



April 5, 2004

Via Courier & Fax (301) 415-2162

Chairman Nils J. Diaz
United States Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852-2738

Dear Chairman Diaz:

I am writing in response to recent media reports regarding MDS Nordion's program to convert isotope production in the MAPLE facilities to targets containing LEU.

The articles have stated that MDS Nordion has broken off co-operation with Argonne National Laboratory (ANL) and imply that we might be "headed for a showdown" with the U.S. This is not true. In accordance with the Schumer Amendment, and in co-operation with ANL, MDS Nordion developed a LEU Target Development and Conversion Program. Through this program, we have undertaken a substantial co-operation initiative with the U.S. government to develop LEU target technology for medical isotopes produced in the MAPLE facilities. The LEU Target Development and Conversion Program that we have undertaken has three distinct phases. As previously reported in our Annual Reports, we are currently in Phase 2, the Conversion Development Program. This scope of work in Phase 2 was developed in co-operation with ANL and, as has been stated publicly, consists of a development program to determine how the additional waste arising from a LEU process to produce medical isotopes, in a commercially viable manner, could be managed within the New Processing Facility. The deliverable from Phase 2 is a technical and economic assessment of the feasibility of implementing a change to the MAPLE facilities to convert to LEU targets. We remain committed to complete this Phase of work.

However, as provided for in the Schumer Amendment, MDS Nordion has consistently stated that implementation of a LEU target technology must be both technically and economically feasible. Furthermore, our view is that implementation of such a target and process, once qualified, must satisfy the primary obligation of uninterrupted supply of medical isotopes to the pharmaceutical manufacturers and the patient community.

A significant consideration in the design of a target for large volumes of molybdenum-99 production, such as that carried out by AECL, Nuclear Technology Products (NTP in South Africa), Institut National des Radioéléments (IRE) and Mallinckrodt, is the cooling of the target. Accordingly, matrix targets containing the uranium and having a large surface area are a common design. The MAPLE reactors, which were designed to be efficient producers of molybdenum-99, have a specifically designed cooling system for the targets that avoid the use of matrix material. The target material is uranium oxide. Because of this relatively simple target design, AECL has been able to show, as part of the LEU Target Development and Conversion Program, that they can modify their target to be able to use LEU. Furthermore AECL has carried out proof of principle experiments to demonstrate that, even with the increased mass of uranium and the resultant increased volume of solution, they can separate molybdenum-99 and achieve high yields. However, the issue that has not been satisfactorily addressed by the partners involved in Phase 2 is how to process the increased volume of liquid and solid waste within the existing hot cell facility that contains the new waste processing equipment.

A new molybdenum-99 process needs to consider not only the capability to reliably and consistently make large volumes of product of the required quality; it must also deal with the waste generated by the molybdenum extraction process, which was the primary technical issue identified for Phase 2 of our Conversion Development Program. This is a complex issue. We are resuming discussions with DOE and ANL to determine if there might be other ways to effectively deal with waste without a significant impact on medical isotope supply. Although we have been considering other technical approaches to Phase 2, timing has been somewhat delayed as key resources are focussed on resolving significant licensing issues on the MAPLE reactors.

In Australia LEU is used to make molybdenum-99. The volume of product is about 2% - 3% of MDS Nordion's volume. The LEU conversion programs that are currently underway in Indonesia and Argentina involve even smaller volumes. There is no demonstrated, qualified, large scale, commercial process for production of medical isotopes produced from LEU targets. In fact, the production and supply of medical isotopes by these producers to their local regions, using LEU target technology, is estimated to be in the order of one percent of the world's requirement.

Canada, through the MDS Nordion-AECL supply partnership, has made a significant contribution to converting isotope supply to LEU technology. The NRU reactor and processing facility, owned and operated by AECL, has been converted to LEU fuel. The MAPLE reactor and New Processing Facility, that will be owned by MDS Nordion and operated on our behalf by AECL, will also utilize LEU fuel. The critical conversion challenge is the development and implementation of the technology for reliable production and processing of commercial quantities of medical isotopes from LEU targets. Today, this technology is not available on a demonstrated, large-scale, commercial basis, in spite of the several co-operative initiatives that have been underway; this technology is, at best, at the experimental or inception stage.

The NCI have stated that if MDS Nordion were to cease supply of molybdenum-99 that there is currently excess global production capacity for medical isotopes and other producers quickly could make up the difference. This is incorrect. Withholding HEU exports to Canada for medical isotope targets will disadvantage patients by creating a shortage of these life critical products.

Yours truly,



Grant Malkoske
Vice-President
Engineering & Technology
MDS Nordion

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