



**Written submission from
United Pharmacy Partners**

**Mémoire de
United Pharmacy Partners**

In the Matter of the

À l'égard de

BWXT Medical Ltd.

BWXT Medical Ltd.

Application for a Class IB nuclear substance
processing facility operating licence

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

Commission Public Hearing

Audience publique de la Commission

June 9-10, 2021

9 et 10 juin 2021



UNITED PHARMACY
PARTNERS

5400 Laurel Springs • Suite 405 • Suwanee, GA 30024
Phone: 770.205.2651 • Fax: 678.947.9111 • Web: www.uppi.org

Commission Secretariat
Canadian Nuclear Safety Commission

April 29, 2021

Re: BWXT Medical Ltd. Application for a Class 1B nuclear substance processing facility operating license.

[A Notice of Public Hearing on [June 9-10, 2021](#)]

Dear Commission Secretariat:

UPPI LLC. (UPPI) is delighted to have the opportunity to intervene and provide a written comment with respect to BWXT Medical Ltd. Application for a Class 1B nuclear substance processing facility operating license. This comment period involves the notice of public hearing to consider the BWXT application. [We decline to provide an oral presentation.]

UPPI was established in 1998 and is a membership association whose 64 nuclear pharmacy members distribute unit dose radiopharmaceuticals to the nuclear (molecular) imaging community in the United States. UPPI members include independently owned and university or academic-based nuclear pharmacies. Each day UPPI members dispense nearly 8,000 radiopharmaceutical doses to 1,800 hospitals and imaging centers. UPPI customers include VA Hospitals, for-profit and non-profit hospitals, imaging centers and other customers in more than 30 states.

Each weekend, and at times during the week, UPPI members receive Molybdenum 99 (Mo99) generators to prepare physician ordered diagnostic imaging procedures for evaluation of disease and/or its progression. From those Mo99 generators thousands of Technetium 99m (Tc99m) unit doses are prepared and distributed each day.

UPPI has been a stakeholder in the Mo99 conversion effort going back over seven (7) years. In fact, UPPI began, and branded, the **UPPI LEU Walk** in 2013 to help distribute the then scarce supply of non-HEU Mo99 and/or LEU Tc99m doses to hospitals and imaging centers across the country. The effort began with three UPPI members supplying non-HEU (LEU) Tc99m unit doses in 2013 and expanded to 41 UPPI members by the end of 2017. The number is nearly the total pharmacies network at this writing as HEU produced Mo99 finally ends.

UPPI recently participated as the only nuclear pharmacy panelist in the 2021 Nuclear Regulatory Commission Regulatory Information Conference discussion entitled: Making an Impact: Innovation in



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the Production of Medical Isotopes. The topic of supply, supply resilience and distribution of Mo99 was addressed to include new production, newly approved production and the supply chain for the critical medical isotope.

UPPI believes the nuclear medical imaging community will be at risk with supply problems regarding Mo99, which have plagued the industry for many years, without near term solutions. The application of the BWXT Class 1B nuclear substance processing facility operating license and its consideration by the Commission will lead to positive solution to the Mo99 supply in North America with the effect of helping to alleviate supply disruptions in molecular imaging doses to help diagnose disease and the management of care.

Without an adequate supply of Tc99m unit doses from Mo99 generators and other medical radioisotopes, the patient needing the molecular, physiological, imaging study will be referred to a less adequate structural imaging modality or might be regulated to watchful waiting or another less-effective course of diagnosis and treatment.

This letter is an appeal to those who will ultimately make the decision on the operating license to BWXT, the development of a new Mo99 manufacturing source and other medical isotopes which will ultimately benefit the patients requiring molecular diagnostic imaging. Consider looking at the supply chain end-on. Look at it too from the fulfilment of the molecular diagnostic or therapy needs of the **patient** (emphasis implied). BWXT and its medical isotope development and manufacture licensing will build supply chain resilience of essential radiopharmaceuticals and will benefit the patients needing the diagnostic studies.

Sincerely,

A handwritten signature in black ink that reads "John Witkowski". The signature is fluid and cursive, with a large loop at the end of the last name.

John Witkowski
President

Email: john.witkowski@uppi.org



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