UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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COMMISSIONERS:

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Shirley Ann Jackson, Chairman
Greta Joy Dicus
Nils J. Diaz
Edward McGaffigan, Jr.
Jeffrey S. Merrifield

In the Matter of	)	
	)	
TRANSNUCLEAR, INC.	)	
	)	Docket No. 11005070
(Export of 93.3% Enriched Uranium)	)	License No. XSNM-03060
	)	
	)	

CLI-99-20
MEMORANDUM AND ORDER

I. BACKGROUND

On October 30, 1998, Transnuclear, Inc., as agent for Atomic Energy of Canada, Ltd. (AECL), filed License Application No. XSNM-03060 with the Commission, seeking authorization to export 130.65 kilograms of highly enriched uranium (HEU) containing 121.8966 kilograms of U-235 in the form of uranium dioxide (UO_2) targets. The HEU targets, to be shipped quarterly over a five-year period, would be irradiated to produce radioisotopes, in particular Mo-99, for medical applications. The targets are to be irradiated in the MAPLE 1 and 2 reactors, currently in an advanced state of construction, and processed in a new facility at AECL's Chalk River Nuclear Laboratories. The MAPLE reactors and associated processing facility will be operated by AECL on behalf of MDS Nordion (Nordion).[(1)]

On December 30, 1998, the Nuclear Control Institute (NCI) filed a petition for leave to intervene and a request for hearing on the application. NCI is a nonprofit, educational corporation which disseminates information to the public concerning the proliferation, safety and environmental risks associated with the use of weapons-useable nuclear materials, equipment, and technology. The Department of State provided the Commission with Executive Branch views on the merits of Transnuclear's application on March 5, 1999. The Executive Branch concluded that the application satisfied the applicable export licensing criteria and requested that the Commission issue the license. After receiving these views and evaluating the pleadings filed in this proceeding, and without ruling on the intervention petition and hearing request, the Commission posed further questions to the participants. Transnuclear, Inc. (Export of 93.3% Enriched Uranium), CLI-99-09, 49 NRC 314 (April 8, 1999). The Commission received responses to the questions from NCI, Transnuclear/AECL on April 22, 1999, and from the Executive Branch on April 27, 1999.

On April 26, 1999, the Commission ruled that Petitioner lacked standing under Section 189a. of the Atomic Energy Act of 1954, as amended (AEA), to intervene and to demand a hearing as a matter of right.[(2)] The Commission further ruled that a discretionary hearing under 10 CFR § 110.84 was not warranted in this proceeding, because such a hearing would pose unnecessary burdens on the participants without assisting the Commission in making its statutory findings. However, to allow the participants to summarize their positions, and respond to questions from the Commission, the Commission invited all participants to make presentations at a public meeting on June 16, 1999. Transnuclear, Inc. (Export of 93.3% Enriched Uranium), CLI-99-15, 49 NRC 366 (1999).

Before that meeting, the Commission posed additional questions to Applicants in a letter, dated May 18, 1999, regarding the possibility of starting up one MAPLE reactor using HEU targets, while delaying the commencement of operation of the second MAPLE reactor until low-enriched uranium (LEU) targets could be developed for use in that reactor. Applicants' June 11, 1999 response detailed Applicants' views that there would be no advantage likely to be gained by such an approach.

The Commission held the public meeting on June 16, 1999, and heard presentations from Applicants, NCI, and the Executive Branch (which included representatives from the Argonne National Laboratory (ANL)). The Commission commends each of the participants for their thoughtful written submissions and oral presentations. The Commission is now confident that it has developed a sufficient record upon which to base its licensing

determination.[3]

Before turning to the merits of the application, it is important to note the current state of medical radioisotope production in Canada. Until 1993, two reactors, NRU and NRX, operated to produce Mo-99 (whose decay product, Tc-99m, is used for diagnostic radioimaging) through the irradiation of targets. In 1993, the NRX reactor was permanently shut down. The MAPLE 1 and 2 reactors are being constructed to replace AECL's remaining NRU reactor, which has been operating since 1957 and is currently scheduled to cease large-scale radioisotope production in the year 2000. Transcript of June 16 Commission meeting, at 70 (Hereinafter "Tr."). Applicants have stated that by the end of that year, it will no longer be possible to operate the NRU reactor because the associated waste storage tank will be full. Moreover, Applicants have expressed concern about whether the reactor is capable of continuous reliable production due to its age. Currently, the NRU reactor produces approximately 60% of the Mo-99 for use in radiopharmaceuticals worldwide; it is an important source of Mo-99 for the United States.[4] Because the lifetimes of Mo-99 and Tc-99m are extremely short (with half-lives of 66 hours and 6 hours, respectively), it is not possible to stockpile the isotopes. Thus, a continued reliable Canadian supply of medical radioisotopes currently hinges on the NRU reactor, operating without backup until the MAPLE reactors are brought on line. MAPLE 1 is expected to begin operation in the fall of 1999, MAPLE 2 in the spring of 2000. Tr., at 18. Following startup of the MAPLE 1 reactor, NRU will revert to the role of a backup unit. Applicants' Response to Commission Questions (Apr. 21, 1999), at 13. Once MAPLE 2 is operational, NRU will operate as a research reactor, with no further role in routine isotope production. Id.

II. STATUTORY REQUIREMENTS FOR AUTHORIZATION OF EXPORT OF HEU TARGETS

Participants' submissions focused primarily on two issues: (1) whether the proposed exports would be in compliance with the "Schumer Amendment;"[5] and (2) whether the proposed exports would be inimical to the common defense and security of the United States.

A. THE SCHUMER AMENDMENT

The Schumer Amendment, added to the Atomic Energy Act by the Energy Policy Act of 1992, Pub. L. No. 102-486, 106 Stat. 2776 (1992), and subsequently codified in the Commission's regulations at 10 CFR § 110.42(a)(9), imposes the following restrictions on exports of HEU fuel and targets:

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

There is no dispute as to whether the first criterion has been satisfied; all participants agree there is currently no LEU target available that "can be used" in the MAPLE reactors.[6]

The arguments in this proceeding thus have focused on whether the other two criteria, and principally criterion three, have been satisfied. NCI argues that these two criteria are not satisfied, and therefore, the Commission must deny Applicants' request for a license.

1. Governmental Assurances That LEU Targets Will Be Used When Available

NCI asserts that the Canadian government has provided insufficient assurances that LEU targets will be used if developed. NCI argues that AECL failed to provide information and cooperation to ANL,[7] which has slowed progress on an active program to develop targets for the MAPLE reactors. Petition of the Nuclear Control Institute for Leave to Intervene and Request for Hearing (Pet.), at 23. In addition, during the June 16 meeting, NCI stated that the lack of a firm agreement between the United States and Canadian governments as to cost-sharing aspects of the ANL target development program undercuts prior governmental commitments to seek to develop LEU targets. Tr., at 85; Statement of Paul L. Leventhal & Alan J. Kuperman, at 2, 4.

Based on its examination of the record, the Commission does not reach the same conclusion. The Embassy of the United States in Canada and the Canadian Ministry of Foreign Affairs exchanged diplomatic notes on September 4, 1997. These notes reflect Canada's assurance that it will use LEU targets when such targets become available, provided that their use does not result in a large percentage increase in the total cost of operating the pertinent reactor (including the necessary associated equipment for the production and processing of medical isotopes). This language in the notes mirrors that used in AEA subsection 134a.(2) and subsection 134b.(3)(B).[8]

We are satisfied that these notes constitute assurances sufficient to satisfy the requirement of subsection 134a.(2). See Transnuclear, Inc. (Export of

93.3% Enriched Uranium, CLI-98-10, 47 NRC 333, 338 n.5 (1998). As discussed more fully below, we further believe that in recent months the interactions between the Applicants and ANL reveal a clearer commitment by the Applicants to utilize LEU targets should they become available at reasonable cost.

2. "Active Development" of LEU Targets for the MAPLE Reactors

The core of NCI's argument is that the third criterion, AEA subsection 134a.(3), is not met because the United States Government is not currently "actively developing" an alternative nuclear reactor target suitable for use in the production of medical isotopes in the MAPLE reactors. NCI contends that, through informal contacts with ANL, it has learned that Applicants have not shared with ANL the information necessary to begin actively developing an LEU target suitable for the MAPLE reactors. See, e.g., NCI Reply, at 14; Leventhal Decl., ¶ 36.

At the time NCI filed its pleadings with the Commission, the continuing existence and extent of an active program to develop LEU targets for use in the MAPLE reactors were not readily apparent. As detailed below, however, actions taken by the participants, particularly since the issuance of CLI-99-09 on April 8, 1999, satisfy us that an active LEU target development program for the MAPLE reactors is currently under way at ANL.

Following review of the Executive Branch's March 5, 1999 letter, and the pleadings of NCI and Applicants, the Commission concluded that it should seek additional information prior to making a decision on the license application. The Commission was particularly concerned that there appeared to be limited progress made on the LEU target development program since the Commission's June 5, 1998 approval of licenses to export HEU for use as target material in the NRU and MAPLE reactors. See CLI-98-10. The participants' initial submissions reflected the following actions:

(1) On November 5, 1998, a meeting was held between representatives of ANL, AECL and Nordion to discuss cooperation in developing LEU targets and processes for Mo-99 production. At that time, the parties executed a non-disclosure agreement to protect proprietary information of ANL, AECL, and Nordion during future discussions.

(2) A December 23, 1998 letter from J. Labrie, AECL, to A. Travelli, ANL, indicated that AECL would require a further agreement, primarily to protect its intellectual property rights, prior to disclosure of its technology to ANL.

(3) In its March 5, 1999 submission of Executive Branch views, the State Department enclosed a letter from T. Dedik, Department of Energy, to R. Stratford, U.S. Department of State, detailing a January 12, 1999 meeting between Nordion representatives and ANL to discuss the program to convert the HEU targets for the MAPLE project to LEU targets.[(9)]

Due to the seeming lack of significant progress on the program implied in the pleadings, the Commission posed a series of questions, contained in an Appendix to CLI 99-09, in order to obtain, inter alia, updates on the status of the NRU reactor and the MAPLE project, and current information as to funding of DOE's RERTR program to develop alternative LEU targets for the MAPLE reactors. The participants' written responses to these questions, as well as presentations made at the June 16 public meeting, furnished new information and evidence of a currently active program at ANL for the development of LEU targets for use in the MAPLE project.

The responses indicated that, on March 18, 1999, representatives from Nordion met with representatives of the Executive Branch. At that time, Nordion again confirmed its move toward the use of LEU targets. During the period March 24-April 19, 1999, the participants continued to meet and work toward completion of a confidentiality agreement.

On June 16, the Commission was informed that ANL, AECL and Nordion executed a tripartite confidentiality agreement on May 13, 1999, after more than a year of meetings on the subject. AECL subsequently forwarded technical information to ANL on May 20, 1999. Although ANL informed the Commission that further technical information is required from AECL, we understand no further confidentiality agreements are required in order to effectuate this transmission of information and allow ANL's work to go forward. We learned at the June 16 meeting that an intellectual property agreement remains to be negotiated, but it is our understanding that this agreement is not essential for ANL to prepare a feasibility study--the next step in the development of LEU targets for the Maple reactors. This study will enable Applicants to determine the probability of success of conversion to LEU targets, address the technical challenges presented by the conversion process, set a meaningful schedule for conversion, and make appropriate cost estimates. Tr., at 115.

In its Response to Commission Questions, the Executive Branch stated that, of $1 million in funding slated for target work under the RERTR program in FY99,[(10)] approximately $75,000 is set aside for work with AECL/Nordion. Executive Branch representatives at the June 16 meeting stated that this seemingly modest sum would be sufficient to enable ANL to complete the feasibility study. ANL representatives also indicated that, once ANL has received additional necessary information from Applicants, this study can be completed in approximately three months. Thus, the expectation is that the feasibility study will be completed well before the end of 1999.[(11)]

Based upon our assessment of the new information the Commission has received, particularly over the last two months, we are satisfied that an active program is under way for the development of LEU targets for the MAPLE reactors, as required under subsection 134a.(3). Thus, all requirements of the Schumer Amendment have been met in this proceeding.

B. OTHER EXPORT LICENSING CRITERIA

As part of its licensing decision the Commission must determine whether the other applicable export licensing criteria have been satisfied. There is no disagreement here that the nonproliferation criteria set forth in AEA Sections 127 and 128 have been met. Thus, the last finding the Commission must make is whether issuance of the proposed export would be "inimical to the common defense and security of the United States." AEA § 57c.(2); 10 CFR §§ 110.42(a)(8); 110.45(a) . NCI contends that the approval of the proposed export would imply a more generalized U.S. approval of the continued use of HEU in research or test reactors which would ultimately discourage foreign reactor operators from converting to LEU. Pet., at 24. NCI is also concerned that the proliferation and terrorism risks associated with increasing the amount of international traffic of HEU outweighs the benefits of the proposed export. Id., at 25. The State Department, in its March 5, 1999 transmittal of Executive Branch views, determined that "the proposed export would not be inimical to the common defense and security of the United States." In making this determination, the State Department consulted with the Defense Department to confirm that physical protection measures will be adequate to deter theft, sabotage and other acts of international terrorism which would result in diversion of the material during the export. Views of the Executive Branch (June 16, 1999), at 2.

Judgments of the Executive Branch regarding the common defense and security of the United States involve matters of its foreign policy and national security expertise, and the NRC may properly rely on those conclusions. See Natural Resources Defense Council v. NRC, 647 F.2d 1345, 1364 (D.C. Cir. 1981). Canada's nonproliferation credentials are exemplary. Canada is a party to the Treaty on the Nonproliferation of Nuclear Weapons and the Convention on the Physical Protection of Nuclear Materials. The Canadian government places all of its peaceful nuclear activities under International Atomic Energy Agency (IAEA) safeguards, and adheres to the IAEA Recommendations on the Physical Protection of Nuclear Materials (INFCIRC/225/rev. 4). The Canadian Atomic Energy Control Board has confirmed that this proposed export would be subject to all the terms and conditions of the existing Agreement for Cooperation concerning the Civil Uses of Atomic Energy between the Government of Canada and the Government of the United States. Moreover, Canada has adopted the Nuclear Supplier Group Guidelines, and is a member of the NPT Exporters Committee ("Zangger Committee.")

Although the Commission is mindful of NCI's concerns, we hold that the Executive Branch conclusions and Canada's longstanding nonproliferation policies support a finding that this proposed export will not be inimical to the common defense and security of the United States. Indeed, as discussed below, the conditioned approval of this license to export HEU targets for use in the short term, promotes a program for use of LEU targets in the long term, which directly serves the objective of the Schumer Amendment and the U.S. policy goal of reducing international commerce in weapons-grade material.

III. ISSUANCE OF THE LICENSE

The Commission has determined that the export licensing criteria set forth in the Atomic Energy Act are satisfied and directs the Office of International Programs to issue license XSNM-03060 to Transnuclear, Inc. Specifically, the Commission finds that the export licensing criteria set forth in AEA Sections 127, 128 and 134 have been met. Moreover, pursuant to AEA Sections 53 and 57, issuance of this license would not be inimical to the common defense and security or constitute an unreasonable risk to the health and safety of the public.

To ensure that the provisions of the Schumer Amendment continue to be met, the Commission directs that the five-year license be conditioned to require the Applicants to submit in writing to the Commission a yearly status report detailing the progress of the program and Canadian cooperation in developing LEU targets for the MAPLE reactors. The first report should be submitted 60 days prior to the first quarterly shipment that will take place after July 1, 2000. Thus, if a shipment is scheduled for July 4, 2000, the NRC should receive a status report no later than May 8, 2000. Further annual reports will be required no later than 365 days after the submission of the first annual report. At the June 16 meeting, the Executive Branch offered to provide the Commission with a similar annual status report communicating the Executive Branch's views on the progress in development of LEU targets for the MAPLE reactors. The Commission accepts this offer and requests that the Executive Branch report be submitted to the Commission annually no later than 30 days after the submission of Applicants' report. The Executive Branch reports should include assurances that the funds necessary to develop the LEU targets in a timely manner have been made available to ANL. The Commission intends to place both the Applicants' reports and the Executive Branch reports in the Public Document Room. Therefore, proprietary information should be handled as an annex to the reports so that the information can be easily segregated from the rest of the reports. Upon examination of the reports, the Commission may hold a public meeting, if necessary, to gather additional information. If the Commission should make a finding, following review of these periodic status reports and a public meeting, if necessary, that the requirements of the Schumer Amendment are not being met, the Commission may modify, suspend, or revoke the license pursuant to Section 186 of the AEA and 10 CFR § 110.52.

From the assurances provided to the Commission in the June 16, 1999 meeting, it is the Commission's understanding that ANL will be able to complete a feasibility study promptly, within approximately three months of receiving the necessary technical information. The Commission further understands that AECL will cooperate fully with ANL to complete a feasibility study as soon as possible. In light of these commitments, the Commission is encouraged that AECL may have a feasibility study in hand in time to consider whether minor modifications could be made prior to the MAPLE reactors and their processing facility coming on line that would permit the use of LEU targets, or take other reasonable measures that would at least preserve the opportunity to move to LEU targets in the future. To ensure compliance with the Schumer Amendment, the Commission expects Applicants to pursue all reasonable measures that would not cause "a large percentage increase in the total cost of operating the reactor." Having said this, we recognize that in determining whether changes are feasible, Applicants will have to consider the commitments it has made to the Canadian Government and its customers with respect to assuring the supply of medical isotopes and otherwise keeping costs to a minimum.

Commissioners Diaz and McGaffigan, believing that the Commission did not have adequate assurance that active development of LEU targets for the MAPLE reactors would continue, voted to limit the license to 60% of the requested amount of HEU.

It is so ORDERED.

For the Commission[12]

[Original Signed by Annette Vietti-Cook]

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ANNETTE VIETTI-COOK
Secretary of the Commission

Dated at Rockville, Maryland
this 20th day of June, 1999.

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1. Transnuclear, AECL and Nordion will be collectively referred to in this Memorandum and Order as "Applicants."

2. Indeed, NCI had conceded that it is unable to meet the judicial standing tests which the Commission applies in export licensing proceedings. See Reply of Petitioner Nuclear Control Institute to the Opposition of Transnuclear, Inc. and Atomic Energy of Canada, Ltd. to the Petition for Leave to Intervene and Request for a Hearing, Feb. 12, 1999 (NCI Reply), at 3.

3. On June 21, 1999, NCI submitted an additional set of comments to the Commission, which restated the main points of its June 16 presentation, to be discussed infra. In addition, this submission offered a new proposal. Under NCI's new plan, the Commission is asked to condition the export license on operating the NRU reactor until a feasibility study and any required modifications are completed at AECL's New Processing Facility (NPF) to accommodate LEU targets. If there are operational problems with the NRU that would interrupt the production of medical isotopes during this time, the MAPLE reactors would commence operation using NRU HEU targets, to produce medical isotopes. The targets would then be processed in the NRU processing facility, in order to keep the NPF "clean" pending modification to accommodate LEU targets. The Commission has considered this proposal, but the Commission is of the view that it would be inappropriate to impose any such condition which would dictate how and when a foreign reactor would be operated. The Commission has not adopted this suggestion, particularly since the Schumer Amendment and other requirements for issuance of this export license have been met.

4. The Executive Branch has asserted that the NRU reactor supplies more than 60 percent of the U.S. supply of Mo-99. Views of the Executive Branch, at 5 (June 16, 1999). Additionally, the U.S. Department of Energy has found that "[a] shutdown of this single remaining reactor would jeopardize the U.S. supply of Mo-99." Record of Decision for the Medical Isotopes Production Project; Molybdenum-99 and Related Isotopes, 61 Fed. Reg. 48,921, 48, 922 (1996). There is currently no reactor in the United States producing Mo-99 but one is being converted at Sandia National Laboratory pursuant to the 1996 Record of Decision.

5. Atomic Energy Act of 1954, as amended, § 134., 42 U.S.C. § 2160d.

6. AEA subsection 134b.(3), which has been codified in the Commission's regulations at 10 CFR § 110.42(a)(9)(ii), states: "a fuel or target 'can be used' in a nuclear research or test reactor if

1. the fuel or target has been qualified by the Reduced Enrichment Research and Test Reactor [RERTR] Program of the Department of Energy, and

2. 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."

7. ANL, under contract with the Department of Energy, is tasked with the implementation of the RERTR program, a program to develop LEU fuel and targets for research and test reactors.

8. Section 134b.(3)(B) does not define "total cost of operating the reactor." For the purposes of this export license, Canada and the United States provided that "total cost" includes costs associated with equipment for processing.

9. The letter included a finding by DOE and the RERTR program managers that the course of action being followed continued to meet the requirements of the third criterion of the Schumer Amendment.

10. DOE intends to fund ANL for target work at the same level for FY2000. Executive Branch Response to Commission Questions, at 1 (Apr. 27, 1999).

11. From the representations at the June 16, 1999 meeting, we expect the Applicants to provide the additional information requested by ANL expeditiously, and we would similarly expect ANL to complete its feasibility study as promptly as possible. Prompt completion of the feasibility study might permit any necessary modifications to the MAPLE reactor processing facility to be made before the processing facility commences operation. See Section III of this Order.

12. Commissioner Diaz was not available for affirmation of this Memorandum and Order. Had he been present, he would have voted to disapprove the five-year license and would have limited the license to 60% of the requested amount of HEU.