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**MDS Nordion**
*Science Advancing Health*



File: XSNM03060/6

May 31, 2005

Ms. Margaret M. Doane
Deputy Director, Office of
International Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0011

Re: License No. XSNM-03060

Dear Ms. Doane:

In accordance with the Commission's request in its June 29, 1999, Memorandum and Order regarding XSNM-03060 and in compliance with condition number 10 of that license, MDS Nordion is pleased to enclose its Annual Report for the Nuclear Regulatory Commission on the Progress of the Program and Canadian Cooperation in Developing LEU Targets for the MAPLE Reactors and the New Processing Facility. For the Commission's convenience, I am enclosing twelve (12) copies of the confidential version of the Report, containing the Confidential Annex and two copies of the public version. With the exception of the Confidential Annex, the Report may be made available to the public.

Pursuant to the NRC regulations governing access to information, MDS Nordion declares that the enclosed Confidential Annex contains confidential commercial information within the meaning of 10 CFR § 2.390. In accordance with 10 CFR § 2.390, I am enclosing my affidavit addressing each of the criteria specified in 10 CFR §2.390(b)(1).

MDS Nordion believes that the progress documented in this Annual Report meets both the letter and spirit of the Commission Memorandum and Order. MDS Nordion will be glad to respond to questions or requests that the NRC staff or the Commission may have with respect to the enclosed Annual Report.

Yours truly,

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

Enclosures: as stated

cc: Kenneth E. Baker, Department of Energy (w/ enclosures)
Richard J.K. Stratford, Department of State (w/ enclosures)

Public

# *MAPLE REACTORS AND NEW PROCESSING FACILITY*

# *YEARLY STATUS REPORT FOR THE U.S. NUCLEAR REGULATORY COMMISSION ON THE PROGRESS OF THE PROGRAM AND CANADIAN COOPERATION IN DEVELOPING LEU TARGETS FOR THE MAPLE REACTORS AND THE NEW PROCESSING FACILITY*

May 31, 2005

G.R. Malkoske
Vice President, Engineering and Technology
MDS Nordion

# YEARLY STATUS REPORT FOR THE U.S. NUCLEAR REGULATORY COMMISSION ON THE PROGRESS OF THE PROGRAM AND CANADIAN COOPERATION IN DEVELOPING LEU TARGETS FOR THE MAPLE REACTORS AND THE NEW PROCESSING FACILITY

**MAY 31, 2005**

## I. INTRODUCTION

MDS Nordion is pleased to submit its sixth Annual Report to the Nuclear Regulatory Commission (NRC), in accordance with condition 10 of XSNM-03060. This Annual Report reviews progress, over the past year, on Phase 2 of the high enriched uranium (HEU) to low enriched uranium (LEU) Target Conversion Development Program for the MAPLE Reactors and the New Processing Facility (NPF). While these reactors were designed to use HEU targets, they also were designed to use LEU driver fuel.

MDS Nordion continues to be a world leader in the production and supply of radioisotopes for medical applications, supplying about two-thirds of the world's requirements and approximately half of U.S. medical isotope needs. Every day, approximately 34,000 patients rely on medical isotopes supplied by MDS Nordion for a nuclear medicine procedure, such as diagnosing the severity of heart disease, the spread of cancer and brain disorders. Since heart disease is the leading cause of death in the United States, effective diagnosis and treatment of this ailment is essential to healthcare in the United States and other countries with aging populations.

In the United States, the use of medical isotopes in cardiology has been growing. MDS Nordion is a leading supplier of the product supporting physicians' response to this disease. During the past year, MDS Nordion continued to supply all the molybdenum 99 (Mo-99) used in Canada and about half of that needed in the United States for medical purposes from AECL's Nuclear Research Universal (NRU) reactor. As discussed in previous Annual Reports

to the Commission, approximately 80% of nuclear medicine procedures rely on Mo-99, including for use in cardiology.

As noted in previous Annual Reports to the Commission, a major challenge in supplying Mo-99 for use in producing the most widely used radiopharmaceutical is its extremely short half life. Consequently, MDS Nordion is unable to stockpile Mo-99 and must therefore reliably produce, on a daily basis, the needed quantities for delivery to manufacturers of radiopharmaceuticals.

A key consideration in MDS Nordion's production of medical isotopes and its ongoing efforts to convert the MAPLE Reactors and NPF to use LEU targets is the unique privately-owned status of the MAPLE Reactors and NPF, compared to the government-owned and funded status of other research reactors used for significant production of medical isotopes. The MAPLE Reactors and the NRU Reactor, which use LEU driver fuel, are capable of producing commercially significant quantities of medical isotopes by irradiating HEU targets.

During their transport storage and use in Canada, the HEU targets are subject to Canada's Agreement with the International Atomic Energy Agency (IAEA) for the application of full-scope IAEA safeguards. IAEA safeguards are applicable to all isotope activities in the MAPLE Reactors and NPF and in fuel production and storage facilities at Chalk River Laboratories (CRL) as well the waste management areas. These targets are also subject to the U.S. - Canada Agreement for Cooperation Concerning Peaceful Uses of Nuclear Energy. In connection with adoption of a 1999 Protocol extending this Agreement for an additional period of 30 years, the President found that "continued close cooperation with Canada in the peaceful uses of nuclear energy will serve important U.S. national security, foreign policy, and commercial interests." The President also stated that "Canada ranks among the closest and most important U.S. partners

in civil nuclear cooperation . . . and is also in the forefront of countries supporting international efforts to prevent the spread of nuclear weapons to additional countries."

## II. PROGRESS DURING THE PAST YEAR REGARDING THE ONGOING PROGRAMS TO CONVERT THE MAPLE REACTORS AND NPF TO OPERATE WITH LEU TARGETS

### A. MAPLE Reactors

#### 1. Status of Efforts to bring the MAPLE Reactors into Commercial Operation

As noted in previous Annual Reports to the NRC, the NPF and the two 10 MWt MAPLE Reactors, located at AECL's Chalk River Laboratories, Chalk River, Ontario, comprise the MDS Nordion Medical Isotopes Reactor (MMIR) Project that will be dedicated to the production of medical isotopes. MDS Nordion of Ottawa, Ontario, will have legal title to the facilities while AECL is the licensed operator.

In its 2004 Report to the NRC, MDS Nordion stated its expectation that the MAPLE 1 Reactor and the NPF would be brought into service in late 2004. This goal was not achieved, since commissioning issues were not resolved on the schedule that AECL and MDS Nordion had foreseen. As explained in MDS Nordion's Annual Reports for 2003 and 2004, the delay in commissioning the MAPLE Reactors for commercial operation has resulted primarily from a finding, during phase C high-power commissioning of the MAPLE 1 Reactor, of a small positive power coefficient of reactivity (PCR) for that Reactor's initial core. As noted in MDS Nordion's 2004 Annual Report, this finding is contrary to the core design characteristic that was analyzed in the Final Safety Analysis Report (FSAR) for the MAPLE Reactors.

During the past year, AECL has continued to work with the Canadian Nuclear Safety Commission (CNSC) Staff to resolve all remaining issues with respect to the above-mentioned positive PCR. A detailed review of this matter by the CNSC Staff is contained in the Staff's

July 8, 2004, Report regarding "Outstanding Issues for the MDS Nordion Medical Isotopes Reactor Project." (CMD 04-M28). This report focused on the "actions and resolution criteria and progress towards resolving the outstanding issues." As noted in the CNSC Report, "AECL agreed that MAPLE 1 would not be re-started until the positive PCR issue could be resolved to the mutual satisfaction of AECL and the CNSC staff." The CNSC Staff established "acceptance criteria" that allowed AECL to resume nuclear commissioning up to specified power levels for the purpose of re-measuring the PCR.

In its summary and conclusions, the Staff stated as follows: "Since the Commission Meeting of March 24, 2004, AECL and CNSC staff have met several times and defined the actions, plans and schedules for resolution of the outstanding issues. Two of the issues that were outstanding at the time of the March 24 Commission Meeting have been closed and substantial progress has been made towards resolving many of the remaining outstanding issues."

During the period covered by this Annual Report, there were no shipments pursuant to XSNM-03060 of HEU targets for use in the MAPLE Reactors. MDS Nordion does not foresee a need to make any shipments pursuant to XSNM-03060 during the remainder of the current calendar year. The timing of such shipments in 2006 and thereafter, will depend primarily upon when the MAPLE Reactors are commissioned and begin irradiating targets on a commercial basis. The inventory of HEU targets that will be required in connection with commercial operation of the MAPLE Reactors and NPF to produce medical isotopes is discussed in the Confidential Annex to MDS Nordion's May 19, 2004 Annual Report to the NRC.

### 2. Application to the CNSC to Extend the Licenses for the MAPLE Reactors and the NPF

On April 29, 2005, AECL, as the company responsible for commissioning and ultimately operating the MAPLE Reactors and NPF, under contract to MDS Nordion, received amendments

to the CNSC operating licenses for the MAPLE reactors and for the NPF. The amendments extend the licenses from May 31, 2005 to November 30, 2005. AECL also filed applications with the CNSC on April 29, 2005 to renew for a two-year time period, starting December 1, 2005, the operating licenses for the MAPLE Reactors and the NPF.

The CNSC has scheduled a two-day public hearing on this matter, to take place on August 18, and October 19, 2005.

B. NRU Reactor

As noted in previous Annual Reports to the NRC, the NRU Reactor began operating in 1957. Since 1991, the NRU Reactor has been operated with LEU fuel.

During the past year, the NRU Reactor continued its long record of reliably providing a large portion of the world's supply of Mo-99.

As noted in MDS Nordion's 2004 Annual Report to the NRC, in May 2003, the CNSC authorized AECL to operate the NRU Reactor through December 31, 2005. AECL has filed an application with the CNSC and proposes to continue to operate the NRU Reactor past December 31, 2005, nominally until 2012. Detailed information on this matter is set forth in AECL's submission to the CNSC on the matter of AECL's proposal to continue operation of the NRU Reactor beyond December 31, 2005. (CMD 05-H12.1)

In connection with AECL's request to continue to operate the NRU Reactor, the CNSC has scheduled a public hearing on June 29, 2005, to consider an environmental assessment of this matter. On April 7, 2005, the CNSC announced that it will "hold a one-day public hearing to consider the results of an Environmental Assessment Screening (EA Screening) of Atomic Energy of Canada Ltd.'s (AECL) proposal to continue operation of the Nuclear Research Universal (NRU) Reactor beyond its currently scheduled shutdown on December 31, 2005." *Canadian Environmental Assessment*, (Ref. 2005-H-6). The CNSC Staff has prepared the

"CNSC's staff's submission on the matter of Atomic Energy of Canada Ltd.'s proposal to continue operation of the Nuclear Research Universal (NRU) Reactor beyond its currently scheduled shutdown on December 31, 2005." (CMD 05-H12). AECL, in consultation with CNSC staff, will take the appropriate steps to obtain a license amendment to enable operation of NRU beyond December 31, 2005.

Because the commercial operation of the MAPLE Reactors and NPF has been delayed well beyond the time when such operation was expected to commence, MDS Nordion has continued to rely on AECL's operation of the NRU Reactor in order to produce Mo-99 and other medical isotopes for MDS Nordion.

## III. COOPERATION WITH THE U.S. GOVERNMENT CONCERNING THE TARGET CONVERSION DEVELOPMENT PLAN

### A. Introduction and Summary

The objectives of MDS Nordion's Target Conversion Development Program for the MAPLE Reactors and the NPF, and the results of the research and development activities pursuant to that program, are set forth in MDS Nordion's previous Annual Reports to the NRC. This program was launched in August 2001 with an initial feasibility study. The Target Conversion Development Program is currently in Phase 2. During Phase 2, MDS Nordion has examined the technical, regulatory and economic implications of dealing with the increased volume of waste arising from processing LEU targets in the NPF and has sought to identify solutions to these problems.

During the past year, MDS Nordion has sought the views and assistance of the U.S. Government with respect to the Target Conversion Development Program. This cooperation has taken place mainly through meetings in the United States and Canada and exchanges of detailed questions and comments concerning that Program. As explained in more detail below, the

framework for most of these mutual efforts over the past year was established as a result of a meeting at DOE headquarters on May 6, 2004, involving representatives of DOE, the Department of State, NRC, MDS Nordion and the Canadian Government.

Consistent with its commitment at the May 6, 2004 meeting, MDS Nordion developed options and principles to guide its pursuit of the Target Conversion Development Program. These options and principles were provided to DOE on August 26, 2004. Another meeting between DOE and MDS Nordion took place on November 20, 2004. On January 10, 2005, MDS Nordion received the questions and comments that DOE had promised to provide after MDS Nordion submitted its options and principles for conversion to LEU targets. On March 24, 2005, MDS Nordion provided a preliminary response to DOE's questions.

Additional U.S.-Canadian cooperative efforts were discussed during a meeting on April 22, 2005, at MDS Nordion's office in Ottawa, Canada. During this meeting, attendees from MDS Nordion, DOE and Argonne National Laboratory (ANL) discussed additional steps that could be taken to overcome economic and technical obstacles to converting the MAPLE Reactors and the NPF to operate with LEU targets to produce medical isotopes. The progress that was achieved as a result of these cooperative efforts and plans for additional collaboration are summarized below.

## B. Overview of Cooperative Efforts

### 1. May 6, 2004 Meeting at DOE Headquarters

The primary purpose of the May 6, 2004 meeting was for MDS Nordion to provide a briefing for the U.S. Government on the status of the Target Conversion Development Program and explore opportunities for the U.S. Government to support MDS Nordion's effort to overcome technical and economic obstacles that have arisen with respect to the Target

Conversion Development Program. These obstacles were discussed in MDS Nordion's May 19, 2004, Annual Report to the NRC.

As Grant Malkoske explained at the May 6, 2004 meeting and in his follow-up letter to DOE on August 26, 2004, substantial technical and economic issues must be successfully addressed in order for MDS Nordion to be able to employ LEU target technology in its large-scale commercial production of molybdenum 99 at the MAPLE Reactors and the NPF, for nuclear medicine applications. As noted in MDS Nordion's May 19, 2004 Annual Report to the NRC, a key aspect of the discussion during the May 6, 2004, meeting was the need to identify and evaluate new approaches to using LEU targets in the MAPLE Reactors and the NPF in order to assure the continued production of a reliable supply of medical isotopes and avoid unacceptable outcomes from the standpoints of increased cost to the medical community and supply disruptions.

During the May 6, 2004 meeting, representatives of DOE and ANL provided their preliminary views with respect to possible options for overcoming the technical, economic, and supply-related issues that Mr. Malkoske discussed at that meeting. In response, Mr. Malkoske stated that MDS Nordion would provide conversion options and criteria for evaluating those options.

### 2. August 26, 2004 Letter from MDS Nordion to DOE

The conversion options and evaluation criteria that MDS Nordion had agreed to provide as a result of the May 6, 2004 meeting were transmitted to DOE as an attachment to Mr. Malkoske's August 26, 2004 letter to Trisha Dedik, Director of the Office of Nonproliferation Policy at DOE's National Nuclear Security Administration (NNSA). His letter enclosed a schedule entitled "MAPLE Facilities Conversion Options" as well as a list of "Key Conversion

Principles." Because they contain MDS Nordion's confidential commercial information, these documents are discussed in the Confidential Annex to this Annual Report.

### 3. Meeting with DOE on November 20, 2004

Another meeting between MDS Nordion and DOE took place in Vienna, Austria on November 20, 2004. At this meeting, Mr. Malkoske provided an update on progress concerning the Target Conversion Development Program. He discussed the options, principles and criteria that were set forth in his August 26, 2004 letter to DOE. Mr. Malkoske also inquired about the status of DOE's development of its questions and comments concerning MDS Nordion's Target Conversion Development Program.

### 4. DOE's January 10, 2005 Letter to MDS Nordion

By letter to Mr. Malkoske dated January 10, 2005, Kasia Mendelsohn, of DOE's Office of Global Nuclear Material Threat Reduction, transmitted DOE's questions that were developed in accordance with MDS Nordion's May 6, 2004 meeting with DOE and Mr. Malkoske's August 26, 2004 letter. DOE requested that MDS Nordion consider these questions in developing and evaluating options for converting the MAPLE Reactors and NPF to LEU targets for the production of molybdenum 99. DOE indicated that its questions were drafted primarily by experts from ANL, which has the technical lead for DOE's Reduced Enrichment for Research and Test Reactors (RERTR) Program.

### 5. Preliminary Responses by MDS Nordion to DOE's Questions

On March 24, 2005, Grant Malkoske provided preliminary responses to many of the questions raised by DOE. As Mr. Malkoske pointed out, MDS Nordion's preliminary responses should be assessed by DOE in light of the options and associated considerations, criteria and principles that accompanied his letter to DOE dated August 26, 2004. In general, he indicated that MDS Nordion has focused its resources primarily on the fundamental conversion issue,

which concerns the capability and capacity of the NPF's waste management process systems in light of the demands that would be placed on them as a result of the additional mass and liquid volume from processing LEU targets.

### 6. April 22, 2005 Meeting at MDS Nordion's Headquarters in Ottawa

A meeting between U.S. Government representatives and representatives of MDS Nordion was held in Ottawa, Canada on April 22, 2005. The purpose of the meeting was for MDS Nordion to provide a briefing for U.S. Governmental officials regarding the status of MDS Nordion's Target Conversion Development Program and to continue the dialogue that was begun with DOE as a result of the questions from DOE and preliminary answers by MDS Nordion, as discussed above.

During the April 22, 2005, meeting in Ottawa, representatives of DOE, ANL and MDS Nordion discussed the need to develop a more detailed LEU conversion plan, in accordance with DOE's questions and requests in its letter to MDS Nordion. As MDS Nordion emphasized during the meeting, successful implementation of such an LEU target conversion program depends ultimately upon solving economic, as well as the technical issues associated with such a program. MDS Nordion reaffirmed its commitment to use LEU targets as soon as it is possible to accomplish this conversion in a technically and economically sound manner that does not jeopardize the reliable supply of medical isotopes from the MAPLE Reactors and NPF.

### 7. Scheduling a Follow-up Meeting with DOE

In his March 24, 2005 letter to DOE, Mr. Malkoske suggested that DOE and MDS Nordion arrange a mutually suitable time for another meeting to continue to pursue feasible options for implementing an LEU target conversion program for the MAPLE Reactors and the NPF. A meeting with DOE for this purpose is now scheduled for June 2, 2005.

## IV. MDS NORDION'S SUPPORT FOR AN INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA) INITIATIVE CONCERNING USE OF LEU TARGETS TO PRODUCE MOLYBDENUM 99

During the past year, MDS Nordion has cooperated with a program under the auspices of the IAEA to foster the use LEU targets to enable small, indigenous suppliers to produce molybdenum 99 and other medical isotopes that heretofore have been produced, at a significant commercial scale, only with HEU targets. Specifically MDS Nordion sent Mr. Malkoske to Vienna, Austria to participate in the establishment of a key program for this purpose, as explained below.

MDS Nordion, represented by Grant Malkoske, was one of the participants in an IAEA-sponsored "consultancy" to prepare a "cooperative research program (CRP) on transfer and adaptation of LEU targets to produce 99Mo through fission." This consultancy was held at the IAEA headquarters in Vienna, Austria, from November 15 through 17, 2004. Mr. Malkoske presented a paper, entitled "The LEU Target Development and Conversion Program for the MAPLE Reactors and New Processing Facility."

As described in the "Full Report" prepared by the IAEA, "the consultancy included seven presentations, including from three of the four major 99Mo producers in the world (L'Institute National Des Radioelements (IRE), Belgium; MDS Nordion, Canada; and Nuclear Energy Corporation of South Africa)." The IAEA's report noted that "Mallinckrodt Medical, Netherlands, the other major producer, was represented at the meeting but did not make a presentation." The IAEA further noted that Atomic Energy of Canada, Ltd (AECL), "which provides technical support to MDS Nordion also made a presentation, as did one small scale domestic producer of 99Mo using LEU targets (CNEA, Argentina), one future 99Mo producer from LEU targets (ANSTO, Australia, which is already producing small amounts of 99Mo), and

Argonne National Laboratory, USA, which is involved in the development of LEU targets under the RERTR program."

It is noteworthy that ANSTO (Australia) had undertaken an initiative to review their current process and develop, in collaboration with Argonne National Laboratory, an alternative LEU foil target with a higher enrichment than is employed in their current process. At the RERTR-2004 meeting in Vienna, Austria in November 2004, Australia reported that the detailed design of their required infrastructure was more complex than had been anticipated from preliminary design estimates, many of the design complexities being linked with ANSTO's production process – an acidic process. As a result, due to budgetary reasons, ANSTO has decided not to continue progress with the implementation of LEU foil targets at the time of the report.

As the IAEA explained in its Full Report, "some developing Member States, with embryonic nuclear programs, are seeking to become small scale, indigenous producers of 99Mo." The IAEA further noted that "consistent with the Reduced Enrichment for Research and Test Reactors (RERTR) program and activities to reduce and eventually eliminate international commerce in HEU, efforts have been undertaken to shift the production of medical isotopes away from the use of HEU."

In its Report, the IAEA pointed out that Australia and Argentina have been producing small quantities of molybdenum 99 from LEU targets. The IAEA acknowledged, however, that "both of these producers are servicing local or regional markets." Moreover, the IAEA stated that "today, about 99% of all molybdenum 99 is produced in research, test or isotope production reactors by irradiation of Highly Enriched Uranium (HEU) targets that are subsequently processed primarily to recover molybdenum 99." As the IAEA further noted, "at this time, the

remaining 1% of global molybdenum production is derived from the irradiation of Low Enriched Uranium (LEU) targets." Finally, the IAEA pointed out that "additionally, very small volumes of molybdenum 99 are being made from the irradiation of molybdenum 98 (neutron activation technique)."

The consultancy recommended that the Cooperative Research Project (CRP) be titled "Developing Techniques for Small Scale Indigenous Molybdenum 99 Production Using LEU Fission or Neutron Activation." Further, the consultancy established the following objectives:

> To develop and deliver education, awareness, training and coaching workshops to provide sufficient information to enable a recipient to make a knowledgeable decision on the technical, regulatory and economic implications of establishing Small Scale Molybdenum 99 Production using the Available Technology.
>
> To assist the recipient in the development activities to research, test, and evaluate the Available Technology and in determining the implications of the options to access Available Technology, build their own technology, or purchase alternative LEU technology.
>
> The Available Technology is defined as either the LEU-modified Cintichem process with LEU foil targets, or the neutron activation of molybdenum 98 and utilization of molybdenum gel generators.

The first Potential Producers Workshop was held in Buenos Aires during the week of May 16, 2005. The workshop was intended, according to the IAEA, to "address all the practical aspects involved in entering this business, as well as options for entering into it, including purchasing of proprietary production technologies or obtaining assistance from other experts."

MDS Nordion intends to continue to participate in this IAEA-sponsored initiative and support its objectives. The consultancy's work, at the November 2004 meeting in Vienna, made clear that there is little in common between the small-scale production of medical isotopes that is the sole focus of this IAEA project and the large scale production of Mo-99 that MDS Nordion

and the other major producers must reliably achieve on a weekly basis in order to meet the needs of physicians, hospitals and patients throughout the world.

While LEU targets have been used in Argentina and Australia on a limited basis to produce small quantities of Mo-99 to meet regional or local needs, such methods have not yet demonstrated the availability of an economically and technically viable means of producing Mo-99 with LEU targets to satisfy the large-scale demands that MDS Nordion must meet. Moreover, unlike MDS Nordion's production efforts, which are not subsidized by any government or other source, the production of Mo-99 in Argentina and Australia using LEU is carried out by governmental entities that are not subject to the same market place economic realities that MDS Nordion must face.

## V. CONCLUSION

As discussed in Section III of this Annual Report, despite substantial efforts in connection with the Phase 2 Conversion Development Program, MDS Nordion has not yet identified a means of converting the MAPLE Reactors and NPF to use LEU targets in a technically and economically feasible manner to produce medical isotopes. However, during the period covered by this Annual Report, MDS Nordion has continued to explore options for redirecting this effort. As discussed in this Annual Report, the U.S. Government has also actively pursued LEU target conversion efforts regarding the MAPLE Reactors and NPF.

Suspension or cessation of the export to Canada of HEU from the U.S. for use in targets for the NRU Reactor and the MAPLE Reactors would jeopardize the reliable supply of medical isotopes to meet the needs of patients. As MDS has repeatedly pledged in its Annual Reports to the NRC, when LEU targets are available for use in MDS Nordion's facilities in Canada, in a technically and economically appropriate manner, MDS Nordion will use such targets. Until that

time, a reliable supply of HEU will continue to be vital to the production of medical isotopes in Canada.

Among the other factors supporting these HEU exports to Canada to produce Mo-99 for medical purposes are the nearly 50 years of peaceful nuclear cooperation between the United States and Canada, Canada's rank "among the closest and most important U.S. partners in civil nuclear cooperation" and the "common non-proliferation goals as well as the singularly close and extensive relationship between the United States and Canada in the peaceful applications of nuclear energy."[1/] Additionally, the U.S.-Canada Agreement is "unique" in many respects, including its provisions allowing the transfer of classified information as well as "the transfer of enrichment, reprocessing and heavy water production technology."[2/] Moreover, in support of the unique provisions of the U.S.-Canada Agreement for Cooperation that allow the transfer of U.S. "sensitive nuclear technology" to Canada, the U.S. Arms Control and Disarmament Agency (ACDA) referred to the United States' "historically close ties with the Canadian nuclear program" and to "Canada's status as a close ally, NPT party and strong supporter of international non-proliferation efforts."[3/]

For the reasons discussed in this Report, MDS Nordion respectfully submits that the requirements of the Schumer Amendment, the NRC license conditions and the terms of the 1997

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1/ See Letter from President William J. Clinton to the Congress of the United States, June 24, 1999. See also, Letter from President Jimmy Carter to the Congress of the United States, concerning the text of a Protocol Amending that Agreement (reprinted in House of Representatives Document No. 96-304, 96th Congress, 2d Session)

2/ Arms Control and Disarmament Agency Nuclear Non-Proliferation Assessment Statement Concerning the Protocol to Amend the U.S.-Canada Agreement for Cooperation (House Document 96-304 at page 29).

3/ ACDA NPAS, House Document 96-304 at page 50.

diplomatic note between the U.S. and Canada[4/] continue to be fully satisfied.

4/ These notes are discussed, as follows, in the Commission's Memorandum and Order directing the Office of International Programs to issue XSNM-03060: "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). In the Matter of Transnuclear Inc. (Export of 93.3% enriched uranium) (License no. XSNM-03060), CLI-99-20, 49 NRC 469, 473-74 (June 29, 1999).

APPLICATION FOR THE NUCLEAR REGULATORY COMMISSION'S WITHHOLDING, FROM PUBLIC DISCLOSURE, OF THE CONFIDENTIAL ANNEX TO MDS NORDION'S ANNUAL REPORT TO THE NRC, DATED MAY 31, 2005, PURSUANT TO CONDITION NO. 10 OF LICENSE NUMBER XSNM-03060

10 C.F.R. § 2.390

AFFIDAVIT OF GRANT R. MALKOSKE

I, Grant R. Malkoske, Vice President, Engineering and Technology, MDS Nordion, do hereby affirm and state:

1. I am authorized to execute this affidavit on behalf of MDS Nordion.

2. MDS Nordion delivered to the NRC its yearly status report, dated May 31, 2005, ("Report") as directed by the Commission in its June 29, 1999 Memorandum and Order and as required by Condition Number 10 of License No. XSNM-03060. The Commission stated its intent to place such Reports in the Public Document Room. Moreover, the Commission stated that "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."[1]

3. The Confidential Annex to MDS Nordion's 2005 Annual Report to the NRC contains confidential commercial and financial information of MDS Nordion. Specifically, Section II.A. summarizes information that MDS Nordion transmitted to DOE in confidence, as confidential attachments to my letter to DOE dated August 26, 2004. The cover letter and each page of these attachments were marked with the caption "Commercial Confidential." This confidential information relates to MDS Nordion's commercial production of medical isotopes to meet the need of customers. It also provides MDS Nordion's cost estimates concerning various options for the Target Conversion Development Program. Consequently, such information is highly sensitive from a commercial perspective and is held by MDS Nordion in confidence.

4. Section II.B. of the Confidential Annex to MDS Nordion's 2005 Annual Report summarizes DOE's questions to MDS Nordion concerning the confidential attachment to my August 26, 2005 letter to DOE. Since they relate directly and substantially to MDS Nordion's confidential attachment to that letter, DOE's

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1 In the Matter of Transnuclear Inc. (Export of 93.3% enriched uranium) (License no. XSNM-03060), CLI-99-20, 49 N.R.C. 469, 478 (June 29, 1999).

questions embody MDS Nordion's confidential information. Public disclosure of the confidential information of MDS Nordion embodied in the DOE's questions would substantially harm MDS Nordion with respect to its ability to compete with other suppliers of medical isotopes.

5. Section II.C. of MDS Nordion's Confidential Annex to its 2005 Annual Report to the NRC summarizes the preliminary responses of MDS Nordion to the questions that DOE transmitted as an attachment to Kasia Mendelsohn's letter dated January 10, 2005. My March 24, 2005 letter to Kasia Mendelsohn, providing preliminary responses to DOE's questions, constitutes commercial and financial information of MDS Nordion that is held in confidence. Each page of my March 24, 2005 letter contains the legend "Commercial Confidential," thus identifying such information as confidential commercial and financial information of MDS Nordion. Public disclosure of such information would seriously harm MDS Nordion's ability to compete.

6. The information in the Annex is commercially sensitive because it could be used by MDS Nordion's competitors to influence purchasers' perceptions of MDS Nordion's ability to continue to be a reliable supplier of Mo-99.

7. The Confidential Annex constitutes confidential commercial and financial information that should be held in confidence by the NRC pursuant to the policy reflected in 10 C.F.R. § 2.390(a)(4) and 9.17(a)(4) because:

   i. This information is and has been held in confidence by MDS Nordion.

   ii. This information is of a type that is customarily held in confidence by MDS Nordion. When MDS Nordion has transferred such information to third parties, it has imposed confidentiality obligations on the third parties with respect to such information. There is a rational basis for holding such information in confidence because it deals with sensitive commercial and financial matters.

   iii. This information is being transmitted to the NRC in confidence.

   iv. This information is not available in public sources and could not be gathered readily from other publicly available information.

   v. Public disclosure of this information would cause substantial harm to the competitive position of MDS Nordion and its successors and affiliates.

8. Accordingly, MDS Nordion requests that the Confidential Annex be withheld from public disclosure pursuant to the policy reflected in 10 C.F.R. § 2.390(a)(4) and because of the requirements of 10 CFR § 2.390(d).

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

Subscribed and sworn before me this 26th day of May, 2005.

Notary Public