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USNRC

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

September 25, 2008 (4:45pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

ATTN: Rulemakings and Adjudications Staff

Re: Comments by Mallinckrodt Inc. on "NRDC's Petition For Rulemaking to Ban Future Civil Use of Highly Enriched Uranium," 73 Fed. Reg. 30,321 (May 27, 2008)

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Mallinckrodt Inc. (Mallinckrodt) respectfully submits the following comments regarding the Natural Resources Defense Council, Inc.'s (NRDC's) "Petition for Rulemaking to Ban Future Civil Use of Highly Enriched Uranium" (Petition for Rulemaking), which was published for comment in the *Federal Register* (73 Fed. Reg. 30,321) on May 27, 2008, and for which the time to submit comments was extended by the Nuclear Regulatory Commission (NRC) until September 25, 2008. (73 Fed. Reg. 49,965).

Mallinckrodt is a leading global supplier of healthcare products, including radiopharmaceuticals that are used in nuclear medicine to diagnose and treat a variety of life-threatening illnesses. Mallinckrodt has radiopharmaceutical facilities located in Maryland Heights, Missouri and Petten, Netherlands. Mallinckrodt does not own or operate reactors that are utilized to irradiate targets to produce Mo-99.

Approximately 95% of the world supply of Mo-99 is currently produced using HEU targets. About 80% of nuclear medicine procedures rely on this key medical isotope, Mo-99. Fifteen million patients (41,000 per day) benefit from these procedures each year in the United States. Seven thousand hospitals and imaging facilities throughout the United States rely on daily supply of medical isotopes. Interrupting this supply of medical isotopes could result in inadequate patient care.

Mallinckrodt's interest in the proposed rulemaking mainly arises from its reliance on medical isotopes, such as Molybdenum 99 (Mo-99), to manufacture radiopharmaceuticals for use in diagnostic and therapeutic procedures for patients who suffer various serious and life-threatening illnesses. Currently, the large-scale commercial scale production of Mo-99 depends on the irradiation of "targets" produced from highly enriched uranium (HEU). Consequently, Mallinckrodt's comments on NRDC's petition are limited to the aspects of NRDC's proposal that seek to phase-out use of HEU for this purpose and halt the NRC's issuance of export licenses for the shipment of HEU from the U.S. to medical isotope producers in other countries.

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Currently, comprehensive security measures required by existing law and regulations ensure that HEU shipments are not subject to a genuine terrorist threat of theft or other diversion. Therefore, NRDC's argument requesting a prompt cessation of all uses of HEU is untenable. Mallinckrodt supports the goal of ultimately converting from HEU targets to low enriched uranium (LEU) targets for the production of medical isotopes. However, this needs to be conducted in a thoughtful planned manner because the medical needs of patients must be weighed against the NRDC's argument regarding the possibility that terrorists will seek to steal HEU during transport or use. NRDC's principal requests are to set a date on which the NRC will no longer license the civilian use of HEU, and to establish a timeline eventually to ban all exports of HEU, including exports for the production of medical isotopes in Canada and other close allies of the United States that implement rigorous measures to protect HEU from diversion. However, NRC and its international counterparts already have regulations which protect against the diversion of HEU shipments. Mallinckrodt urges the NRC to take into account the continuing need for a constant reliable supply of medical isotopes, such as Mo-99, to produce radiopharmaceuticals. Such radiopharmaceuticals are vital to diagnosis and treatment of patients in the United States and elsewhere. Consequently, Mallinckrodt opposes a rule to establish a date or timetable for the conversion to LEU for the production of medical isotopes.

As a manufacturer of radioisotopes, Mallinckrodt must maintain its ability to provide radiopharmaceuticals for the diagnosis and treatment of many serious illnesses. Mallinckrodt is committed to contributing to the availability of affordable, quality healthcare. Therefore, while Mallinckrodt supports the goal of converting medical isotopes production from the current reliance on HEU targets to an exclusive reliance on LEU, that transition must not interrupt the reliable and timely supply of medical isotopes for patient care, nor place an undue cost burden on patients. At this time, LEU targets and associated target processing facilities have not been developed to produce the required commercial quantities of medical isotopes to meet U.S. needs for patient care. Therefore, HEU targets for medical isotopes must continue to be used until commercially viable large-scale LEU alternatives are developed and their capability to reliably meet commercial demand for medical isotopes is well established. Because NRDC's proposed rulemaking would jeopardize the supply of medical isotopes needed to produce radiopharmaceuticals and increase the cost to patients of nuclear medicine procedures, Mallinckrodt opposes the Petition for Rulemaking.

Furthermore, as explained in its appended specific comments, Mallinckrodt believes that NRDC's rulemaking proposals are fundamentally inconsistent with Section 630 (Medical Isotope Production) of the Energy Policy Act of 2005, (EPAct) and thus cannot be accepted by the NRC. In section 630 of the EPAct, Congress established detailed procedures to determine whether it is feasible, from both technical and economic perspectives, to produce medical isotopes entirely with LEU. In accordance with section 630, the National Academy of Sciences (NAS) is currently evaluating the feasibility of producing Mo-99 entirely through the use of LEU targets and LEU fuel. This legislation establishes a timeframe for determining whether production of

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Mo-99, relying entirely on LEU, is feasible, and whether the export of HEU for medical isotope production may continue pursuant to the export criteria established by section 630. In light of section 630's detailed provisions regarding production of medical isotopes by using LEU, it would be premature and contrary to the congressionally-mandated scheme for the NRC to grant this Petition for Rulemaking.

In the enclosure, Mallinckrodt has submitted more detailed comments in response to NRDC's Petition for Rulemaking. In summary, Mallinckrodt urges the Commission to deny NRDC's Petition for Rulemaking.

Sincerely,

A handwritten signature in cursive script, appearing to read "Dale Simpson".

Dale Simpson  
Manager, Research and Development  
Imaging Solutions  
Mallinckrodt Inc.

Enclosure

COMMENTS BY MALLINCKRODT ON NRDC'S PETITION FOR RULEMAKING

1. **Because of the comprehensive physical security measures required by existing law and regulations, HEU shipments are not subject to a genuine terrorist threat or other risk of diversion.**

Mallinckrodt believes that the comprehensive security measures required by existing law and regulations ensure that shipments of highly enriched uranium (HEU) targets for the production of medical isotopes are not subject to a genuine terrorist threat of theft or diversion. Establishment of rigorous physical protection requirements for such shipments has been a paramount concern of the NRC in its decisions concerning issuance of export licenses.

Congress has recently established additional requirements for the physical protection of HEU that is exported for the production of medical isotopes.<sup>1</sup> The criteria established by section 630 of the EAct for the export of HEU to produce medical isotopes are limited to five countries (Canada, France, Belgium, Germany and the Netherlands) that have agreements for peaceful nuclear cooperation with the United States and have been determined by the U.S. Executive Branch to have excellent nonproliferation credentials.

Furthermore, in section 630, Congress specifically addressed the adequacy of physical protection of such shipments:

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

In their rulings on applications to export HEU to produce medical isotopes, the NRC and the U.S. Executive Branch have repeatedly determined that HEU may be exported to Canada without a credible risk of diversion of the material or other security threats.<sup>2</sup>

The delivery and storage of HEU for medical isotope production are highly regulated to ensure that it is accomplished in a safe and secure manner and will not be inimical to the common defense and security. Under the U.S. regulatory framework for the export of HEU to foreign facilities, the NRC issues the export license and approves the physical

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<sup>1</sup> Section 630 of the Energy Policy Act of 2005 (EAct), Pub. L. 109-58, 60 Stat. 755, 42 USC § 2160d(b)(3).

<sup>2</sup> Transnuclear, Inc. Export License, NRC License No. XSNM03060 (July 19, 1999); Transnuclear, Inc. Export License, NRC License No. XSNM03171 (Apr. 30, 2002).

protection arrangements for each shipment.<sup>3</sup> In consultation with the State Department and the Department of Defense (DOD), the NRC must be satisfied that physical security measures are adequate to deter all credible threats and that the export shipment is not subject to a genuine threat of diversion by terrorists. Over approximately the past decade, exports of HEU for the production of medical isotopes have been carried out by the Department of Energy (DOE). As the holder of several NRC licenses to export HEU for the production of medical isotopes, DOE is responsible for ensuring adequate physical protection during transportation of HEU to Canada.

The U.S. and the Canadian governments oversee a secure HEU distribution and storage system that is regulated to the highest standards.<sup>4</sup> The NRC has previously found that physical protection measures that are applicable in Canada during transport and processing of HEU at the Chalk River Facility are adequate to meet the NRC's requirements regarding physical protection.<sup>5</sup>

Reactors and target processing facilities in Canada, Belgium, France, the Netherlands, and South Africa, which collectively serve most of the world demand for Mo-99, are strictly monitored by the International Atomic Energy Agency (IAEA), to assure compliance with IAEA safeguards agreements and are required to meet the security mandates of the countries in which they are located, as well as the mandates of the exporting country<sup>6</sup>. All of these countries abide by the International Atomic Energy Agency's (IAEA's) guidelines for the physical protection of nuclear material (INFCIRC/225/Rev. 4). The NRC recently upheld the adequacy of the "basic

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<sup>3</sup> The NRC recently established additional security measures for HEU shipments, to bolster its physical protection requirements under 10 CFR Part 73. *See* 72 Fed. Reg. 3,025 (Jan. 24, 2007).

NRC's export criteria include (1) assurances that IAEA safeguards will be applied; (2) U.S. consent rights over transfers of the HEU to third countries; and (3) U.S. findings of the adequacy of the physical protection measures. 10 CFR § 110.41.

<sup>4</sup> National Nuclear Security Administration, Workshop Report 20, Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium (Dec. 2-7, 2007) [hereinafter "Final Report"].

On a number of recent occasions, DOE has employed its Safe Secure Transport (SST) system to transport the HEU targets and HEU target material to AECL's Chalk River Facility in Canada. *See, e.g.*, Transnuclear, Inc. Export License, NRC License No. XSNM03060 (July 19, 1999). These armored SST vehicles are accompanied by armed guards. In granting export licenses for the shipment of HEU and HEU targets from the United States to the Chalk River Facility, the NRC has determined that all of its applicable export requirements are satisfied, including the criteria that require a finding of adequate physical protection in the recipient country. *See Transnuclear, Inc.* (Export of 93.3% Enriched Uranium), CLI-99-20, 49 NRC 469 (1999). The physical protection measures used in the transport of HEU are similar to those that the NRC found acceptable with regard to the export of weapons-grade plutonium oxide to France in *U.S. Department of Energy* (Plutonium Export License), CLI-04-17, 59 NRC 357 (2004) ("These include, among other things, advanced communications equipment; around-the-clock, real-time monitoring of the location and status of the vehicle; enhanced structural supports; armed federal officers; and a tractor-trailer combination using various defense technologies to protect crew members and cargo from attack." *Id.* at 361 n.4.).

<sup>5</sup> *See Transnuclear*, 49 NRC 469.

<sup>6</sup> *U.S. Department of Energy*, 59 NRC 357.

international standard embodied in the NRC's regulations for physical security measures – specifically, IAEA INFCIRC/225/Rev. 4.”<sup>7</sup>

In its export license conditions, the NRC strictly controls the quantity of HEU exported and imposes stringent physical protection measures for such shipments. The NRC's rules regarding export of a Category I quantity (5 kilograms or more) of HEU requires the licensee to comply with comprehensive physical security measures, including armed escort and special vehicles, that “provide high assurance that activities involving special nuclear material are not inimical to the common defense and security, and do not constitute an unreasonable risk to the public health and safety<sup>8</sup>.” The NRC also has the authority to require additional physical protection measures if, after a comprehensive review of the current security requirements in place, it determines that additional measures are necessary. Moreover, Section 133 of the Atomic Energy Act (“AEA”), 42 USC § 2160c, requires that before issuing a license authorizing the export of more than five kilograms of HEU, NRC must consult with DOD and DOD must advise NRC whether there is a “genuine terrorist threat” with respect to such shipments and the NRC must require measures to overcome any such threats.

In assessing the risk that terrorists may divert HEU, the NRC is entitled to rely on the Executive Branch. As the Commission has recognized, “Judgments of the Executive Branch regarding the common defense and security of the United States involve matters of its foreign policy and national security expertise, and the NRC may properly rely on those conclusions.”<sup>9</sup>

Medical isotopes are used in approximately 85,000 nuclear medicine procedures globally per day.<sup>10</sup> Over 100 different nuclear medicine applications exist,<sup>11</sup> such as diagnosing heart disease, brain disorders, infections and treating cancer. These tests are among the safest diagnostic tests available. Many nuclear medicine tests can show abnormalities very early on in the progression of a disease, before the medical problem would be apparent with other types of procedures. With the help of nuclear medicine, scientists are making great progress in understanding and treating many devastating diseases.

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<sup>7</sup> *Id.*, at 362.

<sup>8</sup> 10 CFR § 73.20. IAEA Guidelines for the Physical Protection of Nuclear Material and Nuclear Facilities establish strict requirements for protection of Category I nuclear material (including 5 kilograms or more of HEU), as specified in Section 6.2 of INFCIRC/225/Rev. 4 for storage and use, and in Section 8.2, with respect to transport.

<sup>9</sup> *Transnuclear*, 49 NRC at 477.

<sup>10</sup> Grant Malkoske, Vice-President, Strategic Technologies, MDS Nordion, Challenges and Opportunities Related to HEU Conversion: An Industrial Perspective 3, Address at the Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium (Dec. 2-7, 2007) [hereinafter “Malkoske”].

<sup>11</sup> Nuclear medicine involves the use of small amounts of radioactive materials to assist in the diagnosis and treatment of a variety of medical conditions such as breast, lung, and prostate cancer, renal failure in children, and heart disease.

Fifteen million patients (41,000 per day) benefit from these procedures each year in the United States. About 80% of nuclear medicine procedures rely on one key medical isotope, Mo-99. Seven thousand hospitals and imaging facilities throughout the United States rely on daily supply of medical isotopes. Interruption in supply of medical isotopes could result in inadequate patient care.

Approximately 95% of the world supply of Mo-99 is currently produced using HEU targets.<sup>12</sup> The benefits to seriously ill patients that result from radiopharmaceuticals produced from HEU targets should not be jeopardized by abandoning HEU targets prematurely, particularly in view of the stringent physical protection measures that eliminate any credible threat of diversion of such material.

HEU used in fabricating targets for medical isotopes has been handled safely for 55 years without a single instance in which terrorists or other persons have attempted to divert such material from its intended use to produce medical isotopes.<sup>13</sup> Nevertheless, Mallinckrodt supports the conversion to medical isotopes produced entirely with LEU, as soon as a commercially viable alternative to HEU targets is available.

**2. The requested rule would jeopardize the supply of medical isotopes for patient care and increase the cost of nuclear medicine procedures to patients.**

U.S. public health depends on the reliable supply of medical isotopes. Currently more than 100 different nuclear medicine procedures are routinely used to determine the severity of heart disease, the spread of cancer and to diagnosis brain disorders.<sup>14</sup> Eighty percent of nuclear medicine procedures rely on one isotope, Technetium-99 (Tc-99m), which results from the decay of Mo-99.<sup>15</sup> Tc-99m is used in about 35,000 times per day in the United States and is used in approximately 25 million diagnostic procedures annually.<sup>16</sup> Any disruption to the supply of Mo-99 “will have a devastating effect on the U.S. medical community’s ability to diagnose and treat thousands of patients.”<sup>17</sup>

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<sup>12</sup> Final Report, at 5; Malkoske, at 5; George F. Vandegrift, Technical Assistance in Conversion- USA 4, Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium (Dec. 2-7, 2007) [hereinafter “Vandegrift”].

HEU is the primary target material used in Canadian and European reactors to manufacture medical isotopes for the United States. HEU exported from the U.S. is currently used to produce most of the U.S. supply of the medical isotope needed to manufacture the radiopharmaceutical that is used in the large majority of nuclear medicine procedures in the United States. Due to the extremely short half-lives of a majority of medical isotopes, hospitals and physicians cannot stockpile or store radiopharmaceuticals for any considerable length of time. Most radiopharmaceuticals are prepared by a nuclear pharmacy the same day they are to be given to a patient.

<sup>13</sup> Final Report, at 21.

<sup>14</sup> *Id.* at 2.

<sup>15</sup> Vandegrift, at 4.

<sup>16</sup> *Id.*; Ralph A. Butler, Director, MURR, Molybdenum 99 Production at the MU Research Reactor Center 10, Address at the Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium (Dec. 2-7, 2007) [hereinafter “Butler”]

<sup>17</sup> Butler, at 10.

A major challenge in supplying Mo-99 for use in producing the most widely used radiopharmaceutical is its extremely short half-life. With a half-life of only 66 hours, approximately 1% of a given volume of Mo-99 decays each hour.<sup>18</sup> Consequently, an inventory of Mo-99 cannot be accumulated and must therefore be reliably produced, on a daily basis, in the needed quantities for delivery to manufacturers of radiopharmaceuticals.<sup>19</sup> Additionally, the supply of Mo-99 is being strained as world demand continues to increase. Increasing Mo-99 peak production capacities at multipurpose reactors may conflict with the reactors' other missions.<sup>20</sup> Additional radioisotope suppliers are unlikely to enter the commercial market in the near future, due to high barriers to entry, including large capital requirements, an intense regulatory framework, and long "time to market."<sup>21</sup> Despite these challenges, capacity must continue to meet the demanding needs of the nuclear medicine community. The process to convert from HEU targets must ensure that a sufficient global supply of radioisotopes will be maintained to assure that patient needs are fully met.

Currently, 95 percent of the world supply of Mo-99 is produced through the use of HEU targets, which employ a demonstrated and proven technology.<sup>22</sup> While Mo-99 is being produced from LEU targets irradiated and processed in government-owned or supported facilities in Argentina and Australia, such production is a very small fraction of world production of Mo-99 (only 5%) and is used essentially for consumption within these countries respectively.<sup>23</sup> Moreover, according to reports by the Australian operator of the medical isotope production facilities that use LEU, these facilities have encountered operational difficulties over the past year and therefore have not produced Mo-99 and have relied on other major suppliers that use HEU targets to provide this necessary isotope for Australia.

Thus, while LEU targets have been used in Argentina and Australia on a limited basis to produce small quantities of Mo-99 to meet regional or local needs, such methods have not yet demonstrated the availability of an economically and technically viable means of producing Mo-99 with LEU targets to satisfy the large-scale demands.<sup>24</sup> Moreover, the

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<sup>18</sup> *Transnuclear*, 49 NRC at 472; Final Report, at 4.

<sup>19</sup> *Transnuclear*, 49 NRC at 472 ("Because the lifetimes of Mo-99 and Tc-99m are extremely short (with half-lives of 66 hours and 6 hours, respectively), it is not possible to stockpile the isotopes.").

<sup>20</sup> Final Report, at 5.

<sup>21</sup> Ian L. Turner, Australia's New LEU Based Mo-99 Production Facilities Utilising the OPAL Research Reactor 21, Address at the Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium (Dec. 2-7, 2007) [hereinafter "Turner"].

<sup>22</sup> Final Report, at 5; Malkoske, at 5; Vandegrift, at 4.

<sup>23</sup> The IAEA Full Report on the consultancy to prepare a "cooperative research program (CRP) on transfer and adaptation of LEU targets to produce Mo-99 through fission," which was held at the IAEA headquarters in Vienna, Austria on November 15-27, 2004, pointed out that Australia and Argentina have been producing small quantities of Mo-99 from LEU targets. The IAEA acknowledged that "both of these producers are servicing local or regional markets."

<sup>24</sup> Final Report, at 10; Malkoske, at 5, 12.

production of Mo-99 in Argentina and Australia using LEU is carried out by governmental entities that are not subject to market-place economic realities. The use of limited numbers of LEU targets by government-subsidized producers of medical isotopes does not suggest that private sector producers of large volumes of medical isotopes may also convert to LEU targets unless sufficient time is available to complete this complex process and the substantially higher costs of using HEU targets may be passed on to patients or can be off-set by government subsidies.

In summary, efforts by the United States and several other countries to reduce the use of HEU throughout the world must take into account the essential role that HEU targets currently play in the reliable production of Mo-99 and the robust physical security measures that are applicable at the production facilities and during the transportation of the HEU targets and target material. NRDC's Petition for Rulemaking fails to take these factors into account and should therefore be denied. Without a timely supply of medical isotopes, nuclear medicine procedures for hundreds of thousands of U.S. patients each year will be cancelled or delayed, jeopardizing their well being and compromising the quality of the United States health care system.

**3. Any fixed date or timetable established by the NRC to ban the export and use of HEU in the production of medical isotopes before the isotope producers have had sufficient time to design, construct and license the necessary LEU targets and processing facilities would jeopardize the reliable supply of those isotopes.**

There are significant technical, regulatory and economic obstacles to the use of LEU targets to produce medical isotopes. These obstacles include an increase in nuclear waste,<sup>25</sup> a decrease in process efficiency and capacity,<sup>26</sup> target and reactor core qualifications,<sup>27</sup> increased costs from modifications to isotope extraction and waste management process,<sup>28</sup> and U.S. Food and Drug Administration (FDA) qualification

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<sup>25</sup> Five times the mass of uranium, increased fissile liquid waste, and ten times more plutonium-239 would be produced using LEU targets rather than HEU targets. The transuranic content of the waste will increase, which would compound the difficulty of disposing of it. See Malkoske, at 7, 16, 19; Vandegrift, at 7 (“Approximately 25 times more <sup>239</sup>Pu [plutonium] is produced during irradiation of LEU than HEU.”).

<sup>26</sup> The use of LEU targets would result in a five-fold decrease in the molybdenum-99 yield per unit mass of uranium. Dale Simpson, Manger Research and Development, Mallinckrodt: Positive Results for Life: LEU Conversion 7, Address at the Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium (Dec. 2-7, 2007) [hereinafter “Simpson”]; Vandegrift, at 6.

<sup>27</sup> Reactor cores would have to be re-qualified and re-licensed by nuclear regulatory authorities. The primary cost involves the use of complex computer programs to model the thermohydraulics of the cooling system and targets. For each reactor, new targets have to be designed, qualified, and licensed, requiring new safety analysis reviews. Vandegrift, at 12, 14, 18.

<sup>28</sup> The use of LEU targets will add costs from process development, facility modifications and waste storage facilities, as well as costs related to on-going production, processing and radioactive waste management. The increased mass of uranium in LEU targets will increase the processing time and generate an increased volume of fissile waste to be processed for storage. This will result in an on-going increase in the cost of medical isotopes, as well as add an increased waste burden. Vandegrift, at 21; Simpson, at 12.

requirements.<sup>29</sup> Despite making every reasonable effort to convert their reactor and target processing facilities to use LEU targets and cooperating fully with the U.S. Government's conversion program, some operators may be unable to accomplish such a conversion, because of technical, licensing or economic barriers. If the NRC promulgates a rule that includes the LEU conversion dates and timeline proposed by NRDC, those dates and timeline will be applicable long before LEU targets are commercially available to meet U.S. medical needs.

Substantial time will be needed to execute an LEU target conversion development program at each of the following critical stages: (1) design; (2) regulatory approvals; (3) construction; (4) commissioning; and (5) transition to demonstrate reliability of supply.<sup>30</sup> This latter point is an important consideration that will materially affect the timing of such a program as there is a vital need to maintain continuity of supply for patient care during implementation of a conversion program. DOE's National Nuclear Security Agency workshop on the LEU production of Mo-99, held in Sydney, Australia on December 5-7, 2007, estimated that it would take eight years or longer to complete a successful conversion.<sup>31</sup>

The technology development aspects of a LEU target conversion program must encompass a broad range of requirements, including the following: (1) target development; (2) reactor qualification; (3) process development; and (4) waste management.<sup>32</sup> The technology must be proven, robust, reliable, and sized for large-scale, continuous commercial production. Experimental target LEU technology cannot simply be scaled up for large-scale commercial production. In addition, conversion to LEU targets will require additional reactor irradiation capacity, which is currently very limited. Without added irradiation capacity, reactor outages would have more negative impact on availability of product to patients.

A substantial transition period will be needed to demonstrate that LEU targets may be effectively and safely used in reactors and processing systems. A critical aspect of the demonstration is to show that a system to use LEU targets is capable of providing commercial quantities of Mo-99. Thousands of curies of Mo-99 must be supplied each and every week without exception.<sup>33</sup> Even if LEU target technology is deployed for large-scale commercial production, it will be necessary to have a reliable source of Mo-99 supply from the current stream, based on HEU targets, until a new stream based

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<sup>29</sup> The final radiochemical product would have to be re-qualified by all U.S. radiopharmaceutical manufacturers who use Mo-99 to make Technetium-99m generators. A change to LEU targets would require additional FDA approvals. There would be a substantial cost for the validation and approval process for New Drug Application (NDA) supplements. Simpson, at 9 ("Regulatory approvals can take 9 to 21 months"), 10; Vandegrift, at 18.

<sup>30</sup> Simpson, at 12.

<sup>31</sup> Final Report, at 11; Simpson, at 12; Malkoske, at 20 ("Conversion of Mo-99 production to LEU technology is expected to take in the order of 10 years.").

<sup>32</sup> Malkoske, at 12.

<sup>33</sup> Malkoske, at 12.

on LEU targets has demonstrated reliability. Therefore, facilities to process irradiated HEU targets to separate Mo-99 must continue in operation, in parallel with new facilities to process LEU targets, until the new facilities are shown to be capable of reliably producing sufficient Mo-99 to meet world demand.

The cost of implementing an LEU target conversion development program must also be taken into account. These costs include: (1) technology development cost; (2) capital cost; (3) start-up operating costs; (4) incremental operating costs; (5) regulatory costs; (6) increased cost of decommissioning an HEU target processing facility; and (7) cost for transitioning from HEU to LEU targets.<sup>34</sup> These costs will be ultimately borne by the consumer. Moreover, a continued supply of low-use and/or low-cost radiopharmaceuticals, often used to diagnose or treat diseases, may be endangered because producers will be unable to absorb the cost of conversion and ongoing additional manufacturing cost.

In summary, any set target date or forced conversion timetable established by the NRC to ban the use of HEU in the production of medical isotopes before the isotope producers have had sufficient time to design, construct and license the necessary LEU targets and processing facilities would jeopardize the reliable supply of those isotopes. Because of the technical and regulatory complexity of using LEU exclusively to produce sufficient quantities of medical isotopes to meet the needs of patients in the United States, the NRC should not accept NRDC's proposed timetable for converting to LEU. Instead, the NRC should evaluate the findings of the National Academies of Sciences (NAS) when they are available and continue to apply the Congressionally-mandated criteria for HEU exports to produce medical isotopes.

#### **4. A forced MEU conversion target date has the same challenges as with LEU.**

Acknowledging that the conversion to LEU may not be feasible, NRDC's Petition for Rulemaking suggests, as an alternative, that producers convert to use targets that employ moderately enriched uranium ("MEU").<sup>35</sup> However, conversion to 40% enrichment versus 20% in the fissile isotope U-235 does not eliminate the technical hurdles associated with using LEU to produce medical isotopes, as discussed above. Furthermore, if conversion to LEU to produce medical isotopes is the ultimate goal, it should be done in one step, directly from HEU to LEU, rather than using MEU as a first stage in the conversion process. Having an intermediate step would only double the challenges that market participants must overcome by making them confront design, approval, and construction issues at different stages in the conversion process.

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<sup>34</sup> Vandegrift, at 21; Simpson, at 12.

<sup>35</sup> We are aware that in a supplemental comment submitted by the NRDC in a letter to the NRC, dated September 8, 2008, NRDC withdrew this portion of its Petition for Rulemaking, stating as follows: "We recommend that NRC exclude the alternative policy option to establish for a limited number of licensees an intermediate <sup>235</sup>U concentration limit less than 40 percent."

Also, Mallinckrodt believes that the concept of using MEU to produce medical isotopes has not yet been endorsed by the U.S. Government. However, if it is ultimately approved by the U.S. Government as an alternative to LEU targets, and if conversion to MEU is the final goal, the use of MEU targets may be advantageous, when compared to LEU targets, for medical isotope production. As mentioned above, LEU targets will create five times more waste and 25 times more plutonium (Pu).<sup>36</sup> In comparison to LEU targets, MEU targets would decrease the amount of waste and Pu generated in the production of medical isotopes. However, as with a conversion to LEU targets, substantial time and money will be required to successfully complete a conversion process from HEU targets to MEU targets.

**5. NRC should not dictate the time schedule for conversion to LEU because Congress, in the Energy Policy Act of 2005, Section 630, Medical Isotope Production, has enacted a detailed process for determining whether the use of LEU exclusively to produce medical isotopes is feasible from technical, economic and licensing perspectives and the National Academy of Sciences (NAS) is currently evaluating the feasibility of the production of Mo-99 without using HEU.**

HEU export licenses are issued by the NRC in accordance with the export criteria specified in section 134 of the AEA.<sup>37</sup> That section of the AEA was amended by section 630 of the EPAct, which was signed into law on August 8, 2005. The purpose of the amendment was to facilitate the timely export, to the five designated countries, of HEU for medical isotope production in reactors that are either utilizing LEU or have agreed to convert such reactors to use LEU driver fuel<sup>38</sup>. To date, Canada is the only country that has received exports of HEU to produce medical isotopes, pursuant to the export criteria established by section 630 of the EPAct.

As provided by section 630 of the EPAct, NAS is conducting a study and will provide findings and recommendations to DOE concerning the production of medical isotopes without HEU. As mandated by Congress in Section 630(A) of the EPAct, the study will determine the following: (1) the feasibility of procuring supplies of medical isotopes from commercial sources that do not use HEU, using the definition of feasibility set forth in Section 630(B); (2) the current and projected demand and availability of medical isotopes in regular current domestic use; (3) the progress that is being made by DOE and others to eliminate all use of HEU in reactor fuel, reactor targets, and medical isotope production facilities; and (4) the potential cost differential in medical isotope production in the reactors and target processing facilities if the products were derived from production systems that do not involve fuel and targets produced from HEU.

If NAS determines that procurement of medical isotopes from commercial sources without the use of HEU, is not feasible as defined by section 630 of the EPAct, it is required to estimate the magnitude of the cost differential and identify additional steps

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<sup>36</sup> See Malkoske, at 7, 16, 19; Vandegrift, at 7.

<sup>37</sup> 42 USC § 2160d, as added to the AEA, Oct. 24, 1992, Pub. L. 102-486, Title IX §903(a)(1), 106 Stat. 2944.

<sup>38</sup> The NRU reactor in Canada and the HFR in the Netherlands both use LEU fuel.

that could be taken by DOE and medical isotope producers to improve the feasibility of converting medical isotope production to use LEU exclusively. If NAS determines that procurement of medical isotopes produced by commercial sources without the use of HEU is feasible, the Secretary of Energy must submit a report to Congress that describes options for meeting domestic demands by using domestic suppliers. The Secretary of Energy then must submit to Congress a certification that facilities to produce medical isotopes without the use of HEU are capable of meeting domestic medical isotope needs within a prescribed cost increase, after which the criteria specified in section 630 shall no longer be applicable to applications to the NRC for licenses to export HEU to produce medical isotopes.

On April 20, 2006, the NRC promulgated its final rule regarding “Implementation of the Nuclear Export and Import Provisions of the Energy Policy Act of 2005 (EPAct).”<sup>39</sup> Among other revisions to its export and import rules, 10 CFR Part 110, the NRC’s final rule implements the EPAct’s new export criteria regarding certain exports of HEU for the production of medical isotopes. As the NRC recognized in its final rule, where it is applicable, section 630 of EPAct suspends the criteria set forth in section 134 of the AEA that required the NRC, before authorizing the export of HEU targets, to make findings regarding: (1) the availability of LEU targets, (2) where LEU targets are not available, the commitment of the applicant to convert to LEU targets, and (3) the existence of an active U.S. program regarding conversion to LEU targets.

NRDC’s request that the NRC adopt a fixed date or timetable to cease licensing export of HEU to produce medical isotopes is fundamentally inconsistent with section 630 of the EPAct, which provides a timeframe to determine (1) whether the use of LEU exclusively to produce medical isotopes is feasible, (2) when the necessary medical isotope production capacity using LEU, rather than HEU, will be available, (3) whether the criteria in section 630 for exports of HEU for medical isotope production will be terminated. Mallinckrodt respectfully submits that the NRC lacks the authority to promulgate the proposed rule to the extent that the rule would directly conflict with the process and timetable dictated by Congress in section 630 of EPAct for determining the feasibility of producing medical isotopes exclusively with LEU. Furthermore, there is no reason for the NRC to circumvent prematurely this congressionally-mandated study and prescribed course of action concerning conversion to LEU.

Finally, a fundamental reason why the NRC must deny NRDC's petition is that the NRC lacks legal authority to promulgate NRDC's proposed rule. It would be inconsistent with section 134 of the AEA for the NRC to ban all HEU exports. Since section 134 of the AEA, as amended by section 630 of EPAct, directs the NRC to review, on a case-by-case basis, applications to export HEU for medical isotope production in accordance with congressionally prescribed criteria, the NRC may not promulgate a rule to ban such exports. As is clear from Congress' enactment of section 134 in 1991 and amendment of that provision in section 630 of the EPAct, Congress has required that the NRC evaluate

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<sup>39</sup> 71 Fed. Reg. 20336 *et seq.*

HEU export license applications on a case-by-case basis. Only Congress has the authority to change this policy.

**6. The proposed rulemaking is unnecessary because current law and regulations adequately provide for the conversion of medical isotope production from HEU to LEU.**

The existing legal and regulatory framework for LEU conversion has proven to be adequate. At present there is significant development work under way to attempt to establish reliable production of large volumes of medical isotopes from LEU. Reactors in Canada and the Netherlands that are used to produce medical isotopes have already converted to LEU fuel, although they continue to use HEU targets. For example, the High Flux Reactor (HFR) in Petten, Netherlands, which provides 60-70% of European Mo-99 demand, completed its conversion to LEU fuel in May 2006.<sup>40</sup> Participants in the supply of medical isotopes have been fully committed to meeting the requirements of section 630 of EPAct and, in accordance with section 630 of the EPAct, the industry participants are making a substantial effort in working with industry partners, government regulators and outside groups to transition to LEU safely and effectively. The U.S. government and other governments have recognized that they have an important role in ensuring a reliable supply of medical isotopes. In particular, in EPAct, Congress sought to balance the twin objectives of maintaining a reliable supply of medical isotopes while establishing a process to achieve the production of medical isotopes without the use of HEU. NRDC's requested rule would jeopardize the supply of medical isotopes and place an undue cost burden on patients. Current law and regulations ensure a reliable supply while providing a process to convert medical isotope production to LEU.

**7. Conclusion**

The radiopharmaceuticals most commonly used in the U.S. to diagnose life-threatening illnesses are made with medical isotopes that are produced primarily from HEU-based targets. Presently, the continued availability of HEU to produce the targets that are irradiated and processed to obtain Mo-99 and other medical isotopes is essential because more than 95% of the world's Mo-99 is produced from HEU. Comprehensive statutory and regulatory requirements, as well as international agreements, establish a well-tested framework to ensure the safe and secure transportation, storage and use of HEU. The timely use of the products made from HEU is necessary to meet the medical diagnostic needs for tens of thousands of patients on a daily basis and these procedures are critical for the diagnosis of numerous conditions. Nevertheless, Mallinckrodt supports the conversion to LEU targets to produce medical isotopes when a commercially viable means of doing so is available. In the implementation of a conversion to LEU, it is essential to ensure that there will be a sufficient supply of medical isotopes to produce radiopharmaceuticals for patients.

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<sup>40</sup> Nine van Barneveld & Fred J. Wijtsma, HFR After Conversion: Reliable Tool for <sup>99</sup>Mo-production 10, Address at the Global Initiative to Combat Nuclear Terrorism Workshop on the Production of Mo-99 Using Low Enriched Uranium (Dec. 2-7, 2007).

At this time, LEU technology has not been developed to produce the required commercial quantities of medical isotopes to meet U.S. needs for patient care. While two small producers have supplied Mo-99 utilizing targets and fuel produced with LEU, neither of them has sufficient capacity to meet U.S. or global needs. Despite their expenditures of substantial sums of money and human resources to acquire the capability to produce Mo-99 on a large commercial scale exclusively with LEU, no medical isotope manufacturer currently has the capability or capacity to supply sufficient commercial quantities of LEU Mo-99 to meet global demands. Conversion to targets containing uranium that is 40% enriched in the isotope U-235, versus 20%, does not eliminate or significantly reduce the technical hurdles associated with LEU conversion.

Programs to produce medical isotopes without using HEU must ensure that the interests of patients and all other constituent interests are addressed. Non-proliferation, technical feasibility, economic viability, and regulatory/licensing requirements must all be taken into account. The fixed target date and forced conversion timeline in NRDC's Petition for Rulemaking do not provide adequate flexibility to consider the U.S. domestic supply of medical isotopes, nor address issues such as processing LEU targets, handling the greatly increased waste volume and receiving U.S. FDA approval of the product.

Mallinckrodt submits that the NRC should deny NRDC's Petition for Rulemaking because it is fundamentally inconsistent with section 630 of EPAct. The NRC should not initiate a rulemaking that seeks to establish schedules for the production of medical isotopes exclusively from LEU, at the same time that NAS is studying this same subject, pursuant to Congress' direction in the EPAct. Moreover, to the extent that NRDC's petition asks the NRC to establish policies and procedures that are fundamentally inconsistent with the case-by-case export license determinations required by section 134 of the AEA, the NRC must deny that petition.<sup>41</sup>

In summary, for all of the reasons specified in Mallinckrodt's comments to the NRC, Mallinckrodt respectfully submits that the NRC should deny NRDC's Petition for Rulemaking.

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<sup>41</sup> Under Section 630 of EPAct, the NRC does not have the authority to establish a set time table to cease issuing licenses for the export of HEU to produce medical isotopes in the five specified countries because Congress unambiguously established a detailed process, including a study by NAS for determining whether such exports could continue pursuant to the criteria established by Section 630. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984).

Moreover, Section 134 of the AEA, as enacted in 1992, clearly specifies precise criteria for the NRC's review of applications to export HEU to produce medical isotopes. Congress plainly intended that the NRC would determine, on a case-by-case basis, whether these criteria were satisfied. The NRC lacks authority to ban the export of HEU to produce medical isotopes because that would "so completely diverge[] from any realistic meaning of the [statute] that it cannot survive scrutiny under *Chevron* Step Two." *Nuclear Energy Institute v. Environmental Protection Agency*, 373 F.3d 1251, 1270 (D.C. Cir. 2004) (quoting *Natural Res. Def. Council, Inc. v. Daley*, 209 F.3d 747, (D.C. Cir. 2000)).

## Rulemaking Comments

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**From:** Simpson, Dale J [Dale.Simpson@Covidien.com]  
**Sent:** Thursday, September 25, 2008 4:26 PM  
**To:** Rulemaking Comments  
**Subject:** Comments by Mallinckrodt on NRDC Petition  
**Attachments:** Letter and attachments to NRC.pdf

<<Letter and attachments to NRC.pdf>>

Please find attached comments by Mallinckrodt Inc. on "NRDC's Petition For Rulemaking to Ban Future Civil Use of Highly Enriched Uranium"

Received: from mail1.nrc.gov (148.184.176.41) by TWMS01.nrc.gov  
(148.184.200.145) with Microsoft SMTP Server id 8.0.751.0; Thu, 25 Sep 2008  
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Received: from TAHAZE-BE01.thcg.net ([10.97.21.132]) by TAHAZE-BH01.thcg.net  
with Microsoft SMTPSVC(6.0.3790.1830); Thu, 25 Sep 2008 15:25:59 -0500  
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Date: Thu, 25 Sep 2008 15:25:56 -0500  
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X-MS-TNEF-Correlator:  
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Thread-Index: AckfTOpet7iQjNbJQXOtUN2QtVH75w==  
From: "Simpson, Dale J" <Dale.Simpson@Covidien.com>  
To: <rulemaking.comments@nrc.gov>  
Return-Path: Dale.Simpson@Covidien.com  
X-OriginalArrivalTime: 25 Sep 2008 20:25:59.0627 (UTC) FILETIME=[EC2011B0:01C91F4C]