**A Submission by the Canadian Society for Senior Engineers**

**to**

**The Expert Review Panel on Medical Isotope Production**

**July 30, 2009**

## What is the CSSE?

**The Canadian Society for Senior Engineers (CSSE) is a Member Society of the Engineering Institute of Canada (EIC), together with nine other Member Societies that represent specific engineering disciplines. The CSSE reflects all engineering disciplines. It has full voting privileges and the opportunity to represent its members within the EIC on national engineering issues. The CSSE is a charitable organization registered by the Canada Customs and Revenue Agency.**

**Among its objectives, the CSSE endeavours to assist in the broad field of engineering education for youth and to maintain an active role in expressing learned opinions, either alone or in concert with other Canadian engineering organizations, on issues of national or regional interest relating to Canadian engineering and multidisciplinary technologies.**

## SUMMARY

**The CSSE has long recognized the fundamental importance of radio-diagnostic and radio-therapeutic medical procedures in the delivery of health care to more than 1.5 million Canadians and to about 40 million citizens of the world annually. In this context, the CSSE is reassured by the decisive actions taken by the Honourable Leona Aglukkaq, P.C., M.P. and the Honourable Lisa Raitt, P.C., M.P. in addressing the current global shortage of medical isotopes. The establishment of the Health Canada Ad Hoc Group to report on "The Lessons Learned from the Shutdown of the Chalk River Reactor", the Canada-inspired call to the Nuclear Energy Agency of the OECD to create an international High Level Group on the Security of Supply of Medical Radioisotopes and other actions taken by the Government of Canada are very encouraging.**

## INTRODUCTION

**Canada's achievements in many fields of endeavour have been recognized world-wide for more than a century, in peacetime and in wartime. In 1898, Ernest Rutherford, later Lord Rutherford, the New Zealand born British physicist-chemist remembered principally as the Director of the Cavendish Laboratory, University of Cambridge, was appointed to the chair of physics at McGill University where his work gained him the Nobel Prize in chemistry in 1908. However, it was during World War II that Canada vaulted into an unprecedented, quadripartite nuclear development alliance with the United Kingdom, the United States of America and the Provisional Government of France beginning with the opening of the Montreal Laboratory in 1942 as part of the Atomic Energy Division of the National Research Council.**

**The Montreal Laboratory's early work was based upon the 1940 – 1942 "experiments" conducted in NRC's Ottawa facilities by Dr.'s George Laurence and Bernard Sargent with a sub-critical assembly of coke, various oxides of uranium and paraffin wax as an external reflector.**

**Within a few years after the cessation of WW II hostilities, Canada became the unquestioned world leader in the production, processing and application of radioisotopes for diagnostic and therapeutic medical purposes.**

**Thanks to the forethought, knowledge and wisdom of an inspired group of British, Canadian, French and American scientists and engineers (including Austrian born Hans von Halban and Russian born Lew Kowarski), a somewhat disparate but nevertheless innately ingenious and powerfully self-motivated group, the design of the NRX research reactor (Nuclear Reactor Experimental) included provision for the production of certain nuclides for military, agricultural, industrial and nuclear medicine purposes, the latter now referred to as "medical isotopes".**

**Canada's achievements in nuclear science, and in nuclear medicine and materials science in particular, advanced rapidly following the July 22, 1947 "initial approach to criticality" of NRX. One of the milestones in this series of achievements was the 1994 award of a Nobel Prize to Dr. Bertram Brockhouse for physics experiments that he conducted in NRX and NRU in the 1950s and 1960s. The "neutron scattering" technology originated by Dr. Brockhouse is now an essential tool in the development and production of advanced materials for use in aerospace, automotive, manufacturing, medical (prostheses) and other applications.**

**The first radioisotopes for medical purposes produced in NRX were irradiated in "self-serve", horizontally installed facilities and in the in-core "central thimble". Later, engineers designed "tray rods" that were inserted in some of the 198 fuel rod positions, thus permitting much larger amounts of several radioisotopes of much higher "specific activities" to be produced.**

**Canada, and in particular Atomic Energy of Canada Limited (AECL), has produced huge quantities of medical isotopes to meet national and international needs, for more than half a century. The NRU research reactor (first started up in November 1957) backed up by NRX, served this purpose very well until the final shutdown of NRX in 1992. AECL engineers sought a system to replace that worldwide known facility to ensure the reliability of isotope production. Proposals were made, and were turned down due to budget constraints. Eventually, a "low cost" (i.e. "cheap") solution was authorized whereby a small, high neutron flux, reactor named MAPLE would fill the reliability gap.**

**The history of the MAPLE project is long, complex and certainly not disingenuous in its apparent simplicity. Design and construction problems were compounded by major licensing delays. Even today, some very knowledgeable persons argue that a strong case could be made to complete that project (cancelled in May 2008) to provide a significant, long term contribution to the global need for Technetium-99m. There is expertise in Canada necessary to accomplish this challenging task. Currently employed engineers, scientists (physics, chemistry, materials and related fields of science) technologists and technicians and a host of retirees possess this expertise.**

**A very important element in the MAPLE issue is the multiyear, very successful, operation of the HANARO research reactor in the Republic of Korea (ROK). AECL provided much of the SLOWPOKE / MAPLE-based design information to the Korean Atomic Energy Research Institute that KAERI incorporated into the design of HANARO.**

**The ROK is expected by the World Bank to outdistance Canada by 2020 in terms of GNP and to apply for membership in the G 7 + 1. The economy of the ROK is technology-based.**

**The CSSE is well aware that several other options are under consideration; some of which are being actively pursued. The CSSE commends those engaged in pursuing these other options and strongly supports the basic contention that Canada should play her part in providing the solution – by the best available means, quite possibly a multi-pronged approach, based upon sound scientific and engineering principles and practices. The CSSE is confident that "made-in-Canada" solutions can be developed to meet domestic requirements and to form the basis for expanded bipartite and multipartite arrangements with other countries and international organizations. However, the producers of these vital products should not be expected to produce them at a financial loss, as has been the case in the past. A comprehensive, systematic consideration of the alternative options for producing Mo – 99 / Tc – 99m must include the issue of fair pricing of the product delivered to the domestic and international markets.**

**Thus, one of the key elements in pursuing a multi-pronged approach should be a recognition of the importance of ensuring that the price of the product is realistically set at a level moderately above the cost of production thereby providing an incentive to the producers to incorporate the necessary provisions for long-term capacity into their plans for future operations.**

**The establishment by the Government of Canada of a multidisciplinary team of the experts under the leadership of a nationally and internationally recognized Canadian consulting engineering company would constitute a meaningful "next step" in serving the interest of Canadian citizens and the citizens of the world.**

## COLLATERAL INFORMATION

**The international Society of Nuclear Medicine, and with the endorsement of other recognized authorities, has reported that the current shortage of medical isotopes "has left doctors scrambling" and that "the patient community is facing one of its greatest threats in modern times – the lack of access to a reliable, consistent supply of the most important isotopes used in the effective detection and evaluation of patients with cancers, heart and brain diseases and other disorders" due to the shutdown of NRU for repairs.**

**The challenge for Canada is obvious. Leadership is required.**

**Although it is self-evident that continued leadership by Canada in nuclear medicine is clearly required the extent, nature and scope of this vitally important leadership are not well understood by many persons.**

**As noted earlier, the CSSE is reassured by the actions and initiatives taken to date by the Government of Canada, particularly those of the Honourable Leona Aglukkaq, P.C., M.P. and the Honourable Lisa Raitt, P.C., M.P.**

**Clearly, radioisotopes for diagnostic and therapeutic medical procedures are extremely important and recently this fact has become more generally known. Although the NRX (until 1992) and NRU reactors have been major contributors to the supply of medical isotopes throughout the past six decades including most of the Cobalt-60 required for medical teletherapy applications (the first of which went into operation in the Victoria Hospital in London, Ontario, on October 27, 1951) very few persons are aware of the parallel role of CANDU nuclear-electric generating units. These units are the major source of the Cobalt-60 supplied by MDS Nordion Canada to the more than 170 worldwide owners of MDS Nordion manufactured irradiators. The Cobalt-60 is produced in AECL / MDS Nordion designed Cobalt Adjuster Elements of the Pickering A & B, Gentilly 2, Bruce B and Embalse (Argentina) nuclear power stations.**

**Today, over 40% of the world's medical supplies are approved for use after sterilization by Cobalt-60 irradiators manufactured and supplied by MDS Nordion Canada. These medical supplies include surgical kits, gloves, gowns, drapes and cotton swabs. An additional, very important application is the microbial reduction of pharmaceutical raw materials.**

**These are very worthy examples of Canada's nuclear science and engineering contributions to the world.**

## RECENT DEVELOPMENTS

**The combined and coordinated actions of Ministers Aglukkaq and Raitt are indicative of the Federal Government's determination to resolve the challenges posed by the global shortage of medical isotopes. To date, these actions have been both timely and effective. The CSSE is confident that the Federal Government will reinforce these actions as the results of the effort by many persons and organizations continue to emerge and follow-on actions evolve.**

**Health Canada's May 2008 report on "Lessons Learned from the Shutdown of the Chalk River Reactor" is a very instructive document. The CSSE considers the recommendations arising from the many comprehensive analyses upon which the report is based to be quite sound and appropriate to assist in formulating the further actions to be**

**taken by the Government of Canada in fulfilling Canada's obligations to the successful resolution of this global issue. Undoubtedly, the Expert Review Panel will carefully review the Health Canada Report and include in its Report its assessment of the status of the Government's implementation of the recommendations recorded in the Health Canada Report.**

**The Expert Review Panel and the CSSE are well aware that several alternative options to the neutron fission of U-235 for the production of Technetium-99 are being examined.**

**Before commenting on these various options, the CSSE offers the following note regarding NRU.**

**The early return to service of the NRU reactor deserves careful attention. Please remember that the NRU reactor is a research facility. One of NRU's additional functions is the production of medical isotopes. The CSSE has followed very closely the public reports issued regularly by AECL regarding the return to service of NRU. These reports reflect a determination on the part of AECL to return NRU to full operation as soon as safely possible. Recognizing the complexities of this objective, the CSSE considers the return of NRU to service as soon as safely possible to be in the best interest of Canadians and the many other beneficiaries of AECL's operations.**

**One of the very interesting alternative options for the production of Mo - 99 / Tc – 99m, actually a series of options, is that of TRIUMF, one of three preeminent cyclotron-based facilities in the world. With its 500 MeV cyclotron and a number of associated facilities including the Isotope Separator and Accelerator, TRIUMF has indeed triumphed. Its leadership in the proton therapy of eye malignancies and in the development of pion beam therapy for treatment of brain malignancies are standout examples of Canadian contributions to health care.**

**The CSSE has enjoyed a long association with TRIUMF as a result of annual contributions to student awards. As a consequence, several of our members are knowledgeable about TRIUMF's well demonstrated capabilities and its particular interest in pursuing the development of a photo-fission solution using U-238 targets. The CSSE considers this Zero-Enriched Uranium Mo-99 (ZEUM Technology) option to be very**

**worthy of support by the Government of Canada. The CSSE also considers the neutron-capture process on Mo-98 and the photo-neutron process on Mo-100 under study by TRIUMF and its partners to be equally worthy of encouragement by the Government of Canada.**

**Some members of the CSSE have also enjoyed a long association with the McMaster Nuclear Reactor (MNR), beginning with the initial proposal to the Atomic Energy Control Board in 1956 by the University to construct a "pool-type" reactor on the grounds of its downtown Hamilton Campus. During recent years, the MNR has served as a major supplier of Iodine-125 to the Canadian and international medical communities, particularly in the treatment of prostate cancer (60,000 patients per year in Canada).**

**During the June 16, 2009 hearings of the Parliamentary Committee on Natural Resources, a McMaster representative provided information indicating that the MNR could be transformed into a "high-volume isotope producer" at a cost of about $30 million over five years. At the time of this submission the CSSE is awaiting the receipt of substantive information about the McMaster proposal.**

**Another interesting development, albeit very preliminary, was the July 8, 2009 announcement by Premier Brad Wall that the Government of Saskatchewan and the University of Saskatchewan had entered into a partnership agreement to pursue the construction of a nuclear research reactor in Saskatoon that would be used, inter alia, to produce medical isotopes while also serving as a facility capable of enabling Saskatchewan to conduct a broad program of basic research. Although preliminary, the Saskatchewan announcement merits careful consideration recognizing the pioneering and very significant nuclear science and engineering contributions of the Province and particularly the University of Saskatchewan and its graduates.**

**The previously mentioned Cobalt – 60 teletherapy unit installed at Victoria Hospital, London, Ontario, for cancer treatment was developed and supplied by Eldorado Mining and Refining Limited's Chemical Division in Ottawa (now MDS Nordion). However, Dr. Harold Johns, of the University of Saskatchewan, and two of his graduate students Sylvia Fedoruk (later the Honourable Sylvia O. Fedoruk, former Lieutenant Governor of Saskatchewan) and Gordon Whitmore (later Dr. Gordon**

**F. Whitmore of Princess Margaret Hospital renown) shortly after demonstrated a competitor Cobalt – 60 teletherapy unit. Currently, the Saskatchewan Research Council operates a 20Kwt SLOWPOKE research reactor, designed and supplied by AECL, at its Saskatoon Centre.**

**Finally, as stated earlier, there are a number of options being pursued for a "made-in-Canada" solution to the shortage of medical isotopes. One of these is an initiative by Cuttler and Associates Inc. to produce Mo – 99 / Tc – 99m in CANDU nuclear-electric generating stations. The CSSE is currently monitoring this interesting possibility.**

## CONCLUSIONS

**There are several promising options for resolving the shortage of medical isotopes in Canada and the world community. Regardless of the set of solutions pursued, the sine qua non of a reliable, sustainable supply will be a realistic pricing of the products. Continued subsidization by Canadians (taxpayers) of the supply of medical isotopes should be a "non-starter" in governing future operations.**

**After reviewing information presently available regarding these various options, the CSSE herewith submits its ad interim recommendations.**

## RECOMMENDATIONS

**The Government of Canada should:**

- **establish a multidisciplinary, federal – provincial – territorial oversight advisory committee to monitor the progress of Canada's actions in resolving the challenge of the shortage of medical isotopes;**

- **invite proposals from Canadian consulting engineering companies to undertake a multidisciplinary technical assessment of the Expression of Interest responses received by the Expert Review Panel and, based upon this assessment, submit a proposal for overseeing the four, perhaps five, most realistic alternatives to be**

**financially supported by the Government of Canada (taxpayers) and others;**

- **support the early return to service of the NRU research reactor at Chalk River;**

- **support the Zero – Enriched Uranium - Mo – 99 (ZEUM), the Mo – 98 neutron-capture, and Mo – 100 photo-neutron processes being pursued by TRIUMF;**

- **support a re-examination of the MAPLE project;**

- **continue consultations with the Canadian Association of Nuclear Medicine (CANM) and other national and international authorities (particularly the "High Level Group on the Security of Supply of Medical Isotopes" of the Nuclear Energy Agency of the OECD).**

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