POLICY ISSUE
NOTATION VOTE

March 16, 2001 SECY-01-0047

FOR: The Commissioners

FROM: Janice Dunn Lee, Director
Office of International Programs

SUBJECT: **PROPOSED LICENSE TO EXPORT HEU TO CANADA FOR USE IN THE NRU REACTOR TO PRODUCE MEDICAL RADIOISOTOPES**

PURPOSE:

To obtain Commission review and approval of the application (XSNM03171) submitted by Transnuclear, Inc. requesting authority to export 10.05 kilograms (kg) of highly enriched uranium (HEU) to Atomic Energy of Canada, Limited (AECL).

BACKGROUND:

On October 23, 2000, Transnuclear, Inc., submitted an application on behalf of AECL for a license to export 9.377 kg of U-235 contained in 10.05 kg of uranium enriched to a maximum of 93.3 percent for use as targets in the NRU reactor located at the Chalk River Laboratories (CRL) in Canada. Use of the NRU reactor and its associated processing facility to continue production of medical radioisotopes, in particular Mo-99, is necessary because operation of the new MAPLE 1 and 2 reactors and the New Processing Facility (NPF) has been unexpectedly delayed.

AECL and MDS Nordion of Canada (Nordion) signed agreements in 1996, covering the design and construction of the two MAPLE reactors and the NPF to replace the NRU reactor and its associated processing facility (hereafter collectively referred to as NRU). The new facilities, which are owned by Nordion, and which will be operated by AECL, will be used exclusively for Nordion's medical isotope supply business.

Developments Warranting Continued Reliance on NRU

Problems with the MAPLE reactor shut-off rod systems and with tubing installations in the reactors and in the NPF have delayed their operation (Attachment 2). Although NRU had been

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scheduled to cease medical isotope production in May 2001, since it is not certain how long it will take to resolve the technical difficulties and obtain approval from the Canadian Nuclear Safety Commission (CNSC) to commence operation of the MAPLE facilities, AECL/Nordion must rely on NRU to avoid interruption of medical isotope supply.

AECL estimates that its existing HEU inventory for NRU, obtained from the U.S. under NRC export license XSNM03012 (issued on June 8, 1998 for 26.738 kg of HEU containing 24.947 kg U-235 - See SECY-98-112) will be exhausted by July 2001. The 10 kg of HEU requested in the present application will allow continued medical isotope production using the NRU for about one year, until July 2002, if necessary, while efforts continue to bring the MAPLE 1 and 2 reactors and NPF on line. The plan would be to make two shipments of the requested HEU to CRL, in increments of 5 kg each. AECL hopes to bring the MAPLE reactors and the NPF on line well before July 2002, and it is possible that the total amount of HEU requested for NRU may not be needed.

In order to begin manufacturing the targets in sufficient time to ensure that they will be available for use in NRU by July 2001, AECL needs to schedule the shipment of the first 5 kg of HEU requested in the current application so that it reaches CRL by the end of March 2001. Although AECL shipped unirradiated HEU scrap from its target fabrication process to the Dounreay facility in Scotland to be recycled into HEU metal suitable for NRU targets, to date, none of this material has been processed. (The subsequent arrangement authorizing this transfer of U.S.-origin material to Dounreay was approved by DOE in October 1997 -- see SECY-97-236.) It is not clear when the Dounreay facility will be able to process or return any of AECL's recycled HEU fabrication scrap.

In addition to the HEU needed to extend medical isotope production using NRU, AECL must also obtain authorization from the CNSC to either increase the waste storage capacity of NRU's Fissile Solution Storage Tank (FISST) or to utilize an alternative waste storage arrangement. AECL indicated to NRC that it could not rely on NRU beyond the spring of 2001, because of stringent waste storage limitations. Now that the MAPLE reactors and NPF are not available, however, AECL has no other option than to continue relying on NRU and to take actions that it otherwise would not have pursued.

As of the end of February 2001, AECL has not yet obtained authority from CNSC to increase the storage capacity of FISST. The issue is not whether the physical size of FISST can be increased, but whether the uranium concentration level in the facility can be increased without compromising safety margins. AECL submitted a revised Criticality Safety Document to its Nuclear Safety Criticality Panel (NSCP) and to CNSC requesting authority to increase FISST's uranium concentration level from 7.0 g/L to 7.6 g/L. NSCP approved the proposed increase on December 19, 2000, and although AECL expected CNSC to grant approval of the increase by the end of January 2001, it has been a difficult issue and is still under review. The only other near term storage alternative available for NRU waste is cementation. Although AECL is developing this as a back-up storage alternative in case FISST cannot accommodate additional waste, this is not considered an optimum storage arrangement.

According to AECL and based on informal discussions with CNSC, NRC staff confirmed that coupled with overall concerns about the reactor's age, waste storage is the major hurdle for continued medical isotope production using NRU. Increasing the storage capacity of FISST is

problematic because of criticality concerns. Waste cementation increases personnel exposures and introduces additional, new waste form and disposition considerations. The increased personnel exposures from waste cementation would be within CNSC regulatory limits, but they would not be as low as reasonably achievable (ALARA). Thus, both AECL and CNSC have limited options and must make difficult decisions to sustain medical isotope production.

Global Production and Supply of Medical Isotopes

A discussion of the role of Canada, the NRU and the MAPLE reactors in the global production and supply of medical isotopes is provided in Attachment 3.

Requirements of the "Schumer Amendment"

A discussion of the requirements of Section 134 of the Atomic Energy Act relative to this case is found in Attachment 4.

Relationship of the Current Case to the HEU Exports Authorized for MAPLE

The current request for 10 kg of HEU is closely related to the license issued by NRC in July 1999, authorizing the export of HEU to Canada for use in the MAPLE facilities. That license (XSNM03060) authorized the export of a total of 130.65 kg of HEU (121.8966 kg U-235) in the form of uranium dioxide (UO2) targets for startup testing and initial operation of the MAPLE 1 and 2 reactors and NPF. The Commission added the following conditions to that export license to ensure that the provisions of the Schumer amendment would continue to be met over its five-year duration:

> Export of HEU in calendar year 1999 is limited to 40.20 kg (37.5066 kg U-235) and in each calendar year from 2000 through 2003 is limited to 22.6125 kg (21.0975 kg U-235).
>
> Annual status reports detailing the progress of the program and Canadian cooperation in developing LEU targets for the MAPLE reactors are required.

AECL/Nordion submitted its first annual status report required by XSNM03060 in May 2000, and the Commission held a public meeting on July 10, 2000, to discuss this information with representatives of AECL, Nordion, Nuclear Control Institute, Department of State, Department of Energy and Argonne National Laboratory. In a memorandum to staff dated July 27, 2000, the Commission concluded that because the requirements of the Schumer Amendment were still being met, no modifications to export license XSNM03060 were necessary at that time. The Commission also observed that the authorization for export of 40.2 kg HEU in calendar year 1999 had expired without action. The Commission stated that for the remaining 3½ years of the license, the total amount of HEU authorized for export to MAPLE under XSNM03060 was reduced from 130.65 kg to 90.4 kg of HEU subject to the conditions set forth in the license.

Thus, the Commission has the authority to ensure that licensees adhere to the requirements of the Schumer Amendment (as well as other requirements of the Atomic Energy Act) and has demonstrated that it is prepared to exercise that authority.

Executive Branch Views

In a letter dated February 5, 2001, (Attachment 5), the Executive Branch informed NRC that based on its review of the new application for the export of HEU to NRU, it has concluded that the requirements of the Atomic Energy Act, as amended, have been met and that authorizing the proposed export would not be inimical to the common defense and security of the United States. After reviewing the physical security measures applicable to the proposed export and based on consultations with the Department of Defense as required under Section 133 of the Atomic Energy Act, as amended, the Executive Branch determined that the physical protection of the material to be exported will be adequate to deter theft, sabotage, and other acts of international terrorism, which could result in the diversion of that material.

The Executive Branch also concluded that the specific requirements for HEU exports contained in Section 134 of the Atomic Energy Act as amended (Schumer amendment) are met. This finding was based in large part on a meeting that took place at the Chalk River Laboratory on January 10-12, 2001, consisting of Argonne National Laboratory (ANL) RERTR program officials, a DOE representative and AECL/Nordion representatives. The results of that meeting were officially communicated in a letter from Trisha Dedik (DOE) to Richard J. K. Stratford (Department of State). (A copy of this letter dated January 24, 2001, is included as part of the Executive Branch views in Attachment 5.)

DISCUSSION:

Canada remains a close and reliable nuclear trading partner of the U.S. Based on Canada's compliance with the terms of the U.S.-Canada Agreement for Cooperation, its acceptance of IAEA full-scope safeguards under the Nuclear Non-Proliferation Treaty (NPT), and its application of adequate physical security and re-export controls over U.S.-supplied or obligated material and equipment, the Commission has in past export cases concluded that Canada meets the export licensing criteria set forth in sections 127 and 128 of the Atomic Energy Act. Moreover, in such cases, including ones specifically involving exports of HEU to AECL/CRL, in addition to meeting the requirements of the Schumer Amendment, the Commission has concluded that the issuance of such export licenses would not be inimical to the common defense and security or constitute an unreasonable risk to the health and safety of the public, pursuant to sections 53 and 57 of the Act.

As previously discussed, NRC staff reviewed the relationship of the current export license application with the export license (XSNM03060) issued to Transnuclear, Inc. on July 19, 1999, authorizing the export of HEU for the MAPLE reactors, including the information provided for the annual review and discussed at the Commission meeting in July 2000. Based on this review, NRC staff submitted a list of questions to the State Department, seeking additional information to further explore how the delay in operating the MAPLE reactors and NPF might affect the program underway to convert these facilities to LEU targets and whether this delay might ultimately result in a reduction in the amount of HEU needed for those facilities. The State Department forwarded these questions to the applicants, whose response was received on December 22, 2000. (The NRC questions and the responses are also included in Attachment 5, as part of the Executive Branch views.)

Around the same time, the Nuclear Control Institute (NCI) sent a letter dated December 18, 2000 to Chairman Meserve (Attachment 6) providing its views on the application from Transnuclear for export of HEU to Canada. Although not objecting to this new application to export HEU to NRU, NCI urged the Commission to consider: "(1) approving the export of the requested HEU for use at NRU as an amendment to Transnuclear Inc.'s existing license XSNM03060 for the MAPLE reactors, and (2) using this opportunity to encourage further U.S.-Canadian cooperation to facilitate LEU target development for the Maple reactors before the associated New Processing Facility becomes operational." In addition, NCI urged the Commission to convene a public meeting, presumably to consider these recommendations. AECL/Nordion provided additional information under cover letter dated January 5, 2001 (Attachment 7) and NCI sent another letter to Chairman Meserve on February 13, 2001 (Attachment 8).

In spite of the divergent views, there is no disagreement that the current request to export HEU to Canada for use in NRU meets the relevant statutory requirements, and there is no objection to approving it. A question posed is whether the Commission should use this opportunity to impose additional conditions on the related license and further reduce the amount of HEU authorized for export to the MAPLE reactors and NPF. For reasons summarized below, the NRC staff concludes it is not necessary to modify the HEU export license for MAPLE at this time.

First, considering the scale and importance of the Canadian medical isotope production program, it is evident to the NRC staff that continued reliance on NRU, which has been operating since 1957 as the sole producer of medical isotopes, presents substantial risks, is not AECL/Nordion's preferred course, and therefore, is not likely to be pursued any longer than is absolutely necessary. It is also evident that AECL/Nordion are both anxious to resolve outstanding technical issues and bring the MAPLE reactors and NPF on line as soon as possible to ensure the availability of a more reliable supply of Mo-99.

Second, AECL/Nordion has been providing the NRC detailed information describing why the LEU conversion program is structured as it is and extending operation of NRU to provide time to convert MAPLE to LEU has never been part of the equation. Operation of the NRU reactor and its processing facility differ significantly from operation of the MAPLE reactors and NPF. The HEU targets for the NRU and the MAPLE reactors are not interchangeable, i.e, the MAPLE reactors use HEU in the form of UO2 and the NRU requires HEU aluminum metal alloy targets. The performance of the NPF, in particular, needs to be assessed by processing targets irradiated in the MAPLE reactors on a test basis. While conversion of the MAPLE reactors to LEU targets appears straightforward based on paper studies, the conversion of NPF is more complicated largely because of a significantly greater volume of waste that will be generated using LEU.

Third, other than schedule delays, there have been no fundamental changes in the three-phased program that AECL/Nordion committed to for converting the MAPLE reactors and the NPF to use LEU targets. The NRC reviewed and accepted the AECL/Nordion program plan and schedule estimates, including the rationale that gaining experience in the operation of MAPLE is important for moving forward in the evaluation and implementation of LEU conversion. Based on reports from the recent meetings between representatives of AECL/Nordion, ANL and DOE, there is no doubt that an active LEU target development

program continues. As a result, there will be ample opportunity at the appropriate time to review the status of HEU exports for MAPLE when the annual report for this year is submitted in accordance with the requirements of the relevant export license.

Fourth, it is also worth noting that the efforts that must be expended to accomplish and sustain NRU medical isotope production divert resources that otherwise would be devoted to other aspects of the program. It is thus reasonable to assume that the sooner AECL/Nordion successfully produce medical isotopes using HEU targets in the MAPLE reactors and NPF and are confident that a reliable production source is in place, the sooner they will be able to develop the technical basis supporting the performance of and conversion to LEU targets.

Finally, adding a condition to an export license that would effectively require AECL/Nordion to modify its present program, to further delay operation of the MAPLE reactors and the NPF, to convert to LEU targets before all relevant design basis and operational evaluations have been completed would not be consistent with the approach NRC has taken in the past. In this regard, when urged to add a condition to export license XSNM03060 requiring AECL/Nordion to continue relying on NRU indefinitely until a feasibility study and any required modifications are completed at the NPF to accommodate LEU targets, the Commission refrained from imposing such conditions, declaring that it would be inappropriate for NRC “to dictate how and when a foreign reactor would be operated” (Commission Memorandum and Order CLI-99-20, dated June 29, 1999). Clearly, decisions of this nature as they apply to either NRU or the MAPLE facilities reside with Canadian authorities, who are closest and most familiar with all of the pertinent issues.

In summary, the NRC staff believe that the framework for monitoring the Canadian program (in particular the conditions contained in export license XSNM03060), is an effective mechanism for controlling the amount of and conditions under which HEU is exported from the U.S. Moreover, the circumstances forcing AECL/Nordion to rely on NRU for up to one year longer than previously anticipated do not seem to provide an opportunity to alter or expedite plans for converting MAPLE to LEU unless future circumstances permit greater tolerance of the risks and uncertainties associated with relying solely on NRU for medical isotope production and supply.

In response to requests from Commissioners, two NRC staff members have scheduled a trip to Canada to meet with CNSC and AECL/Nordion representatives to obtain current information on (1) the progress of the LEU conversion program, including the new preliminary schedule for the conversion; and (2) the actual HEU requirements (quantity and schedule of shipments) that are required to guarantee the uninterrupted delivery of medical radioisotopes from Canada. Staff will analyze the findings and provide a report on all pertinent information to the Commission as soon as the trip is completed.

CONCLUSION:

The NRC staff concurs with the Executive Branch judgment that authorizing the proposed HEU export for NRU would not be inimical to the common defense and security of the United States and would be consistent with the provisions of the Atomic Energy Act of 1954, as amended. The Office of the Executive Director for Operations and the Office of Nuclear Material Safety and Safeguards concur. The Office of General Counsel has no legal objection.

RECOMMENDATIONS:

Unless new information obtained during the NRC staff visit to Canada is clearly inconsistent with any of the findings presented in this paper, it is recommended that: (1) the Commission authorize the issuance of the license (XSNM03171) to Transnuclear, Inc. for the export of 10.05 kg of HEU to NRU; and (2) the Commission consider whether it is necessary to make an adjustment in the amount of HEU authorized for export to the MAPLE reactors under XSNM03060 as a separate matter to be reviewed following receipt of the next annual report on the subject due to the Commission in May 2001.

/RA/

Janice Dunn Lee, Director
Office of International Programs

Attachments:
1. 10/23/00 Export License Application from Transnuclear, Inc. (XSNM03171)
2. 10/23/00 Letter and Supplemental Information from Transnuclear, Inc.
3. Global Production and Supply of Medical Isotopes
4. Requirements of the Schumer Amendment Relative to this Case
5. 02/05/01 DOS Letter R.J.K. Stratford to J.D. Lee
   12/05/00 Assurances from Canadian Government
   01/24/01 DOE Letter T. Dedik to R.J.K. Stratford
   01/30/01 DOE Memo Sean Oehlbert to Robin DeLaBarre
   12/22/00 Applicant Letter J.A. Glasgow to R.D. Hauber forwarding Responses to Questions
6. 12/18/00 NCI Letter P.L. Leventhal & A.J. Kuperman to Chairman R. Meserve
7. 01/05/01 Applicant Letter J.A. Glasgow to R.D. Hauber forwarding Comments on NCI Letter
8. 02/13/01 NCI Letter P.L. Leventhal & A.J. Kuperman to Chairman R. Meserve

DISTRIBUTION:

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