S. HRG. 112–4

THE AMERICAN MEDICAL ISOTOPES PRODUCTION ACT

HEARING

BEFORE THE

COMMITTEE ON ENERGY AND NATURAL RESOURCES UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

TO

RECEIVE TESTIMONY ON S. 99, THE AMERICAN MEDICAL ISOTOPES PRODUCTION ACT OF 2011

FEBRUARY 1, 2011

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THE AMERICAN MEDICAL ISOTOPES PRODUCTION ACT

TUESDAY, FEBRUARY 1, 2011

U.S. SENATE,
COMMITTEE ON ENERGY AND NATURAL RESOURCES,
Washington, DC.

The committee met, pursuant to notice, 9:59 a.m. in room SD–366, Dirksen Senate Office Building, Hon. Jeff Bingaman, chairman, presiding.

OPENING STATEMENT OF HON. JEFF BINGAMAN, U.S. SENATOR FROM MEXICO

The CHAIRMAN. Why don't we get started. Thank you all for being here. This is a hearing of the Senate Energy and Natural Resources Committee. Let me first, before we get started, welcome Senator Manchin, who has just joined our committee. As other newly assigned members come to the committee, we will certainly welcome them as well. But we'll have our first sort of organizing meeting probably in a week or 2 to discuss committee assignments and all of that.

Today's hearing is on S. 99. That is the American Medical Isotopes Act of 2011. This bill is essentially the same bill that was reported out of this committee last Congress by unanimous consent, except that the program authorization has been lowered by $20 million to account for the fact that we are now in fiscal year 2011.

The purpose of the legislation is to develop a reliable domestic supply of Molybdenum-99, which is used for 18 million, or 85 percent, of the medical isotope procedures performed annually in the United States. We currently have no domestic supply of this isotope and we rely on aging reactors in Canada and Europe to produce it. For the first time, the reactors in Canada and Europe were shut down last July and August for maintenance. That resulted in days when you could not get a Molybdenum-99 procedure.

This bill will correct the problem by authorizing the Department of Energy to work with U.S. companies to produce a reliable domestic supply of Molybdenum-99 in order to avoid a future shortage. The bill also proposes a 14-year phaseout of exporting of highly enriched uranium, which is used to produce these isotopes.

It seems to me that since we're now negotiating with Iran to supply their medical isotope reactor with low enriched fuel, we ought to lead by example and phaseout the export of the weapons-grade uranium to produce these isotopes. The technology exists to produce Molybdenum-99 from low enriched uranium. South Africa and Australia are currently doing so. This bill authorizes the De-

partment of Energy to enter into cooperative agreements and for U.S. companies to do so as well.

I want to thank the witnesses who are appearing today. Two of the witnesses testified on this bill in the last Congress. Dr. Staples, Mr. Brown, I thank you for appearing again today. Ms. Doane is the technical expert from the Nuclear Regulatory Commission, which has submitted formal written comments on the bill. She will not have an opening statement today, but will be at the witness table to answer any questions on how the Nuclear Regulatory Commission manages the export of special nuclear materials such as the highly enriched uranium used to produce Molybdenum-99.

Let me call on Senator Murkowski for any statement she'd like to make.

STATEMENT OF HON. LISA MURKOWSKI, U.S. SENATOR FROM ALASKA

Senator MURKOWSKI. Thank you, Mr. Chairman. It's good to be back at the committee.

I would also like to welcome our new members on your side, Senator Franken and Senator Manchin. I think you will find this is a committee where we jump into the interesting, complex, sometimes contentious issues with great relish, but do so with a degree of civility, honesty, and attention to the work that yields good product. I think you'll enjoy the committee.

We have a handful of new members joining on our side of the aisle. They are Senator Lee, Senator Paul, Senator Coats, Senator Portman, Senator Hoeven. We have a good group of members.

As you point out, Mr. Chairman, our committee has had an opportunity to review the issue of the supply of nuclear medical isotopes, but in fairness to our new members, it is important that we do some reruns. We'll be seeing some of these as we proceed in the early part of this year, but very important issues.

For those of you that are joining us here today, the chairman and I were discussing the new lighting. Apparently, I'm told that we are the first committee room in the Congress to be fully installed with the new LED lights. Of course we like them, because they are more energy efficient, but they do cast a different pall on the rest of you out there.

I do want to thank you for scheduling this hearing.

The CHAIRMAN. Next we're going to see if we can get some heat in the room—our next renovation.

[Laughter.]

Senator MURKOWSKI. One step at a time, sir.

You have given some good background on the issue relating to our domestic supply of nuclear medical isotopes, the fact that we have not had here in this country a domestic supply since 1989. We saw the shortages play out in 2009 and 2010 within our medical communities. I understand that, while the supply currently is meeting a growing demand, the stability and the long-term viability of that supply is in question.

The bill before us seeks to help promote the domestic production of Mo-99 to meet our country's needs. It's been just over a year that we had the hearing on this subject. I look forward to hearing from you, Dr. Staples and Mr. Brown, the progress that has been made

thus far in moving toward a more domestic supply; and also interested in hearing what changes you believe may be needed to the legislation that we discussed last year.

With that, I look forward to the comments.

The CHAIRMAN. All right. Let me also join in welcoming Senator Franken. We're glad he's on the committee and look forward to his active participation.

Dr. Parrish Staples is the Director of the Office of European and African Threat Reduction with the Global Threat Reduction Initiative, Defense Nuclear Nonproliferation, at the National Nuclear Security Administration in the Department of Energy. Mr. Roy Brown is the Senior Director of Federal Affairs with the Council on Radionuclides and Radiopharmaceuticals. We appreciate both of them being here.

Dr. Staples, why don't you start and then Mr. Brown, and then we'll have some questions.

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

Mr. STAPLES. Thank you, Chairman Bingaman, Ranking Member Murkowski, and the other committee members, for the opportunity to testify about the National Nuclear Security Administration's support for accelerating the development of a domestic commercial supply of Molybdenum-99 without using highly enriched uranium. Today I will update you on the testimony provided to this committee in December 2009: first, the nonproliferation and medical benefits of S. 99, the American Medical Isotopes Production Act of 2011; second, NNSA's progress to accelerate the establishment of a non-HEU-based domestic commercial supply of Mo-99; and last, the changing global market conditions that could undermine our efforts for reliable domestic production of non-HEU-based Mo-99.

Currently the United States depends entirely on foreign producers for all of our Mo-99. Of the world's major international suppliers, 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-fueled reactors to low-enriched uranium fuel, has begun LEU-based Mo-99 production.

NNSA frequently meets with the existing major global producers as part of its nuclear nonproliferation agenda to promote the development of a long-term reliable supply of Mo-99 using LEU. 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.

As has been the case in 2009–2010, global shortages can occur with any change in the production schedule of the major producers. Under the leadership of the Office of Science and Technology Policy of the Executive Office of the President, an inter-agency working group which includes NNSA and many others are pursuing actions to minimize these near-term shortages.

The 2009 National Academies report confirmed that production of Mo-99 is both technically and economically feasible. As a result, NNSA is demonstrating the feasibility of non-HEU-based 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, neutron capture, and accelerator-based technologies. 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.

Now, despite the good progress, challenges remain that could obstruct the successful and accelerated establishment of a domestic supply of Mo-99. Just last week I represented the United States at the High-Level Group on Medical Radioisotopes hosted by the Organization for Economic Cooperation and Development's Nuclear Energy Agency. I would like to highlight the following main points of that discussion:

First, there is recognition that the current industry has failed and that both commercial industry and governments cannot become complacent in their actions to reestablish a reliable supply of Mo-99 now that the Canadian and Dutch reactors are once again operational. A primary issue is that the major global producers have been, and generally continue to be, heavily subsidized by their governments. Such subsidies put at risk the economic viability of companies starting up high, tech capital-intensive businesses to produce non-HEU-based Mo-99.

To provide a level playing field for U.S. companies, meet our nonproliferation goals, and build a non-HEU-based industry for Mo-99, 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 also have significant concerns about the scope, cost, and other implications of section 2[c], the Uranium Lease-Takeback provision. In addition, that proposed sub-program could risk lengthening the timeframe to Mo-99 production if the schedule for implementing the proposed Uranium Lease and Takeback sub-program were to have any linkage 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 closely coordinate with the Nuclear Regulatory Commission and the Food and Drug Administration on reliability issues associated with the commercial use of these technologies.

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.

Thank you, Senator Bingaman, Ranking Member Murkowski, and other 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 I'm ready to answer your questions.

[The prepared statement of Mr. Staples follows:]

PREPARED STATEMENT OF PARRISH STAPLES, PH.D., 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 producing 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 Mo-99, 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, 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 linkage 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.

The CHAIRMAN. Thank you very much.
Mr. BROWN.

STATEMENT OF ROY W. BROWN, SENIOR DIRECTOR, FEDERAL AFFAIRS, COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS

Mr. BROWN. Good morning, Mr. Chairman, Ms. Murkowski, members of the committee, and staff. My name is Roy Brown and I'm Senior Director of Federal Affairs for the Council on Radionuclides and Radiopharmaceuticals, or CORAR. I'm representing CORAR here today to testify on behalf of the American Medical Isotopes Act of 2011 and to answer questions from the committee.

CORAR testified before both the Senate and House during the last Congress in support of the proposed predecessor legislation, H.R. 3276. Thus, we support S. 99 and the provisions contained in the legislation. We believe this legislation will provide critical funding, assurance of, and the regulatory framework necessary to establish the reliable medical isotope production capabilities in the U.S. This legislation is an important step toward a reliable source of medical isotopes for our patients and will contribute to enhancing supply well into the future.

In U.S. hospitals and clinics, Technetium-99m, produced from Mo-99, is administered to more than 40,000 patients each day in the detection and staging of cancer, detection of heart disease, detection of thyroid disease, study of the brain and kidney function, and imaging of stress fractures. Thousands of other nuclear medicine procedures are conducted every day in the U.S. with radionuclides, such as I–131, I–125, You-90 and Xenon-133, in the diagnosis and treatment of diseases. These other isotopes are made as a byproduct of the Mo-99 production process. Nuclear medicine procedures not only improve the quality of life, but they save lives. A self-sustaining domestic supply of radionuclides used in nuclear medicine would ensure our patients receive the necessary care while reducing our health care costs.

As a supporter of S. 99, CORAR would like to highlight four specific issues for the committee's consideration to ensure that the bill will accomplish its goals and serve the needs of U.S. patients. First, section 2[c] of the legislation contains an important provision requiring DOE to accept waste created by the production of medical isotopes from the DOE-leased uranium. This provision is important because currently there's no disposal pathway available in the U.S. for the types of radioactive wastes that will be generated in the production of Mo-99 and these other medical isotopes.

It is critically important to the objective of this legislation that DOE accepts such radioactive waste at reasonable prices. These prices should be similar to what we would expect to pay for commercial disposal if commercial disposal waste facilities were available. This will help assure new medical isotope production facilities can be built and operated effectively.

Second, the NRC has a comprehensive regulatory framework for the protection of the environment, workers, and the public. Any new reactor or production facility receiving funding under this legislation will be licensed by the NRC or equivalent Agreement State agency. Various aspects and operations of these facilities will also

be regulated by the Food and Drug Administration, the Department of Transportation, the Environmental Protection Agency, as well as State and local regulatory agencies.

We are concerned that acceptance of money from DOE for the development of medical isotopes for the development of medical isotope capability under this legislation may trigger duplicative nuclear—I'm sorry—National Environmental Policy Act, or NEPA, reviews. With these various levels of regulatory oversight, we do not believe NEPA will offer any more protection of the environment than already provided by NRC, FDA, DOT, and others. The triggering of NEPA by these new production facilities could seriously delay the project, which would not be consistent with the desired schedule and would significantly increase its costs.

The NRC licensing process required for these new facilities is actually a NEPA process. As such, we would like to see NRC as the lead agency in the review to avoid a duplicative regulatory process which would be created by both NRC and EPA conducting their own NEPA review. If the NRC took the lead on this review, these new facilities would be required to pass a rigorous environmental NEPA review by NRC, while still allowing them to meet the time schedule necessary to meet patient demand.

Several groups are working on the development of new types of isotope production reactors or have plans to utilize existing reactors for production of medical isotopes. Some of these reactors may fall into a licensing gap at NRC. These new reactors do not meet the definition of a research reactor under the language in section 4 of the Atomic Energy Act due to their production focus and lack of research being conducted there.

These types of reactors also do not have the inherent risk or security concerns of large commercial nuclear power reactors which are licensed under section 103 of the Atomic Energy Act. CORAR would like to see S. 99 either revise section 104 of the Atomic Energy Act to recognize these types of reactors for the production of medical isotopes or direct the NRC to permit the licensing of these reactors under section 104 of the Atomic Energy Act. If assistance of this type could be included in the legislation, it would help expedite the licensing of these new reactors and bring these new sources of Mo-99 to market more quickly.

Four, CORAR is aware of several promising efforts to develop new medical isotope production technologies. NNSA at DOE has already awarded cooperative grants to a number of projects based on different technological approaches. Given this legislation's intent to broadly serve American patients, future funding should be directed to the project or projects which stand the best chance of producing commercially meaningful quantities of medical isotopes within the timeframe envisioned in this legislation.

We also would like to see the process by which DOE awards development money fully vetted through a regulatory—through a rulemaking or some other process where our industry or other interested parties can review and comment on DOE's proposed evaluation criteria and decisionmaking process for such projects.

I'd like to thank you for the opportunity to testify here today. CORAR is supportive of this legislation and hopes to continue to work with the committee and staff to ensure both a swift and long-

term solution to the medical isotope supply crisis for the benefit of the American patients.

I'd be happy to answer any questions the committee may have. Thank you.

[The prepared statement of Mr. Brown follows:]

PREPARED STATEMENT OF ROY W. BROWN, SENIOR DIRECTOR, FEDERAL AFFAIRS, COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS,

Good morning Mr. Chairman, Ms. Murkowski, members of the Committee and staff.

My name is Roy Brown and I am the Senior Director of Federal Affairs for the Council on Radionuclides & Radiopharmaceuticals, or CORAR[1]. I am representing CORAR here today to testify on behalf of the American Medical Isotopes Act of 2011 and to answer questions from the Committee.

CORAR testified before both the Senate and House during the last Congress in support of the proposed predecessor legislation, H.R. 3276. Thus, we support S. 99 and the provisions contained in the legislation. We believe this legislation will provide critical funding, assurance of, and the regulatory framework necessary to help establish reliable medical isotope production capabilities in the United States. This legislation is an important step towards a reliable source of medical radionuclides for our patients and will contribute to enhancing supply well into the future. In U.S. hospitals and clinics, Tc-99m (produced from Mo-99) is administered to more than 40,000 patients each day in the detection and staging of cancer, detection of heart disease, detection of thyroid disease, study of brain and kidney function, and imaging of stress fractures. Thousands of other nuclear medicine procedures are conducted every day in the U.S. with radionuclides, such as I-131, I-125, Y-90 and Xe-133, in the diagnoses and treatment of diseases. These nuclear medicine procedures not only improve the quality of life, but they save lives. A self-sustaining domestic supply of radionuclides used in nuclear medicine would ensure our patients receive the necessary care while reducing our health care costs.

As a supporter of S. 99, CORAR would like to highlight four specific issues for the Committee's consideration to ensure that the bill will accomplish its goals and serve the needs of U.S. patients:

1. Section 3c of the legislation contains an important provision requiring DOE to accept waste created by the production of medical isotopes from the DOE-leased uranium. This provision is important because currently there is no disposal pathway available in the U.S. for the types of radioactive waste that will be generated in the production of Mo-99 and other medical isotopes. It is critically important to the objective of this legislation that DOE accepts such radioactive waste at reasonable prices. These prices should be similar to what we would expect to pay for commercial disposal, if a commercial waste disposal facility were available. This will help assure new medical isotope production facilities can be built and operated effectively.

2. The NRC has a comprehensive regulatory framework for protection of the environment, workers and the public. Any new reactor or production facility receiving funding under this legislation will be licensed by the NRC or equivalent Agreement State agency. Various aspects and operations of these facilities will also be regulated by the Food & Drug Administration (FDA), Department of Transportation (DOT) and the Environmental Protection Agency (EPA), as well as state and local regulatory agencies. We are concerned that the acceptance of money from DOE for the development of medical isotope capability under this legislation may trigger duplicative National Environmental Policy Act (NEPA) reviews. With these various levels of regulatory oversight, we do not believe NEPA will offer any more protection of the environment than that already provided by NRC, FDA, DOT and others. Triggering of NEPA by one of these new production facilities could serious delay the project and significantly increase its cost. We would like to see a provision in the legislation that any federal money spent on the development of medical isotopes to be exempt from the requirements of NEPA.

[1] The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) is comprised of companies which produce products utilizing many different radionuclides. CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources, and research radionuclides used in the U.S. for diagnostic and therapeutic medical applications and for industrial, environmental and biomedical research and quality control.

3. Several groups are working on the development of new types of isotope production reactors or have plans to utilize existing reactors for production of medical isotopes. Some of these reactors may fall into a licensing gap at the NRC. These new reactors do not meet the definition of a research reactor under the language in Section 104 of the Atomic Energy Act (AEA), due to their production focus and lack of research being conducted. These types of reactors also do not have the inherent risk or security concerns of large commercial nuclear power reactors which are licensed under Section 103 of the AEA. CORAR would like to see S. 99 either revise Section 104 of the AEA to recognize these types of reactors for the production of medical isotopes or direct the NRC to permit the licensing of these reactors under Section 104 of the AEA. If assistance of this type could be included in the legislation, it would help expedite the licensing of these new reactors and bring these new sources of Mo-99 to market more quickly.

4. CORAR is aware of several promising efforts to develop new medical isotope production technologies. DOE/NNSA has already awarded cooperative grants to a number of projects based on different technological approaches. Given the legislation's intent to broadly serve American patients, future funding should be directed to the project or projects which stand the best chance of producing commercially meaningful quantities of medical isotopes within the time frame envisaged in this legislation. We also would like to see the process by which DOE awards development money, fully vetted through a rulemaking or some other process where our industry and other interested parties can review and comment on DOE's proposed evaluation criteria and decision-making process for such projects.

Thank you for the opportunity to testify here today. CORAR is supportive of this legislation, and hopes to continue to work with the Committee and staff to ensure both a swift and long term solution to the medical isotope supply crisis for the benefit of American patients.

I would be happy to answer any questions the Committee may have.

The CHAIRMAN. Thank you both very much.

Let me start with a few questions here. Dr. Staples, let me understand clearly the position that you articulated about this takeback requirement that is in the legislation. Mr. Brown, you've indicated, I think, the first of the four items that you talk about is that it's very important we keep that provision in there and there be some obligation to take this waste back.

I'm just wondering, Dr. Staples, what is your view on that again? You stated it in your testimony, but I wanted to be clear on what it is.

Mr. STAPLES. Our concern is that we cannot anticipate how the Uranium Lease Takeback program for the production of Mo-99 actually would be implemented, and the legislation does not provide funding for that new service. If directed to do so, we would develop an approach that considers the goal of developing a sustainable commercial enterprise with thorough diligence for responsible and safe materials management. We recognize the importance of meeting those program objectives, but we do require further guidance and want to be ensured that the sub-program, the Uranium Lease Takeback program, is not linked to the production of medical isotopes, just to ensure the timely development of isotopes for the medical community.

The CHAIRMAN. We may need to look at that language and be sure that it meets the requirement that at the same time there is an obligation, which Mr. Brown has indicated is very important.

On the question of how we ensure that the cost of the Molybdenum-99 that U.S. companies are producing or supplying will be competitive with that that we obtain overseas, Dr. Staples, what's your view on that?

Mr. STAPLES. We are concerned about that. We are concerned, in fact, of the subsidies provided for the current industry, of how they produce the medical isotope, and that our U.S. companies will be undercut in the commercial market by foreign producers that are heavily subsidized by their governments. This is a serious challenge facing the fragile Mo-99 market and in order to ensure reliable supply we want to ask that a level playing field for all companies be provided, with full cost recovery across the global market.

This actually is an issue that's been under discussion with all participants, both the suppliers and the customers, at the recent Nuclear Energy Agency meeting of the High-Level Group for Medical Radioisotope production. So it is recognized to be a concern throughout the industry for the long-term reliability of isotope supply of Mo-99 for the medical community, while at the same time we can achieve the nonproliferation objectives by using non-HEU-based production technologies.

The CHAIRMAN. Mr. Brown, do you have a concern about this problem of the cost that U.S. companies would incur being undercut essentially by competition from overseas?

Mr. BROWN. As I said in my testimony, we're concerned that the waste takeback provision—that the cost we pay per cubic yard of waste to dispose of to DOE would be done at reasonable prices. We wouldn't want to pay exorbitant prices that would throw the economics of any isotope production off. So what we're asking for is a reasonable commercial rate for waste disposal.

The CHAIRMAN. But you think with that, with a reasonable commercial rate for waste disposal, U.S. companies would be able to compete?

Mr. BROWN. We feel we could, yes.

The CHAIRMAN. All right. Let me ask one other question, Dr. Staples, about what actions the Department is working on to move the Russians to produce Molybdenum-99 with low-enriched uranium.

Mr. STAPLES. Yes. Recently, there were several press releases that came out about a supply being developed in Russia that was utilizing highly enriched uranium for the production of Mo-99. We intend to raise this issue at very high levels in meetings with various Rosatom officials, such as Director Kiriyenko, to dissuade Russia from the use of HEU, to ensure that their actions are consistent with their Presidential-level commitments that they have made at the April 2010 Nuclear Security Summit to minimize and, where possible, eliminate the use of HEU in civilian activities.

The CHAIRMAN. Let me ask you one other question, Mr. Brown. Does your council currently see supply meeting U.S. demand for Molybdenum-99 or do you expect additional shortfalls in the near future?

Mr. BROWN. We are encouraged by some of the new efforts that are under way. We're very encouraged by some of the development work, the cooperative grants that DOE has issued for some new development facilities. We do see some bumps in the road coming out in the future. We hope to have these new facilities up and running to minimize any impact of that. But we're encouraged by the development work that's going on now.

The CHAIRMAN. You're not alarmed by the prospect of shortfalls in the near future?

Mr. BROWN. There may be some shortfalls in the future, but we're encouraged by the development activities that are under way to make up for those.

The CHAIRMAN. All right.

Senator MURKOWSKI. Just to follow onto that, given the legislation that we have in front of us, do you feel relatively comfortable that this will help us avoid those bumps in the road? Is this the level of assurance that you need if we can resolve the issue, for instance, with the takeback and some of the other issues you raised?

Mr. BROWN. This legislation will be very helpful to assuring the long-term supply of medical isotopes in the U.S. It sends us well on our way to developing a domestic supply, too, with the development money put in there for DOE to issue additional development grants.

The CHAIRMAN. Let me ask, what currently happens to the waste product from a highly enriched uranium target? Where is the disposal? Where is it? What does it look like?

Mr. STAPLES. It's stored, typically onsite at the four major global producers, in a variety of waste forms, under physical protection standards that meet IAEA protocol under 255 Rev. 4, which is the guidelines for physical protection for such nuclear materials.

Senator MURKOWSKI. We had a discussion about the low enriched uranium. Is there more residual waste product from LEU as opposed to highly enriched uranium?

Mr. STAPLES. In a simplistic conversion process from HEU to LEU where they would simply use a low enriched uranium target in place of a high enriched uranium target, yes, there would be additional waste that would be generated.

Senator MURKOWSKI. That becomes a significant factor in terms of how we deal with the disposal and how we deal with the waste?

Mr. STAPLES. Disposition of waste in the nuclear industry is always expensive and complicated. However, the isotope production industry actually is not significantly large, that it would be a reasonable and addressable amount of waste that would be produced, be it from HEU or LEU. We are developing in our program, options to minimize the amount of waste produced and in some cases—and this is what the National Academies study validated, that we do have some technologies available that could actually reduce the volumes of waste that are produced with LEU-based production.

Senator MURKOWSKI. Given the current world production levels, how long does it take to accumulate enough of the radioactive waste product that's left over to really pose a proliferation risk?

Mr. STAPLES. Currently on a global basis approximately 40 to 50 kilograms of highly enriched uranium is used by the total global community for isotope production, which according to the IAEA definition of a "significant quantity" is roughly two significant quantities of nuclear material per year that is being accumulated by the current global production using highly enriched uranium.

Senator MURKOWSKI. The question has been raised by some in industry as to whether or not the legislation is technology-neutral. Can either one of you speak to that?

Mr. STAPLES. Yes, I can address that first, and then if Mr. Brown would like to follow. That is part of the strategy behind developing multiple technologies to ensure that we do not have a single point

of failure. That is actually a common term of reference that we use, that we are technology-neutral with the neutron capture, the accelerator-based, and the solution reactor technologies not having any linkage to one of the other technologies, to ensure that we can be successful in implementation of the program.

Senator MURKOWSKI. Mr. Brown, it's technology-neutral in your opinion?

Mr. BROWN. Yes. So far we've seen DOE give development grants or cooperative grants to several different types of technologies. So far their doling out of money has been very fair across the board. One thing we would like to see, we would like to avoid giving out, supporting many, many, many different efforts at one time, some of which may not bear any fruit. We would rather see a focus on just a few areas that look more promising. So far, DOE has been doing a good job, we feel, giving out the development grants.

Senator MURKOWSKI. Here in the United States, where do we currently export our highly enriched uranium to for medical isotope production?

Mr. STAPLES. Currently, we only export our HEU to Canada for the production of medical isotopes.

Senator MURKOWSKI. Just to Canada then. Where do the other reactors that provide the U.S. with the Mo-99, where do they get their HEU?

Mr. STAPLES. The European reactors use European-obligated material, which is inside the European Community's control. Then South Africa utilizes indigenous material for their production of isotope, although as they transition to low-enriched uranium production they are receiving some low enriched uranium from the U.S. for this production process.

Senator MURKOWSKI. Ms. Doane.

STATEMENT OF MARGARET M. DOANE, DIRECTOR, OFFICE OF INTERNATIONAL PROGRAMS, NUCLEAR REGULATORY COMMISSION

Ms. DOANE. We do provide—that's with respect to targets, but for HEU fuel there are HEU exports to the European reactors, to The Netherlands, to Belgium. We have a current application pending for France.

[The prepared statement of Ms. Doane follows:]

PREPARED STATEMENT OF MARGARET M. DOANE, DIRECTOR, OFFICE OF INTERNATIONAL PROGRAMS, NUCLEAR REGULATORY COMMISSION

Mr. Chairman and Members of the Committee on Energy and Natural Resources, thank you for inviting me to participate in this hearing today. As Director of the Nuclear Regulatory Commission's (NRC) Office of International Programs, I am pleased to have this opportunity to discuss NRC's licensing requirements for the exportation of highly enriched uranium (HEU) for the production of medical isotopes. My focus today will be on NRC's regulatory framework for licensing the export of HEU.

Framework for the Export of HEU

I want to describe the NRC's process in detail so that the Committee on Energy and Natural Resources has an understanding of the framework in which the export of HEU from the United States is taking place. The Atomic Energy Act of 1954, as amended, (AEA) grants the NRC exclusive jurisdiction to license civilian exports and imports of source, special nuclear, and byproduct materials to and from the United States. The NRC's regulations governing such exports and imports are set

forth in Title 10 of the Code of Federal Regulations, Part 110, "Export and Import of Nuclear Equipment and Material."

Since 2005, the NRC has licensed seven exports of HEU to Canada and Belgium for fabrication of fuel or targets for the production of medical isotopes. The export licenses to Belgium authorized export of HEU for fabrication of fuel for reactors that produce, among other things, medical isotopes and the export licenses to Canada authorized HEU as targets or for the fabrication of targets that are used in the National Research Universal (NRU) reactor for the production of medical isotopes. Of the seven licenses issued since 2005, there is only one active license. Currently, there are two pending applications from Canada and France for the export of HEU. For additional information on HEU export licenses issued by the NRC since 1992, please see the attached table.*

Prior to issuing a license for the export of HEU for the production of medical isotopes, the NRC works closely with the Executive Branch to ensure that the export is consistent with applicable U.S. non-proliferation laws and policies and is not otherwise inimical to the common defense and security of the United States. HEU may only be exported to countries that have in place an agreement for cooperation with the United States in accordance with section 123 of the AEA. These agreements set out the broad framework under which exports such as this may be authorized.

Even when the United States has in place an agreement for cooperation with a country, the Commission must determine, on a case-by-case basis, whether an individual export to that country meets the applicable export licensing criteria in Sections 127 and 128 of the AEA, as codified in the Commission regulations at 10 CFR § 110.42(a). Based on its evaluation, the NRC may impose additional requirements as conditions to the export license.

Among other criteria, section 110.42(a)(3) requires the NRC to evaluate the adequacy of the physical protection measures in the country requesting the HEU. The physical protection guidelines are established by the International Atomic Energy Agency and are published in INFCIRC/225/Rev. 4, June 1999, "The Physical Protection of Nuclear Material and Nuclear Facilities." The NRC participates in U.S. government physical protection bilateral visits to countries requesting HEU to confirm that the country's implementation of physical protection methods and procedures for U.S.-origin HEU is consistent with these international guidelines. The delegations conducting the physical protection visits include staff from the NRC; National Nuclear Security Administration (NNSA); Department of Energy (DOE); Department of State; and Department of Defense.

Any licensee authorized to export HEU is responsible for compliance with all applicable requirements of Title 10 of the Code of Federal Regulations, including NRC's regulations related to transportation and packaging. Since 2005, all transportation of HEU has been conducted by DOE's Office of Secure Transportation in accordance with the DOE requirements and directives. These measures meet and exceed NRC's and Department of Transportation regulations in this area.

For all HEU export license applications, the NRC would, as it did for each of the seven prior HEU applications, request the Executive Branch's judgment on the proposed export, including whether the proposed export would be inimical to the common defense and security of the United States or otherwise significant for nuclear explosive purposes, and whether the export would comply with the terms of the applicable agreement for cooperation. In the seven prior cases, the Executive Branch determined that the export would not be inimical to the common defense and security, would take place pursuant to the applicable agreement for cooperation, and were consistent with the provisions of the AEA.

In the Energy Policy Act of 1992, Congress amended the AEA to require the NRC to adopt additional, more stringent criteria specifically for licensing exports of HEU. These criteria were designed to discourage the use of HEU and encourage the development and use of low-enriched uranium alternatives. Under Section 134 of the AEA, the NRC may issue a license for the export of HEU to be used as a fuel or target in a nuclear research or test reactor only if, in addition to meeting the other AEA requirements for exports of special nuclear material, the NRC determines that:

> (1) There is no alternative nuclear reactor fuel or target enriched to a lesser percent than the proposed export that can be used in the foreign reactor;
>
> (2) The proposed recipient of the 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 HEU; and
>
> (3) The U.S. Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.

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*Table has been retained in committee files.

More recently, in the Energy Policy Act of 2005, Congress further amended the AEA by adding a new section 134b., "Medical Isotope Production," in which Congress continued to encourage the eventual end of reliance on HEU targets in the production of medical radioisotopes. In the new AEA section 134b., Congress lifted certain restrictions on exports of HEU to Canada, France, Belgium, Germany, and The Netherlands for the production of medical radioisotopes if the recipient country supplies an assurance letter to the United States that the HEU will be used solely for medical isotope production, and if the NRC determines that the HEU will only be irradiated in a reactor that uses alternative fuel or is the subject of an agreement with the United States to convert to alternative fuel when such fuel can be used in the reactor.

The NRC is mindful of the importance of the supply of medical isotopes for diagnostic and therapeutic medical procedures. Therefore, the NRC carries out this export licensing regime in an efficient and effective manner. Our regulations require notice of the application to the public and the opportunity to request a hearing on whether the export is consistent with our regulations. We also accept and review written comments even when a hearing is not requested. Once the various views are obtained, we then reach a carefully considered decision in accordance with nonproliferation policies, laws and regulations.

Conclusion

The NRC's exclusive jurisdiction to authorize the export HEU for production of radio pharmaceuticals for diagnostic and therapeutic procedures is regulatory in nature and exercised only in accordance with the statutory framework and Congressional policies established in the Atomic Energy Act. In carrying out its regulatory responsibilities, the NRC works effectively with the Executive Branch, the recipient countries, the public, exporters and importers to assure the exports will not be inimical to the common defense and security and are consistent with policies to use alternatives to HEU when appropriate.

Again, I appreciate the opportunity to participate today and look forward to answering any questions the Committee may have.

Senator MURKOWSKI. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Manchin.

Senator MANCHIN. Thank you, Mr. Chairman.

First of all, let me just say that it's a pleasure and an honor to be on the committee, and I appreciate it very much. It's very meaningful for my State of West Virginia to be on the Energy Committee, and I'm sure we're going to have some interesting times and I look forward to it. I truly believe that the security of the Nation depends on the independence that we have in our production of energy, from every State doing everything they can.

So I look forward to working with you, Mr. Chairman and Senator Murkowski and the entire committee, for that.

Sir, if I may, trying to get up to speed and being the new kid on the block, but learning a little bit about this, I would just simply ask, what are the implications if we don't pass this legislation, if something for whatever reason—I know it got caught up in the 111th Congress. I don't think that's going to happen, but if it would what would be the scenario for you?

Mr. STAPLES. There are two implications that are really driven by this legislation. One is the nuclear security implications of how we as a government are trying to address HEU minimization for threat reduction. That's actually—our commitment is consistent with the pledge that was made by the leaders at the Nuclear Security Summit in April 2010.

Further implications are for the reliable supply of medical isotopes to the U.S. community. There are indications that the Canadian reactor, the NRU, where they currently produce Mol-99, the bulk of which is used here in the United States, will cease operations in the 2016 timeframe. At that point, our supply of medical

isotopes is at serious risk for providing the various procedures that Mr. Brown alluded to recently, which is primarily the diagnosis of heart disease and then various other operations or activities that are performed.

Senator MANCHIN. You had—in 2009 the National Academy of Science reported it found that the use of highly enriched uranium in the production of medical isotopes could be phased out and replaced by low enriched uranium by the 2016 to 2020 timetable. You don't think that can be met?

Mr. STAPLES. No, we do believe that we can address that concern. I have a significant amount of confidence in the activities that we are putting in place to develop these cooperative agreements with our commercial partners for reliable isotope supply, and we also have a significant amount of confidence to be able to transition the international producers to an LEU-based Mo-99.

Senator MANCHIN. So the elimination from Canada will not cause a problem in the United States?

Mr. STAPLES. If we are successful with developing our domestic cooperative agreements, that will be the replacement production capacity that the global medical community would require to maintain providing their services.

Senator MANCHIN. What are the potential consequences to any of you there if it falls into the wrong hands, as far as our production?

Mr. STAPLES. I believe that you're referring to the use of the highly enriched uranium?

Senator MANCHIN. Yes, correct.

Mr. STAPLES. Highly enriched uranium can be used by either terrorists or rogue states to construct an improvised nuclear device.

Senator MANCHIN. Has there been any breach of that at all or any indication that that might be what they're trying to acquire, or do we have security checks in place to take care of that?

Mr. STAPLES. I probably would like to take that question for the record and get back to you, just to make sure that I am properly attributing all of the events that might or might not have taken place.

[The information referred to follows:]

From the NNSA perspective, we are unaware of any indication of diversions of HEU from the Mo-99 production process.

Senator MANCHIN. So we don't have any reported incidents where that's been breached?

Mr. STAPLES. I am not positive of any definite activity that has taken place related to Mo-99 isotope production and highly enriched uranium.

Senator MANCHIN. Thank you.

The CHAIRMAN. Senator Burr.

Senator BURR. Thank you, Mr. Chairman, and I thank you and Senator Murkowski for calling this hearing and for introducing the legislation.

I think over the last several years, Mr. Brown, we have had a supply interruption affecting not just cancer patients, but all patients. I want to sort of go where Senator Manchin was and let you sort of take that and run.

Dr. Staples' comment alarmed me greatly. He said: If we are successful. OK, let's approach it from another angle. If we're not suc-

cessful, if the legislation is delayed, if we don't get the robust participation, if we can't find the private sector agreements, if the NRC doesn't license, and if production doesn't run on time, what happens to patients? I don't think they're sending us signs. Canada's going to shut down in 2016.

Mr. BROWN. It's clear, coming from Canada, they do plan on, from what we understand, re-licensing the NRU in 2011 for another 5 years, which will terminate in 2016. So that's pretty clear.

We are very encouraged by the development activities that are under way now. There are several different private concerns looking at new technologies and new methodologies, new production facilities for Mo-99. So we're very encouraged by that.

This legislation is very important because it helps us develop a domestic supply of Mo-99.

Senator BURR. But if we don't have Mo-99, if we have an undersupply or no supply, what does that do to patient care?

Senator BURR. It's used in 18 million procedures a year in the U.S. Every year, 18 million procedures. We did see shortages, as you know, in 2010 and it was impacted. Some hospitals were impacted by the shortage of Mo-99 and Technetium-99, so it did have an impact. Other technologies were employed. Other isotopes were used, for example Thalium-201 for stress tests, for heart imaging. Thalium-201 was used instead of Technetium-99m. In some cases Fluorine-18 was used instead of Technetium-99m. In some cases other technologies, ultrasound, was used. Echo cardiography was used in place of Technetium. So there are other technologies.

Senator BURR. If all those techniques, if all those tools were as good as Mo-99, we'd use them today.

Mr. BROWN. You're right. It's clear that Technetium-99m is the preferred method. It collects more diagnostic information. It's better quality information and it's cheaper.

Senator BURR. Over the long run it costs less in the health care system. So we're talking about health care cost reduction.

Mr. BROWN. You're absolutely right.

Senator BURR. Let me ask you. You talked about the waste stream. What is a reasonable price?

Mr. BROWN. I don't have that number off the top of my head. We can get back to you on that. What we're looking for is just we don't want to pay an exorbitant amount that would throw the economics of any new production facility off. We can get together with an answer on that.

Senator BURR. Let me suggest to you that that's an important number to know, and it goes to the heart of what you said, Dr. Staples, that there has been talk, if I understood you correctly, that everybody globally would be guaranteed cost recovery, that all producers would be guaranteed cost recovery. How do we calculate what that is?

Mr. STAPLES. In operating in the commercial industry, the issue now is that governments are providing various subsidies for their operations. Either the facilities are using facilities that were initiated through government construction and then they have transferred over to commercial activity, so they're fully amortized in terms of government funds rather than through the commercial ac-

tivities; or waste disposition is provided for some of the activities that take place with the commercial producers.

What we are discussing at the OECD meetings and the Nuclear Energy Agency is how to implement a full cost recovery for all of the commercial activities that are undertaken in this industry to ensure that they can develop and maintain their production as they would move into the future and that there is no—that there is no oversupply generated in the market, either, from any one entity that might be heavily subsidized and be able to prevent the introduction of another commercial activity from another country.

Senator BURR. Two things. In the past the Department of Energy has asked companies to commit to facilities that can provide approximately 50 percent of the U.S. market demand for medical isotopes. I would suggest to you this could lead to a substantial oversupply in the market if all current suppliers provided 50 percent of the market.

I guess I would ask, if we changed that word to "significant" versus "50 percent" would that be sufficient and would it eliminate the risk of oversupply?

Mr. STAPLES. It could eliminate the risk of oversupply. That's a very important point that you're making. As I stated before in the response with the likelihood of the Canadian reactor ceasing production in 2016, it's the importance that what we are developing in the United States would be replacement production capacity to complement the other production that takes place in the international market.

There are significant dynamic forces at play in the global isotope production community and this is what we are trying to coordinate when we work with OECD to ensure that we can have reliable replacement supply. A significant amount of overcapacity is also required because of the manner in which the isotope is produced in reactors which regularly go through maintenance shutdowns and other periods, to ensure that, while we can maintain a minimum level, the overcapacity does need to be maintained within the industry to ensure that we always have the supply for the medical community.

Senator BURR. Let me just raise for my colleagues this personal observation. When I see a marketplace that is going to be coordinated on reimbursement, government influence from the standpoint of cost calculations, I begin to see a marketplace that doesn't attract private dollars. I think what we're trying to set up in the United States is the injection of private capital to do this, though with the incentive of grants from the U.S. Government.

So let me just say, we ought to be particularly careful that the net result of this is that we don't create something globally that is dominated by government, that takes the health care cost advantages that we have today and raises the cost precipitously to where new technologies for the delivery of care are not developed. I think at the same time you have to consider that 10 years ago we didn't use as many procedures, didn't use this. 10 years from now there may be many more procedures that utilize this. The supply needs may be much greater.

Mr. Chairman, could I ask one question of Ms. "DOWN"?

Ms. DOANE. Yes, "DOANE."

Senator BURR. "DOANE."

I guess my question is this. What's a reasonable timeframe for licensing and production, because the NRC is going to have to license, right?

Ms. DOANE. Yes. I think we've answered—when we answer these questions, typically we say: Of course, it depends on the application.

Senator BURR. No, but let me just state this. There is the health of the American people at play here. So going into this we've got to have some certainty as to what the time line is for licensing.

Then I'll turn to Mr. Brown as an industry person later on and say: Can you make the production capabilities? But if the NRC delays licensing, it doesn't matter how good we do from the standpoint of the NNSA or from DOE or from the industry; this isn't going to happen. We're going to have a gap.

Ms. DOANE. No, understandably. I think that we do understand the importance of licensing these production facilities and we have started pre-licensing review. I can't today give you an exact timeframe because the concepts are not completely developed yet.

Senator BURR. There are no applications yet.

Ms. DOANE. There are no applications. But I can tell you that we are taking it seriously. We're doing a lot of pre-application work and trying to establish processes that—we have processes in place, but actually standards and procedures that will help the proceedings run more smoothly.

Senator BURR. What prescriptive legislation—what prescriptive language needs to be in this legislation to encourage the NRC to license new technologies that may be on the horizon that may not be the standard generation of LEUs today that NRC might be familiar with?

Ms. DOANE. It would be my opinion we don't need new legislation because our legislation—we have broad discretion to license new technologies. You can imagine with new reactors, for example, we're doing all kinds of new types of technology. I think we do have—I can take this back and ask the lawyers, but I think for now we have broad discretion and it's just a matter of setting up the guidelines and the procedures as we get the applications in.

Senator BURR. The chairman's been awfully lenient with me and the only thing that I would say in concluding is that on the electric generation side there has been technology breakthroughs on smaller, compact nuclear generation units that have not been received warmly at the NRC because they're new. Now, I'm not going to tell you that there are applications that are out there, but there are technologies that are advancing and certainly things that show promise. Yet from a regulatory standpoint they don't seem to be moving with the progress that one would like.

I only hope that that's not the case with new technologies as it relates to the LEU market and the production that we need.

Mr. Chairman, I thank you.

The CHAIRMAN. I would just make the point, I think I'm right that there are no applications for these small modular nuclear reactors, either.

Ms. DOANE. No. But we are doing, again, a lot of prelicensing work to make that run efficiently when we do.

The CHAIRMAN. Senator Franken.

Senator FRANKEN. Thank you, Mr. Chairman, and thank you, Senator Murkowski, the ranking member, for welcoming me earlier.

I apologize; I'm kind of jumping between this and the Judiciary Committee hearing. I did read your testimonies last night, but I did miss your oral testimonies today. So forgive me if I ask a question that you've already covered.

I just want to say what an honor it is to be on this committee. It's so clear that energy is central to so many critical issues, the economy, our national security, the future of the planet, just those things.

This is a question for pretty much any of you, probably—for any of you: What is the global buy-in on going to low enriched uranium to make Mo-99, as opposed to highly enriched uranium? In other words, are the other nations that produce this, are they also going to be going to low enriched uranium?

Mr. STAPLES. I can follow on. That again refers back to the discussions we just had last week at the OECD conference on medical isotope production. We also do discuss the issue of conversion of their facilities to low enriched uranium. As I mentioned, the South Africans have already begun converting their process over to LEU and in December provided the first LEU shipment for commercial distribution here to the United States.

We are in discussions both with the Dutch and the Belgians about converting their processes. They have made statements that they are working in that direction. However, they do want to be assured that while they work toward conversion toward LEU that they don't impinge upon their ability to supply isotopes to the market today, because their production facilities have limited resources and they need to carefully manage how we work the conversion program at their facilities while they maintain the production capacity that's required for the medical community.

Senator FRANKEN. Mr. Brown, you just nodded.

Mr. BROWN. I would have to agree. I think there is general concurrence of the need to move from HEU to LEU. CORAR is certainly supportive of that, the philosophy in that bill, in the bill here.

Senator FRANKEN. Let me ask you then about Iran, because Iran is our probably biggest proliferation concern. In 2009 we came close to a confidence-building deal with Iran. Iran would ship its low enriched uranium out of the country; in return it would receive the fuel it needed for a research reactor that produces medical isotopes. But Iran backed out of the deal and now it's claiming that it needs more highly—to enrich more uranium to be highly enriched uranium for the purpose of producing medical isotopes.

So my question is, if we move toward eliminating the use of highly enriched uranium in the production of medical isotopes, would that help to undercut the argument that Iran has and potentially other proliferators might make, that it needs to enrich its low enriched uranium more highly for medical purposes?

Mr. STAPLES. Let me respond to that. I would say yes. Our efforts, in addition to the 2009 National Academies study, Mo-99 production efforts by countries such as South Africa, Australia, and

Argentina, and a recent IAEA-coordinated research project for indigenous production of Mo-99 without the use of HEU have all demonstrated that highly enriched uranium is not needed for medical isotope production.

In fact, there's really no economic justification and very little technical justification for every country to produce its own enriched uranium for medical isotope production. The international commercial supply of LEU for medical isotope production is more than sufficient to meet the needs of the global medical community.

So the global shortage that we face is primarily due to the limited large-scale processing facilities to take the irradiated targets and turn them into the medical commodity that's used by the community.

Senator FRANKEN. So presumably we could—I mean, our arguments with Iran don't necessarily prevail, but we can make the argument to them that they don't need highly enriched uranium to make these medical isotopes?

Mr. STAPLES. That is correct.

Senator FRANKEN. OK. Since my time is up, thank you.

The CHAIRMAN. If you have any other questions, go right ahead. Nobody here but us chickens. We're about to finish the hearing, so go ahead.

Senator FRANKEN. I've got some chickens over at the Judiciary that I've got to go see.

The CHAIRMAN. All right. Thank you very much. Thanks for your very good questions.

Senator Murkowski, did you have additional questions?

Senator MURKOWSKI. Just a couple quick ones.

Mr. Brown, you mentioned the issue of NEPA review and further environmental analysis being something that could potentially delay the process. In addition to Senator Burr's good questions about the regulatory process, I think we recognize when we talk about bumps in the road or things that could be a problem, certainly I think when you interject the unknown morass of regulation or something like NEPA which is difficult to project.

Dr. Staples, please provide your comments about the potential for delay with additional environmental assessment?

Mr. STAPLES. We have been evaluating that process significantly to make sure that we can be successful with our technology-neutral activities. In some cases we do require significant NRC licensing approval for operation. Some of the other technologies have different NRC licensing requirements, such as the accelerator-based technology, which is essentially non-nuclear and utilizes no uranium for the production of medical isotopes.

But regarding the NEPA, we have been in close contact with the Nuclear Regulatory Commission also, to coordinate our NEPA approaches to ensure that we do not have any duplicate processes and that we meet our NEPA obligations as a government and that we do this in the most efficient manner so that we can ensure the accelerated production of Mo-99 for the United States.

Senator MURKOWSKI. You don't view a NEPA review as being duplicative of the other reviews that are currently in place?

Mr. STAPLES. We need to fulfill that obligation and we are working closely to coordinate our efforts with the NRC to accomplish that.

Senator MURKOWSKI. Is there something that we should or should not include in this legislation that would speak to that as an issue?

Mr. STAPLES. I would actually like to take that as a question for the record, because we have put considerable thought into that and I don't think I could do full justice to the response here on the floor.

The information referred to follows:]

To ensure that NNSA's effort is in compliance with the National Environmental Policy Act (NEPA), GTRI is currently proceeding through the required NEPA approval process within the U.S. Department of Energy. The Nuclear Regulatory Commission (NRC) has NEPA requirements for the licensing process, and GTRI has been coordinating with the NRC in order to avoid any duplication of nEPA analysis efforts. We have recognized the potential for this risk to the schedule of the domestic production projects and are working to implement the required procedures while maintaining our accelerated schedule to produce Mo-99 for the U.S. medical community.

After a preliminary technical review of the various candidate technologies to enable the domestic production of Mo-99 within FY10-FY14, important schedule risks and mitigation strategies have been identified. Among the most important of the schedule risks is the obligation to prepare analyses to fulfill the Department's NEPA obligations. In order to mitigate the schedule risk NEPA requirements pose to achieving domestic production within the timeframe of this legislation, high-level political support to expedite all NEPA analyses is necessary.

Senator MURKOWSKI. I would appreciate that.

Let me ask a question just in terms of deliverability and how we move things, recognizing that it has a pretty short lifespan or shelf life, as it relates to the medical isotopes. What happens when you have an incident like we had in Europe with the eruption of the volcano that shut down air traffic for days, a week in certain areas?

We talk about putting a process in place that is going to make sure that we have a good supply. But if we can't stockpile, how do we respond to disruptions like we've seen?

Mr. STAPLES. That speaks perfectly to the point of developing a diverse, reliable supply with very few single points of failure and trying to disseminate the production globally to ensure that any one regional event does not impact the global medical community.

Senator MURKOWSKI. But right now, because you have so much production centered in Europe, you have a stumbling block if something happens.

Mr. STAPLES. Yes. During the volcanic eruptions I do have the impression and understanding that we were impacted in terms of our supply of isotope for some periods of time.

Senator MURKOWSKI. The U.S. was?

Mr. STAPLES. Yes.

Senator MURKOWSKI. I would assume——

Mr. STAPLES. Europe.

Senator MURKOWSKI. Europe and beyond; would it not be?

Mr. STAPLES. Yes.

Senator MURKOWSKI. So at this point in time, we don't have an answer in place as to how to respond.

Mr. STAPLES. No. That's actually why your committee's support for this legislation is very important. We've mentioned last week at

the OECD meeting not to become complacent as a community as we try to address that. Your continued support with this legislation will give us the motivation and the impetus to work with the commercial industry to ensure that we develop solutions as best as possible for the isotope supply.

Senator MURKOWSKI. Mr. Brown.

Mr. BROWN. This legislation also encourages developing of a domestic supply here in the U.S., where if there is another volcano we don't have to worry about flying planes from Europe to the U.S. If we're producing it here locally and have a domestic supply, obviously volcanoes in Iceland wouldn't be a problem. So that's why we're encouraged by this legislation. We think it would help encourage domestic supply.

Senator MURKOWSKI. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

I didn't have any additional questions. Senator Manchin, did you have additional questions?

Senator MANCHIN. I just want to thank you all so much, and the concern that you have and bringing it to our attention. I want to thank the chairman and Senator Murkowski for being so diligent on this issue, and I hope to see that we move quickly on it.

The CHAIRMAN. I think that sums up my views as well. I hope we are able to move quickly on this legislation. Again, I thank all three of you for being here to give us your views, and we will conclude the hearing.

[Whereupon, at 10:54 a.m., the hearing was adjourned.]

APPENDIXES

APPENDIX I

Responses to Additional Questions

RESPONSES OF ROY W. BROWN TO QUESTIONS FROM SENATOR BINGAMAN

Question 1. Can you please explain in more detail how CORAR would determine what it means by a reasonable fee for the fuel take provision in this legislation?

Answer. A contract with DOE to accept the High Level Waste produced as a result of Mo-99 and other medical isotope production is critical. Under S. 99 the uranium would be leased from DOE and taken back. The legislation doesn't appear to determine whether the waste taken back is a commodity or a waste when received by DOE. How DOE categorizes the "waste" is not that important, unless it makes a difference in the "reasonable fee". While industry expects to pay for the waste disposal, we also cannot afford a heavy burden in the form of fees to take back the waste. A DOE program similar to what they do for research reactors might be a model—assuming the cost of providing and taking back uranium is reasonable. A High Level Waste fund, similar to what commercial power reactors have with their standard contracts, would be unworkable. CORAR recommends DOE charges a fee for this waste disposal that would be comparable to what commercial fees would be, if commercial waste disposal for this type of waste were available.

Question 2. Do you see Positron Emission Tomography as a cost effective replacement to Molybdenum-99?

Answer. Positron Emission Tomography (PET) is an emerging technology that provides a complementary option for imaging certain types of tumors and staging cancer. It currently provide approximately 2 million imaging procedures each year in the U.S. compared to approximately 17 million using Tc-99m from Mo-99. It is more expensive than comparable Tc-99m studies, even though the cost for PET scans has steadily decreased over the last ten years. PET currently accounts for a small amount of myocardial perfusion imaging studies (including through use of rubidium-82 generators). F-18 based PET (half life of 110 minutes, as opposed to 70 seconds for rubidium-82) for myocardial perfusion imaging will not become commercially available for at least a few more years. PET is currently more expensive than SPECT, but given the higher quality images, increased diagnostic certainty and potential for blood flow quantification with PET, even at a higher per procedure price, F-18 based PET could rapidly become a cost effective alternative to SPECT in a number of different contexts. Currently, PET is viewed to be complementary rather than a replacement for Tc-99m.

Question 3. In CORAR's opinion what technology do you see as the quickest to market for domestically producing Molybdenum-99?

Answer. There are several new technologies being examined for the production of Mo-99. The traditional methodology entails fissioning U-235 with neutrons for the production of Mo-99 and other medical isotopes. Other technologies being examined include neutron capture using Mo-98, accelerator production of Mo-99 using Mo-100 targets, and production of Tc-99m using a proton beam from an accelerator onto a Mo-100 target. The use of aqueous homogenous reactors, which have cost and waste reduction attributes, is also being developed. Many of these new technologies are being developed simultaneously. It is not clear yet which of these new technologies will lead to the most efficient production of Mo-99 with the shortest development time. For that reason CORAR feels it is important to promote all credible technologies on parallel paths and allow the most efficient method to emerge.

Question 4. How large a market do you see Russia providing for Molybdenum—99 from Highly Enriched Uranium?

Answer. The current supply chain of Mo-99 coming from Russia is the production at the Research Institute of Atomic Reactors in Dimitrovgrad. Initial quantities through the Nordion supply chain are expected to be incremental. Over several years, the expectation is to have supply available from the Russian Federation of up to 20% of global Mo-99 demand to back up Nordion's long-term requirements. The evaluation process, for samples of Mo-99 from the Russian Federation, has been initiated through the Nordion Canada facility. Nordion continues to work with the Russian Federation to bring this commercial back-up supply of Mo-99 on-line. Specific details of the supply agreement are confidential.

The Russian supply agreement provides for the parties to address LEU conversion of the Isotope Mo-99 productions facilities. The timing and approach of conversion are currently under discussion for finalization.

Following a meeting of the Nuclear Energy and Nuclear Security Working Group of the bilateral Russian-US Presidential Commission in Moscow on December 7th, 2010, an agreement was signed between Russian state nuclear energy company Rosatom and the DOE. The two organizations will initially consider the possibility of converting six Russian research reactors from HEU to LEU fuel.

Nordion has also recently entered into a Framework Agreement with the Kurchatov Institute in the Russian Federation to collaborate in the development of medical isotope production capabilities using Liquid Homogenous Reactor technology, utilizing LEU-based production. This initiative is aimed at providing additional LEUbased Mo-99 production capacity from the Russian Federation.

At the Kurchatov Institute in Moscow, the Argus reactor was originally commissioned in 1981 and is currently the only stationary LHR (Liquid Homogeneous Reactor) left in operation in the world. Conversion of the Argus reactor to LEU has been recently approved by Russian Government as a result of the recent agreement signed by Russia with US DOE.

At present a conceptual modular production system with a capacity of 5-10% of the global Mo-99 demand is being considered. Multiple units could ultimately deployed using this technology depending on Markey dynamics. The timeframe to achieve commercial production of Mo-99 using this technology is currently being assessed and is expected to be 3-5 years.

RESPONSES OF PARRISH STAPLES TO QUESTIONS FROM SENATOR BINGAMAN

Question 1. Can you please explain the contract you have undertaken with South Africa to produce Molybdenum-99 (Mo-99) from LEU, specifically technology used, the amount and duration?

Answer. The National Nuclear Security Administration's Global Threat Reduction Initiative's (NNSA-GTRI) Mo-99 program has two separate missions: (1) highly enriched uranium (HEU) minimization through conversion of existing facilities and (2) support for accelerating existing commercial projects in the United States in the production of a domestic, non-HEU-based supply of Mo-99. GTRI entered into a contract with the South African Nuclear Energy Corporation (Necsa), and its subsidiary NTP Radioisotopes, in order to accelerate the conversion of their existing production capability from the use of HEU targets to low enriched uranium (LEU) targets. The technology utilized in the conversion process was developed and implemented by Necsa/NTP and is proprietary. The contract with Necsa is worth up to US$25M and is designed to accelerate the implementation of their technology and to complete the conversion of the facility by the end of 2013. As this contract falls under GTRI's HEU minimization mission, it is intended to support Necsa in maintaining its current production capability as it transitions to LEU-based production. GTRI's support to South Africa is not intended to augment South Africa's ability to produce additional amounts of Mo-99 for the global market.

Question 2. Were you able to convince any U.S. reactor operators to use the LEU technology developed by the NNSA before contracting with South Africa?

Answer. Removing the HEU from South Africa is a high non-proliferation priority, as HEU could be used to make a nuclear weapon if it fell into the wrong hands. NNSA is cooperating with the South Africans to remove the HEU while demonstrating that the reactor can still be used for isotope production. NNSA's efforts in the United States are quite different, as we are working to establish, rather than convert, Mo-99 production facilities. There has been no domestic production of Mo-99 since Cintichem's 1990 decision to decommission the Tuxedo reactor located in Tuxedo, New York.

The decision for the specific technologies being developed for the conversion of existing international Mo-99 producers to LEU, or for development in the United States, is driven by the producers themselves. NNSA's LEU target technology is one

of many possible technologies these producers may have used. The technology utilized in the conversion process in South Africa was developed by and is unique to Necsa/NTP and is proprietary. The contract between NNSA-GTRI and Necsa is designed to accelerate the implementation of Necsa's technology and to complete the conversion of the Necsa facility by the end of 2013.

Each of the U.S. domestic projects uses a technology selected and implemented by the potential producer. As these are independent, commercial projects, GTRI is only providing support to accelerate their timeline to help ensure that the United States and its medical community have access to a reliable domestic supply of Mo-99 as soon as possible. The technology developed by NNSA and Argonne National Laboratory is publicly available and was an option under the recently issued Funding Opportunity Announcement. However, none of the proposals submitted from the domestic commercial entities utilized this specific technology.

RESPONSES OF PARRISH STAPLES TO QUESTIONS FROM SENATOR CANTWELL

Question 3. Washington State University (WSU) in my state has a research reactor that has been fully converted to low enriched uranium (LEU) fuel, and is capable of supplying a significant portion of U.S. demand for molybdenum-99 and other medical isotopes. I commend the Department of Energy and the National Nuclear Security Administration for their efforts to establish grant programs to accelerate the development of a medical isotope industry that does not use highly enriched uranium (HEU). What is the current status of awarding grants for such projects?

Answer. NNSA issued a Funding Opportunity Announcement (FOA) for LEU target technology and accelerator technology on March 26, 2010, which resulted in the selection of two cooperative agreement partners to demonstrate the accelerator technology.

In general, large-scale quantities of LEU-target-based Mo-99 production require a research reactor that operates steady-state, has a short operating cycle, can dedicate operating time to Mo-99 production, and runs with sufficient power and neutron flux to produce Mo-99. There are few facilities in the United States that meet these requirements. While there are some research reactors in the United States that could irradiate LEU targets, a processing facility with dedicated hot-cells, optimally co-located with the reactor, and with a staff experienced in isotope production using FDA good manufacturing practice are also necessary for producing Mo-99. The United States does not currently have hot-cells that are dedicated to this purpose, and the LEU-target technology project will likely require the construction of a new, co-located processing facility.

Question 4. What is involved in converting a reactor from HEU to LEU fuel? What is the typical timeline for such a conversion? What kinds of technological risks affect this timeline? How much reactor and/or Mo-99 production downtime would be required to make this conversion?

Answer. The process to convert a reactor from HEU to LEU fuel follows a few generalized steps. First, feasibility models are calculated to demonstrate the viability of conversion, and to verify that commercially available fuel can be used safely in the reactor without disruption to the basic parameters required to achieve the facility's mission. Next, a detailed analysis and safety report is prepared in order to obtain regulatory approval. Finally, new LEU fuel is manufactured for the reactor for LEU-based operation upon its licensing conditions. The typical timeline for this process varies widely, but is generally not less than two years and in some cases can take as long as five years depending on resource availability.

Additionally, some high performance reactors cannot be converted with existing qualified LEU fuels and require a new high-density LEU fuel, which NNSA is in the process of developing.

Typically, the actual conversion process involving the insertion of LEU fuel is accomplished during a normal shutdown period for maintenance or during refueling operations. In either case, the physical process rarely takes longer than one month.

The conversion process above describes the conversion of the reactor fuel from HEU to LEU. In addition to converting the reactor fuel, the targets used to produce Mo-99 also require conversion to LEU. By converting both the reactor fuel and Mo-99 targets, the use of HEU in civilian applications is significantly minimized worldwide.

Question 5. In your opinion, would it be preferable to produce medical isotopes from an existing LEU-fueled source rather than an HEU-fueled source that would need to be converted at a later date?

Answer. Although LEU-fueled reactors are preferable from the perspective of nonproliferation, the decision of whether an HEU or LEU fueled facility would be considered preferable for isotope production is not determined by the level of enrich-

ment of the fuel. For example, the specific design and size of the facility for isotope production, as well as other R&D projects, are more important for medical isotope production than the fuel enrichment. Isotope production is better suited to a facility specifically designed for large scale production, not necessarily whether the facility operates on an HEU or LEU-based fuel.

That said, all of NNSA's Cooperative Agreement partners use technologies consistent with U.S. nonproliferation objectives, in that they do not utilize HEU in the production process.

Question 6. Please give a brief overview of the technology options available for producing medical isotopes without HEU, and the current status of each from a technical and commercial feasibility standpoint.

Answer. The basic strategy of NNSA's Mo-99 program is to accelerate the commercial establishment of a diverse and reliable domestic supply to avoid any single point of failure. NNSA is supporting three separate non-HEU-based technology pathways: solution reactor, neutron capture, and accelerator. The fourth technology described in this section, LEU target, is an available technology option, but one that ultimately was not pursued under the FOA. The goal of the program is to support the establishment of domestic commercial production as rapidly as possible where economic forces will dictate the future market for medical isotopes.

The following technology options are alternatives to produce medical isotopes without the use of HEU.

1. Solution Reactor Technology—Solution reactor technology has been demonstrated and there is experience in operating homogeneous solution reactors. Production rates for this technology are expected to be among the highest of the different technologies being considered, although additional R&D on fuel solution chemistry during operation and the recovery of Mo-99 from the irradiated fuel solution is required. This production process generates radioactive waste, although total amounts are less than those generated by the standard fission-target technology.

2. Neutron Capture Technology—This process is based on neutron capture in targets of Mo-98. This is a well known technology and is historically how Mo-99 was supplied to the medical community when the industry was first being developed. It is based on utilizing Mo-98 targets and a source of neutrons, which are captured in the target resulting in the production of Mo-99. As with the accelerator-based technologies, this technology has the benefit of resulting in a minimal amount of radioactive waste, compared to the standard fission-target technology, although it has a lower specific activity than fission-based Mo-99 processes. Since current generators in the nuclear pharmacies cannot use the Mo-99 generated from this process, another design would need to be developed.

3. Accelerator Technologies—The first proposed accelerator technology is based on exposing Mo-100 targets to high energy gamma rays to induce a reaction that produces Mo-99. The major components of this option are based on proven technologies. Once the technology is demonstrated in a complete process, it offers the possibility of relatively simple operation from the standpoints both of the accelerator and the target processing facility, because of the reduced radioactive environment in the absence of fission products. This non-fission based technology has the benefits of resulting in minimal radioactive waste compared to the standard fission-target technology. R&D is needed for the Mo-100 target designs and for the overall proof of concept. The lower specific activity of the Mo-99 (compared to fission-based processes) resulting from this process prevents current generators from being suitable for use, requiring the development of another generator design.

The second proposed accelerator technology is based on fissioning an LEU aqueous target through the introduction of accelerator-produced neutrons. Since the technology fits into the existing supply chain, where Mo-99 is extracted from uranium fission products before it is purified, there may be a lowered cost of production. R&D is currently underway to prove the concept and scale up the concept for major production.

4. LEU Target Technology—The irradiation of solid uranium targets with a neutron source to produce Mo-99 is a demonstrated technology currently used by the industry (most current production is done with HEU targets). The overall process (target preparation, irradiation, and dissolution) using LEU targets is nearly identical to that of using HEU targets and may therefore offer an easier transition for HEU-based producers. Production rates for a LEU target facility are expected to be among the highest of the different non-HEU technologies being considered. Development of the processing facilities to dissolve the targets and extract Mo-99 needs to take place to support eventual production; however,

some LEU production facilities are already in existence, such as in Australia, Argentina and others, as listed in the 2009 National Academies report "Medical Isotope Production without Highly Enriched Uranium." In addition, fission-based technology can use existing Tc-99m generators, which will expedite the delivery of Mo-99 to the market. However, among the technologies considered, fission-based production generates the most radioactive waste.

NNSA is not providing support for this technology as the company selected for demonstration of the LEU target technology ultimately declined the FOA award.

The Organization for Economic Cooperation and Development's Nuclear Energy Agency (OECD-NEA) published a report, "The Supply of Medical Radioisotopes: Review of Potential Molybdenum-99/Technetium-99m Production Technologies," that describes both these and additional technical pathways to producing Mo-99. It can be found on the OECD's website at: http://www.oecd-nea.org/med-radio/reports/Med-Radio-99Mo-Prod-Tech.pdf. This report is currently the most conclusive study on the potential technologies for producing Mo-99, and was produced in response to a request by the OECD-NEA's High-Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR), of which Dr. Parrish Staples is one of two U.S. government representatives.

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