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

NRC FORM 7 (9-91)
10 CFR 110

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0027
EXPIRES: 9-31-94
ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 1 HOUR. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0027), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR LICENSE TO EXPORT NUCLEAR MATERIAL AND EQUIPMENT

(See Instructions on Reverse)

1. APPLICANT'S USE	a. DATE OF APPLICATION	b. APPLICANT'S REFERENCE	2. NRC USE	
	10-23-00	MIS-545		11005236 XSNM03171

3. APPLICANT'S NAME AND ADDRESS

a. NAME: Transnuclear, Inc.

b. STREET ADDRESS: Four Skyline Drive

c. CITY: Hawthorne | STATE: NY | ZIP CODE: 10532

d. TELEPHONE NUMBER (Area Code – Number – Extension): 914-347-5064

4. SUPPLIER'S NAME AND ADDRESS (Complete if applicant is not supplier of material)

a. NAME: U.S. Department of Energy, Lockheed Martin

b. STREET ADDRESS:

c. CITY: Oak Ridge | STATE: TN | ZIP CODE: 37831

5. FIRST SHIPMENT SCHEDULED	6. FINAL SHIPMENT SCHEDULED	7. APPLICANT'S CONTRACTUAL DELIVERY DATE	8. PROPOSED LICENSE EXPIRATION DATE	9. U.S. DEPARTMENT OF ENERGY CONTRACT NO. (If Known)
March 2001			One year	To be determined

10. ULTIMATE FOREIGN CONSIGNEE

a. NAME: Atomic Energy of Canada, Ltd.

b. STREET ADDRESS (Facility Site): Chalk River Nuclear Laboratories

c. CITY: Chalk River, Ontario | d. COUNTRY: Canada KOJ 1JO

11. ULTIMATE END USE (Include plant or facility name)

To be used in the fabrication of target material for the production of medical isotopes.

11a. DATE REQUIRED

12. INTERMEDIATE FOREIGN CONSIGNEE

a. NAME:

b. STREET ADDRESS (Facility Site):

c. CITY: | d. COUNTRY:

13. INTERMEDIATE END USE

13a. DATE REQUIRED

14. INTERMEDIATE FOREIGN CONSIGNEE

a. NAME:

b. STREET ADDRESS (Facility Site):

c. CITY: | d. COUNTRY:

15. INTERMEDIATE END USE

15a. DATE REQUIRED

16. COM CODE	17. DESCRIPTION (Include chemical and physical form of nuclear material; give dollar value of nuclear equipment and components)	18. MAX. ELEMENT WEIGHT	19. MAX. WT. %	20. MAX. ISOTOPE WEIGHT	21. UNIT
	Uranium in the form of metal pieces	(U) 10.05	93.3	(U235) 9.377	kg

22. COUNTRY OF ORIGIN.– SOURCE MATERIAL	23. COUNTRY OF ORIGIN.–SNM WHERE ENRICHED OR PRODUCED	24. COUNTRIES WHICH ATTACH SAFEGUARDS (If Known)
To be advised	USA	

25. ADDITIONAL INFORMATION ON CONSIGNEES, END USES, AND PRODUCT DESCRIPTION (Use separate sheet if necessary)

26. The applicant certifies that this application is prepared in conformity with Title 10, Code of Federal Regulations, and that all information in this application is correct to the best of his/her knowledge.

27. AUTHORIZED OFFICIAL	a. SIGNATURE	b. TITLE
		General Manager-Operations

NRC FORM 7 (9-91)

RECEIVED OIP
2000 OCT 24 AM 10:22

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TRANSNUCLEAR, INC.

RECEIVED OIP
2000 OCT 24 AM 10:22

October 23, 2000

Mr. Ronald D. Hauber
Director for Non-proliferation, Exports and Multilateral Relations
Office of International Programs
Mail Station 04E9
U.S. Nuclear Regulatory Commission
Washington, DC 30555

SUBJECT: TNY REF: MIS 545
APPLICATION TO USNRC FOR LICENSE TO EXPORT
NUCLEAR MATERIAL (10 CFR 110)

Dear Mr. Hauber:

In accordance with 10 CFR 110, "Export and Import of Nuclear Equipment and Material", Subpart C, 10 CFR 110.31 "Application for a specific license", and 10 CFR 110.32, "Information required in an application for a specific license/NRC Form 7", Transnuclear, Inc., on behalf of Atomic Energy of Canada, Limited (AECL) requests the U.S. Nuclear Regulatory Commission to issue a USNRC specific license to export, shipments over a one year period, highly enriched uranium (HEU) for the production of targets that will be irradiated by AECL to produce radioisotopes for medial applications.

Enclosed is a completed NRC Form 7, "Application For License To Export Nuclear Material And Equipment", a supplement to Item 25 and a check issued to US Nuclear Regulatory Commission for $9,300 for the licensing fee.

In support of the application, we are also enclosing a "Checklist For Use in Review of Request for HEU to Determine Technical and Economic Justification". Because portions of the checklist contain commercial information and confidential information regarding inventories of HEU, AECL and Transnuclear have prepared confidential and U.S. Nuclear Regulatory Commission public

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versions of the checklist. The public version is enclosed as Attachment A. The confidential portions are enclosed at Attachment B. The confidential version of the checklist is marked "Protected-Commercial". An affidavit, executed by a senior AECL official, is attached to the confidential version of the checklist. For the reasons specified in the affidavit, Transnuclear and AECL request that the confidential version of the checklist (Attachment B) be maintained by the NRC in confidence pursuant to 10 CFR 2.790 and 9.714.

Your expedited review and issuance of the export license is appreciated. If you have any questions, please call me.

Yours truly,

John Mangusi
General Manager – Operations
Transnuclear, Inc.

SUPPLEMENT TO ITEM NUMBER 25 OF NRC FORM 7, SUBMITTED BY TRANSNUCLEAR INC. ON BEHALF OF AECL, REGARDING APPLICATION TO EXPORT APPROXIMATELY 10 KG OF HIGHLY ENRICHED URANIUM TO PRODUCE TARGETS TO BE IRRADIATED IN THE NRU REACTOR, FOR THE PRODUCTION OF MEDICAL ISOTOPES, INCLUDING MOLYBDENUM 99

I. PURPOSE OF EXPORT

For the reasons discussed in section II below, the proposed export to Canada of 10 kilograms of highly enriched uranium (HEU) in the form of uranium metal is needed to ensure the uninterrupted production of radioisotopes for medical purposes, including molybdenum 99 (Mo-99). Pursuant to commercial arrangements between AECL and MDS Nordion, AECL will use the HEU that is the subject of this export license application to produce targets for irradiation in the NRU reactor. After irradiation, those targets will be processed at a facility at AECL's Chalk River site, to extract Mo-99 and other radioisotopes for use in the treatment of seriously ill patients in Canada and the United States.

AECL's request to export 10 kg of HEU is based on the quantity of HEU that was necessary in recent years to produce sufficient HEU targets for irradiation in the NRU reactor, to meet current requirements, by MDS Nordion's customers, for medical isotopes, in particular Mo-99. The HEU metal would be received, over a one-year license term, in two shipments of 5 kg each.

To ensure the uninterrupted production of medical isotopes at the NRU reactor and its associated processing facility, an initial shipment of 5 kg of HEU to AECL's Chalk River site must occur by the end of March 2001, in order to begin the manufacture of targets in sufficient time to ensure that they will be available for use in the NRU reactor by July 2001, when AECL anticipates that the current inventory of targets for the NRU will be exhausted.

II. NEED FOR AN ADDITIONAL QUANTITY OF HEU

The requested export license is necessary because AECL has encountered a delay in operating the MAPLE reactors and associated New Processing Facility (NPF). The delay results from a technical problem with the reactor shut-off rod system and deficiencies in tubing installations in the reactors and NPF. Consequently, AECL must continue the supply of isotopes from the NRU reactor longer than had been anticipated.

As AECL has previously indicated to the NRC, it was anticipated that the supply of medical isotopes from the NRU reactor could not continue beyond May 2001, because of regulatory limitations on the storage capacity of AECL's Fissile Solution Storage Tank (FISST). The above-mentioned delay in operating the MAPLE reactors and NPF, however, forced AECL to renew its efforts to identify solutions to the current limitation on the capacity of the FISST. As a result, AECL has identified potential solutions, including cementation of waste as well as authorization by Canadian regulatory authorities of an increase in the permissible limit of uranium concentration in the FISST.

Because of the above-mentioned delay in operating the MAPLE reactors and NPF, AECL will need to procure more HEU metal to produce targets for the NRU reactor than was anticipated. Export license XSNM 03012, granted by the NRC on June 8, 1998, authorized the export to Canada of 26.738 kg, in the form of metal, for fabrication into targets for the NRU reactor. This export license was obtained by AECL to ensure that sufficient target material for the NRU would be available, in the event that the Dounreay facility in Scotland was unable to process target fabrication scraps containing approximately 24 kg of HEU metal, sent by AECL to Dounreay, and return the recovered HEU to AECL by the time it was needed to produce targets for the NRU reactor.

To date, the Dounreay facility has been unable to process any of AECL's fabrication scraps. AECL was recently advised that Dounreay is unlikely to restart on a schedule that would allow the processing of these fabrication scraps and the return of the recovered HEU to Canada by the time it is needed to produce targets for the NRU reactor.

Because of the unavailability of the HEU that was to have been obtained as a result of processing AECL's fabrication scraps at Dounreay, AECL has used the entire quantity of HEU whose export was authorized under XSNM 03012, to produce targets for the NRU reactor. AECL currently has enough HEU targets to continue isotope production in the NRU reactor until about July 2001.

III. RELATIONSHIP OF REQUESTED EXPORT LICENSE TO XSNM 03060, AUTHORIZING EXPORT OF TARGETS, CONTAINING HEU IN THE FORM OF UO_2, FOR USE IN THE MAPLE REACTORS

In July 1999, the Commission approved the Staff's issuance of XSNM 03060, authorizing Transnuclear, on behalf of AECL, to export a total of 130 kg of HEU, in the form of UO_2 contained in fabricated targets, for irradiation in the MAPLE reactors. Following irradiation, the targets are to be processed at the NPF to extract Mo-99, for use in the diagnosis and treatment of patients who have serious illnesses.

The history, purpose and current status of the MAPLE reactors and the NPF are described in detail in reports that MDS Nordion submitted to the Commission earlier this year. These reports contain a detailed explanation of the status of efforts that are actively underway to develop LEU targets that may be irradiated in the MAPLE reactors and processed in the NPF, consistent with operational constraints and Canadian regulatory requirements.

IV. HEU TARGETS FOR THE MAPLE REACTORS AND NEW PROCESSING FACILITY

Before applying for this export license, AECL evaluated the possibility that some of the HEU whose export for use in the MAPLE reactors is authorized by XSNM 03060 could be used to produce additional targets for the NRU reactor, pursuant to an appropriate export license amendment. However, the HEU UO_2 targets whose export is authorized by XSNM 03060 are

designed specifically for the MAPLE reactors and NPF. The isotope facilities currently in operation are designed to process uranium-aluminum alloy targets irradiated in the NRU reactor. Moreover, a license amendment to permit an export of a different form of material and a different end use, for 10 kg of the remaining authorized quantity of HEU, is not a viable means of obtaining targets for the NRU reactor since all of the HEU UO_2 targets whose export is authorized by XSNM 03060 are likely to be needed for the MAPLE reactors, as explained below.

A delay in operating the MAPLE reactors and NPF will not reduce the quantity of HEU targets that must be irradiated and processed in those facilities, pending completion of the ongoing program to shift those facilities from HEU to LEU targets. Some aspects of the HEU to LEU conversion program for the MAPLE reactors and NPF may be effectively pursued without having access to targets irradiated in the MAPLE reactors. However, the performance of such targets in the MAPLE reactors can only be assessed through experience with those reactors once they become fully operational. Likewise, because the operation of the NRU reactor differs significantly from the MAPLE reactors, the performance of the NPF cannot be assessed until targets irradiated in the MAPLE reactors are available for processing on a test basis. Consequently, an unavoidable consequence of a delay in operation of the MAPLE reactors is a corresponding extension of the time that will be required to complete the HEU to LEU conversion program.

In summary, since the number of HEU targets needed for the MAPLE reactor will not be reduced as a result of a delay in placing the MAPLE reactors and NPF into operation, it is not feasible for AECL to seek an amendment to XSNM 03060, allowing AECL to use 10 kg of the total quantity of HEU whose export is authored by that license for a newly specified end use in the NRU reactor.

V. ANNUAL REVIEW BY THE NRC OF THE TOTAL QUANTITY OF HEU NEEDED BY AECL IN CONNECTION WITH MEDICAL RADIOISOTOPE PRODUCTION AT THE NRU AND MAPLE FACILITIES

On July 10, 2000, the Commission conducted a public meeting on issues related to the export of HEU targets to Canada, for irradiation in the MAPLE reactors to produce radioisotopes for medical uses. In a presentation to the Commission and in responses to Commissioners' questions, representatives of AECL and MDS Nordion reviewed their progress and plans regarding conversion of the MAPLE reactors and NPF to operate with LEU rather than HEU targets and explained their need for the full remaining authorized quantity of HEU to produce targets for those reactors. Following this meeting, a Staff Requirements Memorandum (SRM) issued by the Secretariat expressed the Commission's conclusion that the "licensee has made significant progress over the past year in identifying, analyzing and resolving issues relevant to the conversion of the MAPLE reactors and NPF to LEU targets, particularly within the period immediately proceeding this briefing."

During its next annual review in connection with XSNM 03060, in mid 2001, the Commission will have an opportunity to consider the reports of the Applicants, the Executive Branch and Argonne National Laboratory (ANL) concerning the status of the LEU conversion program for

the MAPLE reactors and NPF, and the then-current inventories of HEU available to produce targets for the MAPLE reactors and the NRU reactor. Based upon such reports, the Commission will be able to evaluate the extent to which continued medical radioisotope production in the NRU reactor will be needed, pending full operation of the MAPLE reactors, and the extent to which HEU metal exported to Canada to produce targets for the NRU reactor could be shifted to the production of targets for the MAPLE reactors.

If the above-mentioned technical issues preventing operation of the MAPLE reactors are resolved more rapidly than is currently anticipated, some portion of the HEU that is the subject of this application may not be needed to produce targets for the NRU reactor. In that event, the Applicants will not use the license to export any quantities of HEU that are no longer needed.

VI. COMPLIANCE WITH THE NRC'S REGULATIONS IMPLEMENTING THE SCHUMER AMENDMENT

AECL and Transnuclear submit that the NRC's regulations implementing Section 134 of the Atomic Energy Act, as amended (the Schumer Amendment) will be satisfied if the requested export license is granted for a one-year term. An alternative low enriched uranium (LEU) target that can be used in the NRU reactor is not currently available and cannot reasonably be expected to become available for use within the one-year term that is requested for this export license.

The NRC's requirements concerning the Schumer Amendment, incorporated in 10 CFR §110.42(a)(9), and a September 1997 exchange of diplomatic notes between the U.S. and Canadian Governments recognize that in order to be available for use within the meaning of the Schumer Amendment, an LEU target must have been "qualified by the relevant authorities". To date, the relevant authorities in the United States and Canada have not qualified such LEU targets for use in the NRU reactor. Moreover, since AECL and MDS Nordion reasonably focused their efforts on constructing the new MAPLE reactors to replace the 43-year old NRU and are developing LEU targets for the MAPLE reactors and associated NPF, there is not sufficient time to develop an LEU target for use in the NRU reactor during the approximately one additional year of operation, beginning in July 2001, that is now anticipated.

VII. CONCLUSION

In summary, the requested export license is needed to ensure the continued availability of a stable and reliable supply of radioisotopes to serve the needs of medical patients in Canada, the United States and elsewhere. The requested 10 kg of HEU metal is needed in order to produce a sufficient number of targets for irradiation in the NRU during a period in which technical

problems will probably continue to prevent operation of the MAPLE reactors and associated NPF. Under these circumstances, the Applicants submit that issuance of this export license is consistent with the Schumer Amendment and all applicable NRC export criteria.

Jean-Pierre Labrie
General Manager, Research and Isotope Reactor Business
Atomic Energy of Canada Limited (AECL)
2000 October 20

Attachment A

PUBLIC VERSION

CHECKLIST FOR USE IN REVIEW OF REQUESTS FOR HEU TO DETERMINE TECHNICAL AND ECONOMIC JUSTIFICATION

1. Name of reactor and facility.

   The HEU is being requested for the NRU Reactor at AECL's Chalk River Laboratories (CRL) to be used for medical isotope production. The HEU being requested for export will be in the form of metal.

   There is no reactor fuel included in this request.

Note 1

Medical isotopes are currently produced in AECL's NRU Reactor located at CRL. However, medical isotopes are scheduled to be produced in the MAPLE 1 and MAPLE 2 Reactors now being built at CRL as part of the MDS Nordion Medical Isotopes Reactors (MMIR) Project. Isotopes will be produced in the MAPLE 1 and MAPLE 2 Reactors by irradiating HEU dioxide targets. In addition to the MAPLE Reactors, AECL is also building a New Processing Facility (NPF) where targets, irradiated in the MAPLE Reactors, will be processed to extract medical isotopes. Production of isotopes in the NRU reactor will end in year 2001 or when the MAPLE Reactors and NPF are in service.

2. Location

   Atomic Energy of Canada Limited
   Chalk River Laboratories
   Chalk River, Ontario
   CANADA, KOJ 1JO

3. Quantity of Uranium requested

   2001 10.0 kg HEU (in the form of metal)

4. Enrichment in the Isotope U-235

   93.15 wt%

5. Quantity of U-235

   2001 9.3 kg U-235

6. Type of Fuel Assembly and Form of Uranium

   12 element U_3Si-Al Fuel Assembly

Note 2

The NRU fuel is 61.4 % U_3Si in U_3Si-Al, 96.04 U in U_3Si and 19.75 wt% U-235.

7. Current Reactor Power Level (MW th)

130 MW

8. Duty Factor, Average Burnup

NRU Duty Factor about 75%
Average Driver Fuel Burnup of all Fuel in Core about 170 MWD

9(a) Current Core Loading (kg U-235)

42.7 kg U-235 (LEU)
0.5 kg U-235 (HEU targets for medical isotope production)

(b) Amount of Fuel Per Assembly (kg U-235)

0.486 kg

(c) Number of Assemblies in Core

90 (LEU)

(d) Average Core Life

Average exit burnup about 305 MWD; on-power re-fueling (avg. 9 rods/month). See Note 3 below.

Note 3

This average fuel rod usage does not include any contingencies.

The NRU Reactor annual fuel rod usage is 108 rods for an average of 9 rods/month.

A contingency of an extra 17 rods/year is required to counter fluctuations in neutron contribution from isotope rods, experimental rods etc.

(e) Active Core Dimensions

3.1 m diameter x 3.1 m in height

(f) Neutron Flux

Average mean neutron flux in the core:
thermal - 1.4×10^{14} $ncm^{-2}s^{-1}$

fast - 4 x 10^{13} $ncm^{-2}s^{-1}$

10. Annual Fuel Usage, (kg U-235)

11. Annual Spare Fuel Requirement (kg U-235)

12. Plans to Increase or Decrease Reactor Power Level

13. Estimated Annual Supply of Current Request

14. Required Manufacturer's Working Stock, if any, included in this request.

15. Fabrication Loss, if any, included in this request (kg U-235)

16. Name of Converter and Fabricator of Fuel

The alloying of the uranium metal and the fuel fabrication of the isotope production targets are done at Atomic Energy of Canada Limited, Chalk River Laboratories.

17. Location

See Section 16.

18. Inventory

19. Date at which current inventory, including 18 (a, b, c) will be expended.

HEU metal - 2001 July (See Note 7)
HEU dioxide - Not Applicable (the date at which the current inventory is expended depends on the date at which the MAPLE 1 and 2 Reactors and the NPF begin producing medical isotopes.

Note 7

This date is based on the available inventory of materials covered under Sections 18 (b) and (c) only. As described in Note 6, the current scrap inventory (Section 18 (a)) must be recovered before it can be used for target fabrication.

20. Date current request fuel will be needed at reactor.

2001 June

21. Date current requested will be needed by converter and fabricator.

2001 March

22(a)Time taken for shipment from USA to Converter/Fabricator

Category I (> 5 kg U-235)	Shipments of metal from the U.S.A to CRL, Canada, would be completed in one day and would be via military airlift.
Category II (< 5 kg U-235)	Shipments would be over-night delivery completed in < 24 hours.

(b)Lead time for ordering in U.S.A.

Normally eight months (Does not include shipping/export license acquisition)

23. Date at which current requested fuel will be expended, i.e. when a further HEU supply will be needed at reactor

2002 June

24. Dates at which reactor could be converted to 45% fuel; to 20% fuel,. Including time required for licensing procedures:

The Government of the United States and the Government of Canada have agreed that whenever a low enriched uranium (LEU) target has been qualified by the relevant authorities and does not result in a large percentage increase in the total cost of operating a reactor, including necessary associated equipment, for the production of medical isotopes, such an alternative LEU target will be used in that reactor in lieu of a high enriched uranium (HEU) target after required equipment has been installed and the necessary licenses have been obtained.

The NRU Reactor uses LEU driver fuel (19.75 wt% U-235).

25. History and Dates of previous HEU supplies by the U.S.A.

See Attachment 2.

26. Amount of Fuel of US origin previously consumed during operation of reactor.

All HEU consumed by AECL research reactors and the medical isotope programs to date has been of U.S. origin.

27.
&
28. Status of cooperation between reactor operator and Argonne National Laboratory in Reduced Enrichment Program (RERTR) and Status of Agreement between Reactor Operator and ANL to reduce enrichment.

The Canadian commercial entities involved in the production of molybdenum 99, MDS Nordion and AECL, are aware of the requirements of Section 134 of the Atomic Energy Act of 1954, as amended (AEA), commonly referred to as the Schumer Amendment, and have confirmed they are prepared to provide on a commercial basis, to the extent of their capabilities, information and services to the United States Government in its LEU target research and development efforts. The status of this cooperation was comprehensively addressed in two reports that Applicants submitted to the Commission earlier this year.

29. Status of cooperation between reactor operator and IAEA reduced enrichment program.

AECL/CRL was represented on an IAEA technical committee that prepared a guidebook for "Safety and Licensing Issues of Research Reactor Core Conversion from HEU to LEU".

ATTACHMENT 3

Global Production and Supply of Medical Isotopes

The NRU, which has been operating since 1957, is currently Canada's sole Mo-99 production source since the NRX reactor was shut down in 1993. Concern has been expressed not only about NRU's age and how long it will be capable of continuous, reliable Mo-99 production, but also about the fact that there is no backup Mo-99 production capability in Canada until at least the MAPLE 1 reactor is brought on line. Thus, there clearly is a sense of urgency to bring the new facilities on line as soon as possible. AECL currently produces Mo-99 exclusively for Nordion, which purifies the product and distributes what constitutes the majority of the world's supply, used primarily to generate technetium-99m (Tc-99), a derivative of Mo-99. It is estimated that more than 60% of Nordion's production of Tc-99, the most commonly used medical isotope, is supplied to markets in the U.S.

The U.S. buys most of its Mo-99/Tc-99 from Canada and uses more than all other countries in the world combined. Because Mo-99 decays rapidly, having a half-life of approximately three days, and Tc-99 even more rapidly with a half-life of about six hours, physicians are unable to maintain a significant inventory of material. Thus, a shortage would occur in a matter of a very few days if the supply from Canada were delayed or disrupted and European or other alternative suppliers were unable to fill in adequately.

According to information provided by the Department of Energy (DOE) as part of the Executive Branch views on XSNM03171 (Attachment 3), there are four major commercial producers of Mo-99, none of which are located in the U.S. In addition to AECL/Nordion in Canada, producers are located in Belgium, the Netherlands and South Africa. In the U.S., a program at Sandia National Laboratories to convert the Annual Core Research Reactor (ACRR) to produce Mo-99 was terminated in 1999. Although ACRR had been converted to full time Mo-99 production and the Hot Cell facility modifications were nearly complete to support 100 percent of U.S. demand for Mo-99, DOE was unsuccessful in its efforts to enlist the private sector to take over Mo-99 production. At this time, ACRR has been converted back to pulse operations to support DOE Defense Programs testing needs and the Hot Cell is in cold standby as a non-nuclear facility.

ATTACHMENT 4

Requirements of the "Schumer Amendment"

In addition to ensuring that the general export licensing criteria in the Atomic Energy Act are met, the NRC must ensure that proposed exports of HEU meet the specific requirements of Section 134 of the Atomic Energy Act, as amended by the Energy Policy Act of 1992 (commonly referred to as the "Schumer Amendment"). Specifically, the Commission is authorized to 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 any other requirement of the Atomic Energy Act, it is also determined that:

> (1) there is no alternative nuclear fuel or target enriched in the isotope U-235 to a lesser percent than that of the proposed export, that can be used in that reactor;
>
> (2) the proposed recipient of that uranium has provided assurances that, whenever an alternative nuclear reactor fuel or target can be used in that reactor, it will use that alternative in lieu of HEU; and
>
> (3) the United States Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.

The phrase "alternative nuclear reactor fuel or target" is defined to mean a fuel or target enriched to less than 20 percent in the isotope U-235. The phrase "can be used" is defined to mean that the fuel or target has been qualified by DOE's Reduced Enrichment Research and Test Reactor (RERTR) Program, and the use of the fuel or target will permit the majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor.

In addition to determining that the requirements of the Schumer Amendment are met before issuing an HEU export license, the NRC also takes steps to ensure that these requirements will continue to be met after the license is issued. The practice of adding case-specific conditions to HEU export licenses makes it clear to the licensee that the NRC will monitor the progress of the programs undertaken to replace HEU with LEU targets for medical isotope production and will consider whether to modify, suspend or revoke an export license if it finds that the requirements of the Schumer Amendment are no longer being met.

ATTACHMENT 4

Requirements of the "Schumer Amendment"

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> (2) the proposed recipient of that uranium has provided assurances that, whenever an alternative nuclear reactor fuel or target can be used in that reactor, it will use that alternative in lieu of HEU; and
>
> (3) the United States Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.

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United States Department of State

Washington, D.C. 20520

February 5, 2001

XSNM03171

Ms. Janice Dunn Lee
Director, International Programs
United States Nuclear Regulatory Commission
Rockville, Maryland

Dear Ms. Lee:

I refer to the letter from your office of October 25, 2000 requesting the views of the Executive Branch as to whether issuance of an export license in accordance with the application hereinafter described meets the applicable criteria of the Atomic Energy Act of 1954, as amended:

NRC No. XSNM03171 -- Application by Transnuclear, Inc for authorization to export to Canada 9.377 kilograms of U-235 contained in 10.05 kilograms of uranium in the form of metal enriched to a maximum of 93.3 percent. The highly enriched uranium (HEU) will be used for the production of medical isotopes in the NRU reactor operated by Atomic Energy of Canada Limited's Chalk River Nuclear Laboratories.

The proposed export to Canada would take place pursuant to the Agreement for Cooperation Between the United States and Canada, as amended, as confirmed in the enclosed letter dated December 5, 2000 from the Canadian Nuclear Safety Commission.

The Executive Branch has reviewed the application and concluded that the requirements of the Atomic Energy Act, as amended by the Nuclear Non-Proliferation Act of 1978 and the Energy Policy Act of 1992, have been met and that the proposed export would not be inimical to the common defense and security of the United States.

The Executive Branch has reviewed the physical security measures that are applicable to the proposed export and concluded that physical security will be adequate. The consultations required under Section 133 of the Atomic Energy Act, as amended, have been completed.

Section 134 of the Atomic Energy Act, as amended, (also referred to as the Schumer amendment to the Energy Policy Act of 1992) adds the following conditions to approval of HEU exports:

> *"a. The Commission may issue a license for the export of highly enriched uranium to be used as a fuel or target in a nuclear research or test reactor only if, in addition to any other requirement of this Act, the Commission determines that--*
>
> > *"(1) there is no alternative nuclear reactor fuel or target enriched in the isotope U-235 to a lesser percent than the proposed export, that can be used in that reactor;*

"(2) the proposed recipient of that uranium has provided assurances that, whenever an alternative nuclear reactor fuel or target can be used in that reactor, it will use that alternative in lieu of highly enriched uranium; and

"(3) the United States Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.

"b. As used in this section--

"(1) the term 'alternative nuclear reactor fuel or target' means a nuclear reactor fuel or target which is enriched to less than 20 percent in the isotope U-235;

"(2) the term 'highly enriched uranium' means uranium enriched to 20 percent or more in the isotope U-235; and

"(3) a fuel or target 'can be used' in a nuclear research or test reactor if --

"(A) the fuel or target has been qualified by the Reduced Enrichment Research and Test Reactor Program of the Department of Energy; and

"(B) use of the fuel or target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor."

The Executive Branch believes that the three conditions of Section 134 are met based on the following:

(1). Argonne National Laboratory has confirmed that there is no low enriched uranium target material currently available that can be used as an alternative to HEU for production of medical isotopes by Chalk River Laboratories.

(2) The Embassy of the United States in Canada and the Canadian Ministry of Foreign Affairs have exchanged diplomatic notes confirming that both Governments agree that all entities producing medical molybdenum-99 be required to use low enriched uranium targets when such targets are available. Moreover, the Department of Energy (DOE), in the enclosed letter dated January 24, 2001, reported a recent meeting between DOE and Argonne National Laboratory RERTR Program representatives with Atomic Energy of Canada and MDS Nordion on cooperation in LEU target development. The letter confirms that DOE and RERTR Program Managers have concluded that the course of action being followed continues to meet the criteria of the Schumer Amendment for the active development of an LEU target for medical isotope production.

(3) Argonne National Laboratory has an active DOE-funded program underway for the development of low-enriched uranium targets for production of medical isotopes.

The Executive Branch has also taken note of the applicant's explanation that this new HEU request is necessary because start-up of the two new Maple reactors and the associated New Processing Facility (NPF) for medical isotope production has been delayed because of problems with the reactor shut-off rod system and NPF tubing installations. As a result Atomic Energy of Canada Ltd (AECL) needs to continue operation of the old NRU reactor and associated processing facility for production of medical isotopes. The 10 kilograms of HEU requested represents a one year supply for the NRU. An initial shipment of 5 kilograms of HEU needs to be made by March 1, 2001 to meet production requirements. AECL had earlier anticipated shutting down the NRU by May 2001 as the first of the Maple reactors came on line and the NPF initiated production of medical isotopes from targets irradiated in the Maple reactor. Dr. Jean Pierre Labrie, General Manager, Research and Isotope Reactor Business, Atomic Energy of Canada, Ltd. has prepared detailed responses to the questions raised by NRC staff with respect to the foregoing situation, which have already been provided to the NRC by the applicant's attorneys. In addition, the Department of Energy has provided the enclosed report regarding the Sandia National Laboratory isotope production program which was terminated in 1999 for lack of private company interest in pursuing Mo-99 production on a commercial basis.

In view of the foregoing, the Executive Branch recommends that the required determinations be made and that the requested license be issued.

Sincerely,

Richard J. K. Stratford
Director
Nuclear Energy Affairs

Enclosures: (1) assurance letter
(2) DOE letters
(3). AECL responses to NRC questions.

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

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Your file Votre référence

Our file Notre référence

11-2-3
IL-Al-3528.0/2001

December 5, 2000

Mr. Richard Goorevich
Acting Director
Nuclear Transfer and Supplier Policy
Office of Arms Control and Nonproliferation
Department of Energy
Washington, D.C. 20585
USA

Dear Mr. Goorevich:

Reference is made to your letter dated November 21, 2000, concerning licence XSNM03171.

I confirm that the transfer of the material as identified on the above-noted licence application will be subject to all of the terms and conditions of the Agreement for Cooperation concerning the Civil Uses of Atomic Energy between the Government of Canada and the Government of the United States, and that the intermediate consignee, Atomic Energy of Canada Limited, Chalk River, Ontario is authorized to receive and possess the material.

Yours sincerely,

W. Angus Laidlaw
Nuclear Non-proliferation Officer
Non-proliferation, Safeguards
and Security Division

c.c.: Sean Ochlbert, US DOE
Betty L. Wright, USNRC

Canada

Department of Energy
National Nuclear Security Administration
Washington, DC 20585

January 24, 2001

Mr. Richard J. K. Stratford
Director
Office of Nuclear Energy Affairs
Department of State
Washington, DC 20520

Dear Mr. Stratford:

I have considered the facts with respect to Canadian efforts to meet the requirements of the Schumer Amendment as they apply to license application XSNM03171 to export ten kilograms of highly enriched uranium (HEU) to Canada for production of medical radioisotopes in the NRU reactor. It is my view that the finding in my letter to you on February 19, 1999, which stated that the criteria of the Schumer Amendment were met still pertains.

In an effort to obtain first hand knowledge of the situation, I sent Drs. Armando Travelli and George Vandergrift of the RERTR Program at Argonne National Laboratory (ANL) and Carl Thorne, an advisor to me, to Chalk River Laboratory on January 10-12 to meet with Atomic Energy of Canada Ltd. (AECL) and MDS Nordian officials.

It was confirmed at the meeting that recently discovered safety problems in the new Maple 1 reactor will necessitate the continued operation of the NRU reactor past the projected May 2001, shutdown if there is to be no break in the supply of radioisotopes by Nordian to its customers in the United States. The new Maple 1 reactor is currently undergoing corrective actions and is projected to be on line by the June or July this year. The Maple 2 reactor is receiving the same modifications as the Maple 1 and will probably be on line in approximately three months after Maple 1. As you may recall these two 10 MW reactors were designed for the single purpose of irradiating targets for the production of medical radioisotopes. Continued operation of the NRU is not without problems either. The AECL must obtain approval from the Canada Nuclear Safety Commission (CNSC) to put additional waste material into the Fissile Solution Storage Tank (FISST) at the NRU. A decision by the CNSC is expected soon.

I am pleased to report that steps were taken at last week's meeting to begin an active program of cooperation between AECL and Argonne in Phase II of the Conversion Plan. The Argonne effort will address the processing of waste in the New Processing Facility (NPF) from Low Enriched Uranium (LEU) targets. This is the area of the conversion to LEU targets that is most technically challenging. The LEU targets will have five times

the mass of Highly Enriched Uranium (HEU) targets. A reduction of the volume of the waste is critical in order to conduct the process within the space constraints of the hot cells in the NPF. The program begins with the preparation of a program plan by Argonne by the end of February 2001. Then begins a series of tests and experiments, followed by an evaluation of the impact of the findings on the NPF process. This part of the Conversion Plan could take as long as two years to complete. Given the above information, I conclude that all requirements of the Schumer Amendment are being fulfilled at this time. Should you have any questions, please do not hesitate to call me at 202-586-2100.

Sincerely,

Trisha Dedik
Director
International Policy and Analysis
for Arms Control and Nonproliferation
Office of Defense Nuclear Nonproliferation

UNITED STATES GOVERNMENT DEPARTMENT OF ENERGY

memorandum

Date: January 30, 2001

To: Robin DeLaBarre, Department of State

From: Sean Oehlbert, Department of State

Subject: Annular Core Research Reactor

I am writing this memo in response to your request for information regarding Sandia National Laboratory's Annular Core Research Reactor. The question you sent to me is provided below:

> What is the status of the Annular Core Research Reactor (ACRR) at Sandia National Laboratory that was in the process of being reconfigured to produce molybdenum 99 (Mo-99)? There had been an expectation that sustained production of Food and Drug Administration (FDA) approved Mo-99 would be achieved in 1999 and it would reach the production capacity of the Canadian reactors sometime in 2000. Are there any other sources of Mo-99?

The program at Sandia National Laboratory was terminated in 1999 after the ACRR had been converted to full time Mo-99 production and the Hot Cell facility modifications were nearly complete to support 100% of U.S. demand for Mo-99. At this time, the ACRR reactor has been converted back to pulse operations to support Department of Energy (DOE)/Defense Programs testing needs and the Hot Cell is in cold standby as a non-nuclear facility.

After careful consideration of the overall isotope program's needs, DOE terminated the program because of the unsuccessful effort to privatize the Mo-99 production. Specifically, program management felt that the increasing diversity of the world's supply of Mo-99 had significantly negated the urgency of establishing an emergency backup capability in the United States.

There are four major commercial producers of Mo-99. These producers are located in Canada, Belgium, the Netherlands and South Africa. All other holders of this technology are believed to be on the laboratory scale.

If you have any questions, please contact me at 586-3806.

1800 M Street, N.W.
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202-467-7000
Fax: 202-467-7176

Morgan, Lewis
& Bockius LLP
COUNSELORS AT LAW

James A. Glasgow
202-467-7464

December 22, 2000

VIA FACSIMILE

Mr. Ronald D. Hauber
Director, Division of Non-Proliferation,
Exports and Miltilateral Relations
Office of International Programs
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
4E9 OIP/NEMR
Rockville, Maryland 20852

Re: Export License Application XSNM- 03171 -- HEU for the NRU Reactor in Canada

Dear Mr. Hauber:

On December 14, 2000, I received a memorandum from Robin DeLaBarre of the Bureau of Nonproliferation Affairs, Office of Nuclear Energy Affairs, enclosing a copy of questions prepared by your office in connection with the above-referenced export license application. His memorandum requested a response from the applicant.

Dr. Jean Pierre Labrie, General Manager, Research and Isotope Reactor Business, Atomic Energy of Canada, Ltd., has now prepared the enclosed responses to each of the NRC's questions. If the NRC or the Executive Branch has additional questions in connection with this application for an export license, we will be glad to respond promptly.

Sincerely,

Jim Glasgow

James A. Glasgow

cc: Robin DeLaBarre

JAG/lrf:

Enclosures: As stated

Export Licence Application XSNMO3171
HEU for the NRU Reactor in Canada
2000 December 22

	US Nuclear Regulatory Commission Questions	AECL Answer
1 (a)	In previous discussions with the NRC, Atomic Energy of Canada Limited (AECL) and MDS Nordion underscored the need to begin operating the new MAPLE reactors and the New Processing Facility (NPF) as soon as possible to ensure a reliable supply of medical radioisotopes. The key rationale was that the NRU reactor has been operating since 1957 and it could not be operated at the required production rate beyond May 2001 because of severe limitation on the storage capacity of AECL's Fissile Solution Storage Tank (FISST). Now in light of unforeseen technical difficulties operating the MAPLE reactors and NPF, an effort is underway to identify options to increase NRU storage capacity to make it possible to extend its operation. What is the status of this effort, when will it likely be completed, and how much additional storage capacity will be possible?	AECL is authorized by the Canadian Nuclear Safety Commission (CNSC) to operate FISST up-to a maximum uranium concentration of 7.0 g/L. The Criticality Safety Document (CSD-01, Rev 7) to increase the uranium concentration from 7.0 g/L to 7.6 g/L has been submitted for approval to AECL's Nuclear Safety Criticality Panel (NSCP) and the CNSC. The NSCP granted approval to increase the uranium concentration in FISST on December 19, 2000. A formal request for approval is being made to the CNSC and a response from the CNSC is expected in January 2001. If approved by the CNSC, the increase in uranium concentration limit would allow use of FISST until July 2002, which represent about 14 months additional storage capacity.
1 (b)	Will there be sufficient storage if it becomes necessary to operate NRU beyond the schedule presently envisioned?	An increase in the uranium concentration limit from 7.0 to 7.6 g/L would provide sufficient storage to operate NRU for medical isotope production until July 2002, which is beyond the schedule presently envisioned for bringing the MAPLE reactors and NPF into operation.
1 (c)	Could this extra time provided by extending the operation of the NRU provide sufficient time to convert	In response to questions from the Commission during the July 10, 2000 Public Meeting, Dr. Ian Trevena stated that the concept

	US Nuclear Regulatory Commission Questions	AECL Answer
	the MAPLE reactors and NPF to LEU?	development phase (Phase 2) was expected "to take about 18 months, going to the end of 2001. Therefore, the implementation phase (Phase 3) cannot begin earlier than the end of 2001." For the reasons discussed at length in the Public Meeting, firm timetables for completion of the Implementation Phase cannot be specified at this time. However, the completion of Phases 2 and 3 will extend years beyond the extended date that is anticipated for use of the NRU. Consequently, AECL's proposed extension of the use of the NRU for about 14 months, until about July 2002, does not present an opportunity to convert the MAPLE Reactors and the NPF to operate with LEU targets.
1 (d)	Has this been evaluated as an option to avoid loading HEU in the MAPLE reactors and NPF? If so, what are the results of the evaluation?	HEU targets have been irradiated in the MAPLE 1 reactor during commissioning, as these are part of the reactor core. As stated above, the increase in uranium concentration in FISST does not provide sufficient time to convert the MAPLE reactors and NPF to LEU.
2 (a)	Have consultations with Canadian Nuclear Safety Commission (CNSC) regulatory authorities begun regarding the continued use of NRU and expansion of storage capacity?	The Criticality Safety Document (CSD-01, Rev 7) was submitted to AECL's Nuclear Safety Criticality Panel (NSCP) for approval to increase the uranium concentration limit in FISST from 7.0 to 7.6 g/L and to the CNSC for information at this time. One meeting was held with the CNSC criticality specialists and licensing staff.
(b)	What factors will need to be (or have been) addressed to obtain necessary approvals by CNSC? What is the projected schedule for CNSC review of continued use of NRU? Are there any other factors that must be addressed?	The formal request to increase the FISST uranium concentration limit to 7.6 g/L is being made to the CNSC, after receiving NSCP approval on December 19, 2000. The request to the CNSC is to amend Chalk River Laboratories Licence NRTEOL-1.00/2002 and change the Molybdenum-99 Facility Authorization, AECL-FA-07, Rev 6, May 2000, to increase the uranium concentration

	US Nuclear Regulatory Commission Questions	AECL Answer
		limit in the FISST from 7.0 to 7.6 g/L. CNSC approval of the change is anticipated in January 2001. There are presently no other factors than those indicated above to address.
3.	What is the status of recovering HEU shipped to the Dounreay facility in the United Kingdom? What is the likelihood the HEU will be processed at Dounreay and has there been any indication when you might expect to know the details?	Dounreay had completed in September 2000 an engineering review and design substantiation of the Uranium Recovery Plant. As of December 15, 2000, there were no indications from Dounreay as to when regulatory approval will be granted to restart the Plant. Dounreay representatives have indicated that assuming regulatory approval was granted in the near future, the earliest time period when recovery of AECL's material would begin is in March to June 2002.
4 (a)	Has any of the HEU authorized for export under licence XSNM03060 been shipped to the MAPLE reactors? If so when and how much?	To date the following shipments have been made: 250 targets 31 January 2000 250 targets 12 October 2000 250 targets 29 November 2000 250 targets 18 December 2000 The total amount of HEU received to-date under export under licence XSNM03060 is about 20 kgU.
4 (b)	Could any of that material or a portion of the remaining balance in the United States be used in the NRU?	The isotope production process in the NRU reactor and existing Molybdenum-99 Facility is based on uranium-aluminium alloy targets. The isotope production process in the MAPLE reactors and New Processing Facility is based on uranium dioxide targets. These process are not interchangeable and consequently MAPLE targets cannot be processed in the existing Molybdenum-99 Facility, similarly, NRU uranium-aluminium alloy targets cannot be processed in the New Processing Facility. The current export

	US Nuclear Regulatory Commission Questions	AECL Answer
		licence XSNM03060 is specifically for manufactured HEU dioxide targets for use in the MAPLE reactors and New Processing Facility. The existing Molybdenum-99 Facility cannot process targets received under export licence XSNM03060. Converting HEU dioxide targets for the MAPLE reactors received under export licence XSNM03060 to HEU aluminium alloy targets for the NRU reactor and existing Molybdenum-99 production facilities is beyond AECL's facilities' current capabilities and would require significant development work to achieve and regulatory approvals to implement. Consequently, this option is beyond the time period required to manufacture HEU aluminium alloy targets and sustain continued supply of medical isotopes from the NRU reactor.
4 (c)	Similarly, given the delay, will it be possible to reduce the total amount of HEU already requested and approved for export to the MAPLE reactors? Or is there a possibility that it will be necessary to amend the export licence XSNM03060 to extend the expiration date as a result of the delays and the licence conditions limiting annual HEU exports to the MAPLE reactors?	The delay in completing the commissioning of the MAPLE reactors and New Processing Facility also delays the build-up of operating experience to identify methods for achieving their conversion to LEU. The delay does not affect the need for the total amount of HEU currently approved for export to the MAPLE reactors. Depending upon the date when the MAPLE reactors assume operational status and the progress of Phases 2 and 3 of the HEU to LEU conversion program, it may be necessary to request an amendment to export license XSNM03060 to extend the expiration date.
5 (a)	What is the current licensing status of the MAPLE reactors and the NPF?	The CNSC operating licences for the MAPLE reactors and NPF NPROL-62.2/2001 and NSPFOL-03.1/2001 remain in effect.
5 (b)	What are the view of the CNSC with respect to the	The view of the CNSC with respect to the technical problems

	US Nuclear Regulatory Commission Questions	AECL Answer
	technical problems associated with the reactor shut off rod system and deficiencies in the tubing installations in the MAPLE reactors and NPF?	associated with the reactor shut off rod system and deficiencies in the tubing installations in the MAPLE reactors and NPF are contained in CMD 00-M74 attached.
6 (a)	Have there been any new developments with respect to the LEU conversion process, even though just discussed in July?	AECL arranged a meeting with MDS Nordion at SGN offices on November 16, 2000, to finalize the scope and schedule of the Phase 2 Conversion Development Program, which is based on increasing the waste solidification capacity of the NPF. MDS Nordion communicated with ANL on the meeting and their participation in Phase 2 work. A meeting with ANL and MDS Nordion at AECL's Chalk River Laboratories is being arranged in January 2001.
6 (b)	For example, have you come to any conclusions about having to build an additional processing facility rather than modifying NPF? In July, it was indicated that a decision on this particular issue would be made by September 2000?	In July 2000, MDS Nordion indicated that the Phase 2 Conversion Development Program would take about 18 months and the outline of the program would be completed in September. In November 2000, MDS Nordion and AECL met with SGN to finalize the detailed scope of work, which includes precipitation studies with ANL. A meeting is being arranged with ANL, MDS Nordion at AECL's Chalk River Laboratories in January 2001. A decision on the construction of an additional processing facility would be premature at this time without the results of the Phase 2 Conversion Development Program. A commitment for a decision on this particular issue by September 2000, was not made by MDS Nordion or AECL at the July 2000 meeting.
6 (c)	Also, have there been any interactions with Canadian and US FDA regulators?	MDS Nordion has not yet had discussions with the USFDA regarding LEU. Interactions have been on the process for receiving approval for medical isotopes produced in the MAPLE reactors.

CMD 00-M74

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(Ref.: CMD 00-M37
CMD 00-H11)

Your file / Votre référence

Our file / Notre référence

2000-11-27

26-1-62-0-0

TO:	Commission Members	AUX :	Commissaires
FROM:	Directorate of Fuel Cycle and Materials Regulation	DE LA :	Direction de la réglementation du cycle du combustible et des matières nucléaires
PURPOSE:	Information	BUT :	Information
SUBJECT:	Failure of Shut Off Rods in the MAPLE 1 Reactor at the Chalk River Laboratories	OBJET :	Défaillances des barres d'arrêt du réacteur MAPLE 1 aux laboratoires de Chalk River

SUMMARY

This report provides an update on the investigations carried out by AECL and by CNSC staff of the failures of shut off rods that occurred during commissioning of the MAPLE 1 reactor. It also provides information on AECL's proposed program of corrective actions and actions to prevent recurrence.

This report is provided for information and in response to a request made at the Commission meeting of August 16, 2000.

RÉSUMÉ

Ce rapport fournit une mise à jour sur les évaluations faites par EACL et par les agents de la CCSN sur les défaillances des barres d'arrêt qui ont eu lieu lors de la mise en service du réacteur MAPLE 1. Il fournit également des renseignements sur le programme des activités correctives proposé par EACL ainsi que sur les mesures pour en prévenir la récurrence.

Ce rapport est fourni à titre de renseignements et en réponse à la demande faite à la réunion de la Commission du 16 août 2000.

Canada

CMD 00-M74

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Failure of Shut Off Rods in the MAPLE 1 Reactor at the Chalk River Laboratories

1. INTRODUCTION

This report provides an update on the investigations carried out by AECL and CNSC staff of the failures of shut off rods that occurred during commissioning of the MAPLE 1 reactor. It also provides information on AECL's proposed program of corrective actions and actions to prevent recurrence. It is provided for information and in response to a request made at the commission meeting of August 16, 2000.

2. FAILURES OF CONTROL ABSORBER RODS AND SHUT OFF RODS

As was reported in CMD 00-H11 and in CMD 00-M37 (Significant Development Report), AECL reported several events that involved failure of a MAPLE 1 control absorber rod (CAR) or shut off rod (SOR) to fall fully into the core when tested. The first failure (of a CAR) occurred on December 23, 1999 and the most recent failure (of a SOR) occurred on July 18, 2000. These failures cast doubt on the reliability of Safety System 1 (SORs) and Safety System 2 (CARs) and prompted in-depth evaluations by both AECL and CNSC staff. The following sections discuss the findings to-date of these evaluations and the status of actions to correct the problem and prevent its recurrence.

2.1 Safety Significance of the Failures

CNSC staff concluded that the SOR and CAR failures had no direct impact on public or worker safety. All failures occurred when the reactor was already shut down. Furthermore, each failure involved only one SOR or CAR. The shutdown systems are designed such that the system remains effective with one SOR (Safety System 1) or CAR (Safety System 2) unavailable.

However, the failures showed that the SORs and CARs were significantly less reliable than was assessed and accepted in the licensing safety assessment. In the case of the SORs, AECL failed to detect this until after fuel loading into MAPLE 1. CNSC staff considers that its failure to detect and correct the problem sooner represented a serious breakdown in AECL's program for management of safety. The status of AECL's proposed course of action to address this is discussed in section 2.3. The CNSC incident Inspection Team (IIT), described in section 2.4, will assess the need for changes in CNSC regulatory processes. CNSC staff plans to present the IIT's findings to the Commission at its January 2001 meeting.

2.2 SOR Design, Operation and Maintenance

AECL concluded that design changes were needed to assure the future reliability of the SORs. Prototype testing of the original SOR design showed acceptable reliability. However, management of the test program was questionable. Some planned testing was not done and some testing was done under conditions not representative of the real reactor. For example, AECL did no qualification tests on production SORs, although its Design Verification Plan called for it. Also, the prototype tests were done with the test rig's circulating pump shut down, which is not representative of conditions in the real reactor.

AECL concluded that the original SOR design was vulnerable to jamming by relatively small particles and that ingress of such small particles cannot be ruled out (even with improved filtering, etc.). As a result, AECL staff recommended design changes to increase the bearing clearances over most of the SOR travel. With the proposed design change, there would still be tight clearances at the end of travel to provide "down" sensing for the SORs. However, a rod sticking near the end of its travel would have little impact on safety system effectiveness. AECL staff also proposed design changes to the SORs and their hydraulic supply system to reduce the likelihood of particles being created or introduced downstream of the filters.

Besides the design changes, AECL proposed changes to operating and maintenance procedures, based on the lessons learned from the MAPLE 1 SOR failures. The original procedures were found to be deficient. This is at least partly attributable to inadequate transfer of design information to operating and maintenance staff.

When this report was prepared, AECL had not yet submitted details on its proposed design changes. CNSC staff expects to receive more details on the proposed change in early-December. The proposed change will require approval of AECL's Office of the Chief Engineer, of AECL's Safety Review Committee and CNSC approval. AECL is currently doing prototype testing of modified SORs and will include the test results in the request for approval of the proposed change.

2.3 Management and Organizational Issues

AECL's investigation identified deficiencies in managed processes that contributed to the occurrence of the SOR failures. These included inadequate engineering supervision, a breakdown in communication between engineering and the project and inadequate design verification. For example, AECL's investigation team found that design changes recommended as a result of feedback from the Korean HANARO reactor were not fully implemented. They attributed this to a desire to avoid design changes for contractual and schedule reasons.

They also found evidence that short-cuts were invoked to complete the job on schedule. For example, as mentioned in section 2.2, prototype testing was done with the pump shut down and some planned tests were not done. Schedule pressures seem to have been a factor in both decisions. They also found evidence of inadequate design completion assurances. Specifically, the completion assurances were signed off although key design documents were incomplete. These included the test reports that could have alerted AECL staff and management to the incomplete state of SOR testing. As a result, AECL's commissioning staff did not have access to documentation that described the testing done and, more importantly, what remained to be done. Several commissioning tests on the SORs, in the MAPLE 1 reactor, were also done with the primary cooling system (PCS) pump shut down.

CNSC staff concluded that the management and organizational issues identified by AECL's investigation team were both serious and widespread. This raised questions on the quality of the "as built" facility that extended beyond the issue of SOR reliability. We therefore requested AECL to address these wider implications of their findings. AECL's response states that it is taking the following actions to address these concerns:

(a) AECL is performing detailed reviews of the as built state of two other systems important to safety. These are the reflector dump system (part of Safety System 2) and the Exhaust Air Filtration System. The investigation will include reviews of the design, construction and commissioning, concluding at the commissioning completion assurance step. This detailed investigation includes reviews of feedback of information, design verification and completion assurance, change control, documentation and quality assurance (QA). These are all areas that were found to be deficient and to have contributed to the SOR failures. AECL's detailed investigation of the as built state of these two systems is scheduled to be completed by November 30, 2000.

(b) AECL is also performing less detailed reviews of the as built state of other MAPLE 1, MAPLE 2 and NPF systems. These are aimed at identifying systems and components that are susceptible to construction deficiencies similar to those found on the SOR hydraulic lines and that may not have been adequately verified after the construction was completed. This assessment is also scheduled to be completed by November 30, 2000.

(c) AECL will prepare a lessons learned report, in accordance with its overall QA manual to ensure that lessons learned are fed back to other AECL projects.

In addition, AECL has proposed corrective actions to address the specific recommendations of its internal root cause investigation report. These include actions to assure proper control of the design, fabrication and testing of the revised SOR design and to ensure that the revised SOR design adequately reflects feedback from HANARO. AECL's proposal includes a review of the project's design verification plan and design completion assurances and actions to correct any gaps found. At the end of this process, AECL will reconfirm the design completion assurances. AECL has committed to ensure that all corrective actions relevant to the MAPLE reactors will be implemented before it seeks approval to proceed with the next phase of commissioning.

CNSC staff reviewed AECL's proposed program of corrective and preventive actions. We concluded that it does address the key issues related to fitness for service of MAPLE reactor systems. However, its effectiveness will depend on how rigorously it is followed. In addition, it may be necessary to expand the program, to address any findings of the reviews described in items (a) and (b). As a result, CNSC staff intends to do its own follow-up review. CNSC staff will be seeking assurance that (1) AECL has done enough to uncover any potential problems beyond the issue of SOR reliability and (2) that AECL has corrected the identified management and organizational deficiencies and any additional problems found so as to assure effective management of safety in the future.

The lessons learned from MAPLE 1 SOR failures may have implications on the adequacy of AECL's quality management processes. CNSC staff will follow up appropriately on this after the IIT report, mentioned in section 2.4, is finalized.

2.4 CNSC Incident Inspection Team Review

Following the SOR failure on July 18, 2000, CNSC staff formed an incident inspection team (IIT) to evaluate the SOR failures and AECL's response to them. The team was led by a specialist from the CNSC's Event and Investigations Section and team members were drawn from Safety Evaluation Division "A" and from the Quality Management and Human Factors sections.

The scope of the IIT's inspection included the following:

- the conditions preceding the series of control and shut-off rod failures;
- the event chronology;
- equipment performance;
- any precursors to the event;
- the safety significance of the event; and
- the adequacy of AECL's investigation.

The IIT evaluated documents submitted by AECL, inspected facilities both at CRL and at AECL's premises in Mississauga and interviewed AECL staff involved in the project. The IIT's inspection is now complete and the IIT expects to complete its final report in December. CNSC staff plans to present the report to the Commission at the January 2001 meeting.

3. DISCUSSION AND CONCLUSIONS

AECL and CNSC staff evaluations revealed deficiencies in how AECL managed and performed work. These deficiencies allowed MAPLE 1 to be started up and commissioned with safety systems that were significantly less reliable than was assessed and accepted in the licensing safety assessment. CNSC staff concluded that these management and organizational deficiencies (described in section 2.3) had implications that extended beyond the specific question of SOR reliability. In particular, they cast doubt on the as-built quality of other systems in the MAPLE reactors and NPF. For example, AECL and CNSC staff found evidence that design and commissioning work on the SORs was incomplete or improperly performed. However, these deficiencies were not found by AECL's internal completion assurance processes. This raised questions on the adequacy of the completion assurances that AECL had submitted for other systems.

Follow-up actions are required both to assure the reliability of the SORs and CARs and to address management and organizational deficiencies. These must be completed before CNSC staff approve any of the following activities:

- Phase C commissioning of MAPLE 1
- fuel loading into MAPLE 2
- hot (radioactive) commissioning of the New Processing Facility.

CNSC staff concluded that AECL's proposed program of corrective and preventive actions does address the key issues. However, its effectiveness will depend on how rigorously it is followed and AECL may need to expand the program, to address any additional findings. As a result, CNSC staff intends to monitor AECL's progress in implementing the proposed program.

In conclusion, CNSC staff finds as follows:

1. The SOR and CAR failures had little direct impact on public safety.

2. The as-installed SORs were significantly less reliable than was assessed and accepted in the licensing safety assessment.

3. AECL's failure to detect and correct the problem earlier constitutes a serious breakdown in its program for management of safety. The SOR reliability problem should have been corrected during the design process. Failing this, it should have been detected by the completion assurance processes.

4. CNSC staff follow-up work is required to confirm that AECL has taken effective action to assure the reliability of the SORs and CARs and to address the identified management issues. This includes confirmation that AECL has done a sufficiently thorough review to identify any problems affecting other systems and has corrected any such problems found. It also includes reviews of AECL's processes for completion assurances. We consider completion of this follow-up and acceptance of the results to be prerequisites to CNSC approval (required by licence condition C2) to proceed with future commissioning phases of the MAPLE reactors and NPF.

5. The lessons learned from the MAPLE 1 SOR failures may have implications on the adequacy of AECL's quality management processes. CNSC staff will follow up appropriately on this after the IIT report, mentioned in section 2.4, is finalized.

ABBREVIATIONS AND ACRONYMS

AECL	Atomic Energy of Canada Limited
CAR	Control Absorber Rod
CNSC	Canadian Nuclear Safety Commission
CRL	Chalk River Laboratories
DIF	Dedicated Isotope Facilities
FME	Foreign Materials Exclusion
IIT	Incident Inspection Team
MMIR	MDS Nordion Medical Isotope Reactor project
PCS	Primary Cooling System
OLC	Operational Limits and Conditions
QA	Quality Assurance
SOR	Shut Off Rod

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December 18, 2000

The Honorable Richard Meserve
Chairman
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New Transnuclear Request for Export of HEU to Canada

Dear Chairman Meserve:

The Nuclear Control Institute (NCI) has carefully reviewed the application of Transnuclear, Inc. for a license (XSNM 03171) to export 10.05 kilograms of highly enriched uranium (HEU) in the form of metal pieces over a one-year period for the production of targets to be irradiated by Atomic Energy of Canada, Limited (AECL), as published in the Federal Register on November 16, 2000 (65 Fed. Reg. 69345).

NCI does not oppose the export of this quantity and form of HEU for use as targets in the NRU reactor, given the unusual circumstances of the application. The applicant states on behalf of AECL that the material is needed to ensure the uninterrupted production of radioisotopes, for medical purposes, in the NRU reactor and its associated processing facility because of an unanticipated delay in the start-up of the new MAPLE reactors and associated New Processing Facility (NPF). For this reason, NCI is not petitioning the Commission for leave to intervene as a party in opposition to the export. Nor are we requesting an adjudicative hearing.

At the same time, we wish to underscore the significance of new and disturbing facts brought to light in this license application that have a direct bearing on the Commission's supervision of the export of a total of 90.4 kilograms of HEU to Canada during the remaining period of another license, XSNM 03060, which was issued on July 19, 1999. Of particular concern is the following statement by the applicant in support of the new license application:

> As AECL has previously indicated to the NRC, it was anticipated that the supply of medical isotopes from the NRU reactor could not continue beyond May 2001, because of regulatory limitations on the storage capacity of

> AECL's Fissile Solution Storage Tank (FISST). The above mentioned delay in operating the MAPLE reactors and NPF, however, forced AECL to renew its efforts to identify solutions to the current limitation on the capacity of the FISST. As a result, AECL has identified potential solutions, including cementation of waste as well as authorization by Canadian regulatory authorities of an increase in the permissible limit of uranium concentration in the FISST.

You will recall that NCI, in its testimony at the Commission's public meeting on July 10, 2000, urged the Commission to examine closely MDS Nordion's changing story about how long it could rely on the NRU facilities on the basis of its contention that the capacity of the waste tank was rapidly being reached. We stated:

> In this context, it should be noted that the applicant's latest assertions about the remaining life of the NRU processing facility directly contradict its testimony of last year. At last year's public meeting, the applicant argued against any delay in starting up the NPF, to permit modifications to be made, on grounds that the NRU would reach capacity by the end of this year. Iain Trevena of Nordion stated that "with respect to NRU we have a storage tank that's used to contain our high-level fission waste. That storage tank will be filled by the end of the year 2000." NCI pointed out that the capacity of the tanks had been increased previously and might be able to be increased again to extend isotope production at the NRU while modifications were made to the NPF. But John Matthews of AECL insisted that "there is a technical barrier and that is the waste tanks will be full at the end of the year 2000." Remarkably, only a year later, the applicant's story has changed. Now it asserts that the NRU waste tank will not reach capacity until "approximately the Spring of 2001." This is unfortunately another indication that the applicant has played fast and loose with the facts, apparently to provide excuses for not making modifications to the NPF prior to start-up, as the Commission had intended.

Grant Malkoske, MDS Nordion's vice-president for engineering and technology, responded in this way at the July 10 meeting:

> In recent letters to the Commission and during the Commission's June 16, 1999, Public Meeting, NCI argued that MDS Nordion and AECL should continue to irradiate HEU targets in the 40-year-old NRU reactor and its

> associated radioisotope processing line while they are converting the MAPLE reactors and the NPF to use LEU targets. However, the availability of the NRU and its processing facility to supply medical isotopes will end by approximately the Spring of 2001, because the fissile liquid waste storage capacity of that facility will be reached. Moreover, as MDS Nordion pointed out at the Commission's Public Meeting on June 16, 1999, there are other important regulatory and operational reasons why NCI's suggestions regarding continued use of the NRU cannot be implemented.

In the new license application, applicant seeks additional HEU for use in targets at NRU until June, 2002---another year beyond what it projected in its testimony last July to be possible to achieve at NRU, based on limited waste tank capacity. Because it is now clear that isotope production in the NRU will be possible at least until June 2002, there was in fact time to develop LEU targets for the NPF prior to startup of isotope production in the MAPLE reactors. Had the Commission been made aware of this capability at the time it was considering the original export license application, it might well have decided not to approve export of HEU targets for the MAPLE reactors. Thus, the applicant's incorrect representation of the potential capacity of the NRU waste tank led the Commission to issue the previous license for HEU targets. This is a compelling example of how the applicant has benefited from conveying inaccurate information to the Commission.

While NCI does not oppose the new export request, we wish to point out that there is no need to issue a new license. The 10 kilograms of HEU needed for NRU targets can be drawn from the quantity of HEU designated for MAPLE. The Commission merely has to modify XSNM 03060 so that 10 kilograms of the already authorized 90 kilograms of HEU in dioxide form can be exported in the form of metallic HEU for use in NRU targets. AECL's contention that all of the HEU targets licensed to be exported to the MAPLE reactors "are likely to be needed for the MAPLE reactors" before conversion to LEU targets can proceed is highly questionable. In any event, this total amount of HEU MAPLE targets will not be irradiated during the period of the license because of the delay in start-up of the MAPLE reactors.

There is no logic to the applicant's assertion that "an unavoidable consequence of a delay in operation of the MAPLE reactors is a corresponding extension of the time that will be required to complete the HEU to LEU conversion program." Since no modifications are necessary to the MAPLE reactors but only to the NPF to achieve conversion, there is no reason to believe that delaying start-up of MAPLE should delay conversion to LEU targets.

However, the delay, and the sudden availability of waste storage capacity at NRU, provides the Commission the opportunity to pursue with the applicants the feasibility of extending production at NRU long enough to complete development of the LEU targets

before the NPF goes hot. The Commission, as it did at the public meeting in July, should avail itself of a knowledgeable official from the Argonne National Laboratory (ANL) to evaluate the applicant's assertions that the NRU waste tank's capacity cannot be further expanded, and that all of the HEU MAPLE targets licensed for export must be used at the MAPLE facilities before conversion to LEU targets. Indeed, there is no evidence that the irradiation of HEU targets in the MAPLE reactors and processing of HEU targets in the NPF must be a precursor for conversion to LEU targets.

The Commission should also invite ANL experts to describe the progress being made in MDS Nordion's target conversion program toward achieving a new calcination process that is essential for introducing LEU targets in the NPF. If progress is being made, it may be possible to have an LEU target ready for demonstration sooner than anticipated, perhaps in as little as six months. If this target can be test irradiated in the NRU, or possibly in a U.S. test reactor like the ATR at Idaho Falls, it could be introduced promptly into the MAPLE reactors and the NPF when they start up. The Commission should inquire of Argonne as to these possibilities. If LEU target development can be expedited, the Commission should also seek advice from Canadian regulatory authorities, as well as the U.S. Food and Drug Administration, as to whether the approval process can be completed in less than the three years originally estimated by MDS Nordion .

The Commission will also have to decide whether shipments of MAPLE HEU targets beyond those exported this year should proceed, given the delay in operation of the MAPLE reactors and the certainty that all of the material authorized for export will not be consumed during the period of the license. The license authorizes annual shipments, and the Commission already has deducted 40 kilograms of HEU from the license after the applicants failed to export that amount during the first year of the license, as authorized. This Commission decision was consistent with NCI's testimony last July: "To avoid export of any HEU surplus to the applicant's needs, in accordance with U.S. law and policy, we urge the Commission to modify the current license immediately to reduce the total amount of HEU under the license...."

The same principle, if applied to future exports, would require deduction of 22.6125 kilograms of HEU, the amount authorized for annual export, each year the material cannot be used for its designated purpose, as stated on the license: "Target material for the production of medical isotopes in the MAPLE 1 and MAPLE 2 Reactors." Until the MAPLE reactors become operational, no HEU targets beyond those already shipped this year should go forward.

The Commission, according to Condition 10 of the license, is due to receive a yearly status report in July on the progress made in developing LEU targets for the MAPLE reactors. However, the Commission might wish to explore now at a public meeting what significance the new license application to export HEU for targets at NRU might have for facilitating conversion to LEU MAPLE targets before the NPF becomes operational. At the public meeting last July, NCI advised the Commission, "[O]nce the [MAPLE] facilities begin operating on HEU, the applicant may cite the risks of interrupting production and costs of conversion as grounds for using HEU in perpetuity.

Indeed the applicant reiterates in its viewgraphs today that conversion will occur only if it is 'economically feasible'."

In October 2000, at the annual International RERTR Conference in Las Vegas, MDS Nordion participated with other medical radioisotope producers in a special session to begin exploring ways to establish a level playing field for universal conversion to LEU targets. If AECL and MDS Nordion could help to ensure economic conversion to LEU targets by continuing to utilize HEU at NRU until LEU targets are developed for MAPLE, their own commercial interests would be served, and they would set an example for the international radioisotope community.

NCI urges, therefore, that the commission consider (1) approving the export of the requested 10 kilograms of HEU for use at NRU, but as an amendment to the existing license rather than as a new license, and (2) using this opportunity to encourage further U.S.-Canadian cooperation to facilitate LEU target development for the MAPLE reactors before the NPF becomes operational. We urge the Commission to convene a public meeting for this purpose.

Thank you for your consideration of these views.

Sincerely,

Paul L. Leventhal
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January 5, 2001

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11555 Rockville Pike
Washington, D.C. 20852

Re: Export License Application No. XSNM 03171

Dear Mr. Hauber:

The NRC's regulations contemplate that the applicant for an export license will have an opportunity to respond to comments submitted by members of the public concerning the application. 10 CFR § 110.81(c). This letter and its attachments constitute AECL's response to the points raised in Nuclear Control Institute's (NCI's) letter, dated December 18, 2000, to NRC Chairman Richard Meserve. AECL's response to NCI's letter is transmitted to the NRC's Office of International Programs because it concerns an export license application that the NRC Staff and the Executive Branch now have under review, in accordance with the Commission's rules and the Executive Branch Procedures pursuant to the Nuclear Nonproliferation Act of 1978. In accordance with §110.81, a copy of AECL's response is provided to the Office of the Secretary of the Commission.

AECL reaffirms its commitment to provide timely and comprehensive responses to the Commission's questions in connection with this export license application.

Sincerely,

James A. Glasgow

JAG/lwr:dgl

Attachment

cc: Robin DeLaBarre, U.S. Department of State
Secretary USNRC: Attention, Rulemakings and Adjudications Staff

January 5, 2001

AECL' s RESPONSE TO NCI'S DECEMBER 18, 2000 LETTER TO CHAIRMAN RICHARD MESERVE, REGARDING AECL's APPLICATION (XSNM 03171) FOR A LICENSE TO EXPORT 10.05kgs OF HEU METAL TO CANADA

I. INTRODUCTION

On October 23, 2000, Transnuclear Inc., on behalf of Atomic Energy of Canada Ltd. (AECL), filed its application for an export license authorizing the shipment of 10.05 kilograms of highly enriched uranium (HEU) metal to AECL's Chalk River site in Canada. As explained in the supplement to that application, AECL needs the HEU metal in order to fabricate targets for irradiation in the NRU Reactor at the Chalk River site. After they are irradiated, the targets are processed by AECL, on behalf of MDS Nordion, in order to extract molybdenum 99 (Mo-99) and other radioisotopes. MDS Nordion distributes such radioisotopes to hospitals and medical clinics for the treatment of patients with life threatening illnesses.

As explained in the supplement to the export license application (XSNM 03171), AECL needs the HEU specified in that application because problems with the operation of safety-related systems of the MAPLE Reactors, coupled with regulatory requirements of the Canadian Nuclear Safety Commission (CNSC), have prevented the MAPLE Reactors from beginning full operational status. Therefore, the production of Mo-99 must be continued at the 43-year old NRU Reactor until the MAPLE Reactors are able to commence operation.

In its December 18, 2000 letter to Chairman Richard Meserve, the Nuclear Control Institute (NCI) states that it does not oppose the export of the 10.05 kilograms of HEU metal requested in AECL's license application, to produce targets for the NRU. Nevertheless, notwithstanding AECL's showing of a clear need for this export, NCI urges the Commission not to issue this export license. Instead, NCI argues that the Commission should amend AECL's

existing license (XSMN 03060) authorizing export of fabricated uranium dioxide targets for the MAPLE Reactors to allow exports of HEU metal for the purpose of producing targets for the NRU Reactors. It also urges the Commission to require AECL for this purpose to draw upon the remaining quantities of HEU whose export is authorized under XSNM 03060. Despite its assertion that it supports this export, NCI asks the Commission to take actions that are clearly inconsistent with AECL's request for a new license. Moreover, NCI's request that the Commission amend AECL's existing export license can only be sought by NCI through a 10 CFR § 2.206 petition, which embodies a standard that NCI can not meet.

In its December 18, 2000, letter to Chairman Meserve, NCI raises arguments concerning the capacity of the Fissile Solution Storage Tank (FISST) at the target processing facility associated with the NRU Reactor and the ability of AECL to continue operating the NRU and its associated target processing facility while converting the MAPLE Reactors and the New Processing Facility (NPF) to operate with low enriched uranium (LEU) targets. NCI's letter includes quotations from NCI's presentations at the July 10, 2000 public meeting held by the Commission and arguments that are based on NCI's theories and scenarios with respect to operation of the NRU, the MAPLE Reactors and the NPF.

In the attachment to this submission, AECL has responded fully to factual and technical contentions raised by NCI in its December 18, 2000 letter to Chairman Meserve. At the outset, however, AECL will demonstrate why NCI's request is inconsistent with the Commission's rules and should not form the basis for the Commission to call a public meeting concerning XSNM 03171.

NCI's request for a public meeting ignores the distinction between the Commission's rules encouraging written comments from members of the public and the Commission's rules

regarding petitions seeking a hearing and to intervene. If organizations such as NCI are routinely able to interact with the Commission, through public meetings, in essentially the same manner that the Commission normally affords only to persons granted the status of intervenor, the important distinction drawn by the Commission's rules between provision of written comments to the Commission and participation before the Commission as an intervenor will be blurred, if not destroyed.

II. NCI's ARGUMENTS ARE OUTSIDE THE SCOPE OF THIS EXPORT LICENSE APPLICATION

Tacitly recognizing that the Commission has twice denied NCI's petitions to intervene in previous proceedings regarding export of HEU to Canada, NCI states that it elected not to file a request for a hearing or a petition to intervene in this proceeding. Nevertheless, NCI asks the Commission to call a public meeting, in lieu of the hearing that it did not seek or attain, to address (1) NCI's argument that AECL's export license application should be denied and its existing license (XSNM 03060) should be amended; and (2) NCI's theories concerning actions that it contends AECL and MDS Nordion should take in place of their ongoing program to convert from HEU to LEU targets for use in the MAPLE Reactors and NPF. As MDS Nordion explained in its annual report to the Commission last year concerning XSNM 03060, this program consists of a Development Phase (Phase 2) and Implementation Phase (Phase 3) that AECL and MDS Nordion have established in consultation with Argonne National Laboratory (ANL).

In setting forth detailed allegations and proposals and asking the Commission to conduct a public meeting to address its arguments, NCI is seeking the functional equivalent of a hearing and the opportunity to participate in that hearing in a role akin to that of an intervenor. For the

reasons set forth below, AECL submits that NCI's request is manifestly inconsistent with the Commission's rules.

The Commission's rules regarding hearings (Subparts H and I of 10 CFR Part 110) are intended to allow an orderly and focused inquiry by the Commission into the factual and legal contentions raised by those who are allowed by the Commission to participate as parties or intervenors. In proceedings conducted pursuant to Subparts H and I, the applicant has an opportunity to review allegations by intervenors and respond in a manner specified in those Subparts. Attempting to avoid the Commission rules regarding intervention and hearings by seeking a "public meeting" rather than a hearing pursuant to Subpart I, NCI's seeks an opportunity to interact with the Commission, the Executive Branch and the Applicants in a manner that the Commission's rules reserve for those who are parties or intervenors in an export license hearing.

Rather than raising policy issues or arguments grounded in the relevant statute and NRC regulations, NCI's contentions primarily address factual matters associated with the design and operation of the MAPLE Reactors, the NRU and their associated target processing facilities. NCI's arguments are based primarily on its assertions related to the operational status and capabilities of reactors and processing facilities operated by AECL. Such arguments are best left to the NRC staff to resolve, in consultation with the U.S Executive Branch. A public meeting is not an appropriate forum for the Commission to grapple with NCI's detailed and wide-ranging allegations concerning safety-related issues pertaining to Canadian facilities licensed by the Canadian Nuclear Safety Commission (CNSC).

In its December 18, 2000 letter and earlier submissions to the Commission with respect to XSNM 03060, NCI has pursued its theories regarding operation of the NRU, the MAPLE

Reactors and associated processing facilities. As shown in the attachment to this submission, and in MDS Nordion's reports and presentation to the Commission last year, NCI's theories are inconsistent with operational and regulatory requirements that govern AECL's use of those facilities. For example, NCI's letter incorrectly charges that AECL has played "fast and loose" with its statements to the Commission regarding the capacity of the Fissile Solution Storage Tank (FISST) that performs the essential function of storing radioactive waste from the processing of HEU targets irradiated in the NRU. NCI has repeatedly challenged the good faith of AECL and MDS Nordion. Such ad hominem charges are without any basis. NCI's injection of inflammatory remarks such as these into its presentations to the Commission are an added reason why the Commission should not indulge NCI's request to participate in a public meeting called by the Commission. AECL has properly advised the Commission of the maximum permissible uranium concentration of the FISST under currently applicable CNSC requirements. Contrary to NCI's assertions, AECL has also given the Commission its best estimates of the remaining capacity of the FISST, based on projections concerning the demand for Mo-99 and the status of the construction and licensing of the MAPLE reactors and the NPF.

AECL is mindful of the Commission's need to base its decision upon all relevant information, including the views of members of the public, such as NCI. AECL has responded promptly to questions and requests from the NRC staff and the Commission regarding this and other applications for licenses to export HEU to Canada to produce radioisotopes for medical purposes. If the Commission determines that the development of an adequate record requires that a public meeting be held in connection with this license application (XSNM 03171), AECL will seek to participate fully. However, AECL submits that, for the reasons set forth in this submission, NCI's request for a public meeting does not present a persuasive basis for holding

such a meeting. The Commission's need for an adequate record will be fully met by the Executive Branch views on this application, the NRC staff's recommendations, AECL's responses to questions and requests from the Executive Branch and the NRC Staff, NCI's December 18, 2000 letter and this response by AECL.

The Commission's rules (10 CFR § 110.81) encourage members of the public to provide "written comments from the public concerning export and import license applications." The Commission clearly is able to consider the views of NCI without taking the added step of holding a public meeting to allow NCI the opportunity to expand on its written comments. Moreover, if the Commission elects not to hold a public meeting in connection with AECL's application for a new export license, the Commission nevertheless will have an opportunity to address NCI's arguments during its annual review of XSNM 03060. Since NCI's letter deals almost entirely with XSNM 03060, the annual review of that license is clearly the appropriate time for the Commission to address these points, including discussion during a public meeting, if the Commission decides to call such a meeting. By the time of the NRC's annual review, MDS Nordion and AECL will have prepared and submitted their annual report concerning progress in converting from HEU to LEU targets for the MAPLE Reactors and the NPF, and the Executive Branch will have had the opportunity to provide its comments to the Commission concerning that report.

Rather than raise issues concerning the existing export license (XSNM 03060) during the annual review of that license, NCI asks the Commission to amend the license now. It is well settled, however, that after the Commission has issued a license, the appropriate means for a person to challenge the issuance of the license or to seek the suspension or amendment of the license is to file a petition, pursuant to 10 CFR § 2.206, requesting that the Commission initiate

enforcement action pursuant to 10 CFR § 2.202. *See Texas Utilities Electric Co.* (Comanche Peak Steam Electric Station, Units 1 and 2), CLI-92-12, 36 NRC 62, 67, 77-78 (1992). Moreover, persons who cannot gain admittance to a construction permit or operating license hearing, as was the case for NCI in the XSNM 03060 proceeding, may file a request under 10 CFR § 2.206 asking the Director to institute a proceeding to address those concerns. *Detroit Edison Co.* (Enrico Fermi Atomic Power Plant, Unit 2), ALAB-707, 16 NRC 1760, 1767, 1768 (1982). *See Washington Public Power Supply System* (WPPSS Nuclear Project Nos. 1 and 2), CLI-82-29, 16 NRC 1221, 1228-1229 (1982).

Despite the fact that 10 CFR § 2.206 governs the Commission's consideration of NCI's request that the Commission amend XSNM 03060, NCI has not availed itself of the 10 CFR § 2.206 process. If NCI had followed the route specified in the Commission's rules for raising such a request, the Director of the Office International Programs would have had the opportunity to rule on that request. Under relevant Commission precedent, it appears that the Director, International Programs would deny the request since non-parties to a proceeding are prohibited from using 10 CFR § 2.206 as a means to reopen issues which were previously adjudicated. *General Public Utilities, supra*, 21 NRC at 564. *See, e.g., Northern Indiana Public Service Co.* (Bailly Generating Station, Nuclear-1), CLI-78-7, 7 NRC 429 (1979), *aff'd, Porter County Chapter of the Izaak Walton League, Inc. v. NRC*, 606 F.2d 1363 (D.C. Cir. 1979). And NCI does not allege that AECL is somehow violating its existing export license. Relitigating the earlier export proceeding (XSNM 03060), to which NCI was not admitted as an intervenor, is precisely the intent of the NCI letter. Holding a public meeting to address NCI's request for an amendment of XSNM 03060 would improperly allow NCI to bypass the process set forth in §2.206.

AECL has an urgent need to begin the exports that are the subject of XSNM 03171 by March of 2001, for the reasons expressed in the attachment to its export license application. Consequently, any deferral of Commission action on application XSNM 03171 until completion of the Commission's annual review of XSNM 03060 will jeopardize the continued production of Mo-99 at the NRU and its target processing facility. A public meeting to address NCI's arguments with respect to XSNM 03171 is unnecessary since those arguments are fully conveyed to the Commission in NCI's written submission and are predominately directed at XSNM 03060.

III. HOLDING A PUBLIC MEETING TO ADDRESS NCI's CONTENTIONS IS UNNECESSARY, INCONSISTENT WITH COMMISSION PRECEDENTS AND CONTRARY TO THE APPLICANT'S WELL-DOCUMENTED NEED FOR A PROMPT COMMISSION DECISION

Although NCI has asked the Commission to call a public meeting rather than a hearing, the nature of NCI's proposed interaction with the Commission is similar (or perhaps more substantial) than it would have achieved through a hearing. Therefore, in considering NCI's request, the Commission's rules and precedents regarding petitions to intervene and for a hearing should be taken into account. When assessing whether to afford petitioners a discretionary hearing, the Commission routinely considers whether the "petitioner possesses expertise" on issues properly brought before the Commission and whether petitioner has "information not presently available to the Commission" on such matters. *In the matter of General Electric Co.*, (exports to Taiwan) CLI 81-2, 13 NRC 67, 71 (1981). *In Westinghouse Electric*, the Commission considered whether "petitioners possess special expertise in the matters they raise or information not presently available to the Commission." *In the matter of Westinghouse Electric Corp.* (export to South Korea) CLI-80-30, 12 NRC 253, 261 (1980). In determining that a discretionary hearing was not warranted in *General Electric Co.*, the Commission also took into

account the fact that petitioners' contentions within the scope of the export license proceeding had been addressed by "both the Executive Branch and the NRC...staff in their submissions to the Commission." 13 NRC at 71. The Commission stated that "in the absence of evidence that a hearing would generate significant new analyses, a public hearing would be inconsistent with one of the major purposes of the Nuclear Nonproliferation Act of 1978—that United States agencies enhance the nation's reputation as a reliable supplier of nuclear materials to nations which adhere to our nonproliferation standards by acting upon export license application in a timely fashion." *Id* at 72.

During the past decade, the Commission has repeatedly concluded that a discretionary hearing in an export license proceeding was not warranted because the Commission "could not conclude from Petitioners' submissions that they would offer anything in a hearing that will generate significant new information or insight" regarding the export license proceeding. *In the matter of Westinghouse Electric Corp.* (Nuclear Fuel Export license Application for Czech Republic), CLI 94-7, 39 NRC 322, 334 (1994); *In the matter of Transnuclear Inc.* (Exports of 93.3% Enriched Uranium) CLI 99-15, 49 NRC 366, 368 (1999).

In 1994, in an export proceeding involving the Schumer Amendment, the Commission denied NCI's petition to intervene and for a hearing on an export license application seeking authorization to ship 280kg of HEU to France for down-blending to LEU. *In the Matter of Transnuclear Inc.* (Export of 93.15% Enriched Uranium) CLI-94-1, 39 NRC 1 (1994). Rejecting NCI's argument that it had standing to intervene as a matter of right, the Commission observed that "the mechanism for increased public participation that NCI urges already is provided for in the Commission regulations" because the "regulations specifically set forth the Commission's policy to hold a hearing or otherwise permit public participation if the Commission finds that

such a hearing or participation would be in the public interest and would assist the Commission in making the required statutory determinations." 39 NRC at p. 6. Refusing to grant NCI a discretionary hearing, the Commission observed that "there is no indication in NCI's pleading, however, that it possesses special knowledge regarding these issues or that it will present information not already available to and considered by the Commission." *Id.* The Commission further observed that "conducting a public hearing on issues concerning matters about which the Commission already has abundant information and analyses would be contrary to one of the purposes of the NNPA, namely 'that the United States Government agencies act in a manner which will enhance the nation's reputation as a reliable supplier of nuclear materials to nations which adhere to our nonproliferation standards by acting upon export license applications in a timely fashion.'" *Id.* at pages 7 - 8.

The Commission's long-established precedents concerning the showings that an organization such as NCI must make in order to obtain a "hearing" are relevant to the circumstances under which the Commission should call a "public meeting." In denying NCI's request for a hearing and to intervene in AECL's application for the license authorized by the Commission on June 29, 1999, (XSNM 03060), the Commission took into account the "numerous pleadings filed by the parties and the additional submissions filed in response to CLI-99-9" and concluded that "a hearing utilizing the procedures set forth in 10 CFR Part 110, Subparts H and I, is not necessary to provide the Commission with the information it needs to make its statutory findings." *In the matter of Transnuclear Inc.* (Exports of 93.3% Enriched Uranium) CLI 99-15, 49 NRC 366, 368 (1999). Declining to hold a discretionary hearing, the Commission also observed that "a discretionary hearing would impose unnecessary burdens on the participants." *Id.*

If NCI were seeking a hearing, the Commission would be required to assess, among other things, whether NCI possesses special expertise with respect to the contentions raised in its December 18, 2000 letter and whether in the absence of a hearing, the Commission will have an adequate record for its decision, based on the submissions of the NRC staff, the Executive Branch and the Applicant. Electing not to hold a hearing with respect to XSNM 03060, the Commission determined that the submissions of the NRC Staff, the Executive Branch and their written responses to the Commission's questions would afford an adequate basis for the Commission's decision-making. The Commission's denial of NCI's petition for a hearing and to intervene in XSNM 03060, was based, in part, on NCI's failure to show that it possessed special expertise or would contribute important information that would not otherwise be available to the Commission.

NCI does not state that it has technical expertise in the operation of the NRU, the MAPLE Reactors or the design of HEU and LEU targets for the production of radioisotopes. Consequently, NCI's participation in a public meeting is not necessary to assist the Commission in establishing the necessary record for its decision-making in XSNM 03171. In any event, many of the points raised by NCI have already been raised by the NRC Staff and Executive Branch and are addressed by AECL in its December 22, 2000 letter to the NRC Staff. If the Commission, the NRC Staff or the Executive Branch requires additional information in connection with their evaluation of XSNM 03171, they may obtain it through written questions or requests, as was the case with XSNM 03060. In any event, NCI has now raised its concerns relating to AECL's export license application, in its December 18, 2000 letter to Chairman Merserve, thus obviating the need for a public meeting.

In sum, NCI is not entitled to a public meeting as a vehicle for gaining the same access to the Commission that it would have obtained if it had successfully sought a hearing and to participate as an intervenor. To the extent that NCI has information that will assist the Commission, NCI is able to present that information in written form, as it did in its December 18, 2000 letter to Chairman Meserve.

AECL recognizes, of course, that the Commission has inherent authority to call a public meeting on this export license application if it decides that such a meeting will assist the Commission. If the Commission determines that such a meeting is desirable with respect to this license application (XSNM 03171), AECL will welcome the opportunity to participate. However, as discussed above, there is no need for such a meeting because the Commission has already been provided with a complete record, including NCI's views.

Holding a public meeting on application XSNM 03171 carries the risk of delaying Commission action on this application even if the Commission expedites such a meeting. For the reasons stated in its supplement to its application filed with the NRC on October 23, 2000, the HEU metal that is the subject of this application is urgently needed at AECL's Chalk River site by March of this year. A delay in exporting this material to Canada will raise a serious risk of disrupting the continued production of Mo-99 in the NRU Reactor pending a decision by the CNSC to allow the MAPLE Reactors to assume a fully operational status. Such a disruption would jeopardize the supply of Mo-99 to treat patients with serious illnesses. Therefore, AECL urges that the Commission rule promptly on this application and defer any decision regarding NCI's request for a public meeting until the Commission has had an opportunity to review the annual submissions of AECL-MDS Nordion and the U.S. Executive Branch in connection with XSNM 03060.

IV. NCI's ARGUMENTS LACK MERIT

In the appended chart, AECL responds to NCI's factual and technical contentions that (1) AECL should be required to continue operation of the NRU Reactor until the MAPLE Reactors and the NPF have been converted to operate with LEU; and (2) AECL's need for HEU targets for the MAPLE Reactors is reduced because of the delay in operating those reactors. NCI's arguments regarding the capacity of the FISST and AECL's continued operation of the NRU do not warrant Commission attention and should be left to the NRC Staff to resolve. Additionally, NCI's contentions are not within the scope of this export licensing proceeding. Moreover, NCI has not shown expertise to support its contentions. Finally, for the reasons set forth in the attachment, NCI's arguments lack merit.

January 5, 2001

AECL's Response to Specific Allegations by NCI Concerning
Export Licence Application XSNM O3171
HEU for the NRU Reactor in Canada

	Nuclear Control Institute Comments – Reference December 18, 2000 Letter from P. Leventhal and A.J. Kuperman to The Honorable Richard Meserve, Regarding New Transnuclear Request for Export of HEU to Canada	**AECL Response**
1.	"The applicant's incorrect representation of the potential capacity of the NRU waste tank led the Commission to issue the previous licence for HEU targets. This is a compelling example of how the applicant has benefited from conveying inaccurate information to the Commission." [NCI Letter at p.3.]	AECL believes that the information it has conveyed to the Commission was accurate and responsive to the Commission's questions. The Canadian Nuclear Safety Commission (CNSC) renewed the site licence for AECL's Chalk River Laboratories (CRL) on November 26, 2000. The current licence NRTEOL-1.00/2002, which is valid from November 1, 2000 to October 31, 2002, authorizes AECL to operate the Fissile Solution Storage Tank (FISST) up to a maximum uranium concentration of 7.0 g/L and aluminium content of 1.51 mol/L. AECL has requested CNSC approval to increase the uranium concentration to 7.6 g/L and the aluminium content to 1.69 mol/L, which, depending on isotope processing yield and market demand for Mo-99, would extend use of FISST to about June 2002. A response from the CNSC is expected in January 2001. If approved, AECL will request an amendment to the CRL through a revision to Facility Authorization AECL-FA-07 for the Molybdenum-99 Production Facility.

	Nuclear Control Institute Comments – Reference December 18, 2000 Letter from P. Leventhal and A.J. Kuperman to The Honorable Richard Meserve, Regarding New Transnuclear Request for Export of HEU to Canada	AECL Response
		In July 1999, the CRL site licence authorized the operation of FISST up to a maximum concentration of 6.5 g/L. On March 24, 2000, the Atomic Energy Control Board (predecessor to the CNSC) approved an increase of the maximum uranium concentration in FISST from 6.5 to 7.0 g/L. AECL completed Rev. 6 of the Facility Authorization AECL-FA-07 in May 2000 and CNSC amended the CRL site licence accordingly. The forecast date for when FISST will reach its maximum authorized concentration of uranium and aluminium is difficult to predict precisely. It depends on the molybdenum-99 yield from each process run, which depends on many factors, including the operating power of the NRU reactor, the target irradiation time between maintenance shutdowns, and the market demand for Molybdenum-99, which has a half-life of only 66 hours.
2.	"Since no modifications are necessary to the MAPLE reactors but only to the NPF, there is no reason to believe that delaying start-up of the MAPLE reactors should delay conversion to LEU." [NCI Letter at p. 3.]	The delay in completing the commissioning of the MAPLE reactors and NPF also delays the build-up of operating experience with radioactive targets. The NPF target processing and waste management systems have been designed for processing HEU targets.

	Nuclear Control Institute Comments – Reference December 18, 2000 Letter from P. Leventhal and A.J. Kuperman to The Honorable Richard Meserve, Regarding New Transnuclear Request for Export of HEU to Canada	AECL Response
		Tests with non-radioactive depleted uranium targets and representative solutions have been completed to demonstrate the operation of the NPF target processing and waste management systems. While these tests provide some information on systems operation, they are not fully representative of the technological requirements and limitations of routine medical isotope production with radioactive targets irradiated in the MAPLE reactors. For example, they do not account for the effects of decay heat in waste solutions and processing time to minimize loss of short-lived medical isotopes, such as Mo-99. Tests with irradiated targets are necessary, but cannot proceed at this time. The CNSC have required, in CMD 00-M74, dated November 27, 2000, that follow-up actions to assure the reliability of the MAPLE shut off rods and control absorber rods be completed before granting approval of any of the following activities: • Phase C commissioning of MAPLE 1 • Fuel loading into MAPLE 2 • Hot (radioactive) commissioning of the NPF.

	Nuclear Control Institute Comments – Reference December 18, 2000 Letter from P. Leventhal and A.J. Kuperman to The Honorable Richard Meserve, Regarding New Transnuclear Request for Export of HEU to Canada	AECL Response
		Consequently, representative tests that are been planned in the NPF with irradiated targets are being delayed until the start up of the MAPLE reactors. These tests will be conducted once AECL is satisfied it is safe to restart the MAPLE reactors and the CNSC grants the above-mentioned approval. The operational experience needed to understand the potential conversion process to LEU of existing NPF equipment will be gained through the processing of irradiated targets according to the same timeline needed to establish routine medical isotope production in the facility. These matters were discussed during the Commission's July 10, 2000 public meeting. AECL and MDS Nordion have advised the Commission that "critical heat flux and irradiation tests of the LEU targets will have to be performed to demonstrate the safety margins in the safety analysis report, and finally we will have to obtain CNSC approval at public hearings." [Transcript, July 10, 2000, Public Meeting at p. 10.] Moreover, AECL must "also establish a qualified program to manufacture test targets before they are available for the critical heat flux and

	Nuclear Control Institute Comments – Reference December 18, 2000 Letter from P. Leventhal and A.J. Kuperman to The Honorable Richard Meserve, Regarding New Transnuclear Request for Export of HEU to Canada	AECL Response
		irradiation test program." In its May 31, 2000 Annual Report to the Commission and during the Commission's July 10, 2000 public meeting, MDS Nordion explained why an integrated approach to LEU targets is necessary since the target affects the processing facility. [Transcript at p. 43.] Delaying the start-up of the MAPLE reactors and NPF does not affect the need for the total amount of HEU currently approved for export to the MAPLE reactors and the need to establish operating experience with existing NPF systems.
3.	"There is no evidence that the irradiation of HEU targets in the MAPLE reactors must be a precursor for conversion to LEU targets." [NCI Letter at p. 4.]	The MAPLE reactors and NPF have been designed and approved by the CNSC for the production of medical isotopes with HEU targets. In response to questions from the Commission during the July 10, 2000 public meeting, Dr. Ian Trevena stated that the concept development phase (Phase 2 of the LEU conversion) was expected "to take about 18 months, going to the end of 2001. Therefore, the implementation phase (Phase 3) cannot begin earlier than the end of 2001." For the reasons discussed at length in the public meeting, firm timetables for completion of the Implementation Phase cannot be specified at this time.

	Nuclear Control Institute Comments – Reference December 18, 2000 Letter from P. Leventhal and A.J. Kuperman to The Honorable Richard Meserve, Regarding New Transnuclear Request for Export of HEU to Canada	AECL Response
		However, the completion of Phases 2 and 3 will extend years beyond the extended date that is anticipated for use of the NRU. Consequently, AECL's proposed extension of the use of the NRU for about 14 months, until about July 2002, does not allow sufficient time to convert the MAPLE Reactors and the NPF and receive regulatory approvals to operate with LEU targets.
4.	The Commission "should consider . . . (2) using this opportunity to encourage further US-Canadian cooperation to facilitate LEU target development for the MAPLE reactors before the NPF becomes operational. [NCI Letter at p. 5.]	As shown during the Commission's July 10, 2000 public meeting and in the Annual Report that MDS Nordion submitted to the Commission on May 31, 2000, the ongoing HEU to LEU conversion program is being expeditiously implemented by MDS Nordion and AECL, working in cooperation with Argonne National Laboratory (ANL). AECL arranged a meeting with MDS Nordion at SGN offices on November 16, 2000, to finalize the scope and schedule of the Phase 2 Conversion Development Program, which is based on increasing the waste solidification capacity of the NPF. MDS Nordion communicated with ANL on the meeting and their participation in Phase 2 work, which includes precipitation studies. A meeting is being arranged with ANL and MDS Nordion at AECL's Chalk River Laboratories in January 2001.

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February 13, 2001

The Honorable Richard Meserve
Chairman
U.S. Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

Dear Chairman Meserve,

We write to follow up our letter of December 18, 2000 and the response to that letter of January 5, 2001 from Atomic Energy Canada Ltd. (AECL), regarding its application (XSNM 03171) to export 10.05 kilograms of bomb-grade, highly enriched uranium (HEU) for production of medical radioisotopes in the National Research Universal reactor (NRU). The applicant argues that the new license should be approved without affecting its previously approved license (XSNM 03060) to export 90.4 kilograms of HEU in targets for production of such isotopes in its new Maple reactors.

We would like to underscore two points. First, we do not oppose issuance of the proposed license, which will enable continued production of vital medical isotopes at the NRU. Second, we are concerned that if the Commission issues the new license without modifying the terms of the previous license, it effectively will grant the applicant an extension of at least one year to meet its commitment to convert isotope production to use of targets of low-enriched uranium (LEU) unsuitable for weapons. As you know, conversion to LEU targets as soon as they can be developed is required by U.S. non-proliferation law (the Schumer Amendment) as a condition for an applicant to receive interim HEU exports for use as targets.

If the Commission approves the new license without modifying the existing license, it will permit the applicant to export from the United States more HEU than is necessary, which is contrary to the Commission's responsibility under U.S. law. The applicant acknowledges that start-up of the Maple reactors has been delayed by at least a year. Thus, the applicant cannot begin using HEU targets in the Maple reactors until at least a year later than it had indicated at the time the Commission approved XSNM 03060. The applicant has given no indication that it plans to increase its originally indicated rate of consumption of HEU targets. Thus, unless the original license is modified, the applicant will be able to use HEU targets for at least a year beyond the date originally indicated to the Commission and delay conversion to LEU by a corresponding period of time. The letter to the Commission conveying the Executive Branch views, dated February 5, 2001, does not address this concern.

The applicant presents no sound argument why delaying the start-up of the Maple reactors should delay conversion to LEU targets. The applicant eventually needs to irradiate prototype LEU targets in its Maple reactors and process them in its New Processing Facility (NPF) as part of its LEU target development effort, as indicated in its response. But these steps never were planned to be carried out during the reactors' first year of operation. The immediate steps on the critical path to conversion are resolution of two technical issues stemming from the higher concentration of uranium in the process solution associated with LEU targets – extraction of molybdenum-99 and calcination of waste. Resolution of these technical issues during the next year or two does not require operation of the Maple reactors and NPF.[1] Accordingly, there is no reason that delaying the start-up of the Maple reactors and NPF should result in any delay in converting to LEU targets.

Given that isotope production with HEU targets will start a year later than anticipated, and will not delay conversion to LEU targets, the applicant will require one year's less worth of HEU targets. Accordingly, we urge the Commission both to approve the pending license (XSNM 03171) for 10.05 kilograms of HEU metal – representing one year's requirement in the NRU – and simultaneously to reduce the amount of HEU approved for export as targets in the existing license (XSNM 03060) by 22.6125 kilograms, representing one year's requirement in the Maple reactors.

Finally, we urge the Commission to determine whether the applicant in fact has been actively pursuing conversion to LEU targets as required by the Schumer Amendment as a condition for interim exports of HEU from the United States. It is our understanding that the applicant did little to address the two technical issues referenced above from the time they were identified in April 2000 until a meeting with U.S. officials in January 2001.[2] If the applicant is seeking an extension of its conversion deadline, it is thus a consequence of the applicant's own dilatory behavior rather than of delays in starting the Maple reactors. The Commission should not reward such foot-dragging by permitting the applicant to export HEU from the United States for an additional year. Such an outcome would undermine the letter and spirit of U.S. law and set a dangerous precedent which will be noticed by medical isotope producers worldwide.

Thank you for your consideration of our views.

Sincerely,

Alan Kuperman (ST)

Alan J. Kuperman
Senior Policy Analyst

Paul L. Leventhal
President

Cc: Senator Charles E. Schumer

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[1] Letter from Trisha Dedik, U.S. Department of Energy, to Richard J. K. Stratford, U.S. Department of State, January 24, 2001, states that "this part of the Conversion Plan could take as long as two years to complete."
[2] Ibid. The letter states that "steps were taken at last week's meeting to begin an active program of cooperation between AECL and Argonne in Phase II of the Conversion Plan." (Emphasis added.)