THE LEU TARGET DEVELOPMENT AND CONVERSION PROGRAM FOR THE MAPLE REACTORS AND NEW PROCESSING FACILITY

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25th International Meeting on Reduced Enrichment for Research and Test Reactors
October 5-10, 2003, Chicago IL., USA

ABSTRACT

The availability of isotope grade, Highly Enriched Uranium (HEU), from the United States for use in the manufacture of targets for molybdenum-99 production in AECL's NRU research reactor has been a key factor to enable MDS Nordion to develop a reliable, secure supply of medical isotopes for the international nuclear medicine community. The molybdenum extraction process from HEU targets is a proven and established method that has reliably produced medical isotopes for several decades. The HEU process provides predictable, consistent yields for our high-volume, molybdenum-99 production. Other medical isotopes such as I-131 and Xe-133, which play an important role in nuclear medicine applications, are also produced from irradiated HEU targets as a by-product of the molybdenum-99 process.

To ensure a continued reliable and timely supply of medical isotopes, MDS Nordion is completing the commissioning of two MAPLE reactors and an associated isotope processing facility (the New Processing Facility). The new MAPLE facilities, which will be dedicated exclusively to medical isotope production, will provide an essential contribution to a secure, robust global healthcare system. Design and construction of these facilities has been based on a life cycle management philosophy for the isotope production process. This includes target irradiation, isotope extraction and waste management. The MAPLE reactors will operate with Low Enriched Uranium (LEU) fuel, a significant contribution to the objectives of the RERTR program. The design of the isotope production process in the MAPLE facilities is based on an established process – extraction of isotopes from HEU target material. This is a proven technology that has been demonstrated over more than three decades of operation. However, in support of the RERTR program and in compliance with U.S. legislation, MDS Nordion has undertaken a *LEU Target Development and Conversion Program* for the MAPLE facilities.

This paper will provide an overview progress on the Conversion Development Program, and further discuss the challenges in converting the MAPLE facilities to molybdenum production from LEU targets

1. Introduction

One of the most satisfying aspects of the new MAPLE facilities is being associated with the benefits that our products bring to people – the patients who receive vital nuclear medicine procedures derived from our medical isotopes. Radiopharmaceuticals, based on medical isotopes, are used to determine the severity of heart disease, the spread of cancer, and the diagnoses of brain disorders. MDS Nordion isotopes are used in about 35,000 of the 45,000 nuclear medicine procedures performed everyday around the world.

There are over 100 medical applications for radioisotopes and some 80% of nuclear medicine procedures rely on just one isotope, molybdenum-99. Moreover, some of these procedures are performed using medical isotopes that we have supplied as soon as 41 hours after leaving the NRU reactor. This is a real just-in-time business. As the radioisotope decays, MDS Nordion must get the product to the customer as quickly as possible. This is a global endeavor. For example, when we consider the hospitals that depend on this supply each week, there are some 5000 in North America, about 850 in Germany and in Japan, over 1000 hospitals.

MDS Nordion's medical isotope business is also providing an exciting new platform in radioimmunotherapy. For example, novel ways are being developed to use radioisotopes to treat disease, such as for non-Hodgkin's lymphoma, a blood-borne cancer. This exciting platform will expand the horizon for applications of medical isotopes. Radioimmunotherapy ensures radiolabelled monoclonal antibodies directly target cancerous tumors to provide the most effective treatment possible.

Ultimately, the MAPLE story, with its planning, construction, commissioning and operation, is about securing the supply of medical isotopes required by the international nuclear medicine community, and, ultimately, the thousands of patients who expect to receive their daily medical procedures.

2. The MAPLE Facilities – Securing the World Supply of Medical Isotopes

Why build the MAPLE facilities?

There are compelling reasons to build the MAPLE facilities. MDS Nordion supplies the majority of the world's isotopes. Notably today molybdenum-99 is the most extensively used isotope. However, new medical techniques are providing opportunities for iodine-131, and the utilization of iodine-125 and xenon-133 are growing.

Molybdenum-99 supply in the pre-1980 era was supported by four capable suppliers: Cintichem and GE in the United States, IRE in Belgium, and MDS Nordion in Canada. MDS Nordion obtained our medical isotopes in the NRU and NRX reactors, owned by AECL. For various reasons, a number of these reactors were shutdown. This caused the global nuclear medicine community to have serious concerns about supply reliability, which was created by the shutdown of these reactors, as there was no viable backup supply to meet global need for medical isotopes.

To fulfill our obligation to our customers and patients using our products, MDS Nordion took specific steps to address concerns the nuclear medicine community had about the long term, secure supply of molybdenum-99. In 1996 MDS Nordion and AECL announced an agreement

to construct two MAPLE reactors and a high volume, commercial, first stage processing facility at AECL's Chalk River Laboratories. MDS Nordion will own the reactors and processing facility and be responsible for managing the business and developing the isotope production planning activities. AECL has been contracted to design, build, and operate the facilities on behalf of MDS Nordion. The MAPLE reactors will be the only reactors in the world totally dedicated to the large-scale commercial production of medical radioisotopes. The New Processing Facility contains five hot cells and a new waste solidification system to ensure isotopes are extracted and process waste managed in an environmentally acceptable manner.

What are the MAPLE Facilities?

The MAPLE facilities are production facilities that will ensure reliable and economic availability of radioisotopes to hospitals and clinics worldwide.

The MAPLE facilities consist of two reactors and a processing facility to extract isotopes and manage the process waste. Figure I shows the MAPLE reactors and the New Processing Facility (NPF) building. The photograph also shows the NRU reactor in the background and the NRX reactor, which was shutdown in 1992, to the right foreground in the photograph. The NRU reactor is on the right, at the back.

Figure 1: MAPLE reactors and New Processing Facility

The MAPLE reactors are 10 MW, open pool, light water reactors, designed for the sole purpose of producing medical isotopes. Figure 2 shows a cross section of the MAPLE reactors. The reactor has a compact core that is surrounded by heavy water reflector tank. The core is about 400mm in diameter and 600mm high. The reactor assembly consists of five major components: the inlet plenum; the grid plate; the core structure consisting of vertical flow tubes containing low enriched uranium (LEU) driver fuel bundles and high enriched uranium (HEU) target assemblies for medical isotope production; the heavy water reflector tank; and the chimney. The light water primary coolant enters the inlet plenum, flows upward through the grid plate, the flow tubes and fuel and target assemblies, and is directed back to the suction of the primary cooling pump via the outlet arms of the chimney.

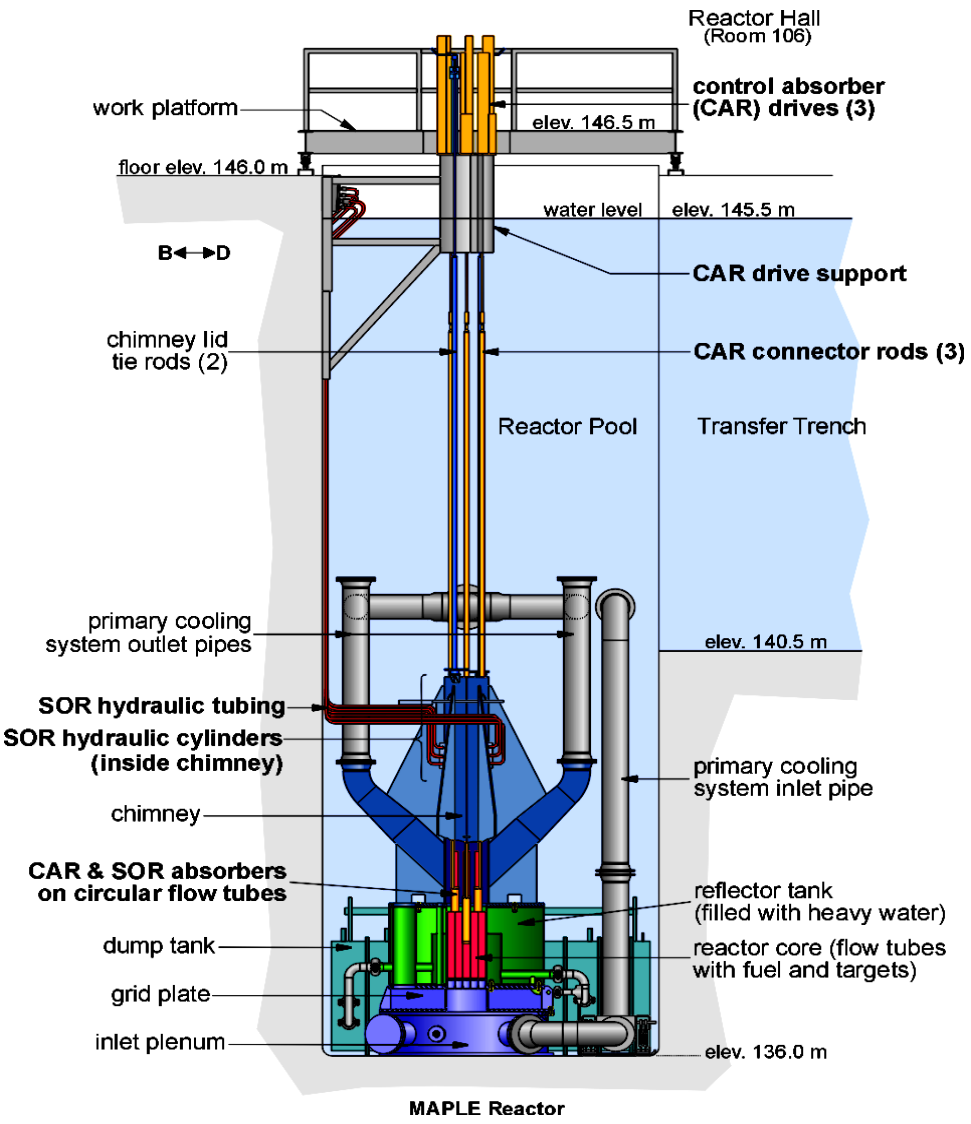

Figure 2: MAPLE Reactors (SOR = Shut-off Rod, CAR = Control Absorber Rod

Figure 3 shows the MAPLE reactor core during low-power commissioning. The core is composed of 13 hexagonal and six circular flow tubes. Four of the 13 hexagonal flow tubes are used for irradiating HEU targets; the remaining nine contain 36 element LEU driver fuel assemblies. The six circular flow tubes contain 18 element driver fuel assemblies. A heavy water reflector surrounds the core and contains irradiation sites for the production of iodine-125 from xenon-124 gas. The MAPLE reactors and the isotope processing facility are licensed to irradiate and process HEU targets to produce the following medical isotopes as fission products of uranium-235: molybdenum-99, iodine-131 and xenon-133.

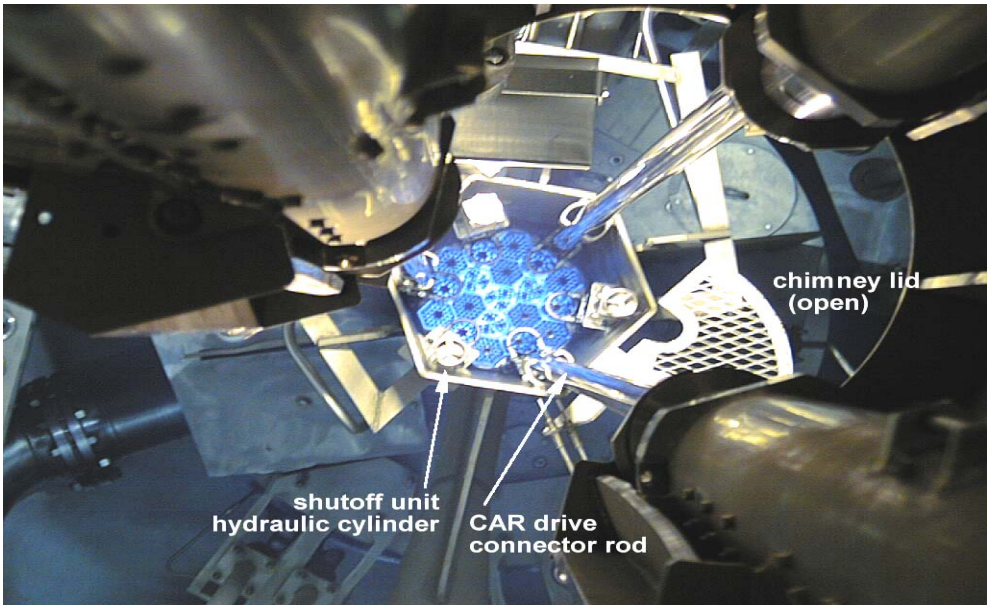

Figure 3: MAPLE Reactor Core (CAR = Control Absorber Rod)

HEU targets irradiated in the MAPLE reactors will be transferred in shielded containers to the processing facility for isotope extraction. The New Processing Facility will extract the radioisotopes produced in the HEU feedstock target material, process the residuals, and transfer the product to containers for shipment to MDS Nordion's Ottawa facility. The radioactive waste from the extraction process will be solidified within the processing facility and transferred to the waste management area on the Chalk River site for storage in concrete canisters. Figure 4 shows the concrete canisters used to store the solid waste. One canister is sufficient for storing waste from about 3 years isotope production with HEU targets.

Figure 4: Canisters for storing waste from isotope production.
(Note: Canisters in the background are used for storing spent reactor fuel.)

In Ottawa, the isotopes are further processed, packaged, and distributed to MDS Nordion's nuclear medicine customers around the world. The timeline from start of target processing to product delivery to the hospital can be as little as 41 hours.

Overall, completion of the MAPLE project was planned to be about fifty months in duration. These new, one-of-a-kind facilities had several challenges to meet during the execution of the project. Advanced technology, a new licensing environment and a compressed schedule created challenges in licensing, design, construction and commissioning. Construction of the facilities had to take place on a crowded site. Existing buildings had to be removed and the ZEEP reactor had to be decommissioned and dismantled**.**

The project, which started in 1996, has been delayed by technical issues related to these one-of-a-kind facilities. The project is to be completed in 2004.

3. Converting the MAPLE Facilities to LEU Targets

Our view is that significant progress has already been made by MDS Nordion to examine technical challenges that must be overcome to convert our facilities to LEU based material. Specifically, based on previous experience with NRU, the MAPLE reactors were designed to operate with LEU fuel, thus achieving a significant contribution to conversion from HEU to LEU. This makes MAPLE unique at this point in time, as it is the only reactor we know of dedicated solely to medical isotope production that uses LEU fuel. The leadership taken by AECL and MDS Nordion to use LEU fuel in the MAPLE reactors for commercial production of medical isotopes is a substantial accomplishment in the Reduced Enrichment for Research and Test Reactors (RERTR) program.

HEU target technology is an integral part of the reactor operating system and target conversion raises additional complex issues. The technology for production of large quantities of molybdenum-99 from HEU targets is based on a reliable process that has been proven for some thirty years in reactors operated by commercial isotope producers. Predictable, consistent yields of molybdenum from HEU targets are the foundation for a reliable supply of medical isotopes. Furthermore, all of the requisite licensing has been approved by the Canadian nuclear regulator and by health care regulators such as the U.S. Food and Drug Administration (FDA), and European national authorities. These links provide a secure chain of medical isotopes for the international nuclear medicine community. For this reason, the medical isotope production process for the MAPLE facilities is based on the well established technology of using HEU targets clad in zirconium alloy. The essential criteria for medical isotope supply are summarized in Table 1.

Table 1: Essential Criteria for Medical Isotope Supply

- Reliable and continuous product flow
- Proven quality and product characteristics
- Predictable and consistent product yields
- Economical supply and timely delivery
- Meets all regulatory requirements

⇒ patient healthcare needs must be met every time, all the time

In addition to the foregoing, each operator must address their unique conversion challenges when considering a switch to LEU technology. These include considerations such as the viability and availability of LEU technology for large-scale continuous isotope supply, regulatory approvals, environmental stewardship, supply continuity during changeover, and economic impact on the business. In other words a thorough risk benefit assessment must be done to ensure obligations to the patient community continues to be met.

All of these factors were considered when MDS Nordion established our three-phase *LEU Target Development and Conversion Program*, comprised of Initial Feasibility Study; Conversion Development Program; and Conversion Implementation Program.

In our case, it was important to understand that the *LEU Target Development and Conversion Program* must be accomplished with minimum change to the MAPLE reactor design and operation, as well as the downstream processing and waste management systems, all of which have been designed, licensed and built based on HEU target technology. Also, it is paramount that medical isotope production capacity must be maintained to ensure continuity of supply as well as sufficient production capability to meet increases in market demand. Lastly, conversion must be economically feasible. To meet the first two conditions, we decided that the same number of targets would be used, in the reactor core but the mass of uranium in each LEU target would be 4.7 times greater than each HEU target. The processing facility must be able to handle the increased uranium mass from the LEU targets and achieve acceptable performance characteristics in the areas of uranium dissolution, molybdenum-99 recovery yields, waste solidification and waste storage. Any incremental operational burden placed on the isotope production and processing system must ensure that the rigorous equipment preventative maintenance program for these facilities is not compromised.
The Phase 2 Conversion Development Program will be completed with an assessment of the technical and economic feasibility of proceeding with the Conversion Implementation Program.

4. The Phase 1 Initial Feasibility Study

The Phase 1 Initial Feasibility Study yielded significant results. A conceptual design for a LEU target for the MAPLE reactors was produced. It was determined that operation of the MAPLE reactors with LEU targets is technically feasible, although there are Canadian nuclear regulatory conditions that must be met before LEU targets can be entered into the reactors. For example, 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 test on LEU targets. It is expected that completion of the nuclear licensing and environmental assessment process could require a minimum of three years. Furthermore, the drug certification requirements of the FDA and the European national authorities must be satisfied for production of radiopharmaceuticals using molybdenum-99 from a new target source material comprised of LEU.

The situation with the New Processing Facility is more challenging and complex. Once LEU targets would be irradiated in the MAPLE reactors, the targets must be transferred to the NPF for LEU dissolution and isotope extraction. Use of LEU targets will require 4.7 times more uranium to be chemically processed in the NPF to extract a similar quantity of medical isotopes that

would be available from HEU targets. This additional uranium mass must also be processed to solidify the waste in stable form for long-term storage. As the isotope processing hot-cell system and equipment is custom designed and solely dedicated to the processing and extraction of molybdenum-99 from HEU targets, a thorough assessment of the processing facility is required to explore the technical viability of converting to LEU. Facility capacity and throughput capability, combined with waste management and storage system capability have emerged as the key technology issues.

5. Status of the Phase 2 Conversion Development Program

The Phase 2 Conversion Development Program is examining ways to address the two main obstacles to LEU conversion. These are:

- high volumes of solution to separate the molybdenum-99 from the LEU targets because of the greater amount of uranium in solution; and
- approximately five times more uranium mass will be present in the wastes to be calcined.

The Phase 2 program is essentially a waste process development program which is examining the technical, regulatory and economic implications for managing the increased volume of waste arising from processing LEU targets in the NPF. The Conversion Development Program Phase will identify and evaluate improvements to the calcining system capacity and capability to process the LEU targets. The waste processing development program will include the following:

- identify throughput and cycle time improvements to the calcining system and equipment;
- identify possible process improvements in the NPF to reduce the waste arising from processing LEU targets;
- ensure adequate LEU technology is available for large scale, continuous commercial production; and
- examine issues related to implementing LEU technology into the existing facilities without causing a disruption in medical isotope supply.

The Phase 2 Program includes a technology development program, in partnership with ANL, the Société Générale pour les techniques Nouvelles (SGN) and AECL. Although the program was scheduled to be completed at the end of calendar year 2003 some slippage has been experienced that will move completion to the second half of 2004. Good progress has been made in Phase 2 on experimental and development work, examining ways to improve throughput and capacity of the calciner and waste management systems. A photo of typical calcined product is shown in Figure 5.

Figure 5: Calcined Uranium Waste Can

ANL have played a key role in examining various precipitates as a means to improve calcination throughput. The designers of the waste management system, SGN, have examined technologies to improve calciner throughput and processing timeline. Some of the complexities of modifying the existing line are evident from the photo of the calcinations cell and equipment shown in Figure 6. The process system integrators, AECL, are providing their overall expertise to ensure the entire process can continue viably as a full scale, continuous commercial operation on their site at Chalk River.

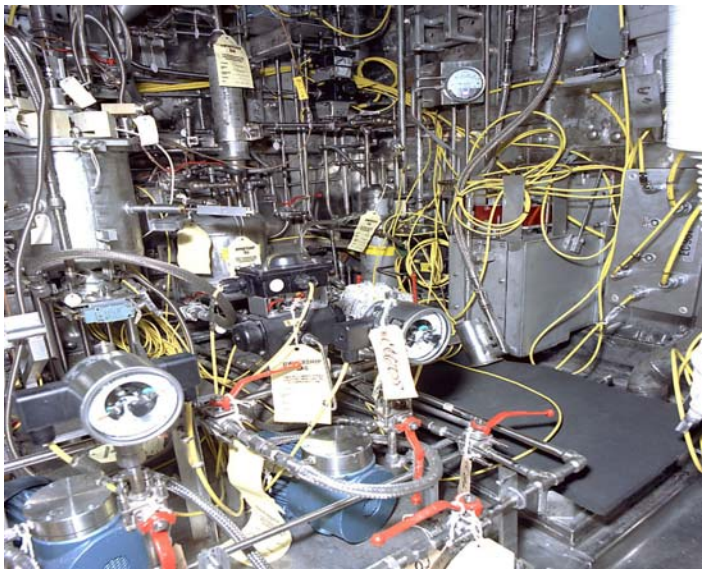

Figure 6: Hot-Cell C4A Calcination

Technical evaluations, bench chemistry, precipitation and calcinations studies have been completed. In Phase 2, technical data on target radionuclide inventory and waste composition from target dissolution was developed. The technical development work also examined several

candidate solution compositions for calcination and precipitation studies. Additional dissolution and molybdenum-99 recovery studies were conducted to establish optimum chemistry conditions and waste composition and volume from dissolution process. Furthermore, a reference set of radionuclide inventory and decay properties of the irradiated LEU molybdenum-99 targets was prepared for use in calcination and precipitation assessments. Work has been done to examine various calcination processes as well as to examine various precipitation methods that could be used to improve the liquid waste solidification process. Facilitated calcination by precipitation is still at an early research stage and will require significant development and testing in the laboratory and pilot-scale levels to determine its viability.

As a result of the studies conducted by the participants in the Phase 2 Program, it has been determined that vitrification is not a viable option and has been dropped from the Program. However, it appears that cementation of additional waste volume produced from the LEU process can be accommodated within the existing design of the NPF.

The Phase 2 Program is approaching the point where preliminary technical information may be available to attain initial views on implement ability, according to the criteria in Table 1 and current legislation.

6. Conclusion

MDS Nordion is fully committed to continue to provide a secure, reliable source of isotopes to the international nuclear medicine community. To comply with the spirit and intent of policy and legislation intended to reduce reliance on HEU material, we continue to believe we have already made a significant contribution to the RERTR Program by using LEU fuel in the MAPLE reactors. Furthermore, we continue to make progress on our *LEU Target Development and Conversion Program.* A key outcome will be the evaluation of the technical and economic feasibility of conversion program options at the end of Phase 2. The option chosen to convert to LEU targets must be both technically and economically feasible, and must ensure the reliable, uninterrupted supply of medical isotopes, particularly molybdenum-99.

In the end, wherever our LEU conversion process leads, MDS Nordion will not lose sight of the fact that there are millions of individual patients that depend on our supply of medical isotopes every year.