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Oral Presentation

Written submission from Nordion

Exposé oral

Mémoire de Nordion

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

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

Canada

Nordion.
A Sotera Health company

April 30, 2021

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RE: Written Intervention by Nordion regarding BWXT Medical Ltd Application for a Class 1B Licence (June 9-10 Public Hearing)

Dear President and Commission Members,

Nordion is providing this written submission in support of BWXT Medical's application for a Class 1B operating licence at 447 March Rd.

To start, it is first important to review Nordion and the history of the 447 March Rd site. This is because BWXT Medical's application is based on Nordion's robust and successful health, safety, and environmental programs that have been approved and audited for many decades.

Nordion is excited to be celebrating our 75th anniversary this year. This is a significant milestone that speaks to the dedication and sustainability of our business. We have been operating safely at the Ottawa site located at 447 March Rd for over 50 years. Over these years, Nordion historically produced various medical isotopes under two of its business units.

The first business unit is dedicated to the medical isotope Co-60. Co-60 sealed sources are used in industrial irradiators to sterilize food, spices, and single-use medical devices. In the past year, these irradiators have played a key role in the fight against COVID-19 through the irradiation of medical supplies needed by hospitals and the general public to control and reduce transmission of the virus. Co-60 sources are also used to provide precise treatment of challenging cancers, such as inoperable brain cancers, using sophisticated stereotactic radiosurgery devices such as the Elekta GammaKnife.

The second business unit historically has focused on other medical isotopes, including Mo-99, Y-90, I-131, I-123, In-111, and many others over the years. These other medical isotopes are used globally for both diagnostic and therapeutic purposes; they are used to image cancer, heart disease, and other healthcare diagnosis as well as to treat cancer and other diseases.

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The facility at 447 March Rd was designed to allow Co-60 production and other medical isotope production to occur in separate areas of the facility. The area associated with Co-60 production is referred to as Cobalt Operations. The two areas associated with the production of other medical isotopes are referred to as the Nuclear Medicine Production Facility (NMPF) and the Kanata Radiopharmaceutical Manufacturing Facility (KRMF).

Currently, all activities undertaken at the 447 March Rd site, in the Cobalt, NMPF, and KRMF areas, are occurring under Nordion's operating license, number NSPFOL-11A.01/2025.

In 2018, Nordion sold the medical isotopes business to BWXT ITG, now known as BWXT Medical. BWXT Medical purchased the equipment (including hot cells, manipulators, equipment, transport packages, and the like), along with the intellectual property and know how (drawings and procedures) required to produce non-Cobalt medical isotopes. In addition, approximately half of Nordion's historical workforce, those related to the production of other medical isotopes, were transferred to BWXT Medical. Nordion and BWXT have also entered into a long-term lease agreement under which BWXT will lease those portions of the facility dedicated to non-Cobalt medical isotopes production. Nordion continues to own the building located at 447 March Rd.

Nordion has provided several letters to the CSNC staff clarifying Nordion's activities should BWXT Medical obtain a license. To be clear, Nordion's business focus is the production and sale of Co-60 sealed sources. The equipment and know-how relating to the NMPF and KRMF for production of non-Co-60 medical isotopes generally was sold and belongs to BWXT Medical.

In order to ensure the uninterrupted supply of essential medical isotopes, such as Y-90 for liver cancer treatment, Nordion continues to operate and oversee all licensed activities on the site under the Nordion Class 1B licence, while BWXT Medical seeks its own Class 1B operating licence. This framework was put in place after review and approval by the CNSC, and operations on this basis were inspected by the CNSC during an inspection in September 2020.

We are proud to report that the 2020 inspection did not find any instances of non-compliance and recognized that Nordion continued to have full and proper oversight of the facility. However, this oversight framework was only put into place as a transitional mechanism to ensure the continuation of the global supply of much needed medical isotopes. Once BWXT receives their own operating licence, Nordion will focus solely on Co-60 sealed sources, which has been our intention since the 2018 sale.

Nordion fully supports BWXT Medical's application for an operating licence and are confident that BWXT Medical will continue to operate the facility in a manner that ensures the protection of the public and the environment.

Nordion has been safely producing various medical isotopes at this site for many decades. We have developed comprehensive and robust procedures and policies that ensure the

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safety of our employees, contractors, the public, and the environment. These policies and procedures have been reviewed, approved, and inspected by the CNSC over the years and decades. These Nordion policies and procedures governed the business that BWXT Medical purchased and were used by BWXT Medical as the basis for their application for a Class 1B operating license. BWXT has not developed a program from scratch but are building off the Nordion world-class programs already in place.

Although BWXT Medical and Nordion will be operating in different portions of the facility and producing different isotopes, we recognize that we will be two licencees within a single facility. As such, we have developed a framework to jointly manage facility-wide programs, including security, environmental monitoring, and facility emergency response programs. Specifically, a joint Nordion/BWXT EHS committee has been developed. This joint Nordion and BWXT committee will oversee the joint programs and ensure that that the combined licensed activities occurring at 447 March Rd remain more than adequate for the protection of the environment and the public.

BWXT Medical has proposed exciting new projects to ensure a robust supply of Mo-99 in Canada and North America, the key isotope for diagnostic nuclear medicine imaging. The production of Mo-99 is something that has been previously undertaken at this facility. It was a key product for Nordion for many years. Although BWXT's proposed Mo-99 production process does differ somewhat from what was previously done, the basis for BWXT policies and procedures regarding safety and security are taken directly from Nordion's approved and inspected policies and procedures and will be undertaken by the same core team that performed these duties while part of Nordion. These policies and procedures provide every assurance that BWXT's operation will continue to remain safe and ensure the protection of people and the environment.

Looking forward, we expect that BWXT Medical will continue to play a key role in providing critical isotopes used for the detection, assessment, and treatment of cancer and other diseases.

In closing, we fully support BWXT Medical's application for a 10-year license. BWXT Medical's application is built on safety and security programs that have successfully been in place for many years. BWXT Medical will continue the important contributions Nordion started with respect to providing essential isotopes for the wellbeing of people in the community, the province, the country and around the world every day. We ask that you give the ongoing need for these critical isotopes due consideration in your decision.

Sincerely,

Kevin Brooks
President