



**Written submission from
Isotopen Technologien Muenchen AG**

**Mémoire de
Isotopen Technologien Muenchen AG**

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

Telephone: +49 (0)89 329 8986 600

Email: steffen.schuster@itm.ag

May 20, 2021

Commission Secretariat

Canadian Nuclear Safety Commission

280 Slater Street

P.O. Box 1046, Station B Ottawa, Ontario

K1P 5S9

Public Hearing Ref. 2021-H-100

Dear Commission Secretariat,

The purpose of this letter is to express ITM's support for Bruce Power's application to amend its Power Reactor Operating License (PROL) 18.01/2028 to allow for the production of Lutetium-177 (Lu-177) through the installation and operation of an Isotope Production System (IPS) at Bruce B Unit 7 in partnership with Isogen.

ITM Medical Isotopes GmbH, a subsidiary of ITM Isotopen Technologien München AG (ITM) based in Munich, Germany, and Isogen, a joint venture between nuclear companies Framatome and Kinectrics, have signed a formal supply arrangement to provide a reliable supply of Lutetium-177 to the world's health-care systems using Bruce Power reactors as a key supply source. The arrangement was made possible through Isogen's partnership with Bruce Power, Canada's only private-sector nuclear energy generator, in combination with ITM's know-how in the development of medical radioisotopes, and will ensure reliable, consistent supply of medical radioisotopes for use in Targeted Radionuclide Therapies for cancer patients around the world for the next 15 years.

ITM is a privately owned radiopharmaceutical biotech company founded in 2004. We are dedicated to providing the most precise cancer radiotherapeutics and diagnostics to meet the needs of patients, clinicians and our partners through excellence in development, production and global supply. With patient benefit as the driving principle for all we do, we are actively advancing a broad pipeline that combines our superior radioisotopes with targeting molecules to create precision oncology treatments. We are leveraging our nearly two decades of radioisotope production expertise combined with our established worldwide network to enable nuclear medicine to reach its full potential for helping patients live longer and better.

Medical radioisotopes, and notably Lutetium-177, are increasingly being used in innovative applications such as Targeted Radionuclide Therapies in the treatment of more prevalent cancers such as prostate cancer and Non-Hodgkin's lymphoma, and rare and complex cancer indications such as neuroendocrine tumors, glioblastoma, bone metastases and ovarian cancer. To meet the needs of the growing number of cancer patients, a stable and high-quality production and supply network is critical. Bruce Power and its reactors are a fundamental part of this network.

No-carrier-added (n.c.a.) Lutetium-177, a highly pure form of Lutetium-177, is produced by irradiating Ytterbium-176. The process involves placing Ytterbium-176 source material in special sealed containers that are then conveyed into one of the Bruce Power reactors using the proprietary Isotope Production System (IPS). The Ytterbium-176 is irradiated for about one week and the resulting intermediate Lutetium-177 is then sent to ITM for further processing into highly pure pharmaceutical grade Lutetium-177 for subsequent distribution to health care facilities worldwide.

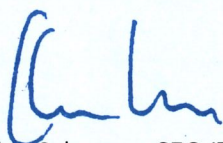
Bruce Power is a critical link in the worldwide network of licensed and expert producers and therefore a lynchpin in this effort to meet patient need. Bruce Power reactors will be relied-upon as a resource

to fulfil the necessary requirements to supply the radioisotope Lutetium-177 on a worldwide basis. It is also important to note that as the demand for this radioisotope grows, the needs cannot be met by research reactors. With our unique international partnership with Bruce Power, we bring together our knowledge for radiopharmaceutical production that is of increasing importance for the treatment of patients across the globe.

In summary, seeing the great progress in the development of the Isotope Production System by Bruce Power and IsoGen, we are confident that this partnership secures another high-quality source of Lutetium-177 for ITM which further increases scalability of our production ensuring a steady supply of n.c.a. Lutetium-177 on a global scale. Our clinical and industry partner's demand for the radiopharmaceutical precursor no-carrier-added Lutetium-177 is constantly growing and as a company we are dedicated to providing our highly pure radioisotope for Targeted Radionuclide Therapy to cancer patients worldwide. We are confident Bruce Power is capable of manufacturing and supplying Lutetium-177 safely and reliably from its Bruce B Unit 7 reactor.

On this basis we whole-heartedly support Bruce Power's application to amend its Power Reactor Operating License to allow for the production of Lutetium-177 through the installation and operation of a Lutetium-177 Isotope Production System at Bruce B Unit 7. If you have any questions or require clarification, please do not hesitate to contact me at +49 (0)89 329 8986 600 or steffen.schuster@itm.ag.

Sincerely,



Steffen Schuster, CEO ITM

ITM Isotopen Technologien München AG

Supervisory Board: Udo J Vetter (Chairman) - Executive Board: Steffen Schuster (Chairman), Thomas Dürre - Registered Office: Garching/Munich District Court of Munich - Commercial Register 154 944 - Phone: +49 (0)89 329 8986 600 - Fax: +49 (0)89 329 8986 650 - Email: info@itm.ag
Tax Number: 143/100/82466 - VAT Number: DE813228901 - Deutsche Bank Freiburg - IBAN: DE52680700300022816300 - BIC: DEUTDE6F