

February 2, 1999

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

In the Matter of)
)
)

TRANSNUCLEAR, INC.,)
on behalf of,)
ATOMIC ENERGY OF)
CANADA, LTD.,)
)

(Export of 93.3% Enriched)
Uranium))
)

Docket No. 11005070

License No. XSNM-03060

OPPOSITION OF
TRANSNUCLEAR, INC. AND ATOMIC ENERGY OF CANADA, LTD.
IN RESPONSE TO PETITION TO INTERVENE

Transnuclear, Inc. ("Transnuclear"), on behalf of Atomic Energy of Canada, Limited ("AECL"), and AECL file this opposition in response to the "Petition of the Nuclear Control Institute For Leave to Intervene and Request For Hearing" ("Petition") submitted on December 31, 1998.^{1/} Nuclear Control Institute ("NCI") seeks leave to intervene as a party in opposition to Transnuclear's October 29, 1998, application for a license to export 130.65 kilograms of 93.3% enriched uranium to Canada to be used as target material (XSNM-03060), in the MAPLE 1 and MAPLE 2 reactors for production of medical isotopes.

1/ Upon inquiry to the NRC, Counsel for AECL and Transnuclear received a facsimile copy of the NCI Petition on January 4, 1999, and are filing this Opposition within thirty days of this first notice of the NCI Petition. Consistent with a telephone conversation with Emile L. Julien of the NRC's Rulemakings and Adjudications Staff on February 1, 1999, counsel for AECL and Transnuclear believe this opposition is being filed in a timely manner.

These two new modern reactors, which are scheduled to begin operation in 1999 and 2000, are designed to be fueled with low-enriched uranium ("LEU"). However, in order to produce medical isotopes, AECL has designed high-enriched uranium ("HEU") targets, which will be irradiated in the MAPLE reactors and then processed in the MAPLE project's New Processing Facility (NPF), using advanced technology that has been developed by AECL.

No LEU target is currently available for use within the meaning of Section 134(a)(3) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2160d(a)(3) (known as, and hereinafter, "the Schumer Amendment"), and the NRC's implementing regulations. In June of 1998, the Commission granted License No. XSNM-03013, which permitted Transnuclear to export HEU test targets to AECL for purposes of developing them for use in the new MAPLE reactors and NPF. In doing so, the Commission implicitly accepted the fact that AECL has no choice but to begin production in the MAPLE reactors and NPF using HEU targets.

The requested export license is necessary to assure the reliable, uninterrupted supply of medical isotopes for use in the care of U.S. citizens suffering from cancer, AIDS, heart disease and other illnesses. NCI opposes this application, requesting extraordinary hearing procedures which would interpose unnecessary delay and could jeopardize the U.S. supply of life-saving radiopharmaceuticals. Transnuclear and AECL respectfully submit that the public interest would not be served if the Commission were to grant any part of NCI's Petition. The enclosed affidavits of Dr. Jean-Pierre Labrie (Enclosure 1) and of Dr. Forrest J. Remick and Harold D. Bengelsdorf (Enclosure 2) are offered in support of the pending application. Copies of affidavits which were submitted in support of License Nos. XSNM-03012 (HEU targets for the NRU reactor) & XSNM-03013 (HEU test targets), approved by the Commission in June 1998, are also enclosed: Affidavit of Dr. Labrie dated January 30, 1998 (Enclosure 3), Affidavit of Dr. Labrie

dated May 7, 1998 (Enclosure 4), Affidavit of Dr. H. William Strauss dated January 31, 1998 (Enclosure 5), and Affidavit of Dr. Martin Nusynowitz dated January 31, 1998 (Enclosure 6). In addition, the diplomatic notes exchanged between the United States and Canada, which were also submitted previously, are provided for ease of reference as Enclosures 7 and 8.

As shown more fully below, the Commission's rules do not provide for adjudicatory hearings in connection with export license applications, and NCI lacks standing to request such a hearing, even if the rules did. Moreover, a discretionary hearing is neither in the public interest nor would it assist the Commission. NCI's Petition could be reviewed as written comments, but NCI's contentions are without merit. The proposed exports are fully consistent with the Schumer Amendment, and both AECL and MDS Nordion have continued to cooperate fully with the active U.S. effort to design, evaluate and qualify LEU targets for the MAPLE reactors. Finally, the approval of the proposed exports to Canada clearly will not be inimical to the common defense and security of the United States, but rather denial of the pending application would jeopardize important foreign policy and public health objectives. For all of these reasons, and the reasons more fully stated below, Transnuclear and AECL respectfully request that the Commission deny the petition to intervene, deny the request for a hearing, and act promptly to issue the requested export license.

BACKGROUND

The license application designated XSNM-03060 would permit the export of 130.65 kg HEU (highly enriched uranium) containing 121.8966 kg of U_{235} in the form of uranium dioxide (UO_2) targets that are to be used as HEU targets for the production of medical isotopes in the modern MAPLE reactors which are replacing AECL's NRU reactor. Export of these HEU targets for development for use in the MAPLE reactors was approved by the Commission, and

use of these HEU targets is necessary to assure a continuous uninterrupted supply of medical radioisotopes until LEU targets are developed, approvals for such targets are obtained, and processing facilities are built and/or converted to accommodate LEU target production. It remains unclear whether production of an Mo-99 product of acceptable quality using LEU targets will be both technically achievable and commercially viable. However, AECL and the Canadian Government have committed to cooperate with the U.S. Government's efforts to achieve this goal. *See* Affidavit of Dr. Labrie (Enclosure 1).

The isotopes, molybdenum (Mo-99) and its decay product, technetium-99m (Tc-99m), are necessary for various diagnostic procedures for detection and staging of cancer, and managing patients with AIDS, heart disease, and many other illnesses. *See* Affidavits of Drs. Strauss and Nusynowitz (Enclosures 5 & 6). In their Brief dated February 2, 1998, in support of the application for License No. XSNM-03013, Transnuclear and AECL explained that "the new HEU target is being developed for use in AECL's new [MAPLE] reactors and development of the target is important to the schedule for bringing the new MAPLE 1 & 2 reactors into operation." *Opposition of Transnuclear and AECL in Response to Petition to Intervene*, at 2-3 (Feb. 2, 1998). The first MAPLE reactor is scheduled to begin operation in the Spring of 1999 and full scale production of molybdenum using HEU targets and processing facilities designed for HEU targets should begin by the end of 1999. The schedule for initial MAPLE 1 operation and impacts of a delay on the schedule are discussed in the Affidavit of Dr. Labrie dated May 7, 1998. (Enclosure 4).

AECL will operate the MAPLE reactors on behalf of MDS Nordion, which has committed to a \$140 million investment in the MAPLE project. When it was determined in the early 1990s that operation of the reactors using LEU targets was not commercially viable, MDS

Nordion made the commitment in 1996 to complete the MAPLE project premised upon initial operation using HEU targets and LEU fuel. Significantly, the Commission has already concluded that this decision was within the rights of AECL and MDS Nordion, and that export of HEU for use in the MAPLE reactors is permissible, consistent with the Schumer Amendment:

For several years, AECL had an Mo-99 production program, with a long-term goal to phase out use of fresh HEU and eventually use LEU targets; but in the early 1990s, AECL determined that the program would not be commercially viable and discontinued it. AECL and MDS Nordion have no requirement that would lead them to undertake the development and use of an LEU target. They are nevertheless prepared to provide on a commercial basis, to the extent of their capabilities, information and services to Argonne in its LEU target research and development efforts. While the dialogue and exchanges toward this effort may be in the early stages, we believe that the U.S. and Canadian principals are acting in good faith toward concluding a formal agreement to complete the LEU target development program linked to the Canadian reactors.

Transnuclear, Inc. (Export of 93.3% Enriched Uranium), CLI-98-10, 47 NRC 333, 339 (1998).

Notably, NCI persists in suggesting that AECL has somehow reneged on a "promise" to "[p]hase-out HEU use by 2000." NCI Petition at 18, footnote 14. However, the Commission has already rejected this notion.

Although not required to do so, AECL has worked at developing LEU targets. However, serious questions remain as to whether an LEU target can be used to produce a quality product on a commercial basis due to the greater levels of plutonium-239 and alpha levels produced from using LEU targets and due to the increased costs of processing LEU targets. Further consultations, LEU target testing, and evaluation of the increased costs of processing LEU targets will be required before the Department of Energy (DOE) can "qualify" an LEU target design and provide the Commission with a basis for determining that the use of such LEU targets will not result in a large percentage increase in the cost of operating the MAPLE project. Even if a DOE-qualified LEU target were currently available and processing facilities for such targets

were commercially viable at the present time, design changes and other approvals necessary to convert the MAPLE reactors and processing facilities would delay full scale production at the MAPLE 1 reactor until well into the year 2001. Any such delay affecting the schedule for AECL's new MAPLE reactors substantially increases the risk of an interruption in the supply of vital medical isotopes, which cannot be stockpiled because of their short half life (approximately 66 hours). Therefore, it is simply not possible to develop LEU targets and modify the MAPLE program to accommodate initial production from LEU targets without seriously jeopardizing the reliable supply of molybdenum to the United States. See Affidavit of Dr. Labrie (Enclosure 1).

Although it has long been established statutorily and judicially that the NRC need not provide an adjudicatory hearing on export license applications,^{2/} NCI requests a "full and open hearing" pursuant to 10 CFR § 110.84 (1993), with an opportunity to present oral and written testimony and to conduct cross-examination and discovery. NCI Petition at 3.^{3/} NCI establishes no basis for such extraordinary procedures. Moreover, NCI has previously conceded that it has no cognizable interest in export license proceedings involving Transnuclear and AECL,^{4/} and it fails to articulate any cognizable interest which will be affected by this proceeding. Thus, NCI fails to establish its organizational standing to request any hearing in this matter. Nevertheless,

2/ *Natural Resources Defense Council v. NRC*, 580 F.2d 698, 699 (D.C. Cir. 1978); see *Transnuclear, Inc. (Export of 93.15% Enriched Uranium)*, CLI-94-1, 39 NRC 1, 4-6 (1994).

3/ The extraordinary procedures of cross-examination and discovery requested by NCI are not provided in 10 CFR Part 110, Subpart I, which contemplates "legislative-type" non-adjudicatory hearings. 10 CFR §§ 110.100-113 (1992).

4/ Reply Brief of NCI, at 3 (February 12, 1998). NCI filed this Reply brief in connection with its intervention petition regarding Transnuclear's License Nos. XSNM-03012 & XSNM-03013.

NCI contends that the proposed export license is inconsistent with the Schumer Amendment, and that these exports to Canada would be inimical to the common defense and security of the United States. These contentions are without merit.

ARGUMENT

I. NCI LACKS STANDING TO REQUEST AN ADJUDICATORY HEARING, EVEN IF THE RULES PROVIDED FOR SUCH A HEARING

The Commission has repeatedly held that NCI has no standing to intervene as a matter of right for purposes of opposing Transnuclear's applications for licenses to export HEU and that hearings requested by NCI would not assist the Commission in reviewing the applications.

Transnuclear, Inc. (Export of 93.15% Enriched Uranium), CLI-94-1, 39 NRC 1, 4-6 (1994);

Transnuclear, CLI-98-10, 47 NRC at 336. In fact, NCI has acknowledged this fact:

Petitioner concedes, as it must, that, in *Transnuclear, Inc.*, CLI-94-1, 39 NRC 1 (1994), the Commission found that NCI did not meet the judicial standing tests which the Commission has consistently applied in export licensings It does not intend in this Reply to argue that it has an "interest" which the Commission has found it does not.

Reply Brief of NCI, at 3 (February 12, 1998).

Despite this prior record, NCI demands a hearing with respect to the pending license application based upon the same institutional interests that previously were found by the Commission to be insufficient. In its 1994 decision, the Commission pointed out that it "has long held that institutional interest in providing information to the public and the generalized interests of their memberships in minimizing danger from proliferation are insufficient for standing under Section 189a." *Id.* at 5. In its 1998 decision, the Commission concluded that this rationale applied "equally with respect to NCI's current intervention and hearing request." *Transnuclear*, CLI-98-10, 47 NRC at 336. It also applies to NCI's most recent Petition.

Unlike NRC's consideration of other license applications, its review of an export license application does not trigger the hearing rights afforded by Section 189 of the Atomic Energy Act of 1954, as amended (42 U.S.C. § 2239 (1988)) ("the Act"). Section 304(b) of the Nuclear Non-Proliferation Act of 1978 ("NNPA") directs that the Commission provide for public participation in export licensing proceedings when it "finds that such participation will be in the public interest and will assist the Commission in making the statutory determinations required by [the Act]." 42 U.S.C. 2155a(b) (1988). Section 304(c) directs that the criteria of Section 304(b) "shall constitute the exclusive basis for hearings in nuclear export licensing proceedings" and "shall not require the Commission to grant any person an on-the-record hearing in such a proceeding." 42 U.S.C. § 2155a(c). This latter subsection "thus directs in unequivocal language that the NRC need not afford any person an adjudicatory hearing in a nuclear export licensing proceeding." *Natural Resources Defense Council v. NRC*, 580 F.2d 698, 699 (D.C. Cir. 1978).

Despite the dictates of the NNPA, NCI seeks a hearing and extraordinary rights such as discovery and cross-examination which would effectively create a full-blown adjudicatory proceeding. Such procedures, however, "are not provided for in the Commission's regulations set forth in 10 CFR Part 110." *Braunkohle Transport* (Import of South African Uranium Ore Concentrate), CLI-87-6, 25 NRC 891, 893 (1987).^{5/} In accordance with Section 304(b) of the NNPA, the NRC's regulations establish procedures for the public to participate in export licensing proceedings by providing their written views. As such, these regulations provide the "only basis for determining the hearing rights of groups such as [NCI]." *See NRDC*, 580 F.2d

^{5/} In *Braunkohle* the Commission granted a discretionary written hearing because it was interested in certain legal issues relating to interpretation of the Comprehensive Anti-Apartheid Act of 1986. CLI-87-6, 25 NRC at 894.

at 700. These procedures do not provide for adjudicatory hearings, or any of the other extraordinary procedures requested by NCI. According to the Commission in *Braunkohle*, Part 110 does not provide for adjudicatory procedures because they would be inappropriate in export and import license proceedings which "frequently involve sensitive foreign policy and national defense considerations." CLI-87-6, 25 NRC at 894. Consistent with this rationale, such procedures would be inappropriate and serve no useful purpose in considering the instant export license application. NCI has now provided its written views and no further proceedings are necessary to assist the Commission regarding this matter.

Even assuming *arguendo* that a party could properly invoke a right to an adjudicatory hearing on an export license application, NCI lacks standing to do so. In order to meet the requirements for standing, *i.e.*, an affected interest within the zone of protected interests, "an organization must show injury either to its organizational interests or to the interests of members who have authorized it to act for them." *Philadelphia Elec. Co.* (Limerick Generating Station, Units 1 and 2), LBP-82-43A, 15 NRC 1423, 1437 (1982). NCI seeks to establish its standing or interest solely on the basis of an alleged generalized injury to its organizational interests, rather than to assert the interests of any members who have authorized it to act for them.^{6/} NCI baldly asserts that it "has important institutional interests which would be directly affected by the outcome of this proceeding." NCI Petition at 6. The only interests asserted, however, are NCI's generalized interest in public information and education regarding its

6/ At least one member with the requisite interest must authorize representation by an organization. *Limerick*, LBP-82-43A, 15 NRC at 1437; *Houston Lighting & Power Co.* (South Texas Project, Units 1 and 2), LBP-79-10, 9 NRC 439, 444 (1979)

concerns about non-proliferation. This type of general grievance does not demonstrate the requisite "injury in fact" to confer standing upon NCI.^{2/}

In addition, the requisite "injury in fact" must be within the zone of protected interests, *i.e.*, "the injury must be fairly traceable to the challenged action, 'or put otherwise, that the exercise of the Court's [or NRC's] remedial powers would redress the claimed injuries.'" *Westinghouse*, CLI-80-30, 12 NRC at 259 (quoting *Duke Power Co. v. Carolina Environmental Study Group*, 438 U.S. 59, 74 (1978)). However, NCI has failed to suggest that it will be injured in any way that the Commission could remedy in connection with its review of this export license application.

The NCI Petition clearly fails to identify any cognizable injury to its interests. In sum, NCI has failed to establish any standing to request an adjudicatory hearing, even if the Commission's rules provided for such a hearing.

II. A DISCRETIONARY HEARING IS NOT IN THE PUBLIC INTEREST AND WOULD NOT ASSIST THE COMMISSION IN MAKING ITS STATUTORY DETERMINATIONS

The NCI Petition fails to make an adequate showing for the Commission to order further proceedings regarding the license application. Section 304(b) of the NNPA provides for limited public participation in export licensing proceedings, such as by submitting written comments, "when the Commission finds that such participation will be in the public interest and will assist

^{2/} An "organization seeking relief must allege that it will suffer some threatened or actual injury resulting from the agency action." *Westinghouse Elec. Corp.* (Export to South Korea), CLI-80-30, 12 NRC 253, 258 (1980) (citing cases). The Commission has also held that under the "injury in fact" test "a claim will not normally be entertained if the 'asserted harm is a "generalized grievance" shared in substantially equal measure by all or a large class of citizens.'" *Transnuclear, Inc.* (Ten Applications for Exports to EURATOM Member Nations), CLI-77-24, 6 NRC 525, 531 (1977) (quoting *Warth v. Seldin*, 422 U.S. 490, 499 (1975)).

the Commission." 42 U.S.C. 2155a(b); *see also* 10 CFR §§ 110.84(a)(1)-(2). Thus, no hearing should be ordered where the Commission is unable to affirmatively make such findings. *See, e.g., General Electric Co. (Exports to Taiwan)*, CLI-81-2, 13 NRC 67, 72 (1981); *Babcock & Wilcox (Application for Consideration of Facility Export License)*, CLI-77-18, 5 NRC 1332, 1349 (1977).

Nothing in NCI's Petition suggests that a hearing would assist the Commission or be in the public interest. Under similar circumstances the Commission has held:

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 Non-Proliferation Act -- that United States Agencies enhance the nation's reputation as a reliable supplier of nuclear materials to nations which adhere to our non-proliferation standards by acting upon export license applications in a timely fashion. A hearing would delay the Commission's decision on the applications for several months. Therefore, we conclude that a public hearing would not be in the public interest or assist the Commission in making its statutory determinations.

General Electric Co., CLI-81-2, 13 NRC at 72; *see also Westinghouse*, CLI-80-30, 12 NRC at 261.

The Commission reached this same conclusion with respect to a 1993 NCI petition opposing another Transnuclear application for a license to export HEU. In that case, the Commission acknowledged that issues raised by NCI, including contentions regarding the common defense and security of the United States and compliance with the Schumer Amendment, "do concern matters that the Commission considers in making an export license decision." *Transnuclear*, CLI-94-1, 39 NRC at 6. However, the Commission concluded, as it should here, that "[t]here is no indication in NCI's pleading . . . that it possesses special knowledge regarding these issues or that it will present information not already available to and considered by the Commission." *Id.* NCI baldly asserts that it has "among its directors, staff

and supporters individuals with broad experience and expertise," but offers no affidavit or other evidence bearing on any issue discussed in the Petition. NCI Petition at 27. At best, NCI is in a position to re-assert its extreme views in opposition to HEU exports and in favor of its over-broad interpretation of the Schumer Amendment. However, the Commission has already rejected NCI's notions regarding the Schumer Amendment, finding instead that "the focus of the statute is on discouraging the continued use of HEU as reactor fuel and not on prohibiting the exportation, per se, of HEU." *Transnuclear*, CLI-94-1, 39 NRC at 7 (emphasis added).

The instant application, involving HEU used as targets to produce medical isotopes (not as fuel), will facilitate AECL's efforts to bring its new LEU-fueled MAPLE reactors on line and help assure a reliable supply of important medical isotopes for U.S. citizens suffering from cancer, AIDS, heart disease and other illnesses. See Affidavits of Dr. Labrie, Dr. Remick and Mr. Bengelsdorf, Dr. Strauss and Dr. Nusynowitz (Enclosures 1, 2, 3, 4, 5, & 6). Denial of these export licenses, as advocated by NCI, will not serve the public interest. Moreover, a Commission order scheduling a discretionary hearing in this case would undermine the NNPA's goal of speedy disposition of export license applications. See 22 U.S.C. 3201(b).^{8/}

8/ In rejecting the 1993 NCI petition to intervene, the Commission concluded:

[C]onducting 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 United States government agencies act in a manner which will enhance this nation's reputation as a reliable supplier of nuclear materials to nations which adhere to our nonproliferation standards by acting on export license applications in a timely fashion."

Transnuclear, CLI-94-1, 39 NRC at 8 (quoting and citing *Westinghouse*, CLI-80-30, 12 NRC 253, 261 (1980)).

An oral hearing to air NCI's views on this matter is unwarranted and will only serve to delay the Commission's decision making on these export license applications.^{9/} However, to the extent NCI's views might aid the Commission, NCI has already presented their views, and these views will undoubtedly be reviewed and taken into account by the Commission.

II. NCI'S CONTENTIONS ARE WITHOUT MERIT

A. The Proposed Exports are Consistent With the Schumer Amendment

Heavily weighing against NCI's argument that the Commission should exercise its discretionary authority to grant NCI's petition is the fundamental fact that NCI is seeking to interject its opinions regarding foreign policy decision-making that has been entrusted to the U.S. Executive Branch. Notably, NCI's arguments are in direct conflict with the terms of the diplomatic notes exchanged by the U.S. Department of State and the Government of Canada. These diplomatic notes, which constitute a binding international agreement between the United States and Canada, specifically deal with the assurances required by the Schumer Amendment with respect to the export of highly enriched uranium to Canada. (A copy of the U.S. Note is appended hereto as Enclosure 7, and a copy of the Canadian Note is appended hereto as Enclosure 8.) These notes clearly satisfy the Schumer Amendment's three conditions for the export of the HEU targets that are the subject of the export license applications that NCI seeks to challenge. Moreover, the notes were obviously intended to satisfy the NRC's regulation

9/ If the Commission determined that further inquiry were required, a written hearing should be sufficient to develop an adequate record on the issues that the Commission deems relevant. See, e.g., *Edlow Int'l Co. (Agent for the Government of India)*, CLI-79-2, 9 NRC 2, 3 (1979) ("[W]e do not believe that oral presentations before the Commission would substantially assist the Commission in its analysis of this license application.").

implementing the Schumer Amendment since they incorporate verbatim the applicable portions of that regulation.

The diplomatic notes first set forth the agreement of the United States and Canada "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 and processing 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." Therefore, the Government of Canada has provided a legally binding assurance that plainly satisfies the second of the three criteria set forth in the Schumer Amendment and the NRC's regulation. Moreover, by expressing this assurance in a binding agreement, the Government of Canada has provided a commitment of the highest order that goes well beyond the assurance letter from a reactor operator that would normally be sufficient to satisfy the Schumer Amendment. No legitimate purpose could be served by conducting a hearing to allow NCI's consultants and staff members to second guess and criticize foreign policy decisions that have already been made.

If the Commission decides that it must look beyond the plain text of the diplomatic notes, deference should be given to the views of the State Department. Pursuant to the Inter-Agency Procedures that implement the NNPA, the State Department is required to respond, on behalf of the U.S. Executive Branch, to the NRC's request for the Department's views as to whether the proposed exports meet the standards specified in the Schumer Amendment and other applicable provisions of the Atomic Energy Act. "Procedures Established Pursuant to the Nuclear Non-Proliferation Act of 1978," 49 FR 20780 (May 16, 1984), as amended, 56 FR 6701

(Feb. 19, 1991). As the U.S. Government entity that entered into the international agreement, the views of the State Department regarding the interpretation and effect of that agreement should be given great weight. As noted in the Restatement (Third) of the Foreign Relations Law of the United States, § 326 n. 4 (1987), "courts give . . . 'great weight' to Executive interpretations of international agreements." *Factor v. Laubenheimer*, 290 U.S. 276, 294-95 (1933). The Commission can and should rely upon the State Department's written views regarding these export license applications in making its own informed decision on this issue.

Having concluded less than a year ago that the Schumer Amendment was satisfied in connection with the shipment of HEU to Canada for purposes of developing the very HEU targets that NCI challenges here, the NRC clearly has no need to conduct a hearing in this matter. The above-mentioned diplomatic notes establish a government to government channel "to ensure that there is a complete understanding of the range of issues associated with the use of uranium targets for medical isotope production so as to provide the basis for a determination whether an alternative LEU target can be used in that particular reactor for the production of medical isotopes." Enclosure 8. Consultations between the United States and Canada, pursuant to diplomatic channels, are clearly the appropriate route to convey any new information that may affect the continued viability of the previous conclusions of the State Department and the NRC that export of U.S.-origin HEU to Canada and other countries for use as targets for the production of medical isotopes is consistent with the requirements of the Schumer Amendment.

B. AECL and MDS Nordion Continue to Cooperate Fully with the Active U.S. Effort to Design, Evaluate and Qualify LEU Targets for the MAPLE Reactors

Contrary to NCI's contentions, AECL and MDS Nordion have cooperated, and will continue to cooperate, with the United States government and its contractors, in the development

and qualification of LEU targets for use in the MAPLE reactors. *See* Affidavit of Dr. Labrie (Enclosure 1). In consultations and meetings with officials of ANL, AECL and MDS Nordion have continued to live up to their previously expressed commitment 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 for the MAPLE reactors and necessary associated facilities."^{10/} AECL and MDS Nordion have met with ANL officials over the last few months to attempt to establish mutually agreed terms for cooperating to support the U.S. Government program for developing an LEU target design that can be "qualified" for use in the MAPLE reactors.^{11/} In accordance with the diplomatic notes exchanged between the United States and Canada, and pursuant to the Schumer Amendment, including its implementing regulations,^{12/} this ongoing U.S. Government program will also need to evaluate whether the facilities for processing any "qualified" LEU target "may be designed, constructed and licensed in a manner that allows the large majority of ongoing and planned . . . isotope production to be

10/ Supplement to Item 25 of NRC Form 7 Submitted to the NRC on October 31, 1998, by Transnuclear Inc., Regarding Application to Export Approximately 130 kg of Highly Enriched Uranium Contained in Targets for the Production of Medical Isotopes, Including Molybdenum-99.

11/ On November 5, 1998, a meeting was held between representatives of ANL, AECL and MDS Nordion to discuss the introduction of LEU targets to the medical isotope production process. As noted in Dr. Labrie's letter, "a non-disclosure agreement was exchanged with ANL on November 5, 1998, to facilitate discussions between our organizations at the outset of this program." *See also* Affidavit of Dr. Labrie (Enclosure 1). This meeting was the subject of memoranda to the Commissioners, dated November 23, 1998, and January 5, 1999, from Janice Dunn Lee, Acting Director Office of International Programs.

12/ 10 CFR § 110.42(a)(9).

conducted in the reactor without a large percentage increase in the total cost of operating the reactor.”^{13/}

AECL and MDS Nordion have not only made every reasonable effort to evaluate the commercial viability of using LEU targets in the MAPLE reactors, AECL has worked towards developing LEU targets for those reactors. Both AECL and MDS Nordion have stated on the record that they are prepared to share this information with ANL, provided that their proprietary interests are protected. As pointed out by Dr. Jean-Pierre Labrie, General Manager of AECL's Research and Isotope Reactor Business, in his December 23, 1998 letter to Armando Trevelli, Manager of the Technology Development Division of ANL's RERTR Program, "AECL has the knowledge and capability for implementing LEU targets and isotope production processes." Dr. Labrie also pointed out that "the conversion of the MAPLE reactors, which use LEU driver fuel, from HEU to LEU targets for medical isotope production can be achieved, but requires additional safety analyses to obtain regulatory approvals for operating the reactors with LEU targets." In addition, AECL will consult with the RERTR program to develop the information regarding the costs of constructing further processing facilities and/or converting the MAPLE processing facilities as foreseen in the U.S.-Canada exchange of diplomatic notes. DOE would then be in a position to provide the Commission with a basis for determining whether or not the use of such LEU targets would result in a large percentage increase in the costs of operating the MAPLE radioisotope program.

AECL and MDS Nordion obviously have expended substantial funds to develop designs for HEU and LEU targets and associated processing facilities for producing Mo-99 in the

^{13/} 10 CFR § 110.42(a)(9)(ii)(B).

MAPLE reactors. Therefore, it is necessary that they take appropriate steps to protect their proprietary information from disclosure or from being used to deprive them of the ability to realize the commercial benefit of their information. One objective of the ongoing discussions between ANL, MDS Nordion and AECL is to determine whether ANL wishes to have access to AECL's LEU target design and performance information and, if so, to develop reasonable commercial terms, such as a licensing agreement, for affording ANL such access. In addition, the parties have had general discussions regarding the possibility of ANL representatives visiting Chalk River to observe the Canadian process, and AECL remains willing to facilitate such a visit. However, AECL is yet to receive any specific request from ANL to establish concrete plans for scheduling such a visit. *See* Affidavit of Dr. Labrie (Enclosure 1). There is, therefore, simply no basis for NCI to imply, as it does, that Canadian authorities are refusing an ANL visit to Chalk River. NCI Petition at 17.

Despite NCI's suggestions to the contrary, NCI Petition at 19, the Schumer Amendment plainly imposes the burden of developing LEU target designs on the U.S. Government. *See, e.g., Transnuclear*, CLI-98-10, 47 NRC at 339 ("AECL and MDS Nordion have no requirement that would lead them to undertake the development and use of an LEU target.") In fact, the Commission explicitly acknowledged that AECL and MDS Nordion's offer to provide information and services to ANL was an offer to do so "on a commercial basis." *Id.* Moreover, neither DOE nor NRC have adopted any rule which requires foreign entities to effectively fund the development of LEU targets as a condition of receiving HEU exports. If DOE or NRC were inclined to adopt such new requirements, such action should only be taken by rulemaking so that the desirability and advisability of such action may be probed as provided by the Administrative

Procedures Act. Such a rule may well be inconsistent with the objectives of the RERTR program because it may hinder cooperation by other nations in LEU conversion efforts.

In granting the previous HEU target export license applications, the Commission found that "[w]hile the dialogue and exchanges toward this effort may be in the early stages, we believe that the U.S. and Canadian principals are acting in good faith toward concluding a formal agreement to complete the LEU target development linked to the Canadian reactors."

Transnuclear, CLI-98-10, 47 NRC at 339. Nothing has occurred in the approximately seven months following the Commission's decision that would justify any change in its conclusion regarding the good faith of the Canadian participants in the MAPLE reactor program.

C. The Proposed Exports to Canada Are Not Inimical to the Common Defense and Security of the United States

NCI contends that the pending export license application must be denied because the proposed exports to Canada would be "inimical to the U.S. common defense and security." NCI Petition at 24. NCI suggests that NRC should interpose its own judgment on this issue without regard to the Executive Branch's inimicality determination which will reflect the views of the State Department, the Department of Energy, the Department of Commerce, the Department of Defense, and the Arms Control and Disarmament Agency. However, the Commission has routinely deferred to the Executive Branch's inimicality determinations. For example, in *Westinghouse*, the Commission deferred to the Executive Branch views on the effect of a change in a recipient nation's government on the continued effectiveness of non-proliferation assurances. CLI-80-30, 12 NRC at 263; *see also Babcock and Wilcox* (Export of a Reactor to West Germany), CLI-77-18, 5 NRC 1332, 1349 (1977); *Westinghouse Elec. Corp.* (Export of a Reactor to Spain), CLI-76-9, 3 NRC 739, 755-56 (1976).

In the scheme established by the NNPA, Congress' assignment to the Executive Branch of the duty to make the finding of "inimicality" reflected the need to base that finding upon the collective expertise of the Executive Departments which have major responsibilities in the areas of nuclear non-proliferation and international nuclear commerce. As the D.C. Circuit has observed, "by adding NNPA on top of the existing Atomic Energy Act, Congress confirmed its intention that assurances of non-proliferation and maintenance of the military balance be the indispensable condition of United States nuclear exporting." *NRDC*, 647 F.2d at 1359.

Discussing the Commission's reliance on the Executive Branch's inimicality determination, the court noted:

The Executive [Branch] has fully reviewed and determined that the export to the Philippines is not inimical to our "common defense and security." I find that the Commission has properly and sufficiently relied on the executive's foreign policy, extraterritorial and national security conclusions.

Id. at 1364 (footnotes omitted).

In *NRDC* the court recognized that the NRC's role in determining whether a proposed export license would be "inimical to the common defense and security" is limited to an assessment of technical factors within the NRC's expertise that bear on this judgment. Recognizing this limited role for the Commission with regard to the "inimicality" determination, the Commission's rules provide, in Section 110.44(a), that "the Commission will issue an export license if it has been notified by the State Department that it is the judgment of the Executive Branch that the proposed export will not be inimical to the common defense and security," and finds that the applicable export criteria (specified in Section 110.42), are satisfied. In reviewing Transnuclear's export license application, the Executive Branch is entrusted with the primary

responsibility to perform the very assessment that Petitioner now invites the Commission to duplicate.

Moreover, no serious questions can be raised concerning Canada's non-proliferation credentials. *See* Joint Affidavit of Dr. Remick and Mr. Bengelsdorf (Enclosure 2). NCI's concerns about HEU diversion by the Iraqis and the desirability of Romanian HEU conversion, NCI Petition at 26, are simply inapplicable to a longstanding and trusted ally, such as Canada, which strongly supports nuclear non-proliferation and is committed to cooperation with the United States on the peaceful uses of nuclear energy, including its RERTR program.

D. Denial of the Pending Application Would Jeopardize Important Foreign Policy and Public Health Objectives

The enclosed Joint Affidavit of Dr. Remick and Mr. Bengelsdorf (Enclosure 2) provides a persuasive assessment of the issues surrounding the pending export license application, and this assessment demonstrates that denial of the pending application would jeopardize important foreign policy and public health objectives. Rather than summarizing the enclosed Joint Affidavit, Transnuclear and AECL respectfully refer the Commission to Enclosure 2 and submit that the views of Dr. Remick and Mr. Bengelsdorf will be helpful to the Commission in reviewing the pending application. Significantly, upon a thorough review, Dr. Remick and Mr. Bengelsdorf conclude that, in light of the considerable amount of work to be done, in their judgment, the Canadian request for a five-year supply of HEU is a reasonable one. *See* Joint Affidavit of Dr. Remick and Mr. Bengelsdorf, ¶ 18 (Enclosure 2).

Significantly, the DOE has concluded that a shutdown of the NRU reactor currently used by AECL to irradiate HEU targets to produce Mo-99, "would jeopardize the U.S. supply of Mo-99." "Record of Decision for the Medical Isotope Production Project: Molybdenum-99 and

Related Isotopes," 61 FR 48921, 48922 (Sept. 17, 1996). In its Record of Decision, DOE pointed out that "a window of vulnerability for the U.S. medical community exists until a reliable backup source of Mo-99 is available." *Id.* Thus, the importance of the MAPLE program to replace the NRU cannot be overstated, because "the current supply of Mo-99 from Canada would be interrupted if the NRU reactor experiences a shutdown of approximately five days or longer for any reason." *Id.* at 48923. In fact, the DOE concluded that "any major problem at the reactor requiring significant time and resources to repair would probably result in a permanent shutdown." *Id.*

Despite the adverse impact that denial of this application could have upon seriously ill patients in the United States and Canada, NCI urges the Commission to thwart AECL and MDS Nordion's pursuit of the conservative, responsible and timely operation of the LEU-fueled MAPLE reactors using proven HEU targets that can be processed in the currently designed facilities. If AECL and MDS Nordion are not granted an NRC export license authorizing the shipment to Canada of a sufficient inventory of HEU targets to ensure the uninterrupted production of Mo-99 at the MAPLE reactor for at least five years, they may be forced to (1) abandon their planned use of the MAPLE reactors to produce Mo-99, with the attendant risk that necessarily entails to diagnosis and treatment of patients in North America; (2) substantially delay the start up of the MAPLE reactors for years while they cooperate with DOE's RERTR program to "qualify" and license LEU targets for the MAPLE reactors and construct and license major new processing facilities needed to process LEU targets, while continuing to rely on the old NRU reactor to produce Mo-99 for as long as it continues to operate; or (3) seek an alternative HEU target supplier. These options are inconsistent with U.S. foreign policy and public health objectives.

It should be noted that DOE's solution to the current "window of vulnerability" is to produce medical isotopes by irradiating HEU targets at the Annular Core Research Reactor operated by Sandia National Laboratories in Albuquerque, New Mexico. 61 FR at 48924. If it were advisable for Canada to move immediately to using LEU targets, with the attendant risks to medical care of patients in North America, it would only seem logical that the United States would have already abandoned its plans to use HEU targets in its own program. In fact, there is little doubt that DOE would not be planning to use HEU targets in the ACRR to produce Mo-99 if LEU targets were available within the meaning of the Schumer Amendment. DOE's decision to proceed with the use of HEU targets, while simultaneously pursuing future conversion to LEU targets, is consistent with AECL and MDS Nordion's plans.

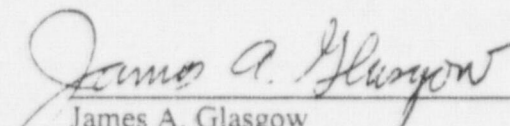
Consistent with U.S. policy, the United States and Canada entered into an international agreement in 1997 in which Canada agreed that once LEU targets have been qualified by the relevant authorities and do "not result in a large percentage increase in the total cost of operating a reactor, including necessary associated equipment, for the production and processing of medical isotopes," such alternative LEU targets would be used "after required equipment has been installed and the necessary licenses have been obtained." See Enclosure 8. Thereafter, in 1998, the Commission properly approved the export of HEU test targets to be developed for use in the MAPLE reactors, based upon the very tight schedule for completing the MAPLE project and assuring an uninterrupted supply of vital medical isotopes. Since that time, AECL has continued to cooperate in the development of LEU targets, while simultaneously planning for initial operation of the MAPLE reactors and new processing facilities using HEU targets. AECL appropriately anticipates that if LEU targets can both be developed and be determined to not result in a large percentage increase in operating costs, it will take at least five years to complete

a transition to using such LEU targets. This approach is plainly contemplated by the U.S.-Canadian agreement, and any changes to the policy reflected in that agreement would need to be pursued through diplomatic channels. Despite this clear set of facts warranting approval of the proposed export of HEU targets and the adverse foreign policy implications of a denial of the export, NCI opposes the export license application and argues that it should be denied. This position is ill-advised. In fact, the denial of the pending application would jeopardize important foreign policy and public health objectives.

CONCLUSION

For the foregoing reasons, Transnuclear, Inc. and Atomic Energy of Canada, Limited respectfully request that the Petition of Nuclear Control Institute be denied in its entirety.

Respectfully Submitted,

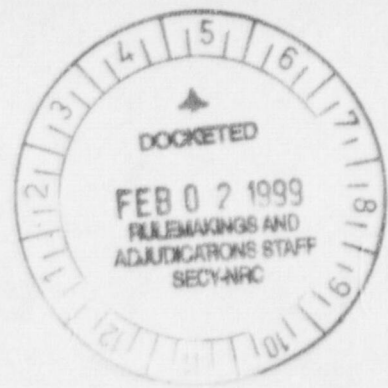


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ATTORNEYS FOR TRANSNUCLEAR, INC. AND
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February 2, 1999

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
BEFORE THE COMMISSION**



In the Matter of)

TRANSNUCLEAR, INC.,)
on behalf of,)
ATOMIC ENERGY OF)
CANADA, LTD.,)

(Export of 93.3% Enriched)
Uranium))

Docket Nos. 11005070

License No. XSNM-03060

NOTICE OF APPEARANCE OF COUNSEL

Notice is hereby given that John E. Matthews enters an appearance as counsel for Transnuclear, Inc., on behalf of Atomic Energy of Canada, Limited (AECL), and AECL, in the above-captioned proceeding.

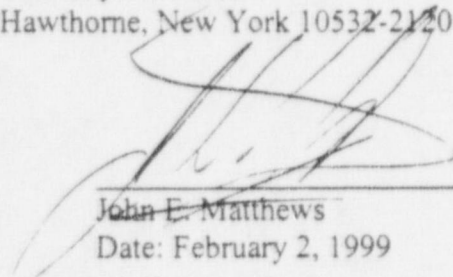
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John E. Matthews

Date: February 2, 1999

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
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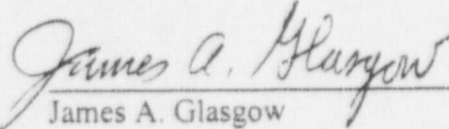
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James A. Glasgow
Date: February 2, 1999

CERTIFICATE OF SERVICE

I hereby certify that on February 2, 1999, copies of "Transnuclear's Opposition in Response to Petition to Intervene," with enclosures, two Notices of Appearance of Counsel, a Certificate of Service, and a letter to the Secretary of the Commission, in the above-captioned proceeding were served by hand on the following:

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Commissioner Greta J. Dicus
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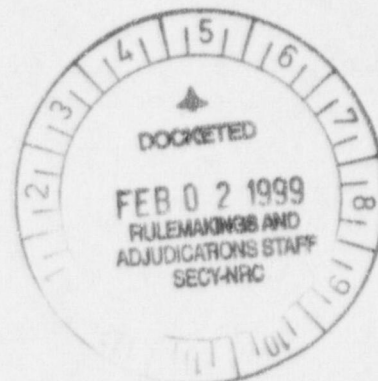
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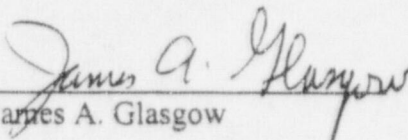
Attention: Rulemaking and Adjudications Staff
(Original plus two copies)



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February 2, 1999

ENCLOSURE 1