Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

CMD 26-H110.5

Date: 2026-06-16

Written Submission from ITM Isotope Technologies Munich SE

Mémoire de l'ITM Isotope Technologies Munich SE

In the matter of

À l'égard du

Bruce Power

Bruce Power

Application to change the lutetium-177 production process at Bruce A and B Nuclear Generating Stations

Demande visant à modifier le processus de production de lutécium 177 aux centrales nucléaires de Bruce A et B

Hearing in Writing

Audience par écrit

July 2026

Juillet 2026

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Canada

PASSION FOR PRECISION

June 16, 2026

Ms. Candace Salmon
Commission Registrar
Canadian Nuclear Safety Commission
P.O. Box 1046, 280 Slater Street
Ottawa, Ontario K1P 5S9

Re: Support for Bruce Power's Application to Operate a Hot Cell at the Central Maintenance Facility

(BP-CORR-00531-06949)

Dear Ms. Salmon:

ITM Isotope Technologies Munich SE (ITM) is writing in strong support of Bruce Power's request for Commission approval to operate a hot cell at the Central Maintenance Facility (CMF) on the Bruce Power site, as described in correspondence BP-CORR-00531-06949, dated November 28, 2025.

ITM is a leading radiopharmaceutical company specializing in the development and supply of targeted radionuclide therapies and diagnostics. As the world's largest supplier of lutetium-177 (Lu-177), the company operates contractual supply arrangements with Isogen and maintains a strong strategic relationship with Bruce Power. These collaborations ensure access to high-quality irradiated targets used in the development and production of cancer treatments. A reliable and efficient supply of Lu-177 is critically important to ITM's operations and, ultimately, to the patients who depend on these therapies.

ITM fully supports Bruce Power's proposal to move the removal of the outer target carrier from the Lu-177 ampoule to an on-site hot cell at the CMF. We understand that this activity is currently performed at offsite facilities in Canada, requiring the transport of irradiated targets to multiple locations within Ontario. The ability to complete this processing step on site at Bruce Power represents a meaningful improvement for the following reasons:

- **Radiation Protection and ALARA:** Consolidating processing activities on site directly supports the ALARA principle by reducing the number of individuals and locations exposed to radiation during the handling and transportation of irradiated material to other sites. This is consistent with best practices in nuclear medicine supply chain management.
- **Improved Supply Chain Reliability:** Reducing the number of off-site shipments and processing steps streamlines the supply chain for Lu-177, improving reliability and predictability of delivery timelines. For ITM a reliable and direct supply is essential to ensure a steady supply to patients worldwide.

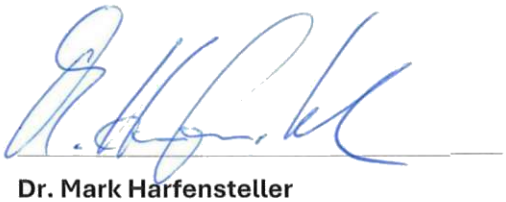
- **Enhanced Safety:** On-site processing within a purpose-built, licensed hot cell environment at the CMF provides robust safety controls that are well suited to the handling of radioactive material. We are confident that Bruce Power's established nuclear safety culture and rigorous regulatory oversight by the CNSC will ensure this operation is conducted safely.

ITM strongly endorses Bruce Power's request for a panel hearing and decision by June 30, 2026. Timely Commission approval is important to ensure uninterrupted progress of the Lu-177 supply program. Any delays in establishing on-site processing capability could affect the efficiency and reliability of the supply chain, with potential downstream impacts on the availability of Lu-177-based therapies for patients and their cancer treatments.

ITM is confident that Bruce Power has the technical competence, safety culture, and regulatory commitment to operate a hot cell safely and in full compliance with its Power Reactor Operating Licence and the requirements of the Canadian Nuclear Safety Commission. We respectfully urge the Commission to give favourable and timely consideration to this application.

Thank you for your consideration of this submission. Should the Commission or CNSC staff require any additional information from ITM in support of this matter, please do not hesitate to contact us.

Sincerely,



Dr. Mark Harfensteller

Chief Operating Officer of ITM

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