



Supplementary Information

Written submission from Bruce Power

In the Matter of

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

Public Hearing - Hearing in writing based on
written submissions

June 2021

Renseignements supplémentaires

Mémoire de Bruce Power

À l'égard de

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

Audience Publique - Audience fondée sur des
mémoires

Juin 2021

June 3, 2021

BP-CORR-00531-01671

Mr. Marc Leblanc
Commission Secretary
Canadian Nuclear Safety Commission
P.O. Box 1046
280 Slater Street
Ottawa, Ontario
K1P 5S9

Dear Mr. Leblanc:

Bruce A and B: Supplement to the Application
for the Amendment of the Power Reactor Operating Licence

The purpose of this letter is to submit additional information that supports the request in Reference 1 to amend the Power Reactor Operating Licence, PROL 18.01/2028, to include isotope production.

Since the initial application was submitted, it has been determined that the scope of the amendment should be limited to the production of Lutetium-177. Further, the overall process for managing the targets has been further developed, and in particular, the nature of the incoming targets has been more clearly described. Due to the limited resource supply of Ytterbium-176, the supplier will be recycling the Lutetium-177 targets by isolating the remaining Ytterbium-176 and sending it back to Bruce Power for irradiation as a new target. This means the incoming targets will be radioactive and are expected to be at levels near the exemption quantity. Their inclusion in the licensed activity to produce Lutetium-177 is described in further detail in Attachment A.

If you require further information or have any questions regarding this submission, please contact Peter McDermid, Director, Medical Isotopes and Business Development, at 226-930-1551, or peter.mcdermid@brucepower.com.

Yours truly,



Maury Burton
Chief Regulatory Officer,
Bruce Power
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Maury Burton
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cc: CNSC Bruce Site Office
L. Sigouin, CNSC - Ottawa

Attach.

BP-CORR-00531-01671

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Reference:

1. Letter, M. Burton to M. Leblanc, "Application for the Amendment of the Power Reactor Operating Licence", November 25, 2020, BP-CORR-00531-00982.

Attachment A

Supplemental Information for the Bruce A and B Lu-177 Isotope Project

Attachment A: Supplemental Information for the Bruce A and B Lu-177 Isotope Project

1.0 Introduction

This supplemental submission addresses the regulatory requirements for the incoming radioactive Yb_2O_3 targets for the licence amendment application to produce Lutetium-177 (Lu-177).

In order to produce Lu-177, as described in Reference A1, Bruce Power will receive Ytterbium-176 (Yb-176) targets. The description in Reference 1 did not fully explain that the incoming Yb-176 will be recycled by the supplier and thus will also be radioactive.

Bruce Power has a robust Radiation Protection Program, which is applicable both to the radioactive encapsulated incoming targets, and the irradiated outgoing targets. Additional details are provided below with respect to receipt of Yb-176 for purposes of producing Lu-177.

2.0 General Nuclear Safety and Control Regulations

2.1 GNSCR 6(a), Description of the Amendment

GNSCR 6(a): [An application for the amendment... of a licence shall contain the following information:] a description of the amendment, revocation or replacement and of the measures that will be taken and the methods and procedures that will be used to implement it

In the application in Reference A1, Bruce Power proposed amending activity (vi) and licence condition 15.10 to include the production of nuclear substances at Bruce A and Bruce B. CNSC staff subsequently recommended that the activity and licence condition should be specific to the production of Lu-177 (and the currently-authorized production of Cobalt-60).

In order to authorize possession of incoming radioactive targets, Bruce Power proposes the amended licence should include the following:

- Section IV, activity (vi): produce Cobalt-60 and Lutetium-177.
 - possess, transfer, use, package, manage and store nuclear substances associated with the production of Cobalt-60 and Lutetium-177
- Section VI, condition 15.10: the licensee shall implement and maintain a program for the production of Cobalt-60 and Lutetium-177

As the isotope production business expands, Bruce Power may propose a subsequent amendment to authorize the production of other nuclear substances.

2.2 GNSCR 6(b), Statement Identifying Changes

GNSCR 6(b): [An application for the amendment... of a licence shall contain the following information:] a statement identifying the changes in the information contained in the most recent application for the licence

There are no material changes from the last renewal (Reference A2, Attachment A), the last application for amendment (Reference A3) or the current application for amendment (Reference A1).

2.3 GNSCR 6(c): Description of Affected Nuclear Substances

GNSCR 6(c): [An application for the amendment... of a licence shall contain the following information:] a description of the nuclear substances, land, areas, buildings, structures, components, equipment and systems that will be affected by the amendment, revocation or replacement and of the manner in which they will be affected

In order to produce Lu-177, Bruce Power will receive targets Yb_2O_3 , which has been enriched in Yb-176. As supplies of Yb-176 are limited, the incoming targets will consist of recycled, previously-irradiated material.

While the activity of each incoming target will be significantly less than the irradiated outgoing targets, this activity is expected to exceed the exemption quantity defined in the Nuclear Substances and Radiation Devices Regulations (NSRDR).

The dominant radionuclide in the incoming targets is Yb-169, with additional radionuclides having significantly lower activities. The supplier will provide targets with a total activity per target not greater than 600 MBq, as per manufacturing specifications. However, the expectation is that the supplier will allow the targets to decay as long as possible before shipping to Bruce Power.

Both the incoming and the outgoing targets will be in powder form, encapsulated in target carriers (Reference A4).

For each unit with an Isotope Production System, Bruce Power plans to possess up to 300 unirradiated, incoming targets (Yb_2O_3) and up to 174 irradiated, outgoing targets (Lu-177), as shown in Table A1.

The maximum quantity of incoming (Yb-176) targets is based on the amount that can be accommodated in inventory, as per usable design space and storage, prior to being inserted into the Isotope Production System (IPS). The maximum quantity of outgoing irradiated (Lu-177) targets is based on the amount that can be accommodated in the reactor components and storage containers.

Table A1: Nuclear substance overview

Dominant nuclear substance	Form	Maximum Quantity per unit
Incoming radioactive target: Ytterbium-176	Powder form encapsulated in target carrier	300 targets
Outgoing irradiated target: Lutetium-177	Powder form encapsulated in target carrier	174 targets

Bruce Power has a robust Radiation Protection Program that applies to the possession, transfer, use, packaging, management, and storage of the incoming and outgoing targets. BP-PROG-12.05 defines the organizational framework for the management of radiation protection, defines the responsibilities and expectations for individuals to ensure management control over work practices, includes the process for planning radiological work and providing oversight of that work, and defines the process for setting and complying with corporate and regulatory dose limits. It also outlines the verification methods used to confirm, by measurement or observation, that planned results have been achieved. Verification processes are integrated at all levels of radiation protection activities, and the results are used to assess the performance of the program and to identify where improvements are required. With support from BP-PROG-00.02, Environmental Management, radioactive nuclear substances are monitored, the presence of

radiation dose rate is detected and monitored, the spread of radioactive contamination is limited, and the response to radiological incidents is defined.

Bruce Power will follow existing processes for receiving and sending radioactive shipments, as identified in BP-PROC-00188, Radioactive Material Transportation, and BP-RPP-00013, Radioactive Shipments. The incoming targets will arrive at site in a Type A container and will be stored in a locked cabinet. The outgoing irradiated targets will be packaged in Type B(U) container for shipping after being removed from the reactor components.

Please note that incoming and outgoing targets will not be treated as a sealed source pursuant to the NSRDR. A sealed source, as defined by the IAEA, is radioactive material that is permanently sealed in a capsule or bonded and in a solid form. Based on this definition, Bruce Power asserts that the targets do not fit the definition of a sealed source as the encapsulated material is being removed from the ampule after each irradiation cycle. Since the radioactive material is extracted from the ampule after each irradiation, and is not permanently sealed in the quartz ampule, this material will not be treated as a sealed source and thus sealed source requirements from the NSRDR do not apply.

2.4 GNSCR 6(d): Proposed Starting and Complete Date of Modifications

GNSCR 6(d): [An application for the amendment... of a licence shall contain the following information:] the proposed starting date and the expected completion date of any modification encompassed by the application

The installation of the isotope production system is still planned in Unit 7 in 2021 Q4, with production beginning in 2022 Q1.

Decisions with respect to other units and other nuclear substances will be made at a future time, subject to safety, feasibility, and global health demands.

3.0 Conclusion

The information provided in this supplemental submission demonstrates that:

- Bruce Power has provided the relevant information required by regulations under the *Nuclear Safety and Control Act*, as applicable to the amendment of PROL 18.01/2028;
- Bruce Power is qualified to carry on the licensed activities, as described in the *Nuclear Safety and Control Act*, Section 24(4)(a); and,
- Bruce Power will make adequate provision for the protection of the environment, the health and safety of persons, and the maintenance of national security and measures required to implement international obligations to which Canada has agreed, as described in the *Nuclear Safety and Control Act*, Section 24(4)(b).

4.0 References

- A1. Letter, M. Burton to M. Leblanc, "Application for the Amendment of the Power Reactor Operating Licence", November 25, 2020, BP-CORR-00531-00982.
- A2. Letter, F. Saunders to M. Leblanc, "Application for renewal of the Power Reactor Operating Licence", June 30, 2017, NK21-CORR-00531-13493 / NK29-CORR-00531-14085 / NK37-CORR-00531-02768.

- A3. Letter, M. Burton to M. Leblanc, "Request for Amendment of the Nuclear Power Reactor Operating Licence Bruce Nuclear Generating Stations A and B – PROL 18.00/2028", November 11, 2019, NK21-CORR-00531-15378 / NK29-CORR-00531-16213.
- A4. Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotope Project: Final Integrated Safety Analysis Report", February 01, 2021, BP-CORR-00531-01217 (confidential).