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Via Fax # (301) 415-1101

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Ms. Annette L. Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20553-0001

Attention: Rulemakings and Adjudications Staff

Subject: Docket No. PRM-50-90; NRC-2008-0279
Federal Register, Vol. 73, May 27, 2008
Natural Resources Defense Council
Receipt of Petition for Rulemaking

Dear Ms. Vietti-Cook:

We are writing to you with regards to the above referenced Petition for Rulemaking. This Petition has a direct impact on end users of Technetium generators worldwide.

Every day there are 40,000 nuclear medicine procedures performed in the U.S.; more than 15 million annually. Worldwide there is roughly double this number of procedures. Approximately 95-98% of the medical radionuclides used in these diagnostic and therapeutic procedures are produced using HEU targets. HEU-based isotope production technologies are well-demonstrated and proven to be reliable; with over thirty years of experience base. At present all large scale production of Mo-99 occurs using HEU targets. Only smaller scale regional supply is being done using LEU targets at present. The proven reliability of HEU technologies at a large production scale is crucial to ensure a supply of isotopes to meet the daily needs of patients worldwide. The importance of such a reliable supply was evidenced in 2007 when daily isotope shortages occurred due to an extended outage of the NRU Reactor at AECL's Chalk River Laboratories (AECL-CRL).

Based on our analysis of isotope production from LEU, the use of HEU material is also more cost-effective and produces less nuclear waste that needs to be handled and stored as a result of isotope production activities.

MDS Nordion supports the conversion to LEU in an economical, technical and commercially viable manner. However, we do not believe that the NRDC position supports LEU conversion in this manner. MDS Nordion has examined LEU conversion and has several specific comments related to the NRDC Petition for Rulemaking and the export of HEU to Canada for isotope production as follows;

1. HEU is Highly Secured and Controlled

We reject the assertion that the export of HEU to Canada constitutes a terrorist threat or proliferation risk to either U.S or Canadian security. The delivery and storage of HEU exported for medical isotope production are highly regulated with significant oversight by both the U.S. and Canadian governments. Transfers from the U.S. to Canada have taken place for over 55 years, with no security incidents or loss of material occurring with those transfers. The U.S. Military conducts the actual transport of HEU from the U.S. to Canada. As outlined in a letter to the Armed Services Committee Chair in 2005 from the Canadian Ambassador to the U.S.¹, the HEU is stored at a government facility in Canada and U.S. Government security officials have reviewed the security arrangements in place and have expressed complete satisfaction with these arrangements. Any allegations that physical security arrangements for nuclear materials in Canada are inadequate have no factual basis.

Additionally, Canada's nuclear non-proliferation credentials are impeccable and have been repeatedly recognized by the U.S. Government. Canada is committed to Nuclear Non-Proliferation and has been non-nuclear weapon state party to the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) since the Treaty entered force in 1970. Also, Canada has a full-scope comprehensive safeguards agreement in place with the International Atomic Energy Agency (IAEA) that covers all nuclear materials and facilities in Canada. This agreement requires regular reporting by Canada to the IAEA of all movements of nuclear material to, from and within Canada, regular inspections by IAEA inspectors, and the installation of IAEA containment and surveillance measures at all establishments containing nuclear material under safeguards.

Canada and the U.S. have been successful partners in nuclear cooperation for over sixty years. National security arrangements in Canada and bilateral arrangements with the U.S. are designed to eliminate any genuine risk that unauthorized parties could gain access to HEU during the transport, storage, processing or use in Canada. Our view is that this successful partnership can continue into the future, to the benefit of medical patients in both Canada and the U.S.

2. Commercial Viability of Conversion and Ensuring Reliable Isotopes Supply

MDS Nordion supports the conversion to LEU produced medical isotopes in an economically, commercially and technically feasible manner. MDS Nordion has examined LEU conversion and identified several issues that need to be addressed for LEU conversion to meet these parameters. These issues have been conveyed to the U.S. Nuclear Regulatory Commission and the U.S. Department of Energy in the Annual Reports that MDS Nordion has submitted on the Progress of the Program and Canadian Co-Operation in Developing LEU Targets for the MAPLE Reactors and the New Processing Facility.

Furthermore, the U.S. Department of Energy's National Nuclear Security Administration (NNSA) conducted a workshop on LEU production of Mo-99 in Sydney, Australia on December 5-7, 2007 to examine issues related to the production of Mo-99 from LEU. This Workshop was attended by, amongst others, the world's major isotope producers. One of the conclusions at the workshop was that large scale production of Mo-99 using LEU is technically feasible and has been demonstrated, but that it had not yet been proven to be commercially viable. There are several factors impacting the commercial viability of Mo-99 production using LEU including but not limited to LEU target

¹ Letter from Mr. F. McKenna to Senator Warner and Senator Levin, dated November 28th, 2005.

and isotope extraction process development, qualification and licensing, characterization and minimization of new waste streams, environmental assessments associated with conversion, and transition to the new LEU production technology. Ultimately, the new LEU production technology (target and associated processes) must be developed in a manner that does not significantly increase the cost of medical isotope production, as any cost increase caused by conversion has to be passed onto the final customer (the nuclear medicine patient).

Aside from the significant technical challenges of conversion to LEU in a commercially viable manner, there is the significant matter of the transition from HEU-based isotope production to LEU-based isotope production. At present there are over 15 million nuclear medicine procedures performed each year in the U.S. and the worldwide number is roughly double this figure. Approximately 95-98% of these products are produced using HEU-based technology. Therefore, reliability of isotope supply is a key factor to be considered for LEU conversion. If the industry is forced to convert to LEU before all of the technical factors are addressed, there could be significant supply reliability issues upon implementation. Furthermore, it is likely that when LEU-based technologies are deemed ready to implement there will be the need to maintain an HEU-based supply for some period of time. This will ensure that there is a smooth transfer of technology and will assure supply reliability during the early stages of large-scale LEU isotope production. At present we have estimated this timeframe to be greater than two years. This need for dual supply drives up costs and reduces the commercial viability of conversion. Also, transition of technology is an uncertain process therefore a date is difficult to set as it is unclear how long of a transition period with dual supplies would be required.

The global supply chain for medical isotopes is complex and fragile. Disruptions in production at (or supply from) one or more of the large-scale production facilities can cause isotope shortages on a global scale. It is the obligation of the isotope current producers to ensure that there is minimal unplanned production and/or supply disruptions for the continued good of patients worldwide. Disruptions in isotope production from key producers in 2007 and 2008 have shown how delicate the global supply chain for these products can be when problems occur. The need to ensure a regular, continued supply of medical isotopes is supported by having an extended transition period with dual production capability, both HEU and LEU based. Disruptions in the LEU-based supply stream could stem from process immaturity. Supply could then be covered using the well-established HEU-based technology and global shortages to patients would be avoided during the transition period.

3. Timeline For Conversion

The NRDC Petition for Rulemaking states that two to three years will be sufficient for conversion of Canada's HEU-based isotope production technology to LEU-based technology. This timeline is not practical and we do not agree that conversion could be completed within two to three years in Canada.

The NNSA workshop in Sydney estimated that it would take eight years or longer to complete a successful conversion. The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) has estimated the time required to be ten years. We concur with these longer time estimates based on the work that MDS Nordion has performed to date on LEU conversion. These estimates include the time required for the various regulatory approvals that are associated with LEU conversion such as; Environmental Assessments, Nuclear Regulatory Approvals and FDA Approval of the LEU-based Mo-99. Environmental Assessments of the reactor, processing facility, waste handling

and storage facilities and process environmental releases would be required. Nuclear regulatory approvals will be required for the reactor conversion, the processing facility, materials handling and storage and for the new waste stream(s) and waste handling and storage technologies. Additionally, new processes will need to be developed and qualified, as well as new facilities constructed and commissioned for LEU based processes. The timeframe for these regulatory approvals alone would preclude conversion to LEU within a two to three year timeframe.

The timeline for conversion is also significantly impacted by the required transition period once LEU-based isotope production technology has been deemed ready to implement. In order to ensure a reliable supply of medical isotopes, a period of dual supply, from both HEU and LEU-based processes, will be required for a period of time. This transition period will significantly add to the overall time required to complete the conversion from HEU to LEU and does not allow for a fixed date by which conversion must occur.

While MDS Nordion supports the conversion to LEU, we cannot support a fixed target date for the conversion based on these factors, nor agree that conversion of Canadian technologies can be complete within the two to three years stated in the NRDC Petition for Rulemaking.

4. Conversion of Mo-99 Targets to MEU

The NRDC Petition for Rulemaking contained suggestions for a staged conversion from HEU to LEU, with an intermediate stage of converting targets to an enrichment of 20-40% (hereafter referred to as Moderately Enriched Uranium (MEU)). It is our understanding that the concept of MEU has not been accepted by the global nuclear community and policy makers. Enrichment to this level is in fact still considered to be HEU and as such this material could still be used to manufacture a nuclear weapon by terrorists.

From a technical perspective, there are likely advantages to processing MEU targets instead of LEU targets. This would result in less of an increase in the overall waste volume, which would have technical, financial and environmental benefits. However, a significant development program and fit-out of a processing facility would be required and the technical, economic and commercial merits are yet to be determined.

However, if conversion to MEU targets is viewed as an intermediate step for ultimate conversion to LEU targets, we do not agree that this is a commercially viable approach to conversion. We view the efforts required to convert to MEU targets to be equivalent to that required to convert to LEU targets. Similar conversion issues would be faced in both cases and either would require the regulatory approvals discussed above. Therefore the cost to convert from HEU to MEU is viewed to be similar as that to convert from HEU to LEU. Adding this stage would dramatically increase the cost associated with the ultimate conversion from HEU to LEU.

Also, the equipment and systems required to convert from HEU to MEU and from MEU to LEU may not be the same in all cases. Therefore, staged conversion will likely require more physical changes to the operating nuclear facilities being converted. The need for an increased number of changes in an operating nuclear facility does not follow the ALARA principal for protecting facility and maintenance workers.

It is our opinion that if conversion to LEU is the ultimate goal, then direct conversion from HEU to LEU is the path to take to preclude discontinuity in supply, technical disruptions, extraordinary and redundant costs as well as safety.

5. Government Funding for LEU Conversion

There will be significant costs associated with conversion to LEU-based Mo-99 production. Given that the exports of HEU to Canada for medical isotope production are highly regulated and have extensive security measures in place, it is our view that ceasing these exports is a policy driven by the US government to address their concerns about proliferation and reduce the global threat risk by minimizing civilian use of HEU. As such, government funding should be provided to assist with LEU conversion and to achieve this security policy. Such funding would serve to accelerate the on-going conversion initiatives for large-scale Mo-99 producers currently using HEU-based technologies, such as MDS Nordion.

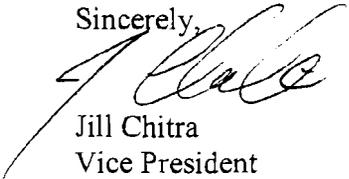
Summary

In summary, MDS Nordion supports the conversion to LEU in an economical, technical and commercially viable manner. We have reviewed the referenced NRDC Petition for Rulemaking related to LEU conversion and the exportation of HEU material for civil uses. However, based on our examination of LEU conversion to date, we do not support the NRDC Petition for Rulemaking based on the following points;

- HEU is highly secured and controlled,
- The commercial viability of conversion is unproven,
- The need to ensure a reliable isotope supply stream is paramount to ensure patient needs are met,
- The timeline for conversion is significantly understated by NRDC,
- Intermediate conversion to MEU not practical, cost-effective, nor an internationally accepted end result
- The need for government funding for LEU conversion is required to support US policy initiatives

MDS Nordion would like to thank the NRC for the opportunity to comment on the NRDC Petition for Rulemaking. We support the conversion to LEU-based technologies, but do not support the approach proposed by NRDC in the Petition. We believe that a more structured approach is required with longer time lines to ensure that conversion is performed in a manner that ensures a continued reliable supply of important medical isotopes to end users worldwide.

Sincerely,



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Facsimile

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