



**Oral Presentation**

**Exposé oral**

**Written submission from  
Boston Scientific**

**Mémoire de  
Boston Scientific**

In the Matter of the

À l'égard de

**BWXT Medical Ltd.**

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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**

Wayne Mullett, Ph.D  
Global Director, Supply Chain and Development  
Operations  
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03 May 2021

Senior Tribunal Officer, Secretariat  
Canadian Nuclear Safety Commission  
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P.O. Box 1046, Station B  
Ottawa, Ontario K1P 5S9  
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**Re: BWXT Medical Ltd. Application for a Class IB Licence (June 9-10 Public Hearing)**

Dear President and Commission Members,

My name is Wayne Mullett and I am the Global Director, Supply Chain and Development for Boston Scientific Corporation (BSC). BSC is a manufacturer of medical devices used in interventional medical specialties, including interventional radiology/oncology, interventional cardiology, peripheral interventions, neuromodulation, neurovascular intervention, electrophysiology, cardiac surgery, vascular surgery, endoscopy, urology and gynecology. I work in the interventional oncology division in the BSC Ottawa Office, where I am also the site lead for the facility.

My primary responsibilities as Global Director at BSC is overseeing the supply chain for the TheraSphere™ product. TheraSphere™ is a radiotherapy treatment for liver cancer that consists of millions of microscopic, radioactive glass microspheres being infused into the arteries that feed liver tumors. The product is currently approved by Health Canada (Canada Medical Device License number 67286), the FDA (pre-market authorization #P200029) and an additional 27 other countries across Europe, Middle East, Asia and Australia. Since our first approval by the FDA (Humanitarian Device Exemption H980006) in 1999, we have treated over 35,000 liver cancer patients globally.

I have a very close working relationship with BWXT Medical as they are the contract manufacturing organization (CMO) for the TheraSphere™ product. As a critical supplier for this life extending product, they are responsible for manufacturing and shipping this radiotherapy to treat liver cancer patients all around the world.

In my frequent (near daily) interaction with the staff at BWXT Medical, I can comfortably say they are highly skilled, competent and committed to a safety culture. All activities and decisions are driven by a commitment to the applicable nuclear and health regulatory requirements. BSC is very confident in BWXT Medical's

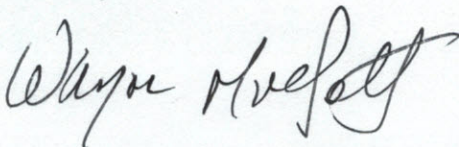
operational capabilities, and beyond routine manufacture, we are presently developing new innovative uses of Therasphere in cancer indications like glioblastoma with BWXT Medical.

At present, the manufacturing of TheraSphere™ at BWXT Medical is providing over 10,000 liver cancer patient treatments per year. Due to the increasing incidence and poor prognosis of liver cancer, physicians are highly reliant on the work being completed at BWXT Medical as they are supplying a product that is extending patients' lives all over the globe. BWXT Medical Technetium-99m Technology will also be a very important additional nuclear medicine as this is a critical isotope for diagnostic imaging procedures, including its combination with macro aggregated albumin (MAA) as pre-treatment surrogate to Therasphere™.

Based on BWXT Medical's strong safety culture, commitment to meeting or exceeding regulatory guidelines and reliable manufacturing for a life sustaining oncology product that positively impacts thousands of patients globally, I believe they should be granted their own 10-year Class IB license.

I am very happy and enthusiastic to support BWXT Medical application for a Class IB license by way of this written intervention letter and oral presentation at the June 9-10 Public Hearing.

Sincerely,



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