

Section 4 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.

Section 5 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 6 requires the Secretary to report to Congress one year after the date of enactment of H.R. 3276, 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 7 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 H.R. 3276.

Section 8 defines terms used in the Act.

COST AND BUDGETARY CONSIDERATIONS

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

H.R. 3276—American Medical Isotopes Production Act of 2009

Summary: H.R. 3276 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 the act would cost $165 million over the 2010–2015 period. CBO also estimates that enacting H.R. 3276 would have a negligible net impact on direct spending for any given year. The act would not affect revenues.

H.R. 3276 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 H.R. 3276 is shown in the following table. The costs of this legislation fall within budget function 270 (energy).

	By fiscal year, in millions of dollars—						
	2010	2011	2012	2013	2014	2015	2010–2015
CHANGES IN SPENDING SUBJECT TO APPROPRIATION							
Estimated Authorization Level	165	0	0	0	0	0	165
Estimated Outlays	12	25	30	30	33	35	165

Basis of Estimate: H.R. 3276 would authorize the appropriation of $163 million to support projects to produce molybdenum-99, a radioactive isotope produced from uranium, for use in certain medical procedures. In addition to direct financial support for those projects, the act 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 radioactive waste generated by the irradiation, processing, or purification of LEU.

CBO estimates that providing funding for proposed projects, completing related studies and reports, and managing radioactive

waste resulting from leases of LEU would cost $165 million over the 2010–2015 period. We also estimate that leasing LEU would have a negligible net impact on direct spending.

SPENDING SUBJECT TO APPROPRIATION

CBO estimates that implementing H.R. 3276 would require appropriations totaling $165 million over the 2010–2015 period. That amount includes $163 million specifically authorized to support projects to produce molybdenum-99 and $2 million for related studies, reports, and regulatory activities. Assuming appropriation of those amounts, CBO estimates that spending would total $165 million over the 2010–2015 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 H.R. 3276 and takes into account historical spending patterns for similar activities.

Under H.R. 3276, the federal government would be responsible for disposing of radioactive waste generated by molybdenum-99 producers who lease LEU from DOE. Because the act would prohibit DOE from using certain existing barter authorities to obtain waste-disposal services in exchange for commercially valuable uranium owned by DOE, CBO believes that any spending to dispose of waste generated under such leases would be subject to the availability of appropriated funds. Based on information from DOE about the relatively small volume of LEU the agency anticipates would be leased under H.R. 3276, CBO expects that resulting quantities of waste would be small. While such costs would be incurred over many years and may reach significant levels over time, CBO estimates that increased costs over the 2010–2015 period would not exceed $500,000 in any year.

DIRECT SPENDING

H.R. 3276 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 act would otherwise generate offsetting receipts totaling about $1 million annually. Because H.R. 3276 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 act would be negligible in any given year.

The act also would require the Secretary to charge lessees a fee to offset the net present value of DOE's anticipated costs to dispose of radioactive waste generated from leased LEU. As discussed above (under "spending subject to appropriation"), CBO expects that such costs would be small and estimates that resulting fees would not exceed $500,000 in any year.

Intergovernmental and private-sector impact: H.R. 3276 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Previous CBO estimate: On October 27, 2009, CBO transmitted a cost estimate for H.R. 3276 as ordered reported by the House Committee on Energy and Commerce on October 21, 2009. The two versions of the legislation are similar, and our estimates of spending over the 2010–2014 period are the same. This estimate of H.R.

3276 as ordered reported by the Senate Committee on Energy and Natural Resources includes anticipated spending in 2015.

Estimate prepared by: Federal Costs: Megan Carroll and Kathleen Gramp; Impact on State, Local, and Tribal Governments: Ryan Miller; Impact on the Private Sector: Sam Wice and 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 H.R. 3276.

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 H.R. 3276.

CONGRESSIONALLY DIRECTED SPENDING

H.R. 3276, 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 H.R. 3276 follows:

STATEMENT OF DR. PARRISH STAPLES, DIRECTOR, OFFICE OF EUROPEAN AND AFRICAN THREAT REDUCTION, GLOBAL THREAT REDUCTION INITIATIVE, 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) efforts to minimize and, where possible, eliminate the use of highly enriched uranium (HEU) in civilian nuclear applications, including in the production of medical radioisotopes. My testimony will include a description of the benefits of the proposed American Medical Isotopes Production Act of 2009, the NNSA's effort to mitigate the impact of the current and anticipated shortages of the medical isotope Molybdenum-99 (Mo-99), and the efforts to accelerate the establishment of a domestic commercial supply of Mo-99 without using HEU.

As described in Section 2 of the American Medical Isotopes Production Act of 2009, Mo-99 is the parent isotope of Technetium-99m, which is used in approximately 50,000 diagnostic medical isotope procedures every day in the United States. It has a very short half life and therefore

cannot be stockpiled. It must be produced on a continuous basis to meet the needs of the medical community, and any interruptions in production can place patients' health at risk if diagnostic tests cannot be performed. Currently, the United States depends entirely on foreign producers for all of its Mo-99, and these producers use highly enriched uranium (HEU) targets to produce this vital medical isotope.

Historically, Mo-99 production processes have utilized the same form of HEU that can be used to produce nuclear weapons and nuclear explosive devices. Underscoring the global recognition of the grave threat posed by HEU falling into the wrong hands, including the risk of terrorists or rogue states acquiring such material, new technical advances in Mo-99 production processes—just as in other civilian applications—are demonstrating that HEU is no longer required. Provisions of this legislation, in particular Section 2, paragraph (11) are aligned with the NNSA's mission to convert or assist in the conversion of research reactors worldwide from the use of HEU-based to LEU fuels and to convert medical isotope production from HEU to non-HEU based production.

The American Medical Isotopes Production Act of 2009 under review by this committee would provide a long-term authorization to address this critical medical need by developing a domestic source of Mo-99 as well as furthering global HEU minimization efforts by ensuring that new domestic supplies of Mo-99 are non HEU-based. The proposed legislation will greatly 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.

The Mo-99 shortages over the last few years are due to both unforeseen and required maintenance to the aging reactors around the world that provide the global supply. In May 2009, the fragile supply chain for Mo-99 was significantly threatened by the unexpected shutdown of the primary supplier for the U.S. due to a serious maintenance concern. In 2010, this unexpected supply interruption will be exacerbated by the required scheduled maintenance of the second largest global supplier. The Office of Science and Technology Policy of the Executive Office of the President is directing an Inter-agency working group, which includes NNSA and other Department of Energy offices, to investigate 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, and prior to the development of new longer-term production capabilities. The current Mo-99 shortages are being mitigated as effectively as possible in the near-term through industry-wide communication, scheduling and more efficient use of available Mo-99 supplies, the application of alternate diagnostic technologies and increased production from all of the global producers. Near-term production and the significant amount of attention focused to address this problem needs to be carefully balanced with other efforts to ensure the

development of a long-term reliable supply of non-HEU based Mo-99. With appropriate Congressional support, the long-term options could be readily achievable and available for steady state production with the objective to create a consistent supply of the medical isotope to health care providers.

The National Academies published a report on January 14, 2009 confirming that the production of Mo-99 without the use of HEU is both technically and economically feasible. It was the National Academies' determination that there are "no technical reasons that adequate quantities [of medical isotopes] cannot be produced" without the use of HEU, and furthermore, that ". . . the greatest single threat to supply reliability is the approaching obsolescence of the aging reactors that large-scale producers utilize to irradiate HEU target to obtain Mo-99." The report positively supports HEU minimization by establishing that it is feasible for global producers to convert to LEU, and identifying the risk to the domestic supply reliability.

To address the longer-term production of Mo-99, NNSA is developing projects to accelerate the establishment of domestic commercial sources of Mo-99 without HEU. To prevent the single point of failure scenario facing today's U.S. Mo-99 supply, NNSA is helping demonstrate the feasibility of non-HEU based Mo-99 production by working with commercial entities and national laboratories on four technology pathways. These include: LEU fission technology; LEU solution reactor technology; neutron capture technology; and accelerator technology. The goal is for each technology to be commercially successful, and NNSA's approach is technology neutral. NNSA is working with the one commercial partner in each of the four areas whose projects on Mo-99 are most advanced for that technical pathway. NNSA also makes available the technical expertise of the U.S. national laboratories gained over many years in the non-HEU based Mo-99 production technologies. The commercialization of these different non-HEU based technologies supports the strategy to diversify the Mo-99 supply and move away from reliance on a sole technology and a limited number of facilities, as is the case with today's foreign producers.

NNSA is planning to spend approximately $20 million in FY 2010 to establish these technologies. Funding would come from within the Global Threat Reduction Initiative budget. As with any major technology initiative, there are challenges that could affect the acceleration of these technologies that must be addressed. We must overcome the technical difficulty involved in extracting the final medical product and processing it into a form that meets Food and Drug Administration (FDA) standards, and doing so steady-state on a commercial scale suitable to meet the needs of the medical community. The production of this valuable commodity is a complex endeavor and lessons learned from two experienced commercial-scale producers that have initiated recent projects to construct new produc-

tion capabilities must be considered to minimize difficulties as we proceed. There are many research reactor operators globally that contend they can produce Mo-99, but we must not underestimate the difficulties to be overcome in the process to provide material at the standards required and on a scale to satisfy global demand. We must maintain our focus on supporting the demonstration of commercial scale Mo-99 production by those few specific entities that are most advanced under the technology-neutral process we have developed. 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.

This legislation will provide the national visibility necessary to address this critical medical need as rapidly as possible and will also achieve important nonproliferation goals. I thank Senator Bingaman and the Committee for your continued leadership by supporting this legislation.

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 H.R. 3276, 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

Act of August 1, 1946, ch. 724, as Amended

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

ATOMIC ENERGY ACT OF 1954

TABLE OF CONTENTS

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; 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.

CHAPTER 11. INTERNATIONAL ACTIVITIES

* * * * * * *

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 ar, 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 pro-

duction to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor.]

(b) 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.

(c) 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.

(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.

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

(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.

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