TRANSNUCLEAR, INC.

Mr. Ronald D. Hauber
Deputy Director
Office of International Programs
United States Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

August 9, 2001

Dear Mr. Hauber:

SUBJECT: APPLICATION TO USNRC FOR AN AMENDMENT TO EXPORT LICENCE XSNM03171 TO AUTHORIZE THE EXPORT OF AN ADDITIONAL 10.0 KILOGRAMS OF HIGHLY ENRICHED URANIUM TO AECL'S CHALK RIVER, CANADA, FACILITY TO FABRICATE TARGETS FOR IRRADIATION IN AECL'S NRU REACTOR, TO PRODUCE RADIOISOTOPES FOR MEDICAL PURPOSES, AND TO EXTEND THE EXPIRATION DATE FROM APRIL 30, 2002, UNTIL SEPTEMBER 30, 2002

This letter is to request an amendment to USNRC Export Licence XSNM03171 to extend its valid date from April 30, 2002, to September 30, 2002 and to add 10 kilograms of HEU metal, thereby increasing the authorized quantity from 10.05 to 20.05 kilograms.

The application is made to continue the production of medical isotopes in AECL's NRU reactor at the Chalk River Laboratories. The additional material is needed because of delays in bringing the MAPLE reactors and associated New Processing Facility into commercial operation. A detailed justification for the application is provided in the attached Addendum.

In accordance with regulations regarding fees, we are also enclosing a check issued to the US Nuclear Regulatory Commission for the amount of US$9,300.

Your expedited review and issuance of an amendment to the export licence will be appreciated.

Do not hesitate to contact me if you have any questions.

Yours sincerely,
Transnuclear, Inc.
Mathew George
Mathew George
Traffic Coordinator

Encl.:

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Attachment 1

c. J.-P. Labrie, AECL
J.A. Glasgow, Morgan, Lewis & Bockius LLP

AECL EACL

Jean-Pierre Labrie, Ph.D.

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ADDENDUM TO THE APPLICATION OF TRANSNUCLEAR INC., ON BEHALF OF AECL, TO AMEND XSNM03171 TO AUTHORIZE THE EXPORT OF AN ADDITIONAL 10.0 KILOGRAMS OF HIGHLY ENRICHED URANIUM TO AECL'S CHALK RIVER, CANADA, FACILITY TO FABRICATE TARGETS FOR IRRADIATION IN AECL'S NRU REACTOR, TO PRODUCE RADIOISOTOPES FOR MEDICAL PURPOSES, AND TO EXTEND THE EXPIRATION DATE FROM APRIL 30, 2002, UNTIL SEPTEMBER 30, 2002

I. INTRODUCTION

This Addendum sets forth the reasons why Transnuclear Inc., on behalf of AECL, seeks to amend XSNM03171, to increase, by ten (10.0) kilograms, the quantity of highly enriched uranium (HEU) whose export is authorized by XSNM03171, from the currently licensed amount (10.05 kilograms) to a total of 20.05 kilograms. As discussed below, a delay in the operation of the MAPLE Reactors and the New Processing Facility (NPF) has forced AECL to continue the production of medical radioisotopes in the NRU Reactor for at least 4-6 months longer than AECL had planned when it applied, on October 29, 2000, for XSNM03171. As a result of this delay, AECL will need an additional supply of targets for irradiation in the NRU Reactor.

Although AECL had estimated that 10.05 kilograms of HEU currently authorized by XSNM03171 would produce sufficient targets for irradiation in the NRU to meet medical demands until approximately July 2002, the demand for medical isotopes has been greater than expected. Because of the increased demand for targets, AECL now estimates that the 10.05 kilograms of HEU currently authorized by XSNM03171 will be fully used to manufacture targets that will have been irradiated by approximately March 2002.

To continue the reliable supply of radioisotopes needed to treat seriously ill patients in the United States and Canada, after the HEU currently authorized by XSNM03171 is consumed, AECL must receive an additional supply of HEU. AECL anticipates that an additional 5.0 kilograms will be needed in December 2001, to allow sufficient time for AECL to fabricate the HEU into targets that are required to continue production of molybdenum 99 (Mo-99) in the NRU from

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approximately March 2002, until approximately August 2002. AECL also anticipates that an additional shipment of 5.0 kilograms of HEU will be needed in early 2002 to produce targets for use in the NRU from about September 2002 until approximately the end of that year, which AECL estimates is the earliest time that the MAPLE Reactors and the NPF could operate on a commercial basis.

To avoid the accumulation of any excess inventory of HEU for the NRU, AECL and Transnuclear will initially ship no more than 5.0 kilograms of the additional total of 10 kilograms of HEU that is requested by this application for an amendment. Before shipping the final 5.0 kilograms authorized by this amendment, AECL and Transnuclear will notify the NRC Office of International Programs at least 60 days in advance of the proposed shipping date. If AECL needs the final 5.0 kilograms to produce targets for the NRU, as it currently anticipates, its notice to the NRC will set forth current information concerning the operational status of the NRU, the MAPLE Reactors and the NPF as well as other information that may be relevant to AECL's receipt of this material.

II. RATIONALE FOR INCREASING THE AUTHORIZED QUANTITY OF HEU BY AMENDMENT TO XSNM03171 RATHER THAN A NEW LICENSE

AECL understands that the NRC is often asked to amend export licenses, to increase the authorized quantity and extend the term of the license. For this reason, AECL and Transnuclear Inc. are submitting this application for a license amendment to increase the quantity of HEU authorized by XSNM03171 and to extend the expiration date of the license from April 30, 2002, until September 30, 2002. The end user and end use are unchanged and the facility in which the HEU will be used remains the same.

During its consideration of the application for XSNM03171, the NRC Staff and the Executive Branch conducted a thorough review of the reasons why the HEU covered by this license was needed by AECL to ensure the reliable production of Mo-99 for use in medical radioisotopes. The record of this proceeding also includes comprehensive information concerning the NRU and the processing of targets irradiated in the NRU. Submission of this application as a request for an amendment of XSNM03171 avoids repetition of information that is contained in the record of that proceeding.

AECL understands that the Commission must itself review this request, whether it is styled as an amendment or an application for a new license.

III. STATUS OF THE SHIPMENT OF THE 10.05 KILOGRAMS OF HEU AUTHORIZED BY XSNM03171

After providing the required notice to NRC, Transnuclear shipped 4.998 kilograms uranium metal to AECL on April 17, 2001. A window for shipping the second shipment has been confirmed with the NRC. The shipment of about 5 kilograms uranium metal will be made in September 2001, at which time the entire quantity of HEU that may be exported pursuant to

XSNM03171, except for tiny residual amounts, will have been received at AECL's Chalk River facility in Canada.

IV. REASONS FOR THE DELAY IN ACHIEVING COMMERCIAL PRODUCTION OF RADIOISOTOPES IN THE MAPLE REACTORS AND PROCESSING THEM IN THE NPF

The Annual Report that MDS Nordion filed with the Commission on May 31, 2001, ("Report") discusses the technical difficulties that have significantly delayed the date when the MAPLE Reactors and the NPF are expected to begin commercial operation. As discussed in detail in the Report, problems with the operation of the shut-down rods of the MAPLE 1 Reactor, coupled with the regulatory review being conducted by the Canadian Nuclear Safety Commission (CNSC), have prevented the MAPLE Reactors from achieving commercially operational status. On June 25, 2001, the CNSC renewed the operating licenses for the MAPLE Reactors and NPF for a period of sixteen months, ending October 31, 2002. The CNSC also directed that an additional public hearing be held before the CNSC issues a decision concerning resumption of low-power commissioning of the MAPLE 1 Reactor, fuel loading in the MAPLE 2 Reactor and active commissioning of the NPF. Although CNSC has scheduled a public hearing for October 4, 2001, the CNSC has indicated that resumption of the above-mentioned commissioning activities will not be on the agenda of that meeting. AECL will seek to have the CNSC consider these matters at public hearings that are currently scheduled for November 15 and December 13, 2001.

If the CNSC takes up these re-commissioning matters at public hearings in November or December of 2001, and a ruling allowing re-commissioning to commence is issued soon thereafter, AECL anticipates that it will be able to bring the MAPLE 1 Reactor and the NPF into full commercial operation in the fall of 2002, and the MAPLE 2 Reactor by end of calendar year 2002, at the earliest. Full commercial operation of those facilities will be further delayed if the CNSC does not hold a public hearing on these matters until 2002.

Once commercial production of radioisotopes has been established in the MAPLE 1 Reactor and their processing in the NPF, the NRU reactor will be available as backup until commercial production is achieved in the MAPLE 2 reactor. Irradiation of HEU targets in the NRU reactor should considerably reduce once the MAPLE 1 reactor and NPF could sustain commercial production and be halted after the MAPLE 2 reactor are in commercial production.

V. ACTIONS BY AECL TO USE THE NRU AND ASSOCIATED TARGET PROCESSING FACILITY BEYOND THE SUMMER OF 2002

The steps that AECL has taken to allow continued production of Mo-99 in the NRU until the MAPLE Reactors and NPF begin commercial operation are discussed in the responses that AECL submitted, on December 22, 2000, to questions raised by the NRC Staff in connection with the application of Transnuclear, Inc., on behalf of AECL, for XSNM03171. Additional

information on this matter was provided in MDS Nordion's May 31, 2001 Report to the Commission.

As noted in MDS Nordion's Report, in the Fall of 2000, AECL submitted an application to the CNSC, seeking to increase the uranium concentration in the Fissile Solution Tank (FISST) from 7.0 to 7.6 g/L. On July 13, 2001, the CNSC approved an amendment to AECL's Chalk River site license, allowing AECL to increase the uranium concentration in the FISST from 7.0 to 7.3 g/L.

AECL is currently preparing responses to questions raised by the CNSC with respect to increasing the concentration limit from 7.3 to 7.6 g/L. A decision by CNSC with respect to increasing the limit to 7.6 g/L is not expected before early 2002.

AECL is currently developing an operations plan to use FISST until the end of calendar year 2002, by cementing some of the fissile waste from isotope production runs while maintaining potential exposure doses to a minimum. AECL anticipates that its operations plan to use FISST will allow AECL to continue to irradiate targets in the NRU to produce Mo-99 until the MAPLE Reactors and NPF become fully operational on a commercial basis.

VI. CONTINUED OPERATION OF THE NRU REACTOR UNTIL THE MAPLE REACTORS AND NPF BEGIN COMMERCIALPRODUCTION OF MO-99 IS ESSENTIAL TO MAINTAINING A RELIABLE SUPPLY OF THIS MEDICAL ISOTOPE FOR TREATMENT OF PATIENTS IN NORTH AMERICA

AECL and MDS Nordion have advised the Commission that the NRU and its associated HEU target processing facility are essential to the production of Mo-99 for medical purposes until the MAPLE Reactors and NPF are in full commercial operation. As the U.S. Executive Branch and the NRC have recognized, other sources of Mo-99 are not available to meet the needs of medical patients in the United States and Canada in the event that the NRU is unable to continue irradiating targets during the period before the MAPLE Reactors and the NPF are able to begin commercial production of Mo-99 for medical purposes. (See, memorandum from the Department of Energy to the Department of State, dated January 30, 2001, concerning XSNM03171)

There are four major commercial producers of Mo-99 located in Canada, Belgium, the Netherlands and South Africa. Based on their familiarity with these other producers of Mo-99, AECL and MDS Nordion believe that adequate supplies of Mo-99 needed for medical use in North America will not be available from these other sources, in the event that AECL is unable to continue irradiating targets in the NRU during the period before the MAPLE Reactors and NPF have begun commercial operation.

VII. CONCLUSION

For the reasons stated above, AECL respectfully submits that this application should be granted. AECL clearly has an urgent need for an amendment to XSNM03171, authorizing the export to

Canada of the additional quantity of HEU that is needed to produce targets to continue production of Mo-99 in the NRU until the MAPLE Reactors and NPF are able to begin commercial operation.

Jean Pierre Labrie
General Manager
MMIR Project & Isotope Sales
AECL

United States Department of State

Washington, D.C. 20520
October 22, 2001

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 August 15, 2001 requesting the views of the Executive Branch as to whether amendment 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. XSNM03171/01--Application by Transnuclear, Inc to amend its existing license to authorize the export to Canada of an additional 10.0 kilograms of uranium in the form of metal enriched to a maximum of 93.3 percent, and to extend the expiration date of the license from April 30, 2002 to September 30, 2002. 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 (AECL) 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 October 17, 2001 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.

The Executive Branch has also determined that the requirements of Section 134 of the Atomic Energy Act, as amended, (the Schumer Amendment) 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.

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(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. The Department of Energy (DOE), in a previously provided letter dated January 24, 2001 reported continued cooperation between Argonne National Laboratory and AECL on LEU target development.

(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 applicant explains that this additional 10 kilograms of HEU for fabrication of medical isotope production targets for the NRU reactor is needed for two reasons:

1. The steps ordered by the Canadian Nuclear Safety Commission (CNSC) prior to commissioning the two new Maple reactors and the associated New Processing Facility (NPF) for medical isotope production will require more time than originally anticipated.

2. Demand for medical isotopes has increased HEU target consumption. Atomic Energy of Canada Limited (AECL) now estimates that the 10.05 kilograms of HEU for NRU targets authorized for export to Canada under license XSNM03171 will be used up by March 2002, instead of July 2002 as originally estimated.

AECL estimates that it will have to continue using the 40 year old NRU reactor and its associated isotope production facility for a least 4 to 6 months longer than previously planned; that is, until December 2002. AECL estimates that it will need 5 kilograms of HEU by December 2001 to allow sufficient time for fabrication of the HEU into targets. A second tranche of 5 kilograms of HEU will be needed by early 2002 to be fabricated into targets for NRU isotope production from September to December 2002. AECL estimates that December 2002 is the earliest date that the MAPLE reactors and the NPF could be ready for commercial operation.

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

Sincerely,

Alex R. Burkart, Acting
Director
Nuclear Energy Affairs

Enclosure: assurance letter

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-AI-3657.0/2002

October 17, 2001

Mr. Adam M. Scheinman
Director
Office of Nuclear Transfer and Supplier Policy
National Nuclear Security Administration
Department of Energy
Washington, D.C. 20585
USA

Dear Mr. Scheinman:

Reference is made to your letter dated September 14, 2001, concerning licence application XSNM3171/01.

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 Laboratories, Chalk River, Ontario is authorized to receive and possess the material.

Yours sincerely,

W. Angus Laidlaw
Senior Advisor

c.c.: Robin Delabarre, US DOE
Betty L. Wright, USNRC

Canada