CMD 21-H100.21

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Written submission from Boston Scientific

Mémoire de Boston Scientific

In the Matter of

À l'égard de

Application to allow the production of lutetium-177(Lu-177) at the Bruce Nuclear Generating Station (NGS)

Demande de modification de permis visant à permettre la production de lutécium 177 à la centrale nucléaire de Bruce

Public Hearing - Hearing in writing based on written submissions

Audience Publique - Audience fondée sur des mémoires

June 2021 Juin 2021





Wayne Mullett, Ph.D Global Director, Supply Chain and Development Operations Boston Scientific 11 Hines Road Ottawa, ON K2K 2X1

27 May 2021

Senior Tribunal Officer, Secretariat Canadian Nuclear Safety Commission 280 Slater Street P.O. Box 1046, Station B Ottawa, Ontario K1P 5S9 Email: cnsc.interventions.ccsn@canada.ca

Re: Bruce Power Licence Amendment Application (June 25, 2021 Hearing in Writing)

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 at 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 TheraSphereTM product. TheraSphereTM 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 counties 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.

As part of the TheraSphereTM supply chain, we critically rely on reactors to generate medical isotope(s), which are used to extend the life of liver cancer patients. Based on the close proximity of Bruce Power to our manufacturing facility in Ottawa, ON and the outstanding operational reliability and schedule of the reactor, the isotope production system (IPS) being developed at Bruce Power will be a potential game changer for TheraSphereTM manufacturing and other critical medical isotopes. Accordingly, I have started to develop a close working relationship with Bruce Power and we are exploring opportunities to utilize the IPS and power reactor(s) at Bruce Power for the generation of medical isotopes to treat liver cancer patients in Canada and globally.

In my interactions with the staff at Bruce Power, 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 regulatory requirements. BSC is confident in Bruce Power's operational capabilities.

Based on Bruce Power's strong safety culture, commitment to meeting or exceeding regulatory guidelines and potential to provide life sustaining medical isotopes that will positively impact thousands of patients globally, I believe they should be granted the requested amendment licence.

In conclusion, I am very happy to support Bruce Power's licence amendment by way of this written intervention letter.

Sincerely,

Wayne Mullett, Ph.D

Global Director, Supply Chain and Development

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