



## Record of Decision

DEC 21-H100

In the Matter of

Applicant Bruce Power Inc.

Subject Application to Amend Power Reactor Operating  
Licence PROL 18.01/2028 for the Production of  
Lutetium-177 at Bruce Nuclear Generating  
Stations A and B

Date of  
Decision September 22, 2021

**RECORD OF DECISION – DEC 21-H100**

Applicant: Bruce Power Inc.

Address/Location: P.O Box 1540, Building B10, 177 Tie Road, Municipality of Kincardine, Tiverton, Ontario N0G 2T0

Purpose: Application to Amend Power Reactor Operating Licence PROL 18.01/2028 for the Production of Lutetium-177 at Bruce Nuclear Generating Stations A and B

Application received: November 25, 2020

Hearing: Public Hearing in Writing – Notice of Hearing in Writing published on January 19, 2021

Date of decision: September 22, 2021

Panel of Commission: S. Mckinnon, Presiding Member

**Licence: Amended**

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## 1.0 INTRODUCTION

1. Bruce Power Inc. (Bruce Power) has applied to the Canadian Nuclear Safety Commission<sup>1</sup> (CNSC), under subsection 24(2) of the [Nuclear Safety and Control Act](#) (NSCA), for an amendment to the Power Reactor Operating Licence (PROL) for its Bruce Nuclear Generating Stations (NGS) A and B, located in the Municipality of Kincardine, Ontario. Bruce Power has requested an amendment to its licence to authorize the production of Lutetium-177 (Lu-177), a medical isotope used for cancer treatment. With regard to radioisotope production, Bruce Power's current licence, PROL 18.01/2028, authorizes only the production of Cobalt-60 at Bruce B. PROL 18.01/2028 expires on September 30, 2028.
2. If the amendment that is sought is made, Bruce Power, in partnership with IsoGen (a joint venture between Kinectrics Inc. and Framatome), plans to install an Isotope Production System (IPS) at Bruce B Unit 7 to produce Lu-177. Bruce Power would be responsible for the irradiation of the targets and Isotopen Technologien Munchen (ITM), an entity licenced in Germany, will handle all other parts of the medical radioisotope supply chain. In the future, if Bruce Power plans to produce radioisotopes other than Cobalt-60 and Lutetium-177 at Bruce A and B, a Commission decision would be required. If Bruce Power plans to produce Lu-177 in a unit other than Unit 7, it would have to demonstrate to the satisfaction of the CNSC that this would remain in accordance with the licensing basis, and have a neutral or positive impact on health, safety, the environment, security, and safeguards.

### Issues

3. The Commission is required to determine whether and what requirements the [Impact Assessment Act](#) (IAA) imposes in relation to the activities sought to be authorized in Bruce Power's licence amendment application.
4. The Commission must determine, under paragraph 24(4)(a) and (b) of the NSCA, whether it is satisfied that:
  - a) Bruce Power is qualified to carry on the activities that the amended licence would authorize; and
  - b) in carrying on that activity, 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.
5. As an agent of the Crown, the CNSC recognizes its role in fulfilling the Crown's constitutional obligations, along with advancing reconciliation with Canada's Indigenous peoples. The Commission's responsibilities include the duty to consult and, where appropriate, accommodate Indigenous interests where the Crown contemplates conduct which may adversely impact potential or established Indigenous or treaty rights.<sup>2</sup> As such, the Commission must confirm whether the duty to consult is engaged by this

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<sup>1</sup> The *Canadian Nuclear Safety Commission* is referred to as the "CNSC" when referring to the organization and its staff in general, and as the "Commission" when referring to the tribunal component.

<sup>2</sup> *Haida Nation v. British Columbia (Minister of Forests)*, 2004 SCC 73; *Taku River Tlingit First Nation v. British Columbia (Project Assessment Director)*, 2004 SCC 74

licence amendment and what engagement and consultation steps and accommodation measures are called for, respecting Indigenous interests.

### Panel

6. Pursuant to section 22 of the NSCA, the President of the Commission established Dr. Stephen D. McKinnon as a Panel of the Commission to consider the licence amendment application. A [notice of hearing in writing and participant funding](#) was published on January 19, 2021. The Commission, in conducting a public hearing based on written materials, considered written submissions from Bruce Power ([CMD 21-H100.1](#), [CMD 21-H100.1A](#), [CMD 21-H100.1B](#)), CNSC staff ([CMD 21-H100](#), [CMD 21-H100.A](#), [CMD 21-H100.B](#)) and 20 intervenors.<sup>3</sup>

### Mandate of the Commission

7. Many intervenors provided the Commission with information and views about the economic impact of Lu-177 production at the Bruce NGS. The NSCA provides the extent of the Commission's statutory authority which does not include an economic mandate and its decisions are not based on economic impact.

## **2.0 DECISION**

8. The Commission is satisfied that an impact assessment under the IAA was not required in relation to the licence amendment.
9. The Commission is satisfied that the duty to consult was not engaged, and finds that the Indigenous engagement activities carried out by CNSC staff in respect of this licence amendment satisfy the fiduciary duty on the CNSC and uphold the honour of the Crown.
10. Based on its consideration of the matter, as described in more detail in the following sections of this Record of Decision, the Commission concludes that Bruce Power satisfies the conditions of subsection 24(4) of the NSCA. Therefore,

The Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the Power Reactor Operating Licence issued to Bruce Power Inc. for its Bruce Nuclear Generating Stations A and B located in the Municipality of Kincardine, Ontario. The amended licence, PROL 18.02/2028, remains valid until September 30, 2028.

11. The Commission amends the licence to authorize the activities related to the production of Lu-177 and includes in the licence the amendment to condition 15.10 as recommended by CNSC staff in CMD 21-H100 and 21-H100.A. The regulatory hold point as described by CNSC staff shall be applied pursuant to condition 15.10 and the Commission authorizes the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch to remove the IPS regulatory hold point to confirm operational readiness of the IPS upon completion of the prerequisites, as recommended by CNSC staff.

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<sup>3</sup> See Appendix A for a list of interventions

### 3.0 APPLICABILITY OF THE IMPACT ASSESSMENT ACT

12. In coming to its decision, the Commission was first required to determine whether the IAA had requirements to be met, including whether an impact assessment of the proposal was required. CNSC staff determined the proposed activities are not captured in the IAA's [Physical Activities Regulations](#) nor are they considered a project on federal lands. Based on the information provided for this hearing, the Commission is satisfied that an impact assessment under the IAA is not required.

### 4.0 ISSUES AND COMMISSION FINDINGS

13. Bruce Power submitted its licence amendment application on [November 25, 2020](#) and supplemented its application on [June 3, 2021](#). In its consideration of this matter, the Commission examined the completeness of the application and the adequacy of the information submitted by Bruce Power, as required by the NSCA, the [General Nuclear Safety and Control Regulations](#) (GNSCR), and other applicable regulations made under the NSCA.
14. The Commission considered a number of issues and submissions relating to Bruce Power's qualification to carry out the activities the licence amendment would authorize. The Commission considered the adequacy of Bruce Power's proposed measures for protecting the environment, the health and safety of persons, national security and international obligations to which Canada has agreed. The Commission also examined CNSC staff's review of the impact of Lu-177 production on all [14 safety and control areas](#) (SCAs) and several other matters of regulatory interest.
15. CNSC staff proposed the use of a regulatory hold point to confirm operational readiness of the IPS prior to the start of Lu-177 production. Bruce Power would finalize a number of documents closer to the commissioning of the IPS, and CNSC staff would review commissioning test results to verify that the IPS meets its design and safety analyses requirements. The use of regulatory hold points is further discussed in Section 4.4 of this Record of Decision.
16. In considering the matter, the Commission posed questions to Bruce Power and CNSC staff, through [CMD 21-H100Q](#), seeking further information. A key consideration by the Commission was the potential effects of a target stuck in the reactor core. The Commission is satisfied with the completeness of the responses provided by Bruce Power ([CMD 21-H100.1B](#)) and CNSC staff ([CMD 21-H100.B](#)) to the questions raised by the Commission.

#### 4.1 Safety and Control Areas

##### 4.1.1 Physical Design

17. Lutetium-177 is produced via the irradiation of Ytterbium-176 (Yb-176). Bruce Power submitted that the IPS design consists of a pneumatic delivery system that will use an inert gas to deliver and retrieve Yb-176 targets into and out of the reactor core during full power operation. The targets consist of Yb-176 powder encapsulated in a sealed quartz

ampule and aluminum carrier. A delivery device outside of containment will be used to add and remove targets. Tubing will connect the delivery device, the gas supply, and the reactor penetration. The targets will be pushed pneumatically through the tubing into a target finger tube, which will be installed within an existing vacant vertical tube assembly in the reactor core. The guide tube serves as the pressure boundary separating the IPS and the reactor's D<sub>2</sub>O moderator.<sup>4</sup> The IPS will be controlled via a local control panel and will not require instrumentation in the main control room. Once irradiated, after approximately seven days, the IPS will transfer the targets into a shielded transport container to be shipped offsite for processing.

18. CNSC staff performed an evaluation of the IPS design against regulatory requirements for the following areas: mechanical and process systems, pressure boundary, instrumentation and control, electrical power systems, environmental qualification, seismic qualification, civil structure design, human factors in design, and core neutronics. CNSC staff was satisfied that Bruce Power has sufficiently demonstrated that the installation and operation of the IPS will have a negligible impact on existing systems, structures, and components, and that the reactor containment boundary will remain intact. CNSC staff are proposing to use a regulatory hold point to verify the completeness of Bruce Power's final IPS design manual.
19. Asked about the status of structural floor loading plan for the IPS design, CNSC staff explained that it had reviewed the plan and determined it to be acceptable. The loading assessments are required due to the significant weight of the IPS and associated shielding. The Commission directs CNSC staff to verify that the design requirements are satisfied as part of the commissioning hold point.
20. The Commission is satisfied that the installation and operation of the IPS will not pose an unreasonable risk to safety, and that the proposed regulatory hold point will ensure that the IPS meets regulatory requirements prior to operation.

#### 4.1.2 *Management Systems and Human Performance*

21. The Commission examined Bruce Power's management system and human performance programs related to the Lu-177 project. Specific areas included change management, management of contractors, OPEX, human factors, job design, and personnel training.
22. Bruce Power submitted that it is following its management system processes in developing an irradiation services program to govern the production of Lu-177. Bruce Power provided a draft irradiation services program to CNSC staff and communicated the roles and responsibilities for positions involved in the proposed Lu-177 production to CNSC staff. CNSC staff determined that the draft program addresses general elements from the Bruce Power's management system and that Bruce Power has a management system in place that meets regulatory requirements, specifically CSA Group standard CSA N286-12, *Management system requirements for nuclear facilities*. CNSC staff propose the use of a regulatory hold point to verify the completion of the irradiation services program documentation.

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<sup>4</sup> CANDU reactors have a heavy water (D<sub>2</sub>O) moderator. The moderator slows down or "moderates" neutrons to speeds at which nuclear fission can occur effectively. The large volume of D<sub>2</sub>O also acts as a heat sink.

23. Bruce Power submitted that it considered applicable operating experience (OPEX) from internal sources, other CANDU nuclear facilities, and international sources in designing the IPS. The IPS design is not a First-of-a-Kind technology, and there is international OPEX for similar types of pneumatic systems. CNSC staff also performed an independent OPEX review of the International Atomic Energy Association's (IAEA) databases for incidents involving target delivery systems. CNSC staff reported that Bruce Power has incorporated the applicable lessons learned during the IPS project.
24. With respect to contractor management, Bruce Power submitted that IsoGen is a qualified contractor under Bruce Power's approved vendor list, and that IsoGen has a quality management system in place that meets Bruce Power's requirements. Bruce Power, as the licensee, has the ultimate responsibility in ensuring the safe production of Lu-177. CNSC staff verified that IsoGen is qualified, and that Bruce Power has sufficient plans in place to oversee and verify its work. CNSC staff reported that Bruce Power's management of contractors and supply chain programs is adequate for the IPS project.
25. The Commission asked for confirmation that CNSC staff had verified ITM's credentials. CNSC staff confirmed that ITM holds, in Germany, all appropriate licences to satisfy its role in the Lu-177 supply chain. CNSC staff noted that Bruce Power had not yet finalized transportation requirements for the targets; however, once the requirements are finalized, CNSC staff will verify that ITM has met all applicable transportation requirements.
26. With respect to human factors, Bruce Power provided to CNSC staff a Human Factors Engineering Program Plan and an interim Human Factors Engineering Summary Report that included preliminary information about the staffing requirements for Lu-177 production. CNSC staff reviewed Bruce Power's submission and determined that Bruce Power has a sufficient plan in place to guide human factors engineering activities during the design of the Lu-177 IPS. The Commission directs CNSC staff to verify the completion of the tasks in the Human Factors Engineering Summary Report via a regulatory hold point.
27. With respect to training, Bruce Power submitted that it will use its existing systematic approach to training (SAT) framework to train and qualify workers to carry out duties related to Lu-177 production. SAT is the framework endorsed by the CNSC for establishing and maintaining training for persons working in nuclear facilities. CNSC staff reported that Bruce Power has a well-established SAT-based training system, which is compliant with CNSC [REGDOC 2.2.2, Personnel Training](#). CNSC staff submitted that Bruce Power has sufficient plans in place to ensure that workers will be qualified to carry out the work associated with the production of Lu-177. For future training actions that can be finalized only following commissioning of the IPS, the Commission directs CNSC staff to verify completion via a regulatory hold point.
28. Bruce Power created a mock-up facility to evaluate the safety and efficacy of the IPS design and to use as a training facility for all required IPS personnel. At the time of Bruce Power's licence amendment application, CNSC staff had observed the initial operation of the mock-up system. CNSC staff will assess the results of functional testing when the mock-up is fully completed.



29. Based on the evidence on the record for this hearing, the Commission is satisfied that Bruce Power has adequate management systems and human performance programs in place to manage contractors, manage design changes, and train personnel with regard to the production of Lu-177.

#### *4.1.3 Operating Performance*

30. CNSC staff assessed the impact of Lu-177 production on reactivity management and existing fuel and physics procedures, and reported that Bruce Power sufficiently demonstrated that Lu-177 production would not affect Bruce Power's ability to continue to comply with reactor power limits. Bruce Power submitted that the reactivity impact of target insertion and retrieval will be within the control capabilities of the reactor regulating system and will not affect normal unit operation. Bruce Power will provide CNSC staff with a full set of IPS operating documentation, including updates to existing documentation, prior to commissioning of the IPS. CNSC staff proposes to verify Bruce Power's IPS operating documentation, as well as the commissioning test results related to the reactivity impact of targets, via use of the regulatory hold point.
31. The intervention from A. Tilman ([CMD 21-H100.3](#)) expressed concern over the impact of a stuck target in the reactor core. Bruce Power submitted that, if a target were to be stuck in the reactor core, no further targets would be inserted into the IPS, but the IPS containment boundary valves would remain operable, and that targets in the IPS that had already exited the core would be removed as usual. The Commission asked about the activity of stuck targets. Bruce Power submitted that the activity of the targets would plateau after 30 days in the reactor core, and that the targets could safely remain inside the core until the next planned unit outage. The IPS design includes sufficient shielding to account for maximum target activity and all harvested targets will be returned to ITM, regardless of activity. CNSC staff assessed that Bruce Power's analysis of target activity was acceptable. The Commission directs CNSC staff to verify that Bruce Power's target retrieval procedures meet regulatory requirements as part of a regulatory hold point.
32. Further on the topic of stuck targets, the Commission asked for more information concerning pressure build-up. Bruce Power clarified that, though stuck targets could increase pressure in the target finger tube, the design pressure of the tubing is such that rupture is not a concern. There is also sufficient capacity to cool the targets due to the volume of the moderator. After construction of the IPS, Bruce Power will validate tubing strength using pressure testing.
33. The Commission asked for further information on the impact of an unplanned unit shutdown on Lu-177 production. Bruce Power reported that, in the event of an unplanned unit shutdown, targets in the core could either be retrieved early or left in the reactor core for further irradiation following the outage.
34. The Commission concludes that Bruce Power will have the appropriate programs in place to safely carry out the Lu-177 production activities that the amended licence would authorize. The Commission is satisfied that Bruce Power has appropriately considered and addressed potential scenarios involving stuck targets or unplanned shutdowns.

#### 4.1.4 Safety Analysis

35. Bruce Power completed reviews of the impact of Lu-177 production on the existing Bruce NGS hazards assessment, severe accident analysis, and deterministic and probabilistic safety assessments. Bruce Power submitted that the production of Lu-177 will have negligible impact on the internal and external hazards assessments, severe accident response and recovery, or the ability of the Bruce B NGS to meet the safety goals for severe core damage frequency and large release frequency. CNSC staff reported that the reviews performed by Bruce Power are adequate and that the existing safety case for the Bruce B NGS remains valid.
36. Based on the information on the record for this hearing, the Commission concludes that the production of Lu-177 will not affect the existing safety case for the Bruce B NGS.

#### 4.1.5 Fitness for Service

37. CNSC staff submitted that Bruce Power has met the fitness for service requirements for the IPS. To assess fitness for service, CNSC staff evaluated Bruce Power's maintenance, ageing management, and chemistry control programs for the IPS project. Bruce Power submitted that its existing station maintenance governing documents are applicable to the IPS. CNSC staff confirmed that Bruce Power's existing aging management program meets regulatory requirements and is capable of managing the effects of aging on the IPS. The IPS is not expected to have an impact on reactor chemistry, as it will be isolated from the moderator and auxiliary systems. CNSC staff propose the use of a regulatory hold point to verify that the final IPS maintenance and aging management program documentation meet regulatory requirements.
38. The Commission is satisfied that Bruce Power has adequate programs in place for the maintenance and aging management of the IPS. The Commission directs CNSC staff to verify that the final IPS maintenance and aging management program documentation meet regulatory requirements.

#### 4.1.6 Radiation Protection

39. Bruce Power submitted that it will source the Yb-176 targets from ITM, and that the targets may contain previously recycled radioactive material with a total activity per target no greater than 600 megabecquerel (MBq). CNSC staff assessed that Bruce Power has adequate programs in place to possess, transfer, and store nuclear substances associated with the production of Lu-177.
40. Bruce Power submitted that it used As Low as Reasonably Achievable (ALARA) principles during the design of the IPS to minimize radiation dose to workers and the public. This included incorporating shielding into the IPS design and optimizing equipment locations to minimize worker exposure. Bruce Power will also use administrative controls to keep doses ALARA. Bruce Power will use its existing radiation protection program to monitor and control doses to workers during operation and maintenance of the IPS. CNSC staff determined that Bruce Power sufficiently assessed the potential radiation hazards associated with the operation of the IPS, and adequately applied ALARA principles in the IPS design. CNSC staff propose to use a regulatory hold point to verify supporting information related to worker dose control.

41. The Commission is satisfied that Bruce Power's radiation protection programs will ensure the protection of workers and members of the public from radiological hazards associated with the production of Lu-177. The Commission directs CNSC staff to verify supporting information related to worker dose control.

#### 4.1.7 Environmental Protection

42. CNSC staff submitted that Bruce Power has an existing environmental protection program that meets the requirements of the following environmental protection regulatory documents and standards applicable to Lu-177 production:

- [CNSC's REGDOC-2.9.1 \(2017\), \*Environmental Protection: Environmental Principles, Assessments and Protection Measures, Version 1.1\*](#)
- ISO 14001:2015, *Environmental Management Systems – Requirements with guidance for use*
- CSA N288.4-2010, *Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*
- CSA N288.5-11, *Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*
- CSA N288.6-12, *Environmental Risk Assessments at Class I Nuclear Facilities, and Uranium Mines and Mills*
- CSA N288.1-14 Update 3, *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities.*

CNSC staff noted that CSA N288.7-15, *Groundwater protection programs at Class I Nuclear Facilities and Uranium Mines and Mills*, does not apply to Lu-177 production activities, as the IPS is a pneumatic system that will not produce environmental releases to groundwater.

43. Bruce Power's Environmental Risk Assessment (ERA) was completed in 2017. Bruce Power submitted an ERA gap analysis for isotope production activities in 2020 and a revised gap analysis in 2021. The gap analysis stated that Lu-177 production will contribute a minimal portion of the environmental releases for the Bruce NGS site, and that the releases would be negligible compared to the derived release limits for the site. CNSC staff assessed that the 2017 ERA remains applicable. The Bruce NGS ERA will be updated in 2022.
44. The Commission asked about the capture of contaminated carrier gas in the unlikely event of an ampule failure. Bruce Power submitted that the IPS will be connected to the station's existing contaminated exhaust stack by high-efficiency particulate air (HEPA) filters that will attenuate particulates but not noble gases. Bruce Power reported that it expects a negligible increase in activity released through the stack as a result of Lu-177 production, which it will confirm during commissioning via analysis of the filters. CNSC staff will verify this analysis. Bruce Power continuously monitors all releases through the stack, including noble gases, and reports this data to the CNSC annually, in accordance with CNSC [REGDOC 3.1.1 Reporting Requirements for Nuclear Power Plants](#).

45. The Commission is satisfied that Bruce Power's existing ERA remains applicable for the proposed Lu-177 production activities, and that releases would be negligible compared to the derived release limits for the site. The Commission concludes that Bruce Power has made, and will continue to make, adequate provision for the protection of the environment and the public in relation to the Lu-177 production activities that the amended licence will authorize.

#### *4.1.8 Emergency Management and Fire Protection*

46. CNSC staff reported that Bruce Power's existing emergency preparedness and response procedures are sufficient to deal with any potential emergency event that may arise due to operation of the IPS. Based on information submitted by Bruce Power, CNSC staff is also of the view that the IPS equipment will not pose a significant fire hazard, and that that Bruce Power's emergency response workers will be able to respond effectively to fire emergencies at the IPS location. Bruce Power is expected to revise its fire hazards assessment and fire safe shutdown analysis during the next review cycle, taking into account the new IPS equipment.
47. The Commission concludes that Bruce Power has sufficient response capabilities and provisions for emergency preparedness that would protect the health and safety of persons and the environment in the case of an emergency related to Lu-177 production.

#### *4.1.9 Waste Management*

48. Bruce Power's existing waste management procedures will manage any waste generated during installation of the IPS. Bruce Power is also developing a specific Waste Management and Demobilization Plan for the IPS project. CNSC reported that the waste program that Bruce Power has in place is adequate and meets the requirements of CSA Group standard N292.3 *Management of Low and Intermediate-level Radioactive Waste*.
49. The intervention from A. Tilman ([CMD 21-H100.3](#)) raised questions regarding the disposal of radioactive waste associated with the production of Lu-177. Bruce Power submitted that the production of Lu-177 will have minimal impact on the waste produced at the Bruce NGS and that the only waste generated from the production of Lu-177 will be from the use of personal protective equipment. The radioisotope targets will arrive and leave the site in the same form, and ITM will be responsible for managing its own waste.
50. The Commission is satisfied that the production of Lu-177 will have minimal impact on the amount of radioactive waste generated at Bruce Power and that Bruce Power's existing waste management program is sufficient to manage any radioactive waste associated with the installation of the IPS.

#### *4.1.10 Packaging and Transport*

51. CNSC staff reported that Bruce Power's existing packaging and transport program meets the requirements of [Packaging and Transport of Nuclear Substances Regulations, 2015](#) (PTNSR 2015), and Transport Canada's [Transportation of Dangerous Goods Regulations](#) (TDGR). For the production of Lu-177, Bruce Power will be responsible for the packaging and shipment of the shielded transport containers. The specified shielded transport container design is undergoing certification by CNSC staff. Once the container is approved for use in Canada, Bruce Power must apply to the CNSC to be a registered user.
52. The Commission is satisfied that Bruce Power has sufficient processes in place to safely manage the packaging and transport of radioactive material associated with the production of Lu-177.

#### 4.1.11 Security, Safeguards, and Conventional Health and Safety

53. CNSC staff reported that the existing security and safeguards processes in place at Bruce NGS are sufficient to protect and monitor the production of Lu-177. In addition, CNSC staff reported that Bruce Power has a well-established conventional health and safety management system in place to ensure that the work associated with the installation and operation of the IPS will be executed safely.
54. The Commission is satisfied that Bruce Power's existing security, safeguards, and conventional health and safety programs are sufficient to ensure the safe production of Lu-177.

## 4.2 Indigenous Engagement and Public Information

55. The common law duty to consult with Indigenous peoples applies when the Crown contemplates action that may adversely affect established or potential Indigenous and/or treaty rights. The CNSC, as an agent of the Crown and as Canada's nuclear regulator, recognizes and understands the importance of building relationships and engaging with Canada's Indigenous peoples. The CNSC ensures that its licensing decisions under the NSCA uphold the honour of the Crown and consider Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the [\*Constitution Act, 1982\*](#).<sup>5</sup>
56. The duty to consult is engaged wherever the Crown has "knowledge, real or constructive, of the potential existence of an Indigenous right or title and contemplates conduct that might adversely affect it".<sup>6</sup> Licensing decisions of the Commission, where Indigenous interests may be adversely impacted by its decision, will therefore engage the duty to consult, and the Commission must be satisfied that the duty has been met prior to making the relevant licensing decision.
57. The proposed physical modifications associated with this licence amendment are confined to the Bruce site and environmental impacts beyond the limits of the Bruce site are expected to be negligible. CNSC staff submitted that the duty to consult is not engaged by this decision because the proposed licence amendment is not expected to cause any adverse impacts to any established or potential Indigenous and/or treaty rights. The Commission finds that the licensed activities authorized under this proposed licence amendment will not give rise to novel adverse impacts that engage the consultation duty.
58. CNSC staff identified the First Nation and Métis groups who may have an interest in the proposed licence amendment due to their proximity to the Bruce site, or previously expressed interest. These groups include the Historic Saugeen Métis (HSM), the Métis Nation of Ontario (MNO), and the Saugeen Ojibway Nation (SON), which is comprised of the Chippewas of Saugeen First Nation and the Chippewas of Nawash Unceded First Nation. CNSC staff sent letters to the identified groups in January 2021 to notify them of the Lu-177 project and of their opportunity to participate in the proceedings. Follow-up discussions were held with each group in January and February 2021. No specific concerns with regards to the licence amendment application were expressed to CNSC

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<sup>5</sup> *Constitution Act, 1982*, Schedule B to the Canada Act 1982, 1982, c. 11 (U.K.).

<sup>6</sup> *Haida Nation v. British Columbia (Minister of Forests)*, 2004 SCC 73 at para 35.

staff. The HSM, MNO and SON each submitted interventions ([CMD 21-H100.5](#), [CMD 21-H100.2](#), and [CMD 21-H100.20](#), respectively) in which they expressed satisfaction with their engagement in the Lu-177 project and raised no concerns.

59. Bruce Power and the SON have had a Protocol Agreement since 2011 and have worked together on a number of initiatives, including environmental protection, education, and contracting. In May 2021, Bruce Power and the SON entered into a collaboration and marketing partnership agreement on the production of Lu-177.
60. Bruce Power engaged the HSM and MNO communities early in the Lu-177 project process and gave presentations to the communities to increase their understanding of the project. Bruce Power provides updates on the Lu-177 project to the communities during regular engagement meetings.
61. In addition to the above engagement, Bruce Power held public information sessions in August 2019 in Southampton, Walkerton and Kincardine to discuss medical isotopes and the Lu-177 production project. During the sessions, Bruce Power staff were available to answer questions.
62. The Commission is satisfied that this licence amendment would not cause adverse impacts to any potential or established Indigenous and/or treaty rights. The Commission recognizes the efforts by Bruce Power and CNSC staff to engage with Indigenous groups and the public, and concludes that the engagement activities related to this licence amendment have been sufficient.

#### **4.3 CNSC Participant Funding Program**

63. Pursuant to paragraph 21(1)(b.1) of the NSCA, the Commission has established a Participant Funding Program (PFP) to facilitate the participation of Indigenous peoples, members of the public and stakeholders in Commission proceedings. In [January 2021](#), up to \$50,000 in funding to participate in this licence amendment process was made available through the CNSC's PFP. A Funding Review Committee (FRC), independent of the CNSC, reviewed the funding applications received and made recommendations on the allocation of funds. Based on the recommendations from the FRC, the [CNSC awarded](#) a total of \$1,000 to one applicant. This applicant was required, by virtue of being awarded participant funding, to submit a written intervention respecting Bruce Power's application.

#### **4.4 Licence Conditions and Delegation of Authority**

64. CNSC staff proposed amendments to licence condition 15.10 and licensed activity (vi) of PROL 18.01/2028. CNSC staff's CMD 21-H100 included a proposed draft licence and CMD 21-H100.A proposed an additional change to a licensed activity.
65. CNSC staff proposed the use of a regulatory hold point to track the completion of identified actions prior to the beginning of Lu-177 production. The proposed hold point details are not safety-related; rather their purpose is to confirm operational readiness of the IPS. Section 4.4 of CNSC staff CMD 21-H100 described the hold point details and Section 1.2 of CNSC staff's supplemental CMD 21-H100.A provides further

clarification. CNSC staff recommended that the Commission authorize the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch to remove the IPS regulatory hold point upon confirmation of the prerequisites being satisfied.

66. The Commission includes in the licence the condition and licensed activity as recommended by CNSC staff in CMD 21-H100 and CMD 21-H100.A. Based on the evidence on the record for this hearing, the Commission concludes that the production of Lu-177 at Bruce B Unit 7 is a low risk activity that will remain within the station's existing safe operating envelope. The Commission recognizes that if Bruce Power plans to produce Lu-177 in a unit other than Unit 7, it must demonstrate that it will remain in accordance with the licencing basis and have a neutral or positive impact on health, safety, the environment, security, and safeguards.
67. The Commission is satisfied with the delegation of authority for removal of the regulatory hold point. The Commission does not consider the hold point details to be safety concerns, and recognizes the benefit of using a regulatory hold point to verify the operational readiness of the Lu-177 IPS. The CNSC has successfully used hold points in larger projects such as the Bruce Power Major Component Replacement project.

## **5.0 CONCLUSION**

68. The Commission has considered the licensing amendment application submitted by Bruce Power. Based on its consideration of the information submitted, the Commission is satisfied that the application submitted by Bruce Power meets the requirements of the NSCA, the GNSCR and other applicable regulations made under the NSCA.
69. The Commission has also considered the information and submissions of Bruce Power, CNSC staff and all participants as set out in the material available for reference on the record, as well as the written interventions provided by intervenors for the hearing.
70. The Commission is satisfied that this licence amendment application does not propose any new activities under the *Physical Activities Regulations* and that an impact assessment under the *Impact Assessment Act* was not required in this matter.
71. The Commission is satisfied that the duty to consult was not engaged, and finds that the Indigenous engagement activities carried out by CNSC staff for this licence amendment were adequate.
72. The Commission is satisfied that Bruce Power meets the test for licensing set out in subsection 24(4) of the *Nuclear Safety and Control Act*. That is, the Commission is of the opinion that Bruce Power is qualified to carry on the activities that the proposed licence will authorize and that it 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.



73. Therefore, the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the power reactor operating licence issued to Bruce Power for the Bruce Nuclear Generating Stations A and B located on the Municipality of Kincardine, Ontario. The amended licence, PROL 18.02/2028, is valid until September 30, 2028. As recommended by CNSC staff in CMD 21-H100 and CMD 21-H100.A, PROL 18.02/2028 includes the following amendments to Part IV, licensed activity (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).”*

and to licence condition 15.10;

*“The licensee shall implement and maintain a program for the production of the nuclear substances Cobalt-60 and Lutetium-177”*

In the administration of licence condition 15.10, the Commission authorizes the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch, to remove the IPS regulatory hold point to confirm operational readiness of the IPS, as recommended by CNSC staff.

**Stephen D.  
McKinnon** Digitally signed by  
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Stephen McKinnon  
Member,  
Canadian Nuclear Safety Commission

September 22, 2021

Date



## Appendix A – Intervenors

<b>Intervenor</b>	<b>Document Number</b>
Métis Nation of Ontario	CMD 21-H100.2
Anna Tilman	CMD 21-H100.3
North American Young Generation in Nuclear	CMD 21-H100.4
Historic Saugeen Métis	CMD 21-H100.5
Women in Nuclear	CMD 21-H100.6
BWXT Canada Ltd.	CMD 21-H100.7
Pediatric Oncology Group of Ontario	CMD 21-H100.8
Canadian Nuclear Isotope Council	CMD 21-H100.9
Westinghouse Electric Canada	CMD 21-H100.10
Toronto Region Board of Trade	CMD 21-H100.11
Power Workers' Union	CMD 21-H100.12
Canadian Nuclear Association	CMD 21-H100.13
McMaster University	CMD 21-H100.14
Isotopen Technologien Muenchen AG	CMD 21-H100.15
Kinectrics	CMD 21-H100.16
Brain Tumor Foundation of Canada	CMD 21-H100.17
Cameco Corporation	CMD 21-H100.18
Canadian Nuclear Workers' Council	CMD 21-H100.19
Saugeen Ojibway Nation	CMD 21-H100.20
Boston Scientific	CMD 21-H100.21