

September 9, 2009

**TO: Expert Review panel**  
**FROM: Canadian Association of Nuclear Medicine (CANM)**  
**RE: Recommendations regarding the supply of medical isotopes**

The Canadian Association of Nuclear Medicine was founded in 1971. The CANM is the national voice of the Nuclear Medicine Physicians across Canada and the two million patients that they serve every year.

Since the first dramatic shutdown of the NRU reactor in December of 2007, the Canadian Association of Nuclear Medicine (through its President and other members of our association) has worked relentlessly on the Ad Hoc Health Experts Working Group constituted by the Ministry of Health to mitigate the effect of the isotopes shortage on the well being of Canadians.

In May of 2008, the Ad Hoc Health Experts Working Group on Medical Isotopes published and submitted to the Ministry of Health a report detailing the lessons learned from the December 2007 shutdown of the NRU reactor. In that report, the Working Group emphasized the need to:

1. Ensure efficient and effective communication with the medical community and the public.
2. In decision-making, ensure a balance between the health and safety of the public and the health outcomes of individual patients.
3. Assure appropriate physician participation and input into the decision-making process.
4. Establish a clear and appropriate alignment of authority and accountability for the management of medical radioisotopes supplies.

Among other recommendations, our working group also proposed that the Government of Canada:

1. Secure a “made-in-Canada” solution for the supply of isotopes particularly Molybdenum and Technetium 99m by expeditiously commissioning the Maple I and II reactors.
2. Work with its international partners to review global capacity to produce medical isotopes, encourage the development of international protocols, and remove current barriers or obstacles to international movement of radioisotopes during periods of shortages.
3. Actively engage in developing and approving other medical isotopes technologies such as Positron Emission Tomography (PET) which could very effectively mitigate shortages of reactor produced isotopes.

On May 16, 2008, and while we were finalizing our report in open consultation with Health Canada, the Federal Government made the unilateral decision and announcement to abandon the Maple I & II reactors project to produce medical isotopes.

In December 2008, in a letter to Minister Raitt, the CANM stated that “over the past half century Canada has developed an unprecedented expertise in the production of medical isotopes in the world and that the ongoing isotopes crisis represented a unique opportunity for Canada to export its “savoir faire” beyond its border, reaffirm its prominence and leadership in the world and to improve the Canadian health care system”.

Upon the May 18<sup>th</sup> announcement that the NRU reactor had to be shutdown again for 1 month due to a leak, the CANM expressed major concerns regarding the ability of its members to deliver 21<sup>st</sup> Century Medicine to the Canadian citizens with diagnostic and therapeutic tools from the 20<sup>th</sup> century.

The CANM also advised that Canada was not only loosing credibility on the international scene to procure, as promised more than a decade ago, 50% of medical isotopes to the rest of the world but that Canada was also jeopardizing the present and future of its own superb Canadian Nuclear Industry.

With the chronic and drastic shortage of technetium 99m, the Nuclear Medicine Community in Canada has now to fall back on the use of medical isotopes from the 20<sup>th</sup> century and structural Radiology imaging tools rather than functional diagnostic tests to diagnose and treat their patients and that Canadians still do not have widespread access

to the worldwide proven alternative Positron Emission Tomography technology and its numerous physiologic isotopes.

The absence of availability of the PET technology and isotopes in Canada singularly contrasts with the situation in Western Europe where PET has been available routinely in clinical practice since 1990. PET's widespread use is in Western Europe, the United States of America, numerous South American countries, Japan, China, Taiwan, India, and the Middle Eastern Countries. When considering the nuclear medicine technologies and isotopes available to its citizen, Canada is now seen by our international colleagues as a third if not a fourth world country.

Upon successful graduation from Medical School and before licensing by the medical regulatory bodies, all physicians across the world must take the Hippocratic Oath to practice their Medical Art. By taking the oath, we swear to practice and prescribe to the best of our ability for the good of our patients, and to try to avoid harming them and to keep the good of our patients as the highest priority.

On behalf of the CANM organization I would like to reaffirm the unequivocal commitment of the CANM to MEDICAL CORRECTNESS and the procurement to the Canadian Citizen of the very best Nuclear Medicine diagnostic and therapeutic procedures available in the 21<sup>st</sup> century.

Based on an average of more than 20 years of nuclear medicine practice per member and a total of more than 600,000 years of worldwide physician experience and expertise in the field of nuclear medicine, the CANM would like to recommend to this committee and the Government to urgently consider that:

1. The decision to abandon the Maple I & II reactors to produce medical isotopes be immediately and thoroughly revisited by an international experts panel and that the conclusions of the panel be released to the public and medical organizations.
2. The Federal Government, through Health Canada, expeditiously approved the use of the Positron emitting isotopes and their radiopharmaceuticals; specifically 18F-Fluorodeoxyglucose, 18F-Sodium Fluoride, 13N-Amونيا, the strontium 82 and germanium 68 generators and their rubidium 82 and gallium 68 daughters isotopes as well as, the therapeutic isotopes Yttrium 90 and Lutetium 177 and their radio-labelled pharmaceuticals based 1) on the preclinical and clinical trials performed in Europe and the United States and 2) the criteria established by the United States and the European Union Regulatory agencies for the safe clinical use of these radio-isotopes.

3. For a period of 5 years, the Federal Government work with the Provinces and Territories to support and subsidize the recent increase of Technetium 99m cost imposed by the manufacturers and distributors and the cost of the deployment and implementation of the Positron Emission technology and its radiopharmaceuticals across Canada.
4. The Ministry of Natural resources and Health Canada work formally and expeditiously with the relevant medical organizations rather than rely on expert individuals and establish rapidly the processes to implement these recommendations.

In addition to the deployment of PET in Canada and in order to mitigate the chronic and drastic shortage of technetium, the CANM also believes that a short, middle and long term and immediately implementable solution is the use of newer gamma cameras that use solid state crystals detectors (cadmium zinc telluride-CZT detectors) and resolution recovery software. These new and clinically available technologies reduce by a factor of 2 the amount of technetium 99m needed to perform the nuclear medicine procedures and the radiation exposure to the patients and personnel. To accomplish this a Nuclear Medicine equipment fund will have to be established to allow Clinics and Hospitals to replace older equipment with more modern and efficient equipment and software.

As stated in our letter to Minister Raitt last December, the CANM strongly believes that the current challenges still represent a unique opportunity for Canada to salvage its nuclear technology and industry, to reaffirm its leadership and prominence in the world and to update the Canadian Health Care system with 21<sup>st</sup> century Nuclear Medicine diagnostic and therapeutic tools that Canadians deserve.

The Canadian Association of Nuclear Medicine would like to reiterate its offer to provide its ongoing support, experience, expertise and testimony to achieve these goals.

Respectfully, on behalf of the Canadian Association of Nuclear Medicine,

Jean-Luc Urbain, M.D., Ph.D., FRCPC  
President, CANM

Norman Laurin, M.D., FRCPC  
Vice-President, CANM

Peter Hollett, M.D., FRCPC  
Immediate Past-President, CANM

Christopher O'Brien, M.D., FRCPC  
Past-President, CANM  
President, OANM

Francois Lamoureux, M.D., M.Sc., FRCPC  
Past Vice-President, CANM  
President AMSMNQ

Al Driedger, M.D., Ph.D., FRCPC  
Past President, CANM  
Chair, CANM foundation