

1800 M Street, N.W.

Washington, D.C. 20036-5869

202-467-7000

Fax: 202-467-7176

James A. Glasgow  
(202) 467-7464  
jaglasgow@mlb.com

**Morgan, Lewis  
& Bockius LLP**

C O U N S E L O R S   A T   L A W

*Rec'd 6/30/00 3:50 PM  
Jany Weather*

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.  
June 30, 2000  
Page 2

Dr. Jean Pierre Labrie  
General Manager  
Research and Isotope Business  
AECL

James A. Glasgow  
Partner  
Morgan, Lewis & Bockius, LLP

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.

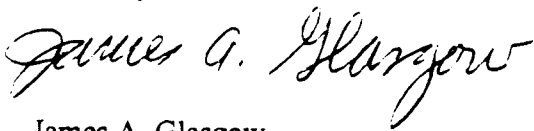
As the slides and the above-mentioned reports clearly demonstrate, the Applicants, in consultation with the U.S. Executive Branch, Argonne National Laboratory and Canadian regulatory authorities, have worked diligently to evaluate the technical, regulatory and economic aspects of converting the MAPLE 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  
Page 3

Morgan, Lewis  
& Bockius LLP

Sincerely,

A handwritten signature in cursive script that reads "James A. Glasgow". The signature is written in dark 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**