

June 29, 2000

**Statement of Paul L. Leventhal and Alan J. Kuperman  
Before the U.S. Nuclear Regulatory Commission  
Briefing on Proposed Export of High Enriched Uranium to Canada  
July 10, 2000**

Mister Chairman, and members of the Commission, we appreciate your convening this public meeting and inviting the Nuclear Control Institute to make a presentation. We are Paul L. Leventhal, president, and Alan J. Kuperman, senior policy analyst, at NCI. With your permission, and to avoid repetition, we would like to append to this testimony our letters to the Commission dated December 17, 1999, and May 9, 2000.

We are gratified by the close attention that the Commission is paying to ensure that the applicant fulfills its commitments to convert its medical isotope production from reliance on bomb-grade, highly enriched uranium (HEU) – which poses risks of nuclear proliferation and nuclear terrorism – to low-enriched uranium (LEU) that is unsuitable for weapons. Not only is this the crucial test case of relevant U.S. nonproliferation law (the Schumer Amendment to the Energy Policy Act of 1992) to come before the Commission, but the successful conversion of Canada's isotope production to LEU is essential to fulfilling the long-standing mission of the international Reduced Enrichment for Research and Test Reactors (RERTR) program, to phase out all remaining civil commerce in bomb-grade uranium. The successful conversion of Canada's program, the single largest commercial isotope production program in the world, will pave the way for universal implementation of this conversion norm.

**Last Year's Commission Order**

Just over a year ago, on June 29, 1999, the Commission issued a conditional approval of the applicant's request for a license to export 130 kilograms of HEU – a material that can be used to make nuclear weapons – over five years in the form of targets for production of medical radioisotopes. The Commission required that the applicant and the U.S. Executive Branch submit annual progress reports to the Commission on efforts to convert this isotope production to LEU, which is unsuitable for weapons. Such an active conversion program is required by U.S. nonproliferation law (the Schumer Amendment) as one of several pre-conditions for HEU exports, which are permitted only on an interim basis prior to conversion to LEU. The Commission's order stated:

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 . . . <sup>1</sup>

Accordingly, this public meeting today is intended to gather additional information to assist the Commission in deciding whether to modify, suspend, or revoke the export license granted last year. The Commission's order further stated:

It is the Commission's understanding that ANL [Argonne National Laboratory] will be able to complete a [conversion] feasibility study promptly, within approximately three months of receiving the necessary technical information. The Commission further understands that AECL [Atomic Energy Canada, Ltd.] 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.<sup>2</sup>

### **Positive Aspects of the Applicant's Response to the Commission Order**

During the last year, the applicant carried out its own feasibility study, which determined that most aspects of its isotope production process can be converted to LEU targets with little or no modifications. The MAPLE reactors require no modifications to accept LEU targets for irradiation, although regulatory approvals would be required before such targets could be introduced to the reactors. Processing of targets at the New Processing Facility (NPF) entails three steps – dissolution of targets, extraction of molybdenum, and waste processing. Of these three steps, the first two can be carried out on LEU targets in the NPF with only a modest increase in the liquid volume of the process flow, up to 1.7 times the volume used for HEU targets.

The applicant reports in its feasibility study that only the final step in the NPF – the processing of waste from liquid to solid form – still presents an obstacle to conversion to LEU targets. This is due to three factors. First, the liquid volume of LEU waste may be up to 1.7 times that originally planned for HEU, potentially exceeding the capacity of the holding tanks for liquid waste prior to solidification (calcining) of the waste. Second, because this LEU waste contains 1.7 times the liquid volume and five times the mass of uranium as HEU waste, the capacity of the existing calciner to solidify waste at a

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<sup>1</sup> U.S. NRC, Memorandum and Order, CLI-99-20, June 29, 1999, pp. 12-13.

<sup>2</sup> *Ibid.*, p. 13.

sufficient rate may be exceeded. Third, if the increased mass of uranium resulted in more waste containers, the capacity for storing dry waste eventually could be exceeded.<sup>3</sup>

In subsequent presentations, the applicant has indicated that the second of these concerns presents the only significant obstacle to conversion – i.e., the capacity of the calciner. As we understand it, the calciner converts liquid to solid waste by evaporating off the liquid. In order to maintain the same process rate and number of solid waste containers, the liquid would have to be evaporated more quickly, and each waste container would have to hold five times the mass of uranium waste. The mass of uranium is apparently the ultimate constraint, because the marginally higher liquid volume can be dealt with. As the applicant has stated more recently: "Research to date indicates that we must consider one key issue before converting. We must determine how to manage the increased solid waste in the NPF which would arise from the use of LEU targets. This concern can be described as a capability and capacity issue with the calcination process in the NPF."<sup>4</sup>

Thus, the single remaining question-mark about conversion is whether the calciner can be modified so that each waste container can hold a significantly higher mass of uranium – ideally five times as much, although a slightly smaller multiple would probably still allow for conversion to LEU. The technical problem as we understand it is that as the liquid evaporates, the waste solution becomes viscous and tends to bubble and spurt. The mass of uranium in each container is kept low to prevent any waste spurting outside the waste container. The technical question is whether there is any way to increase the mass of uranium in each waste container while still preventing such spurting out of the container. One possibility is the installation of baffles within each waste container. Another possibility is that the uranium could be chemically precipitated out of the liquid waste solution, which would reduce its viscosity and thereby reduce spurting during the calcining process. The applicant was scheduled to meet this month with the French company SGN, which originally designed the calciner, about possible measures to resolve this problem. If it is not possible to increase sufficiently the capacity of the existing calciner module, the applicant reports that the alternative would be to build a second calciner to process the extra volume of liquid waste.

In short, the good news is that the applicant has determined during the past year that there are no obstacles to conversion of the MAPLE reactors and NPF to LEU targets except for the calciner capacity, which should be able to be resolved in short order if a good faith effort is made.

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<sup>3</sup> MDS Nordion, "Report in Response to the Nuclear Regulatory Commission's Request That Argonne National Laboratory Prepare a Study of the Technical Feasibility of Converting the Maple Reactors and the New Processing Facility to use LEU rather than HEU Targets," Submitted to the U.S. NRC, April 17, 2000, Annex, pp. 5-6, hereafter referred to as "Nordion Conversion Feasibility Study."

<sup>4</sup> Letter from Grant Malkoske, Vice President, Engineering and Technology, MDS Nordion, to Dr. Agnes Bishop, President, Canadian Nuclear Safety Commission, June 8, 2000, p. 2.

## **Troubling Aspects of the Applicant's Response to the Commission Order**

The bad news is that the applicant was unresponsive to several aspects of the Commission's order during the past year. As cited above, the Commission's order expressed the expectation, based on assurances from the applicant, that the applicant would share information with Argonne National Laboratory that would enable ANL to complete a conversion feasibility study within three months after the Commission's order – i.e., by September 1999. Such expeditious completion of the feasibility study was intended to provide sufficient time for the applicant to make modifications to the NPF prior to its start-up in order to facilitate subsequent conversion to LEU targets. This was based on the assumption that modifications after start-up would be more expensive – because the facility would be radioactive – and more likely to interrupt production, so that conversion would be less likely to occur. Regarding the sharing of information, the Commission's order stated: "Although ANL informed the Commission that further technical information is required from AECL, we understand that no further confidentiality agreements are required in order to effectuate this transmission of information and allow ANL's work to go forward."<sup>5</sup>

During the past year, however, the applicant refused to provide the necessary information to ANL, preventing ANL from preparing any feasibility study. Instead, the applicant prepared its own feasibility study, but did not present it to the Commission until April 2000, ten months after it was requested, seven months after the Commission expected it to be delivered, and only two months prior to scheduled start-up of the NPF. After delaying preparation of the study in this manner, the applicant then argued that too little time was left for any modifications to be made to the NPF prior to start-up. Indeed, it identified one modification that could facilitate future addition of a second calcining module – installing an extra pipe prior to start-up – but rejected this option because it would require six months to obtain regulatory approval and complete the modification.<sup>6</sup> Had the feasibility study been completed on time, in September 1999, this modification could have been completed by March 2000, well before start-up of the NPF. Similarly, had the feasibility study been completed on time, the applicant would have had at least nine months prior to start-up to work with SGN to resolve the question of the capacity of the existing calcining module, and perhaps to modify it prior to start-up, to facilitate subsequent prompt conversion to LEU targets. Thus, not only did the applicant blatantly fail to live up to its commitments to provide the necessary information to ANL, but by delaying the feasibility study it undermined the Commission's primary intent of enabling modifications to the NPF to be made prior to start-up.

This apparent dilatory strategy by the applicant is made more troubling by other evidence. According to the applicant's own progress report, it appears that the feasibility study was essentially completed by January 17, 2000, when AECL and Nordion held a

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<sup>5</sup> U.S. NRC, Memorandum and Order, p. 9.

<sup>6</sup> "Nordion Conversion Feasibility Study," p. 6.

meeting to "review results of conversion feasibility study."<sup>7</sup> Yet the study was not submitted to the Commission until three months later, which suggests that the applicant deliberately delayed submitting the study to the Commission so as to have an excuse for not making modifications to the NPF prior to start-up. Further, Nordion did not even propose a "preliminary conversion development program" until May 2000,<sup>8</sup> even though the Commission expected this to begin in 1999 and Nordion has said repeatedly that it is committed to expeditious conversion.

After refusing for more than a year to provide ANL the necessary information to prepare a feasibility study, Nordion now touts its own "voluntary preparation" of a "report to the Commission on a matter that the Commission entrusted to ANL." Indeed, Nordion inexplicably claims that its own much belated preparation of a feasibility study - necessitated by its refusal to abide by commitments to provide information to ANL - is evidence of Nordion's "strong commitment to the expeditious and definitive conclusion of this project to convert" to LEU targets. This is positively Orwellian. Nordion further claims that it will now "await ANL's preparation of its own feasibility study, as required by the Commission," as if it were ANL rather than the applicant who is responsible for ANL's study not being prepared to date. If ANL does now prepare such a feasibility study, it will be completed more than one year late, owing exclusively to the malfeasance of the applicant.<sup>9</sup>

Unfortunately, this failure of the applicant to live up to a prior commitment on conversion repeats a troubling pattern established over the last decade. The Commission will recall that as early as December 1990, nearly ten years ago, AECL declared in support of a license application for export of HEU that it was committed to develop an LEU target by 1998 and to "phase out HEU use by 2000."<sup>10</sup> Despite this early commitment, the applicant intentionally designed the NPF to handle a process flow and level of waste adequate for HEU targets but which it knew would be inadequate for LEU targets. Subsequently, in September 1997, in support of another license application for export of HEU, Canadian representatives signed an exchange of notes, again committing to develop and convert to LEU targets. But, more than a year later, when the applicant submitted still another application for export of HEU (the license now under review), there was still no progress on conversion. As the Commission noted in last year's order, "At the time NCI filed its pleadings with the Commission [in December 1998, petitioning to intervene in the license currently under review], the continuing existence and extent of

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<sup>7</sup> MDS Nordion, "Yearly Status Report to the USNRC on the Progress of the Program and Canadian Co-operation in Developing LEU Targets for the Maple Reactors," May 31, 2000, p. 5, hereafter referred to as "Nordion Annual Progress Report."

<sup>8</sup> *Ibid.*, p. 2.

<sup>9</sup> *Ibid.*, pp. 6-7.

<sup>10</sup> J.B. Slater, General Manager, Major Facilities Business Centre Operations, AECL Research, "The Program on Future HEU Supply for AECL's Radioisotope Production Operation," December 4, 1990, submitted in support of XSNM-02667.

an active program to develop LEU targets for use in the MAPLE reactors were not readily apparent."

### **Recommendations Regarding the Commission's Authority to Modify, Suspend, or Revoke the License**

The Nuclear Control Institute offers the Commission several recommendations for carrying out its statutory authority to modify, suspend, or revoke the license currently under review. Because the applicant has repeatedly violated aspects of its commitments to the Commission, and indeed undercut the primary intent of the Commission's most recent order – to enable modifications to be made to the NPF prior to start-up – our primary recommendation is for the Commission to establish stricter conditionality in the license. The Commission should modify the license to require that the applicant develop and adhere to a strict timetable for conversion in order to continue to qualify for exports of HEU under the license. There is ample precedent for such conditionality. In a recent exchange of notes with the EU regarding the Petten research reactor, the United States agreed to export HEU fuel for the reactor on an interim basis during conversion, in return for the EU and the reactor operator committing to convert to LEU as quickly as possible and to cease using HEU no later than 2006. In regard to the present license, we believe the timetable for converting the applicant's production of isotopes to LEU targets should be shorter, but the basic principle is the same.

We would note that the Commission's order last year expressed the expectation that completion of the feasibility "study will enable Applicants to . . . set a meaningful schedule for conversion."<sup>11</sup> Despite this, the applicant has expressly refused to establish such a schedule since completing the feasibility study more than two months ago. Indeed, the applicant recently stated: "It is difficult at this time to provide firm dates for meeting project milestones for Phase 2 and the follow-on Phase 3, involving implementation of the LEU conversion program. . . . Therefore, it appears advisable not to attempt to specify precise dates for the initiation or completion of the Preliminary Conversion Development Program or the implementation of the Conversion Program."<sup>12</sup> What is, in fact, inadvisable, given the applicant's track record, is to continue providing it HEU without first insisting that it establish and stick to a firm timetable for conversion.

It is essential that the timetable be as expeditious as realistically possible in order to prevent the applicant from further foot-dragging. Insight on what a realistic timetable for expeditious conversion should look like can be drawn from a variety of sources. The entire conversion process constitutes a series of discrete tasks, some of which already have been at least partially completed and some which can be performed in parallel: (1) developing an LEU target, (2) modifying the NPF if necessary, (3) obtaining Canadian regulatory approval for use of the LEU target in the Maple reactors and NPF (including environmental assessments, safety analyses of neutronics and chemical processes, and

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<sup>11</sup> U.S. NRC, Memorandum and Order, p. 9.

<sup>12</sup> "Nordion Annual Progress Report," pp. 7, 10.

waste permits), (4) obtaining approval of the U.S. Food and Drug Administration (FDA) of the isotopes produced with LEU targets.

The applicant reports that the Canadian Atomic Energy Control Board (AECB), which has since been renamed the Canadian Nuclear Safety Commission (CNSC), "indicated its expectation that at least three years will be required for AECL to conduct analyses, tests, and assessments of operating conditions in order to demonstrate to AECB that AECB regulatory conditions have been satisfied."<sup>13</sup> We called Dr. Aly Mortada Aly of the CNSC to confirm this information. He reports that the CNSC believes that the entire Canadian regulatory process will require three years - from the beginning of LEU target development through final approval of the use of LEU targets.<sup>14</sup> The applicant reported in May 2000 that "AECL's preparation of an LEU target design for the MAPLE reactor was a major accomplishment of the LEU conversion program during the past year."<sup>15</sup> Thus, the three-year timetable discussed by Canadian regulatory officials started sometime during the past year. In other words, the CNSC expects that all Canadian regulatory approvals can be granted less than three years from today if the applicant proceeds in good faith.

On top of this period of less than three years must be added the time required for FDA approval. In response to a question at last year's NRC public meeting about the length of time for FDA approval, Dr. Trevena of Nordion said: "I am not sure there's a typical process. It could be six months. It could be a year."<sup>16</sup> However, it appears that FDA approval for the new HEU targets to be used in the MAPLE reactors will be obtained much more quickly than that. According to Dr. Trevena's testimony, the FDA approval process cannot begin until targets are actually processed in the NPF. But the NPF is not due to start up until later this summer. And Nordion has to get FDA approval for the isotopes produced with the MAPLE targets before Nordion ceases production at NRU, which will occur during the fall because that is when the NRU's waste tank will be full according to the applicant's testimony. Thus, Nordion apparently plans to get FDA approval in only about three months, after starting the NPF in the summer and before it must halt production at NRU in the fall. This indicates that FDA approval only requires about three months, when an applicant is sufficiently motivated. Although initially there was some concern as to whether isotopes produced with LEU targets could obtain FDA approval as quickly due to possible higher levels of transuranic impurities, the applicant now appears confident that there will not be higher levels of such impurities in the finished isotopes produced with LEU targets. Moreover, the applicant has stated that "it strongly desires to successfully complete all Phases of this project and accomplish the conversion objective in the shortest time possible."<sup>17</sup> We ask only that you hold the applicant to this latest commitment.

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<sup>13</sup> "Nordion Conversion Feasibility Study," p. 4.

<sup>14</sup> Personal communication of Alan J. Kuperman, NCI, with Dr. Aly Mortada Aly, CNSC.

<sup>15</sup> "Nordion Annual Progress Report," p. 6.

<sup>16</sup> Transcript, "Briefing on Proposed Export of High Enriched Uranium to Canada," U.S. NRC Public Meeting, June 16, 1999, p. 31.

<sup>17</sup> "Nordion Annual Progress Report," p. 8.

In sum, it appears that all Canadian and American regulatory approvals for converting the applicant's isotope production to LEU targets can be acquired within approximately three years if the applicant pursues them expeditiously. We urge the Commission to require the applicant to present to the Commission within three months a timetable for expeditious conversion to LEU targets. We further urge the Commission to submit this timetable, once received, to independent review by ANL, to ensure that it represents an expeditious schedule, and to public review in the Commission's Public Document Room. Again, our expectation is that the timetable would provide for the completion of conversion to LEU targets within three years from today. We further urge the Commission to make clear to the applicant that should it fall significantly behind on this conversion schedule, once submitted, during the course of the current license without the existence of legitimately extenuating circumstances, the Commission will act to terminate the license. We note that based on our estimates above, the applicant would complete conversion at the end of the fourth year of the current license, obviating the need for HEU exports during the fifth and final year of the license. This would serve to minimize exports of HEU as required by U.S. law and policy.

Our second recommendation regards the total amount of HEU approved for export under the license. The total amount in the current license is 130 kilograms, premised on the applicant's originally expressed need for 26 kilograms annually for five years. More recently, however, the applicant told the CNSC that "the annual consumption of HEU for molybdenum-99 targets is estimated to be 20 kg/year for a total amount of 100 kilograms over five years."<sup>18</sup> To avoid export of any HEU surplus to the applicant's needs, in accordance with U.S. law and policy, we urge the Commission to modify the current license immediately to reduce the total amount of HEU under the license from 130 to 100 kilograms.

Our third recommendation regards the fact that the conversion feasibility study still is not complete because no solution has yet been found to the capacity problem of the calcining module. It appears that a solution to this problem can be found within a few months at most, if the applicant has sufficient motivation to make a good faith effort. One way to provide the applicant this motivation would be to suspend the license for HEU exports until the applicant completes this last aspect of the feasibility study. In this manner the applicant would be compelled at least to complete the feasibility study prior to starting up the NPF, even if no modifications actually were made. The Commission has considerable influence in this regard, owing to the fact that the applicant apparently did not transfer any HEU targets under the license last year,<sup>19</sup> and thus does not yet have any targets to begin irradiating. Were the Commission to suspend the license until the applicant completed this final aspect of the study, the applicant would have strong motivation to do so expeditiously. We believe that with such motivation the applicant could complete this final aspect of the feasibility review in less than two months, at which time it could transfer HEU targets from the United States and commence isotope production in the new MAPLE reactors and NPF. Such a schedule would permit isotope

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<sup>18</sup> Letter from Grant Malkoske, June 8, 2000, p. 3.

<sup>19</sup> *Ibid.*, p. 4.

production to begin at the new facilities before it must stop at the existing NRU facilities due to the waste tank reaching capacity in the fall, thereby avoiding any interruption in the supply of vital medical isotopes. Such a license condition might appear punitive, but that is appropriate, because there is a need to convey to the applicant that its flouting of Commission orders has consequences.

Finally, our fourth recommendation is for the Commission to insist that the applicant provide a better blueprint for how conversion is to be accomplished after start-up without interrupting production of isotopes. The applicant testified last year that such conversion would, in fact, result in such a production interruption, in part because the facility's pipes would have to be cleaned out for safeguards accounting purposes.<sup>20</sup> As we have stated previously, such potential interruption may be cited as an excuse for not converting, because of the risk of interrupting the supply of vital medical isotopes. It may be possible, through ingenuity and technology, to carry out conversion after start-up without such an interruption. But if the applicant has a plan for carrying this out, the applicant should be required to present it to the Commission. If the applicant does not yet have such a plan, it should be required to develop one and then present it to the Commission. Otherwise, the Commission runs the risk – as we testified at last year's hearing – of path dependency. That is, once the facilities begin operating on HEU, the applicant may cite the risks of interrupting production and costs of conversion as grounds for using HEU in perpetuity.

In closing, we would only reiterate the importance of this case for the larger U.S. and international policy goal of eliminating civil commerce in bomb-grade uranium. During the past two decades, international commerce in HEU for use as fuel in research reactors has declined precipitously, owing to nearly universal embrace of the conversion norm, but progress has been slower with regard to HEU commerce for isotope production. The applicant is the single largest producer of medical isotopes in the world. Thus, if it converts successfully from HEU to LEU targets, it will pave the way for adherence to this nonproliferation norm by remaining isotope producers not yet committed to conversion. Indeed, a number of such producers have expressed interest in conversion, but also have expressed concern about the lack of a level playing field that permits the largest producers to continue relying on HEU targets. Once the largest producer converts to LEU targets, the Commission and the Executive Branch can work together to ensure that this norm is adopted universally. Indeed, we expect this topic to be addressed at the annual meeting of the international RERTR program, in Las Vegas, from October 1-6, 2000, organized by ANL. The Commission may wish to send a high level representative to this meeting – or one or more of the Commissioners may wish to attend themselves, as has occurred in the past – to facilitate this international nonproliferation effort to phase out remaining civil commerce in bomb-grade uranium.

Thank you for this opportunity to present our views.

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<sup>20</sup> Transcript, pp. 28, 38.



United States Department of State

Washington, D.C. 20520

**BUREAU OF NONPROLIFERATION AFFAIRS  
OFFICE OF NUCLEAR ENERGY AFFAIRS**

July 6, 2000

**TO: Mr. William M. Hill, Jr.  
Office of the Secretary  
U.S. NUCLEAR REGULATORY COMMISSION  
11555 Rockville Pike  
Rockville, MD 20852-2738  
Ph: 301 415 1661 fax: 301 415 1101**

**FROM: NP/NE – Robin DeLaBarre  
ph: 202 647 3978; fax: 202 647 0775**

**SUBJECT: July 10, 2000 Public Meeting Concerning XSNM03060**

**REF: June 29, 1999 Memorandum and Order in the matter of Transnuclear, Inc. (Export of 93.3% Enriched Uranium) CLI-99-20, 49 NRC 469 (1999)**

As discussed with Ms. Vietti-Cook, transmitted is an advance copy of the Executive Branch views on the progress in development of low-enriched uranium targets for the Canadian MAPLE reactors. The Argonne National Laboratory report on this subject is in process of revision to take into account the results of Argonne's visit to SGN, the French company that designed the process for disposal of the isotope production waste in MDS Nordion's New Production Facility. We expect the revised Argonne report to be ready by tomorrow, July 7, and will forward copies to you as soon as the report is received.

Arrangements will be made tomorrow to courier the originals and copies of our letter to your office.

Attending the July 10, public meeting for the Executive Branch will be:

Richard J.K. Stratford, Director Office of Nuclear Energy Affairs, Department of State;

Robin DeLaBarre and Christine Martin of the Office of Nuclear Energy Affairs, State;

Richard Goorevich, Director of the Nuclear Transfer and Supplier Policy Division, Department of Energy;

Sean Tyson, International Policy and Analysis Division, Department of Energy; and

Dr. Armando Travelli, Manager RERTR Program, Argonne National Laboratory.



United States Department of State

Washington, D.C. 20520

July 6, 2000

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

Dear Ms. Lee:

I refer to the June 29, 1999, Memorandum and Order in the matter of Transnuclear, Inc., (Export of 93.3% Enriched Uranium) CLI-99-20, 49 NRC 469 (1999), in which the Commission accepted the Executive Branch's offer to submit its views on the progress in development of low enriched uranium (LEU) targets for the MAPLE reactors. The Commission requested that such views be submitted no later than thirty days after the submission of the annual status report by the Applicants. I refer also to the May 31, 2000, yearly status report submitted to the Nuclear Regulatory Commission (NRC) by the Applicant, MDS Nordion. The Executive Branch has reviewed the yearly status report and has concluded that the requirements of the Atomic Energy Act, in particular Section 134, continue to be met and that the further export of highly enriched uranium (HEU) targets under export license XSNM3060 would not be inimical to the common defense and security of the United States.

The Executive Branch assures the Commission of the continued cooperation between MDS Nordion and Argonne National Laboratory (ANL) in the development of LEU targets for the MAPLE reactors and the associated New Processing Facility (NPF). The Executive Branch believes that considerable progress has been made toward the resolution of the many technical difficulties in converting the reactors and NPF to use LEU targets. In a meeting at the Department of State on April 20, 2000, MDS Nordion representatives stated that they have completed the initial study of the feasibility of converting to LEU. They have accepted the new design for the LEU target as feasible and have stated that many of the dissolution difficulties resulting from the increased uranium concentration in the new targets, considered a major obstacle last year, have since been resolved. In view of MDS Nordion's acceptance of the LEU target design, ANL has not done a specific feasibility study on this issue. Rather, the focus of the ANL analysis was on the major remaining technical obstacles identified in MDS Nordion's report.

MDS Nordion and ANL agree that the major technical obstacle remaining involves the calcination process used to condition the waste. Further technical study of the current process is needed. As a first step, ANL personnel accompanied MDS Nordion on a visit to SGN, the French company that designed the calcination process for MDS Nordion. That visit took place on June 30, 2000.

The MDS Nordion status report indicates that they have identified no minor modifications that can be made to the NPF at this time, before it begins processing radioactive material, that will minimize the future costs of conversion. Indeed, SGN verified at last week's discussions that the addition of a line to introduce a controlled precipitating agent into the calciner would not present special difficulties even after the facility has begun operations with HEU. ANL agrees with SGN that modifications toward conversion to an LEU process could be made to the NPF after operations had begun with HEU. The Executive Branch therefore sees no reason to forestall operation of the facility and risk disruption of production of critically important medical isotopes in view of the fact that substantial progress that has been made this year and is expected to continue.

We believe that MDS Nordion continues to be committed to the conversion of the MAPLE reactors and NPF. In their report, MDS Nordion noted that they are ready to begin to Phase 2 of the effort to convert the reactors and NPF. In addition to pursuing the resolution of the outstanding technical issues with ANL and AECL employees, MDS Nordion is prepared to begin to work with Canadian and U.S. regulatory agencies to develop the procedures that will be needed to test and certify the new target design and facility operation. We are encouraging MDS Nordion to move forward on these issues as quickly as possible.

In summary, we believe that MDS Nordion has demonstrated substantial progress towards resolving technical impediments to converting the MAPLE reactors and NPF. The Executive Branch supports the continued export of the HEU targets for production of molybdenum-99 at the MAPLE reactors. The Canadians will need to continue to use HEU until the LEU target design has been tested and approved by Canadian and U.S. regulatory authorities. We continue to support cooperation between MDS Nordion and ANL on the remaining technical issues. Funds have been made available in the FY01 budget for continued work by ANL in conjunction with MDS Nordion, SGN, and AECL on the calcining process.

We appreciate the opportunity to provide our views on this very important matter. Should you have any further questions, please do not hesitate to contact me.

Sincerely,



Richard J.K. Stratford  
Director  
Nuclear Energy Affairs

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June 30, 2000

Mr. William M. Hill, Jr.  
Office of the Secretary  
U.S. Nuclear Regulatory Commission  
11555 Rockville Pike  
Rockville, MD 20852-2738

Re: July 10, 2000, public meeting concerning XSNM 03060

Dear Mr. Hill:

As requested by Ms. Annette L. Vietti-Cook, in her letter of June 13, 2000, I am providing information concerning the persons who will participate in the July 10, 2000 public meeting, on behalf of MDS Nordion and Atomic Energy of Canada Ltd. (AECL). I am also enclosing 20 copies of a Statement by Grant R. Malkoske, Vice President, Engineering and Technology of MDS Nordion, and slides that Mr. Malkoske will employ as the basis for his presentation to the Commission at the July 10, 2000, public meeting. Other representatives of MDS Nordion and AECL who are listed below may also address the Commission, in response to questions that may arise.

The representatives of MDS Nordion and AECL who will participate in the July 10 meeting are as follows:

Grant R. Malkoske, P.Eng.  
Vice President, Engineering and Technology  
MDS Nordion

Dr. Iain Trevena  
Senior Vice President, Nuclear Medicine  
MDS Nordion

Mr. William M. Hill, Jr.  
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Dr. Jean Pierre Labrie  
General Manager  
Research and Isotope Business  
AECL

James A. Glasgow  
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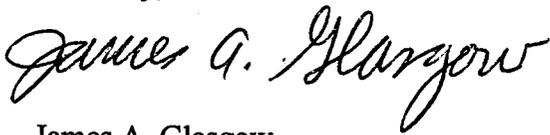
The enclosed Statement by Mr. Malkoske and slides are intended to facilitate a concise presentation by MDS Nordion and AECL, within the ten minutes allotted for this purpose. MDS Nordion recently submitted more detailed information to the Commission in two reports described below. On April 17, 2000, MDS Nordion submitted the Applicants' Report in Response to the Nuclear Regulatory Commission's Request that Argonne National Laboratory Prepare a Study of the Technical Feasibility of Converting the MAPLE Reactors and the New Processing Facilities to Use LEU Rather than HEU Targets. A comprehensive review of the Applicants' progress toward conversion to LEU target is contained in MDS Nordion's May 31, 2000, Yearly Status Report to the NRC on the Progress of the Program and Canadian Co-operation in Developing LEU Targets for the Maple Reactors.

As the slides and the above-mentioned reports clearly demonstrate, the Applicants, in consultation with the U.S. Executive Branch, Argonne National Laboratory and Canadian regulatory authorities, have worked diligently to evaluate the technical, regulatory and economic aspects of converting the MAPLE reactors and the New Processing Facility to operate with LEU targets. The above reports and the enclosed Statement and slides summarize the LEU conversion program that Applicants are expeditiously pursuing, in cooperation with ANL. In its reports to the Commission, MDS Nordion reaffirmed its commitment to timely completion of the LEU Conversion Development Program and the prompt implementation of the Conversion Program in accordance with the results of the Development Program.

In summary, the Applicants submit that the progress toward conversion of the MAPLE Reactors and the NPF to use LEU targets meets both the letter and spirit of the Commission's June 29, 1999, Memorandum and Order as well as the Schumer Amendment and the Commission's regulations implementing that Amendment. The Applicants look forward to discussing these matters with the Commission at the July 10, 2000, public meeting.

Mr. William M. Hill, Jr.  
June 30, 2000  
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Sincerely,

A handwritten signature in cursive script that reads "James A. Glasgow". The signature is written in black ink and is positioned above the printed name.

James A. Glasgow

JAG/lwr:

Enclosures

STATEMENT OF

Grant R. Malkoske, P.Eng.  
Vice President  
Engineering & Technology  
**MDS NORDION**

TO THE  
NUCLEAR REGULATORY COMMISSION

CONCERNING AN EXPORT LICENSE (XSNM 03060)  
AUTHORIZING THE SHIPMENT OF HIGHLY ENRICHED  
URANIUM TO CANADA FOR USE IN PRODUCING  
RADIOISOTOPES FOR MEDICAL PURPOSES

July 10, 2000

More than five years ago, MDS Nordion elected to construct the MAPLE reactors and the New Processing Facility (NPF), at a cost of more than \$140 million, to provide a reliable and secure supply of molybdenum 99 (Mo-99) and other medical isotopes. MDS Nordion supplies about two-thirds of the world's medical isotopes, which are used to diagnose cancer and heart disease as well as problems with the liver, thyroid, kidneys and bone. Radioisotopes produced by MDS Nordion are used in over 5,000 hospitals in North America, mostly in the United States, and are shipped routinely to over 60 other countries.

Low enriched uranium (LEU) fuel will be used in the MAPLE reactors. MDS Nordion continues to seek to convert those reactors, and their associated processing facilities, to operate with low enriched uranium (LEU) targets while serving reliably as the primary North American source of Mo-99 and other radioisotopes used annually in thousands of medical procedures. Over the past year, MDS Nordion, together with Atomic Energy of Canada Ltd. (AECL), has carried out a series of important studies and programs to achieve this objective as rapidly as possible. These efforts, described in detail in the appended slides, for presentation to the Commission, produced a design for an LEU target for the MAPLE reactors and contributed to a better understanding of the technical and regulatory aspects of converting the New Processing Facility (NPF) to operate with LEU rather than highly enriched uranium (HEU) targets.

HEU targets have long been used for the commercial production of Mo-99, which cannot be stockpiled because of its very short half life. To meet the significant challenges of implementing a first-of-a-kind large-scale commercial utilization of LEU targets to produce Mo-99, MDS Nordion, with the help of AECL and SGN, completed an Initial Feasibility Study concerning the use of LEU targets in the MAPLE reactors and a large scale Mo-99 processing facility. This study determined that operation of the MAPLE reactors with LEU targets is technically feasible and identified the key Canadian regulatory conditions that must be met to use LEU targets in those reactors.

Before LEU targets may be used in the MAPLE reactors, the Canadian Nuclear Safety Commission (CNSC) must review and approve environmental assessments and safety analyses performed by AECL, including critical heat flux tests and irradiation tests. Under new CNSC regulations, public consultation and public meetings must be carried out by the CNSC in connection with its consideration of whether the MAPLE reactors will be authorized to use LEU targets. Completion of this review process will require a minimum of three years. In addition, the drug certification requirements of the U.S. Food and Drug Administration (FDA) and its Canadian counterpart (Health Canada) must be satisfied for a new LEU source of Mo-99.

To acquire the technical data needed to determine how the NPF can be converted to operate with LEU, MDS Nordion funded a study, performed by AECL, which showed that the increased uranium mass of LEU targets places increased demands on waste solidification and storage systems for solid waste. The primary technical and regulatory challenge is calcining and storing the increased volumes of high level radioactive wastes resulting from processing of LEU rather than HEU targets.

Soon after the Commission's July 10, 2000, Public Meeting, MDS Nordion will embark on a Conversion Development Program that should be completed by the end of next year. Building upon the results of the Initial Feasibility Study, this Program will examine the technical, regulatory and economic implications of the following options for dealing with the increased volume of waste arising from processing LEU targets in the NPF: (1) identification of possible process improvements in the NPF, coupled with possible limitation of Mo-99 production, to reduce the waste arising from processing LEU targets; (2) commencement of a development program to reduce the waste cycle time; or (3) construction of a new processing facility.

The Commission has requested that the Applicants address the requirements of the Commission's June 29, 1999, Memorandum and Order as well as contentions raised by the Nuclear Control Institute (NCI). As discussed in detail in MDS Nordion's reports to the Commission on April 17 and May 31, 2000, and as summarized in the attached slides, a careful study of the feasibility of making minor modifications to the NPF prior to its coming on line did not reveal any such modifications that would help achieve the goal of processing LEU targets in the NPF. Based on its studies to date, MDS Nordion believes that, because of the high cost of installing waste cells outside the NPF, it may be preferable, from the perspectives of processing redundancy and economic efficiency, to construct a duplicate facility if processing improvements in the NPF will not adequately deal with increased volumes of waste. Consequently, MDS Nordion respectfully submits that installation of a waste pipe leading to an outer wall of the NPF is unnecessary and should not be considered by the Commission to be a minor modification that MDS Nordion is required to pursue. As MDS Nordion has shown, installation of such a pipe would have caused significant delays in operating the NPF, with adverse implications for the reliable supply of Mo-99.

During its June 29, 2000, public meeting concerning AECL's application for an operating license for the MAPLE 2 reactor, the CNSC considered NCI's May 3, 2000 letter to the CNSC opposing AECL's application. At this public meeting, the President of the CNSC concluded, after hearing testimony from the CNSC staff and AECL, that installation of a pipe from the NPF's waste processing cell to an outer wall of that facility is not a "minor modification" to the NPF. Under these circumstances, it is clearly appropriate for the Applicants to defer to the CNSC's determination of what constitutes a "major"-- as opposed to a "minor"-- modification to a facility licensed by the CNSC. Consequently, AECL may not install such a pipe without first preparing a detailed safety analysis report and subjecting the report to the detailed and lengthy CNSC review process that is required for major modifications to a licensed facility.

In recent letters to the Commission and during the Commission's June 16, 1999, Public Meeting, NCI argued that MDS Nordion and AECL should continue to irradiate HEU targets in the 40-year old NRU reactor and its associated radioisotope processing line while they are converting the MAPLE reactors and the NPF to use LEU targets. However, the availability of the NRU and its processing facility to supply medical isotopes will end by approximately the Spring of 2001, because the fissile liquid waste storage capacity of that facility will be reached. Moreover, as MDS Nordion pointed out at the Commission's Public Meeting on June 16, 1999,

there are other important regulatory and operational reasons why NCI's suggestions regarding continued use of the NRU cannot be implemented.

In its June 29, 1999, Memorandum and Order, the Commission directed the issuance of XSNM 03060, based on the Executive Branch's favorable recommendation and its own finding that the requirements of the Schumer Amendment were satisfied. MDS Nordion submits that, because of the significant efforts it has made over the past year, in cooperation with ANL as well as Canadian and U.S. governmental authorities, the requirements of the Schumer Amendment continue to be satisfied. MDS Nordion remains committed to keeping the U.S. Government and ANL informed of these efforts. In this regard, MDS Nordion hosted a meeting in France, on June 30, 2000, attended by representatives of Argonne National Laboratory (ANL), AECL and SGN, the designer of the calcining equipment used in the NPF. In many respects, MDS Nordion has done more than the Schumer Amendment requires, by developing the LEU target design and conducting substantial research and development programs. MDS Nordion has taken the lead in ensuring that an LEU target design was produced in a timely manner. Moreover, MDS Nordion remains committed to working with the U.S. Government and ANL to ensure that the remaining steps in this precedent- setting effort can be successfully completed.

**Meeting with the  
U.S. Nuclear Regulatory Commission  
July 10, 2000**

**MAPLE REACTORS and  
NEW PROCESSING FACILITY**

**LEU TARGET DEVELOPMENT/  
CONVERSION PROGRAM**

**MDS Nordion**

**(Export of 93.3% Enriched Uranium  
License No. XSNM 03060)**

# **LEU Target Development & Conversion Program Key Elements**

- **Meets the letter and spirit of the NRC Order and license**
- **Complies with the intent of the Schumer Amendment**
- **Active US-Canadian co-operation on a target development and conversion program**
- **Consistent with the terms of the Canada-U.S. diplomatic note**
- **Maintains a reliable supply of medical isotopes**

# **LEU Target Development & Conversion Program 3 Phases**

- **Initial Feasibility Study (complete)**
- **Conversion Development Program**
- **Conversion Program Implementation**

# **Initial Feasibility Study: MAPLE Reactors**

- **determined that MAPLE reactor operation with LEU targets is technically feasible**
- **developed configuration for LEU target**
- **identified key Canadian regulatory conditions that must be addressed to use LEU target in MAPLE reactors**
- **identified minimum regulatory timeline for CNSC to determine that regulatory conditions have been met**

## **Initial Feasibility Study: New Processing Facility**

- **provided technical process information to ANL**
- **consulted with experts on molybdenum process (AECL) and waste management process (SGN)**
- **performed molybdenum recovery tests and determined uranium concentration to achieve recovery efficiencies comparable to HEU targets**
- **identified site space at CRL for a new facility**

## **Initial Feasibility Study: New Processing Facility (Cont'd.)**

- **determined that increased LEU target uranium mass places increased demands on waste solidification and storage systems for solid waste**
  - **capability and capacity of calcination system are the main issues**
- **identified key Canadian regulatory conditions that must be addressed to process LEU targets**

## **Initial Feasibility Study: New Processing Facility (Cont'd.)**

- **identified options to address waste system limitations**
  - **additional calcination equipment in existing hot cell: *no space***
  - **additional waste processing cell: *no space***
  - **operational experience to identify process improvements**
  - **development program to improve waste process cycle time**

## **Consideration of “minor modifications to NPF prior to its coming on line ...”**

- **No minor modifications to facilitate later conversion have been identified**
  - **no additional liquid storage tanks are needed**
  - **mass of uranium in LEU constrains the calcining system**
  - **the existing cell size cannot accommodate larger calcining equipment**
    - **supplier cannot identify changes to in-cell equipment to address throughput problem**

## **Consideration of “minor modifications to NPF prior to its coming on line ...”**

- adding a pipe from the liquid waste vault for future hook-up to waste processing lines is not a solution to waste throughput problem**
  - cells, equipment and nuclear ventilation still required**
  - front end of process all must go through original cell**
  - installation would have created regulatory concerns, delayed start-up, and jeopardized medical isotope supply**
  - significant implementation costs are involved**

## **Consideration of “minor modifications to NPF prior to its coming on line ...”**

- CNSC commented at the June 29th Public Meeting that adding a pipe was not a minor modification**

***Because of the high cost to install waste cells, construction of a duplicate facility to have processing redundancy is preferred .***

# **Conversion Development Program Next Steps**

- **evaluate NPF calcining system capacity and capability**
  - **ANL visit to SGN for assessment in June 2000**
  - **technical evaluation with AECL/SGN/MDS Nordion**
  - **gain operational experience to identify process improvements**

# **Conversion Development Program Next Steps (Cont'd.)**

- **develop regulatory milestones/timeline to implement conversion program**
  - nuclear regulations (CNSC)
  - environmental regulations (CNSC)
  - drug regulations (FDA, Health Canada)
- **assess technical and economic feasibility of LEU target conversion program**
- ***The option chosen must:***
  - be both technically and economically feasible
  - ensure the reliable supply of medical isotopes, particularly molybdenum-99

## **Compliance with the Schumer Amendment**

- **there is no alternative target that can be used currently in the reactor**
- **the U.S.-Canada development program is being undertaken to provide assurances that an alternative (LEU) target will be used**
- **the applicants believe they have the capability to develop and qualify the target for use in reactors licensed in Canada**
  - **in co-operation with the active US program**

# **LEU Target Development & Conversion Program - Summary**

- **an active LEU target conversion development program is underway**
- **capability of the waste calcination system is key technical constraint**
- **no prudent minor modifications have been identified**
- **MAPLE start-up is critical to ensure isotope supply**
- **supply of HEU targets for MAPLE reactors is necessary to maintain security of medical isotope supply until LEU target can be implemented**
- **compliant with the spirit and intent of our export license and the Schumer Amendment**