



UNPROTECTED/NON PROTÉGÉ

**SUPPLEMENTAL/COMPLÉMENTAIRE**

**CMD: 21-H100.A**

**Date signed/Signé le : 17 JUNE 2021**

Reference CMD(s)/CMD(s) de référence : 21-H100

A Licence Amendment

Une modification de permis

**Bruce Power Inc.**

**Bruce Power Inc.**

**Bruce Nuclear Generating  
Station A and B**

**Centrale nucléaire de  
Bruce A et B**

Hearing in writing based solely on  
written submissions

Audience fondée uniquement sur des  
mémoires

Scheduled for:  
June 2021

Prévue pour :  
Juin 2021

Submitted by:  
CNSC Staff

Soumise par :  
Le personnel de la CCSN

e-Doc 6566942 (WORD)

e-Doc 6581799 (PDF)

**Summary**

This CMD presents supplemental information about the following matters of regulatory interest with respect to Bruce Power Inc.:

- Amendment of the Power Reactor Operating Licence (PROL) for the production of radioisotopes at the Bruce Nuclear Generating Station (BNGS) A and B

The following items are attached:

- The proposed (revised) PROL 18.02/2028
- The draft (revised) Licence Conditions Handbook

**Résumé**

Le présent CMD présente de l'information supplémentaire sur un ensemble de questions d'ordre réglementaire concernant Bruce Power Inc.:

- Modification du permis d'exploitation d'un réacteur nucléaire de puissance (PERP) pour la production de radioisotopes à la centrale nucléaire de Bruce-A et de Bruce-B (BNGS)

Les pièces suivantes sont jointes :

- permis proposé (révisé) – PERP 18.02/2028
- version provisoire (révisée) du manuel des conditions de permis

**Signed/signé le**

17 June 2021

---

Alexandre Viktorov, Ph. D.

**Director General**

Directorate of Power Reactor Regulation

**Directeur général**

Direction de la réglementation des centrales nucléaires

This page was intentionally left blank.

## TABLE OF CONTENTS

<b>EXECUTIVE SUMMARY .....</b>	<b>7</b>
<b>1. OVERVIEW.....</b>	<b>9</b>
1.1 Background .....	9
1.2 Additional clarifications related to the Regulatory Hold Point .....	9
1.3 Incoming targets for the production of Lu-177 .....	10
<b>2. OVERALL CONCLUSIONS AND RECOMMENDATIONS.....</b>	<b>11</b>
<b>REFERENCES .....</b>	<b>13</b>
<b>PROPOSED LICENCE CHANGES .....</b>	<b>15</b>
<b>PROPOSED LICENCE.....</b>	<b>16</b>
<b>PROPOSED LICENCE CONDITIONS HANDBOOK .....</b>	<b>17</b>

This page was intentionally left blank.

## EXECUTIVE SUMMARY

In Commission Member Document (CMD) 21-H100 [1], CNSC staff presented their review of Bruce Power's licence amendment application [2] for the production of Lutetium-177 (Lu-177) at Bruce B Unit 7, including conclusions and recommendations to the Commission. The purpose of this supplemental CMD is to provide:

- Additional clarifications and CNSC staff recommendations related to the regulatory hold point that will be placed on Bruce Power to track completion of identified work activities associated with the installation and operation of the Isotope Production System (IPS)
- CNSC staff's review and recommendations related to Bruce Power's supplemental CMD [3] related to the incoming recycled targets containing Ytterbium (Yb) that will be used in the production of Lu-177

In CMD 21-H100, CNSC staff discussed the regulatory hold point associated with Lu-177 production and its process for release. This supplemental CMD provides an additional detail on where the hold point will be placed, specifically: prior to the turnover of the Isotope Production System (IPS) to the Bruce Power operations staff. The hold point would allow CNSC staff to confirm operational readiness of the IPS for the staged progress from the commissioning phase to the initial operation for the production of Lu-177.

In June 2021, Bruce Power submitted a supplemental CMD [3] indicating that the incoming targets will include recycled targets – predominately Yb-169 with additional radionuclides having significantly lower activities. This aspect had not been addressed in the initial application. The current Power Reactor Operating Licence (PROL) does not allow Bruce Power to possess, transfer, use, package, manage and store the incoming and outgoing targets containing nuclear substances. CNSC staff reviewed the supplemental CMD and concluded that Bruce Power has adequate program in place to possess, transfer, store, etc. nuclear substances associated with the production of Lu-177; Bruce Power will continue to meet radiation protection and transportation requirements. As such, CNSC staff recommend that the Commission also amend the PROL to allow for such an activity (possess, transfer, use, etc. of nuclear substances) specifically for the production of Lu-177.

CNSC staff conclude that these changes do not impact the overall conclusions found in CMD 21-H100, and that:

Bruce Power is qualified to carry out the proposed activity (production of Lu-177), and 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.

This CMD is presented in two parts.

Part One includes:

1. An overview of the matter being presented;
2. Overall conclusions and overall recommendations;

Part Two provides all available information pertaining directly to the proposed licence and the proposed Licence Conditions Handbook.



## PART ONE

### 1. OVERVIEW

#### 1.1 Background

In Commission Member Document (CMD) 21-H100 [1], CNSC staff presented their review of Bruce Power's licence amendment application [2] for the production of Lutetium-177 (Lu-177) at Bruce B Unit 7, including recommendations and conclusions to the Commission. The purpose of this supplemental CMD is to provide:

- Additional clarifications and CNSC staff's recommendations related to the regulatory hold point that will be placed on Bruce Power to track completion of identified work activities associated with the installation and operation of the Isotope Production System (IPS)
- CNSC staff's recommendation arising from a review of Bruce Power's supplemental CMD [3] related to the incoming recycled targets containing Ytterbium (Yb) that will be used in the production of Lu-177

#### 1.2 Additional clarifications related to the Regulatory Hold Point

In Section 4.4 of CMD 21-H100, CNSC staff proposed to use a regulatory hold point to track actions associated with the design, installation and commissioning phases of the IPS project, including its process for release to production. CMD 21-H100 did not provide the detail on where the hold point will be placed (i.e., CNSC staff is not placing a new hold point); this supplemental CMD provides this additional detail, as well as changes made to the proposed draft Licence Conditions Handbook (LCH) in CMD 21-H100. The proposed hold point is not an indication of a safety concern; rather, its purpose would be to confirm operational readiness of the IPS for the staged progress from the commissioning phase to the initial operation of the IPS for the production of Lu-177.

As part of Lu-177 commissioning activities, Bruce Power will need to perform component functional checks such as valve actuation and the use of dummy targets for simulating a target seeding and harvest cycle. These component functional checks can be completed while the unit is offline. Additional commissioning tests will need to be performed once the unit is brought back online, including loading of Yb targets into the core. CNSC staff will verify the completion of these activities as part of the hold point.

Therefore, to confirm that the installation and commissioning activities have been completed and that the IPS has met its design and safety analyses objectives, CNSC staff recommend that the hold point be placed prior to the turnover of the IPS to Bruce Power operations staff. In other words, while Bruce Power will be allowed to load in Yb targets for commissioning tests only, Bruce Power shall not

be authorized to use the IPS to commercially produce Lu-177 until the regulatory hold point has been released.

Once CNSC staff have verified that the IPS has met its commissioning specifications, CNSC staff will follow the proposed process in Section 4.4.3 of CMD 21-H100 for releasing the regulatory hold point, including the recommendation that the Commission delegate its authority for the consent to remove the IPS regulatory hold point to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

Based on the above, the following changes (highlighted in **bold**) have been made to the pre-requisites for the release of the hold point in the revised draft LCH:

1. All licensee commitments **prior to the turnover of the IPS to the operations staff are complete**;
2. Completion of licensee's governing program and **implementing** procedures, **including interfacing procedures for the IPS**;
3. Provision of supporting information related to the safety analysis for the IPS;
4. Completion of Interim Design Manual;
5. Provision of radiation protection committed actions and information; and
6. **Demonstration of the compliance of the commissioning results with the commissioning specifications.**

### 1.3 Incoming targets for the production of Lu-177

In June 2021, Bruce Power submitted a supplemental CMD [3] providing an update related to the Yb targets that will be used for the production of Lu-177. Bruce Power informed CNSC staff in April 2021 that the targets are sourced from a third party company (external from Bruce Power) and that the targets may contain previously recycled radioactive material -- predominately Yb-169 with additional radionuclides having significantly lower activities. The supplier will provide targets to Bruce Power with a total activity per target not greater than 600 MBq, as per manufacturing specifications. However, Bruce Power's expectation is that the supplier will allow the targets to decay as long as possible before shipping to Bruce Power. The incoming targets will be delivered to the Bruce site in a Type A container and will be stored in a locked cabinet, while the outgoing irradiated targets will be shipped out in a Type B(U) container.

The current Power Reactor Operating Licence (PROL) 18.01/2028 only allows Bruce Power to possess, transfer, use, package, manage and store nuclear substances that are required for the operation of Bruce A and B, Class II nuclear facility and industrial radiography. As such, the PROL will need to be amended to allow to possess, transfer, use, etc. of nuclear substances as required for the production of Lu-177.

CNSC staff reviewed the application and concluded that Bruce Power has an adequate program in place to possess, transfer, store, etc. nuclear substances associated with the production of Lu-177. With respect to transport, CNSC staff concluded that Bruce Power will continue to meet the requirements of CNSC *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR

2015) and Canada's *Transportation of Dangerous Goods Regulations* (TDGR) for the transport of the incoming and outgoing targets. The containers used to transport the material meet the applicable requirements of the International Atomic Energy Agency (IAEA) regulations. In addition, CNSC staff concluded that Bruce Power has an adequate radiation protection program in place to ensure that the protection of its workers.

Therefore, in addition to CNSC staff's recommendations in CMD 21-H100 to amend the PROL, specifically, under IV) licensed activities, to allow for the production of Lu-177, CNSC staff are also recommending the Commission to accept the following amendment in **bold**:

(vi) produce Cobalt-60 and Lutetium-177; **and**

- (1) possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities described in (vi).**

The following text will also be added to the LCH:

The Bruce Power licence authorizes the production, possession, transfer, packaging, managing and storage of Lutetium-177. Furthermore, the licence also authorizes the possession, transfer, use, packaging, managing and storage of nuclear substances associated with the production of Lutetium-177: radioactive ytterbium oxide (Yb<sub>2</sub>O<sub>3</sub>) targets. Bruce Power will require up to 300 unirradiated targets in ampules containing Yb-169, with additional radionuclides having significantly lower activities. Bruce Power is authorized to receive ampules of up to the manufacturer's specification of 600 MBq/ampule, which is greater than the Exemption Quantity (EQ).

## 2. OVERALL CONCLUSIONS AND RECOMMENDATIONS

CNSC staff conclude that the changes identified in this supplemental CMD do not impact the overall conclusions found in CMD 21-H100. CNSC staff have concluded the following with respect to paragraphs 24(4)(a) and (b) of the *Nuclear Safety and Control Act* (NSCA), in that Bruce Power:

1. Is qualified to carry on the activity authorized by the licence.
2. Will in carrying out that activity, 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.

In addition to CNSC staff's recommendations to accept the process defined in Section 4.4 of CMD 21-H100 for the release of a regulatory hold point and delegate authority, CNSC staff recommend the Commission to accept the regulatory hold point to be placed prior to the turnover of the IPS to the Bruce Power operations staff. The proposed hold point is not considered to be an indication of a safety concern; rather, it will be established to confirm operational readiness of the IPS for the staged progress from the commissioning phase to the

initial operation for the production of Lu-177. As a result, the following proposed changes have been made to the draft LCH (changes are highlighted in **bold**):

1. All licensee commitments prior to **turnover of the IPS to the operations staff**;
2. Completion of licensee's governing program and **implementing procedures, including interfacing procedures for the IPS**;
3. Provision of supporting information related to the safety analysis for the IPS;
4. Completion of Interim Design Manual;
5. Provision of radiation protection committed actions and information; and
6. **Demonstration of the compliance of the commissioning results with the commissioning specifications.**

CNSC staff also recommend the Commission to amend the PROL to allow Bruce Power to possess, transfer, use, package, manage and store nuclear substances that are required for, associated with the production of Lu-177.

Specifically, in addition to CNSC staff's recommendations in CMD 21-H100 to amend the PROL, CNSC staff recommend the Commission to accept the following amendment to the PROL under IV) licensed activities in **bold**:

(vi) produce Cobalt-60 and Lutetium-177; **and**

- (1) **possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities described in (vi).**

## REFERENCES

1. CMD 21-H100, Request for licence amendment for the production of radioisotopes at Bruce Nuclear Generating Station, April 9, 2021, e-Docs 6411164.
2. Letter, M. Burton to M. Leblanc, “Application for the Amendment of the Power Reactor Operating Licence”, November 25, 2020, BP-CORR-00531-00982, e-Docs 6430874.
3. Letter, M. Burton to M. Leblanc, “Bruce A and B: Supplement to the Application for the Amendment of the Power Reactor Operating Licence”, June 3, 2021, BP-CORR-00531-01671, e-Docs 6578210.

## PART TWO

Part Two provides all relevant information pertaining directly to the licence, including:

1. Any proposed changes to the conditions, licensing period, or formatting of an existing licence;
2. The proposed licence;
3. The proposed licence conditions handbook; and
4. The current licence.

## PROPOSED LICENCE CHANGES

### Overview

CNSC staff have noted that Bruce Power will be utilizing targets in its proposed Lu-177 IPS that contain nuclear substances. Therefore, it is necessary to include a licensed activity statement to authorize this. The proposed addition to the Bruce A and B PROL will be presented in this section of the CMD.

### Licence Conditions

No change to the existing Licence Conditions beyond what is given in CMD 21-H100. CNSC staff propose a change to a licensed activity in the PROL as presented in the table below. Changes from CMD 21-H100 are highlighted in **bold**.

PROPOSED LICENCE CHANGES	
Current PROL	Proposed PROL
IV) LICENSED ACTIVITIES  (vi) produce Cobalt-60 at Bruce B.	IV) LICENSED ACTIVITIES  (vi) produce Cobalt-60 and Lutetium-177; <b>and</b> <b>(1) possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities described in (vi).</b>

### Licence Conditions Handbook

The following text will be added to the LCH (under LC 15.10):

The Bruce Power licence authorizes the production, possession, transfer, packaging, managing and storage of Lutetium-177. Furthermore, the licence also authorizes the possession, transfer, use, packaging, managing and storage of nuclear substances associated with the production of Lutetium-177: radioactive ytterbium oxide (Yb<sub>2</sub>O<sub>3</sub>) targets. Bruce Power will require up to 300 unirradiated targets in ampules containing Yb-169, with additional radionuclides having significantly lower activities. Bruce Power is authorized to receive ampules of up to the manufacturer's specification of 600 MBq/ampule, which is greater than the Exemption Quantity (EQ).

### Licence Format

No change.

### Licence Period

No change.

## PROPOSED LICENCE

The proposed licence (PROL 18.02/2028) is provided in the following references.

Word: e-docs 6411221	PDF: e-docs 6462573
----------------------	---------------------



## PROPOSED LICENCE CONDITIONS HANDBOOK

The proposed LCH (LCH-PR-18.02/2028-R003) is provided in the references.

Word: e-docs 6573485	PDF: e-docs 6462968
----------------------	---------------------