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MDS Nordion
Science Advancing Health

Reference:
XSNM03060
(25 pages)

May 31, 2007

Ms. Margaret M. Doane
Deputy Director, Office of
International Programs
U.S. Nuclear Regulatory Commission
One White Flint North Bldg.
11555 Rockville Pike
Room 04 D2
Rockville, MD 20852-2738

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 11 of that license, as amended, 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)(4).

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, Strategic Technologies

Enclosures: as stated

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

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, 2007

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Vice President, Strategic Technologies
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, 2007

I. INTRODUCTION

MDS Nordion is pleased to submit its Annual Report to the Nuclear Regulatory Commission (NRC), in accordance with condition 11 of XSNM-03060, as amended. This Annual Report reviews key developments, over the past year, with respect to MDS Nordion's continuing evaluation of the feasibility of producing medical isotopes in the MAPLE Reactors and the associated New Processing Facility (NPF) by irradiating and processing targets containing low enriched uranium (LEU) rather than the highly enriched uranium (HEU) for which these reactors and the NPF were designed. As discussed in previous Annual Reports, the MAPLE Reactors 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 more than one-half of the world's requirements and approximately half of the medical isotope needs for patients in the United States. Every day, approximately 43,000 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.

Medical isotopes are used daily in about 85,000 nuclear medicine procedures around the world. Many require more than one radiopharmaceutical dose. Currently, there are more than 100 medical applications for radioisotopes. Eighty percent of nuclear medicine procedures rely

on one isotope, Technetium-99, which is produced from Molybdenum 99 (Mo-99). Such procedures are used for a broad range of applications, including determining the severity of heart diseases, the spread of cancer and for diagnosis of brain disorders. Novel ways of treating disease, such as radioimmunotherapy, are expanding horizons for medical isotopes applications. Mo-99 and other medical isotopes are essential to the adequate diagnosis and treatment of patients.

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 Mo-99 used in Canada and about half of that needed in the United States for medical purposes from Atomic Energy of Canada Limited's (AECL's) National Research Universal (NRU) Reactor.

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, which at 66 hours, means that approximately 1% of the Mo-99 decays away per hour. Consequently, MDS Nordion is unable to accumulate an inventory of Mo-99 and must therefore reliably produce, on a daily basis, the needed quantities for delivery to manufacturers of radiopharmaceuticals.

Currently, 95-98 percent of world Mo-99 production is based on HEU targets, which employ a demonstrated and proven technology. While Mo-99 is being produced from LEU targets irradiated and processed in government-owned or supported facilities in Argentina and Australia, such production is a very small fraction of total world production of Mo-99 and is used essentially for consumption within these countries respectively.

Efforts by the United States and several other countries to reduce the use of HEU throughout the world should take into account the essential role that HEU targets currently play in the reliable supply of Mo-99 from AECL's facilities in Canada and the robust physical security measures that are applicable at those facilities and during the transportation of the HEU targets or target material to Canada.

During early 2006, a major change took place with respect to the ownership and operation of the MAPLE Reactors and the associated NPF in which targets irradiated in those reactors will be processed to produce medical isotopes, for use in producing radiopharmaceuticals. On February 22, 2006, MDS Nordion and AECL publicly announced their successful completion of mediation concerning commercial contractual issues related to the construction, commissioning and operation of the MAPLE Reactors and the NPF. As a result of the mediation, AECL and MDS Nordion entered into a 40-year isotope supply agreement. Under this agreement, AECL has assumed ownership of the MAPLE Reactors and the NPF, which are called, collectively, the Dedicated Isotope Facilities (DIF). MDS Nordion has transferred to AECL the legal title to the DIF and AECL will receive a share of net revenues from isotopes produced by AECL for MDS Nordion. AECL is responsible for safe storage and long-term management of wastes produced from the processing of isotopes at MDS Nordion's Kanata facility.

II. ATOMIC ENERGY ACT CRITERIA FOR HEU EXPORTS AND THE NATIONAL ACADEMY OF SCIENCES STUDY

The export license that is the subject of this Annual Report was issued by the Commission in accordance with the export criteria specified in section 134 of the Atomic Energy Act of 1954, as amended (AEA). That section of the AEA was amended by section 630 of the Energy Policy Act of 2005, which was signed into law on August 8, 2005. The purpose of the

amendment was to facilitate the timely export to a "Recipient Country" of HEU for medical isotope production in reactors that are either utilizing LEU or have agreed to convert such reactors to use LEU driver fuel. A "Recipient Country" is defined in section 630 as Canada, Belgium, France, Germany, and the Netherlands. It is noteworthy that current NRC export licenses authorize exports of HEU from the U.S. for targets for production of medical isotopes only to Canada. Moreover, the U.S. is Canada's sole source of supply for such HEU targets and target material.

As provided by section 630 of the Energy Policy Act of 2005 (Public law 109-58), the National Academy of Sciences is conducting a study and will provide findings and recommendations to the Department of Energy concerning the production of medical isotopes without HEU. As mandated by Congress in Section 630(A) of the Energy Policy Act, the study will determine the following:

- the feasibility of procuring supplies of medical isotopes from commercial sources that do not use HEU, using the definition of feasibility set forth in Section 630 (B).
- the current and projected demand and availability of medical isotopes in regular current domestic use.
- the progress that is being made by the Department of Energy and others to eliminate all use of HEU in reactor fuel, reactor targets, and medical isotope production facilities.
- the potential cost differential in medical isotope production in the reactors and target processing facilities if the products were derived from production systems that do not involve fuels and targets with HEU.

If the National Academy of Sciences determines that the procurement of medical isotopes from commercial sources is not feasible as defined in Section 630 of the Energy Policy Act, it is required to estimate the magnitude of the cost differential and identify additional steps that could be taken by the Department of Energy and medical isotope producers to improve the feasibility

of such conversions. As specified in section 630 of the Act, one of the factors that the National Academy of Sciences must consider in its study is "the potential cost differential in medical isotope production in the reactors and target processing facilities if the products were derived from production systems that do not involve fuels and targets with highly enriched uranium." Furthermore, in order to determine that the production of medical isotopes without using HEU is "feasible," within the meaning of Section 630, the National Academy of Sciences must find, among other things, that "the average anticipated total cost increase from production of medical isotopes in such facilities without use of highly enriched uranium is less than 10 percent." As clearly provided in Section 630, the facilities that are the subjects of this cost comparison are the "reactors and target processing facilities" that produce "medical isotopes." Section 630 defines "medical isotopes" as follows: "The term 'medical isotope' includes Molybdenum 99, Iodine 131, Xenon 133 and other radioactive materials used to produce a radiopharmaceutical for diagnostic, therapeutic or research and development."

In Section 630, Congress properly recognized that the operators of reactors and target processing facilities that produce medical isotopes , such as MDS Nordion and AECL, must consider the impact of converting to LEU targets on the cost of producing medical isotopes and continuing to supply such isotopes reliably each day without interruption. As provided in Section 630, an average anticipated total cost increase of ten percent or more in such production cost means that conversion to LEU targets is not "feasible," as that term was defined by Congress. While the cost of radiopharmaceuticals may not be significantly affected by an increase of ten percent or more in the cost of the medical isotopes used to produce them, Congress recognized that such a cost increase, as a result of a conversion to LEU targets, would

have a major impact on medical isotope producers who convert to LEU targets, particularly if their competitors continue to use HEU targets.

Significantly, the cost differential that the National Academy of Sciences must address relates to the cost of producing the medical isotope (Mo-99) as opposed to the cost of producing the radiopharmaceutical. Clearly, the producers of the medical isotopes must focus on their costs as opposed to the costs that radiopharmaceutical manufacturers bear in producing the radiopharmaceutical itself. In estimating the magnitude of cost differentials, the National Academy of Sciences has stated that it will consider facilities utilized by both large and small producers. The National Academy of Sciences has noted that it will also identify any reliability of supply issues that could arise as a result of such conversions.

MDS Nordion has advised the National Academy of Sciences that it will continue to work toward the production of medical isotopes through the irradiation and processing of LEU targets and noted its view that the essential criterion governing a conversion program is that a reliable and uninterrupted supply of medical isotopes must be assured to meet patient healthcare needs.

In its interactions over the past year with the U.S. Government and the National Academy of Sciences, MDS Nordion has continued to communicate its view that the key considerations in developing and implementing a commercial, large-scale LEU target technology are the technical, economic, safety and medical certification requirements.

III. STATUS REPORT ON THE MAPLE REACTORS, THE NRU REACTOR AND THE NEW PROCESSING FACILITY

A. MAPLE Reactors

The MAPLE 1 and 2 Reactors are located at the Chalk River Laboratories (CRL) in Chalk River, Ontario. The MAPLE 1 and 2 Reactors are constructed from the same design

specifications. Each reactor is a 10 MW(t), pool type, light-water moderated and cooled, radioisotope production reactor. The MAPLE Reactor core consists of driver fuel assemblies using LEU and Mo-99 target assemblies using HEU, arranged in a close-packed array. The core is surrounded by an annular reflector tank filled with heavy water that also contains a number of vertical tubes for isotope irradiation. The core is cooled by low-temperature and low-pressure light-water pumped through the core. The reactor power level is controlled with three Control Absorber Rods (CARs), which slide over extended flow tubes in the outer ring of the core. The reactor has two separate, independent and diverse shutdown systems. One shutdown system uses three absorbers similar in design to the control rods and the second shutdown system relies on partial draining of the heavy water reflector tank. The MAPLE 1 Reactor building also contains the MAPLE Iodine Production Facility, a facility for the production of Iodine-125.

On November 24, 2005, the Canadian Nuclear Safety Commission (CNSC) renewed AECL's license for the MAPLE Reactors, through November 30, 2007. In April 2006, the CNSC authorized the removal of the MAPLE 1 Reactor from Guaranteed Shutdown State and for operation up to 2 kW thermal power. AECL has requested CNSC approval to resume nuclear commissioning at high power for the purpose of re-measuring the Power Coefficient of Reactivity (PCR) to identify the causes for the discrepancy between the predicted negative PCR and the small positive PCR that had been measured from commissioning the reactor at powers up to 8 MW thermal.

To date, AECL has completed MAPLE 1 commissioning activities up to those specified for 8 MW operation. However, further nuclear commissioning activities have been suspended, since early in 2004, to address technical issues concerning the MAPLE facilities. Some commissioning activities have been performed during the first half of the current license period.

changes to the reactor to resolve the positive PCR issue. Tests are underway and will be completed in the Fall of 2007, at which time the reactor is to be used to irradiate HEU targets for the active commissioning of the New Processing Facility.

Initial fuel load into the MAPLE 2 Reactor occurred during the period from September to October 2003. First criticality was achieved in the MAPLE 2 core on October 9, 2003. At present, the MAPLE 2 Reactor remains in the Guaranteed Shutdown State. In its Report on December 13, 2006, the CNSC Staff noted that it had identified the "following prerequisite for approval to restart the MAPLE 2 reactor: AECL must install redesigned target cluster holders to resolve the issue of sticking target cluster holders." (Report at page 12). AECL has completed the redesign of the target cluster holder and have been granted approval by the CNSC to install these units in the MAPLE Reactors.

Results to date under confidential commercial arrangements between AECL and MDS Nordion in connection with efforts to produce medical isotopes by irradiating LEU targets are discussed in the Confidential Annex to this Annual Report.

AECL has made an application to the CNSC to renew the operating licenses for the MAPLE Reactors and the New Processing Facility. The Day 1 Commission Hearing to review AECL's application is scheduled on June 22, 2007. The Day 2 Commission Hearing is scheduled on September 12, 2007. The CNSC staff has issued CMD 07-H16 for the Day 1 Commission Hearing. In CMD 07-H16, the CNSC staff recommend that the current separate operating licenses for the MAPLE Reactors and New Processing Facility be renewed and replaced with one operating license for the Dedicated Isotope Facilities for a period of 47 months, until October 31, 2011.

B. NEW PROCESSING FACILITY

As noted in a December 13, 2006, Report (Commission Member Document, CMD 06-M63), "AECL staff has continued to work to resolve a number of technical problems discovered during the non-nuclear commissioning of the facility and during the NPF Inactive Integrated Testing performed in 2003." The Report also observed that the "two most significant issues concern the operability of the Cementation and Calcination systems, which are being redesigned." Furthermore, "work is progressing on other systems, such as modifications to the Closed Loop Cooling System . . . and the installation and commissioning of the small diesel generator added to supply certain NPF systems, as a back-up to the current diesel generator that provides class III power to the Dedicated Isotope Facilities." However, the Report concluded that "the schedule for NPF activities has slipped considerably with respect to the one given to the Commission at the time of the NPF license renewal, with the NPF being ready to start active commissioning in October 2007, as opposed to the December 2006 target date given then."

C. NRU REACTOR

During the past year, MDS Nordion continued to rely upon the NRU Reactor, at Chalk River Canada, as the source of the medical isotopes that are needed to produce radiopharmaceuticals for use in the United States, Canada and other countries. The NRU Reactor is a heavy-water cooled and moderated reactor, which began operation in 1957. Previously fueled with HEU, the NRU was converted to LEU fuel in the early 1990's. The NRU Reactor currently operates at power levels up to 130 megawatts thermal.

As the world's largest source of medical radionuclides, the NRU provides medical isotopes for more than 43,000 patients every day. The NRU produces the majority of the world's medical isotopes, including Mo-99 and several longer lived isotopes such as Cobalt-60 used for cancer teletherapy applications. Over the last 18 months, the NRU Reactor has significantly

stepped up through-put production by up to fifty percent (50%) on four (4) occasions for a combined period of over 30 weeks to ensure that treatment of U.S. patients would not be disrupted during the period of time when one of the two U.S. companies that use Mo-99 to manufacture Tc-99 generators was not able to manufacture or supply such generators.

The CNSC has extended the NRU's Operating License until 2011. Since commercial operation of the MAPLE Reactors has been delayed, continued production of medical isotopes in the NRU Reactor until at least October 2010 will be necessary.

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

A. Introduction

MDS Nordion has been examining options for converting the MAPLE Reactors and the NPF to use LEU targets since mid-1999. Concerns about the long-term viability of the NRU Reactor and the need to maintain a reliable supply of medical isotopes clearly were a critical constraint affecting the decision by MDS Nordion to convert the MAPLE Reactors and the NPF. By October 2003, MDS Nordion had concluded that conversion of the MAPLE Reactors and the NPF to LEU targets would have either delayed the MAPLE Reactors or caused a later extensive shutdown of the MAPLE Reactors and the NPF. Either of these eventualities would have caused an immediate and significant discontinuity of medical isotope supply to meet patient needs.

B. Cooperation With The National Academy of Sciences

MDS Nordion's cooperation with the U.S. Government during the past year, with respect to the LEU target conversion development program, has focused primarily on cooperation with the study that the National Academy of Sciences is carrying out, pursuant to Congress's directive in section 630 of the Energy Policy Act of 2005. That cooperation has included presentations by MDS Nordion to the National Academy of Sciences on February 15, 2007, and April 11, 2007.

In these presentations, MDS Nordion reviewed the above stated key principles and essential supply criteria that continue to guide MDS Nordion's ongoing efforts to assess the feasibility of converting the MAPLE Reactors and NPF to operate in a reliable manner by using LEU targets rather than the HEU targets for which they were designed.

A major theme of MDS Nordion's presentations to the National Academy of Sciences is that conversion of the MAPLE Reactors and the NPF to use LEU targets must address both generic and site-specific issues, including the following issues: (1) technology development/implementation; (2) configuration of existing isotope production facilities; (3) safety and other issues regarding use of LEU targets in the reactors and processing facility; (4) handling and long-term waste management in a safe and secure manner; (5) impact of the conversion, including substantially higher amounts of radioactive waste, on the eventual decommissioning of the reactors and processing facilities; and (6) amendment of existing licenses from the CNSC for the MAPLE Reactors and the NPF.

MDS Nordion also noted that in order for an LEU target conversion plan to be technically and economically feasible, the licensee of the reactors and target processing facility must demonstrate that it is consistent with applicable environmental requirements and complies with non-proliferation laws and policies.

C. Cooperation With the U.S. Government

During the past year, MDS Nordion has continued to cooperate with the Department of Energy (DOE) concerning the development of LEU targets for medical isotope production. On February 15, 2007, Grant Malkoske participated in a discussion with Dr. Parrish Staples, Director of the National Nuclear Security Administration (NNSA) Office of Global Threat Reduction, Reactor Conversion Program. On April 11, 2007, Mr. Malkoske met with Dr. Staples, Edward Fei, Foreign Affairs Specialist, NNSA and Dan Fenstermacher, Physical

Scientist, Division of Nuclear Energy Safety & Security of the Department of State.

Mr. Malkoske had a conference call on May 23, 2007, with Nicole Nelson-Jean, Director of the NNSA Office of Global Threat Reduction, to discuss cooperation with DOE regarding LEU target conversion. Through these meetings and conversations, MDS Nordion continued to keep the U.S. Government currently informed regarding the progress of MDS Nordion's efforts to determine the feasibility of using LEU targets to product medical isotopes. MDS Nordion has continued to seek DOE's support for its studies of the technical, regulatory and economic aspects of conversion to LEU targets.

D. Key Factors Regarding Large-Scale Commercial Production of Medical Isotopes Using LEU Targets

1. Introduction

The technology development aspects of a LEU target conversion program must encompass a broad range of requirements, including the following: (1) target development; (2) reactor qualification; (3) process development; and (4) waste management. The efficiency of the Mo-99 extraction process is a key consideration. The technology must be proven, robust, reliable, and sized for large-scale, continuous commercial production. Experimental target LEU technology cannot simply be scaled up for large-scale commercial production.

2. Transition Period and Maintenance of a Reliable Supply

A substantial transition period will be needed to demonstrate that LEU targets may be effectively and safely used in reactors and processing systems, such as the MAPLE Reactors and the NPF. A critical aspect of the demonstration is to show that a system to use LEU targets is capable of providing commercial quantities of Mo-99. Thousands of curies of Mo-99 must be supplied each and every week without exception. Even if LEU target technology is deployed for large-scale commercial production, it will be necessary to have a reliable source of Mo-99

supply from the current stream, based on HEU targets, until a new stream based on LEU targets has demonstrated reliability.

3. Common Aspects of Developing HEU as well as LEU Targets

Many of the steps and requirements in developing LEU targets are the same as those that were followed in the development of HEU targets. The development of a comprehensive processing system for targets, whether HEU or LEU, must take into account the following: (1) process system qualification; (2) isotope extraction and qualification; (3) quality assurance programs; and (4) product quality specifications.

4. Unique Aspects of Developing LEU Targets

An essential aspect of an LEU target conversion plan is that the LEU targets are an integral part of a reactor operating system and must be integrated into the system in a manner that does not lead to unexpected adverse impacts on safety. Extensive interaction with governmental regulators will be necessary with respect to each reactor and target-processing facility that undertakes a program to convert such facilities to use LEU targets.

LEU target design must be qualified to the quality standards for fuel in nuclear power plants. Target design qualification will rely on irradiation of the LEU target in the qualification program, which will include the following essential elements: (1) heat transfer measurements; (2) hydraulic measurements for the target cluster, including vibration measurements to assess the impact of the larger mass of an LEU target compared to HEU; and (3) endurance testing of the target cluster in a full-scale hydraulic test rig, in which hydraulic load analysis encompasses loads from seismic events.

The ability to service target assemblies from both MAPLE Reactors is another vital consideration with respect to an LEU target conversion program for those reactors and the NPF. The facilities that must be considered include hot cells, liquid waste vault, nuclear ventilation

system, target processing, medical isotope extraction, waste processing and solidification, and product shipment. The impact of conversion to LEU targets on the implementation of a rigorous maintenance management program must also be considered, taking into account that these facilities must be operated to achieve continuous large-scale, commercial operation all day, every day.

Acceptable quality has been reported for Mo-99 produced in certain small-scale facilities that have irradiated LEU targets and extracted Mo-99 for use in producing radiopharmaceuticals. The Mo-99 product quality achieved by using LEU targets during large-scale commercial production will have to meet the acceptable quality results that have been achieved in a small-scale facility.

5. Cost of Conversion to LEU Targets

The cost of implementing an LEU target conversion development program must also be taken into account. The costs include the following: (1) technology development cost; (2) capital cost; (3) start up operating costs; (4) incremental operating costs; (5) regulatory costs; (6) increased cost of decommissioning an LEU target processing facility; and (7) cost for transitioning from HEU to LEU targets.

Development costs for converting to LEU targets include the following: (1) designing the target and qualifying the design and manufacturing process for a new LEU target; (2) re-licensing the MAPLE Reactor core for a new LEU target design; (3) confirming calcine technology to deal with the five-fold increase in the uranium concentration of high-level liquid radioactive waste (HLLRW); (4) scaling up the cementation process to process the increase in mid-level liquid radioactive waste (MLLRW); (5) confirming Al column efficiencies with increased uranium concentration; and (6) validating Mo-99 extraction chemistry.

Capital costs of converting to LEU targets include: (1) designing, licensing and commissioning of new hot cell facilities to accommodate larger waste processing equipment; (2) performing an environmental assessment and additional safety analysis of the MAPLE Reactors, (3) acquiring and installing new target handling and other ancillary equipment (e.g., flasks, handling tools); (4) developing site infrastructure; and (5) identifying and implementing necessary revisions to site support services (ventilation, waste, utilities, fire protection).

Start-up operating costs of converting to LEU targets include: (1) additional staffing costs associated with start-up of a new LEU target processing line without interrupting the supply of isotopes; (2) two years of additional training of reactor operators will be necessary before conversion to LEU targets; (3) operators must be trained to operate new equipment and facilities; and (4) overlapping of resources for downstream activities for both start-up of the new processes required for LEU targets and existing production.

Operating costs of converting to LEU targets include: (1) increased costs of operating the MAPLE Reactors with LEU targets compared to operating them with HEU targets; (2) an increase in calcine waste that requires interim storage and disposal, with the disposal cost of LEU calcine being similar to HEU and contingent upon obtaining approval for disposal in the National Repository; (3) an increase in cemented MLLRW waste requiring interim storage and disposal; and (4) a larger hot cell nuclear footprint results in higher operating costs and increased staffing requirements.

Factors that cannot presently be determined include the following: (1) the cost differential between LEU and HEU targets is unclear; (2) the quantity of LEU targets required to obtain required product volumes of Mo-99; (3) manufacturing cost of oxide targets and cost of

LEU foil technology; and (4) whether target design is proprietary and must be licensed for a fee or is "freeware." No significant reduction in security costs is foreseen since the MAPLE Reactors and the NPF are on the site of a Class 1 Nuclear Facility with all of the requisite security for such a site. LEU target transport costs compared to HEU target transport costs must still be determined.

As is also the case with respect to HEU targets, regulatory costs of converting to LEU targets include: (1) nuclear licensing, which requires (a) an environmental assessment of waste and site releases; and (b) a safety analysis of reactors and the processing facility, including the following factors: (i) the critical heat flux; (ii) onset of nucleat boiling; (iii) operating conditions; and (iv) licensing and documentation; (2) product acceptance (medical isotope acceptance to specification, medical isotope Drug Master File); and (3) integration with Tc-99m generator manufacture (acceptance to specifications and New Drug Application (NDA)).

Implementation of an LEU target conversion program will also be dependent upon the availability of LEU feedstock to produce the targets and LEU target technology. Technology development for this purpose will, in turn, be dependent on the availability of suitable technology and acceptable commercial arrangements for the supply of LEU material and for the transfer of that technology.

6. Summary

Each LEU conversion project will be process, facility and site-specific, with differing economic impacts. Substantial time will be needed to execute an LEU target conversion development program at each of the following critical stages: (1) design; (2) regulatory approvals; (3) construction; (4) commissioning; and (5) transition to demonstrate reliability of supply. This latter point is an important consideration that will materially affect the timing of such a program as there is a vital need to maintain continuity of supply for patient care during

implementation of the conversion program. At most commercial-scale facilities, it should be expected that conversion of Mo-99 production from HEU to LEU technology will take on the order of 10 years.

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

MDS Nordion continues to monitor and support progress being made in the IAEA to assess the applicability and transferability of LEU technology for the production of large-scale, commercial quantities of Mo-99 from LEU targets and the related technologies to extract medical isotopes and manage the waste stream from such technologies. Specifically, during the past year, MDS Nordion has continued to support the IAEA-sponsored Coordinated Research Project (CRP) to develop LEU technology for Mo-99 production. While this program is aimed at small indigenous producers, the outcomes will increase the body of knowledge related to conversion of Mo-99 production from HEU to LEU targets and this will influence major producers of medical isotopes. In cooperation with the CRP, medical isotope producers in Argentina and Australia continue to enhance production methods using LEU targets. Also, using DOE funding, Argonne National Laboratory continues to pursue the development of foil targets that use the Cintichem process, which may be used by small-scale medical isotope producers who are starting a new operation. The transfer of this technology to existing large-scale producers would have to be examined on a case-by-case basis.

As observers, MDS Nordion attended the inaugural CRP meeting in 2004 and also participated in the First Research Coordination Meeting (RCM) held in Vienna in December 2005. In May 2006, MDS Nordion attended the 10th International Topical Meeting on Research Reactor Fuel Management (RRFM) meeting in Sofia, Bulgaria and participated in planning discussions with representatives from the IAEA in preparation for the next RCM. In November

2006, MDS Nordion participated in the IAEA "Workshop on Operational Aspects of Mo-99 Production" held in Vienna, Austria. MDS Nordion provided presentations on "Overview of Mo-99 Production" by Mr. Malkoske and "Environmental Overview" by Mr. Damhaut.

While recognizing the efforts in the IAEA CRP, under the auspices of the IAEA and the DOE, and conversion efforts being undertaken by individual regional producers of medical isotopes, including conversion of some reactor cores to use LEU targets for isotope production, such efforts have yet to be demonstrated as feasible or may be possible only with a major sacrifice in isotope production capability. Process technology and waste management are the primary obstacles to converting some facilities to LEU targets. The development of new process technology may help overcome these obstacles.

Major suppliers of medical isotopes will each need to assess their issues regarding conversion. MDS Nordion continues to expend substantial funds and make major commitments of senior personnel in connection with its ongoing study of the feasibility of meeting its obligations to the medical community and patients through the use of LEU rather than HEU targets. Information concerning this effort is provided in the Confidential Annex to this Annual Report.

VI. CONCLUSION

Efforts to use LEU targets in place of the current large-scale production of Mo-99 from HEU targets must ensure that patient needs are not compromised. An uninterrupted, reliable supply of medical isotopes for patient care is essential and such deliveries must be made each day without exception. Programs to produce medical isotopes without using HEU must ensure that the interests of patients and all other constituent interests are addressed. Non-proliferation, technical feasibility, economic viability, and regulatory/licensing requirements must all be taken

into account. Adhering to the key success factors discussed in section IV of this Report will increase the likelihood of a successful conversion program.

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 not contribute to the success of a program to produce Mo-99 without using HEU targets. In fact, such a suspension or cessation would jeopardize the reliable supply of medical isotopes to meet the needs of patients in the United States, Canada and elsewhere.

As MDS Nordion has 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 for distribution of those products globally, including more than 50% to the U.S. to meet patient needs.

Among the other factors supporting these HEU exports to Canada to produce Mo-99 for medical purposes are the 50 years of peaceful nuclear cooperation between the United States and Canada. As several U.S. Presidents have pointed out, Canada ranks among the closest and most important U.S. partners in civil nuclear cooperation and nuclear non-proliferation initiatives.

For the reasons discussed in this Report, MDS Nordion respectfully submits that the requirements of the AEA and the NRC license conditions for XSNM-03060 continue to be fully satisfied.

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, 2007, PURSUANT TO CONDITION NO. 11 OF LICENSE NUMBER XSNM-03060

10 C.F.R. § 2.390

AFFIDAVIT OF GRANT R. MALKOSKE

I, Grant R. Malkoske, Vice President, Strategic Technologies, 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, 2007, ("Report") as directed by the Commission in its June 29, 1999 Memorandum and Order and as required by Condition Number 11 of License No. XSNM-03060, as amended. 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 information provided to the Commission in Section II of the Confidential Annex includes data regarding the inventory of targets for irradiation in the MAPLE Reactors, and processing in the New Processing Facility ("NPF"). The Confidential Annex also contains information regarding the shipment from the United States of highly enriched uranium (HEU) contained in those targets to Canada for irradiation in the MAPLE Reactors and processing in the NPF. This information, which is held in confidence by MDS Nordion, is sensitive from a business perspective since it discloses MDS Nordion's operational plans with respect to the production of Mo-99 and the extent to which it can serve as a reliable supplier by maintaining a sufficient reserve inventory and operational inventory of HEU targets. The above-mentioned inventory information contained in the Confidential Annex relates to the physical security of HEU stored under physical protection measures approved by the Canadian Nuclear Safety Commission ("CNSC"). The Nuclear Safety and Control Act of Canada requires that MDS Nordion and AECL maintain the confidentiality of information regarding the amount of HEU that AECL stores and uses, on behalf of MDS Nordion, at AECL's facilities at Chalk River, Canada. I have been informed that

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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 NRC 469, 478 (June 29, 1999).

AECL's physical security program, established in accordance with CNSC regulations, requires that information regarding the quantity of HEU at those facilities be protected from public disclosure.

4. The Confidential Annex to MDS Nordion's 2007 Annual Report to the NRC contains confidential commercial and financial information of MDS Nordion. Specifically, Section III discusses a recent agreement between MDS Nordion and AECL regarding the feasibility of producing medical isotopes through the irradiation and processing of LEU targets. The discussion of this study in the Confidential Annex relates to MDS Nordion's commercial production of medical isotopes to meet the need of customers. Consequently, such information is highly sensitive from a commercial perspective and is held by MDS Nordion in confidence.

5. Public disclosure of the confidential information of MDS Nordion embodied in the Confidential Annex would substantially harm MDS Nordion with respect to its ability to compete with other suppliers of medical isotopes.

6. The information in the Annex is commercially sensitive because it could be used by MDS Nordion's competitors to influence MDS Nordion's customers with respect to its 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 C.F.R. § 2.390(d).

Grant R. Malkoske
Vice President, Strategic Technologies
MDS Nordion

Subscribed and sworn before me this 29th day of May, 2007.

Notary Public