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Oral Presentation

Written submission from the Canadian Nuclear Isotope Council

In the Matter of the

BWXT Medical Ltd.

Application for a Class IB nuclear substance
processing facility operating licence

Commission Public Hearing

June 9, 2021

Exposé oral

Mémoire du Canadian Nuclear Isotope Council

À l'égard de

BWXT Medical Ltd.

Demande pour un permis d'exploitation d'une
installation de traitement de substances
nucléaires de catégorie IB

Audience publique de la Commission

9 juin 2021

April 20, 2021

Senior Tribunal Officer, Secretariat
Canadian Nuclear Safety Commission
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Re: BWXT Medical Ltd. Application for a Class IB Licence (June 9-10 Public Hearing)

Dear President and Commission Members,

On behalf of the Canadian Nuclear Isotope Council (CNIC) we are pleased to offer our support for BWXT Medical's application for a Class IB Licence.

The Canadian Nuclear Isotope Council (CNIC) is an independent organization consisting of representatives from various levels within the Canadian health sector, nuclear industry, and research bodies, convened specifically to advocate for our country's role in the production of the world's isotope supply. The CNIC serves as a voice in safeguarding the continued availability of isotopes, ensuring our public policies are risk-informed and science-based, and support the highest levels of public health and safety.

BWXT Medical was a founding member of the CNIC and continues to demonstrate its broader impact by providing its customers, who conduct life-saving medical procedures for patients around the world, the benefit of decades of experience in the development, manufacturing, and delivery of medical isotopes and radiopharmaceuticals.

In Canada and around the world the need for medical isotopes used in modern diagnostic imaging is ever increasing and concerns about an adequate supply to diagnose heart disease and cancer, are also on the rise. BWXT's work in this field through agreements with Ontario Power Generation (OPG) to produce Technetium-99m, demonstrated a critical step forward in ensuring reliable and stable supply of these critical isotopes.

At the same time BWXT Medical continues to contribute to both its local community and the Canadian economy. Since the 2018 acquisition by BWX Technologies, Inc. (BWXT), BWXT Medical has significantly expanded its workforce from approximately 120 to approximately 200 skilled professionals. Coupled with this growth is uncompromising industry leading safety from BWXT, operating in one of the most highly regulated industries in the world, who's number one priority has always been the safety of its employees, members of the public and the environment.

For more than a half-century, Canada has led the way internationally when it comes to the research, development and production of medical isotopes and pharmaceuticals. The world has counted on us and the Canadian Nuclear Isotope Council was established to ensure we continue this role in improving people's lives. BWXT's impact on the medical isotope sector as an experienced manufacturer and supplier of critical medical isotopes and radiopharmaceuticals for research, diagnostic and therapeutic uses, cannot be understated.

Quite simply BWXT Medical's products are relied upon by clinicians and patients all over the world. BWXT Medical's Kanata operations produce and supply:

- Indium In 111 Oxyquinoline: a diagnostic radiopharmaceutical used in the assessment of inflammation and infection. This helps in the assessment of inflammation and infection, for example diabetic foot.



- TheraSphere™ a sterile, active implantable Class III medical device used to treat liver cancer. BWXT Medical is under contract by Boston Scientific Corporation to supply this product; and
- In the very near future will produce Technetium-99m.

In 2018, BWXT announced its innovative technology to produce Molybdenum-99 (Mo-99), the parent isotope of Technetium-99m (Tc-99m) which is used in over 40 million diagnostic imaging procedures every year worldwide to diagnose cancer, coronary artery disease and other adverse medical conditions. Pending approval from FDA and Health Canada, BWXT Medical expects to provide a stable, reliable, long-term supply of Tc-99m - supporting the growing demand for diagnostics across the continent for many years to come. This is transformational leadership for the Canadian isotope sector.

Canada's nuclear industry is among the most highly monitored and regulated industries in the world. BWXT embodies excellence putting the health and safety of its workers as well as the health and safety of the surrounding communities in which it operates the highest priority. BWXT Medical is in full compliance with all regulatory requirements and engages the community through a variety of services such as a dedicated public information website, to ensure transparency and frequent information sharing.

BWXT also distributes, and posts to its website, community newsletters as a tool to share information with the local communities about the company's operational performance, health and safety, activities in the community and general information.

For these reasons, the CNIC is happy to support BWXT Medical's Application for a Class IB Licence. BWXT Medical is an integral part of the Ontario nuclear ecosystem, supporting jobs and prosperity while never sacrificing safety standards.

The CNIC welcomes the opportunity to intervene in this process and wishes to provide its insight through this written submission as well as an oral presentation.

Sincerely,

Andrew Thiele

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