Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

UNPROTECTED/NON PROTÉGÉ

ORIGINAL/ORIGINAL

CMD: 21-H100

Date signed/Signé le : 9 APRIL 2021

A Licence Amendment

Une modification de permis

Bruce Power Inc.

Bruce Nuclear Generating Station A and B

Bruce Power Inc.

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 6411164 (WORD)
e-Doc 6502921 (PDF)

Summary

This CMD presents 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

CNSC staff recommend the Commission take the following actions:

- amend the PROL for the production of Cobalt-60 and Lutetium-177 at BNGS
- accept the process as set out in Section 4.4 of this CMD for the release of a regulatory hold point and delegate authority

The following items are attached:

- The proposed PROL 18.02/2028
- The draft Licence Conditions Handbook
- The current PROL 18.01/2028

Résumé

Le présent CMD présente de l'information 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 radio-isotopes à la centrale nucléaire de Bruce-A et de Bruce-B (BNGS)

La Commission pourrait considérer prendre les mesures suivantes :

- modifier le PERP pour la production de Cobalt-60 et lutétium-177 au BNGS
- accepter le processus pour la libération d'un point d'arrêt réglementaire décrit dans la section 4.4 du présent CMD et déléguer l'autorité

Les pièces suivantes sont jointes :

- permis proposé – PERP 18.02/2028
- version provisoire du manuel des conditions de permis
- permis actuel – PERP 18.01/2028

Signed/signé le

9 April 2021

Digitally signed by Viktorov, Alexandre
DN: C=CA, O=GC, OU=CNSC-CCSN, CN="Viktorov, Alexandre"
Reason: I am approving this document
Location: your signing location here
Date: 2021-04-09 07:43:42
Foxit PhantomPDF Version: 9.7.1

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

EXECUTIVE SUMMARY 1

1. OVERVIEW 3
1.1 Background 3
1.2 Highlights 7
1.3 Overall Conclusions 9
1.4 Overall Recommendations 10

2. MATTERS FOR CONSIDERATION 12
2.1 Environmental Assessment 12
2.2 Relevant Safety and Control Areas (SCAs) 12
2.3 Other Matters of Regulatory Interest 13
2.4 Regulatory and Technical Basis 13

3. LU-177 DESIGN AND SAFETY ANALYSIS REVIEW 14
3.1 Summary of CNSC staff's design review of the IPS 14
3.2 Summary of CNSC staff's safety analysis review of the IPS 22
3.3 Summary of application review of other 14 SCAs 24
3.4 Lu-177 design and safety analysis review conclusion 25

4. OTHER MATTERS OF REGULATORY INTEREST 27
4.1 Indigenous Engagement 27
4.2 Participant Funding 28
4.3 Nuclear Liability Insurance 29
4.4 Regulatory hold point for the production of Lu-177 29

5. OVERALL CONCLUSIONS AND RECOMMENDATIONS 33

REFERENCES 36

A. SAFETY AND CONTROL AREA FRAMEWORK 38
A.1 Safety and Control Areas Defined 38
A.2 Specific Areas for this Facility Type 41

B. GENERAL ASSESSMENT OF SCAS 44
B.1 Management System 44
B.2 Human Performance Management 47
B.3 Operating Performance 50
B.4 Safety Analysis 52
B.5 Physical Design 57
B.6 Fitness for Service 63
B.7 Radiation Protection 65
B.8 Conventional Health and Safety 68
B.9 Environmental Protection 69
B.10 Emergency Management and Fire Protection 71

B.11 Waste Management 74
B.12 Security 75
B.13 Safeguards and Non-Proliferation 78
B.14 Packaging and Transport 80

C. ACRONYMS 82

PROPOSED LICENCE CHANGES 86

PROPOSED LICENCE 91

PROPOSED LICENCE CONDITIONS HANDBOOK 92

CURRENT LICENCE 93

This page was intentionally left blank.

EXECUTIVE SUMMARY

The Bruce Nuclear Generating Stations (NGS) A and B are located in the Municipality of Kincardine, in the County of Bruce, Ontario. Bruce A and B are part of the Bruce Nuclear Power Development site on the shores of Lake Huron.

In November 2020, Bruce Power submitted a request to amend the Power Reactor Operating Licence (PROL) 18.01/2028 to produce Lutetium-177 (Lu-177). The current PROL only allows for the production of Cobalt-60 at Bruce B. The production of Lu-177 in a CANDU reactor will enable Bruce Power to provide a constant and reliable supply of Lu-177 to meet the growing demand for radiotherapy treatment of cancer. Bruce Power, in partnership with IsoGen, has chosen Bruce B Unit 7 as the location for the installation and operation of a Lu-177 Isotope Production System (IPS).

In the medical radioisotope supply chain, Bruce Power will be responsible for the irradiation of the targets. All other parts of the overall process (radioisotope enrichment, radioisotope processing, and drug manufacturing), including disposal of radioactive wastes associated with the production of Lu-177 will be handled by a third party (name of third party withheld due to commercial confidentiality) that is a licensed entity outside of Canada.

The chosen IPS design is not overly complex nor First-of-a-Kind. The IPS includes a pneumatic delivery system (similar to commercial pneumatic systems used to transport documents) that will deliver and retrieve targets into and out of the reactor core. Once irradiated, the IPS will transfer the targets into a shielded transport container to be shipped offsite for processing. Packaging and shipment of the transport container will be performed in accordance with CNSC's *Packaging and Transport of Nuclear Substances Regulations*, 2015 and Transport Canada's *Transportation of Dangerous Goods Regulations*.

Based on the review of the licence amendment application, and the supporting information on the design and safety analyses of the IPS, CNSC staff determined that Bruce Power has adequate provisions in place to ensure the safe production of Lu-177. Production of Lu-177 is a low risk activity, and the activity will remain within the facility's existing safety envelope. The installation and operation of the IPS will not result in significant doses to workers or members of the public, nor in significant releases to the environment. In addition, the existing security and safeguards program in place is sufficient for Lu-177 production. Bruce Power has been engaged with interested Indigenous groups on this licence amendment.

CNSC staff conclude 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. Therefore, CNSC staff recommend the Commission accept Bruce Power's licence amendment request, specifically, by authorizing the activity for the production of Lu-177 at Bruce B Unit 7.

This Commission Member Document (CMD) is presented in two parts.

Part One includes:

- An overview of the matter being presented
- CNSC staff's Lu-177 design and safety analysis review
- Discussion about other matters of regulatory interest
- Overall conclusions and recommendations
- Appendix A (SCA framework)
- Appendix B (SCA review)
- Appendix C (acronyms list)

Part Two provides all available information pertaining directly to the current and proposed licence.

PART ONE

1. OVERVIEW

1.1 Background

Bruce Power, in partnership with IsoGen, has chosen Bruce Nuclear Generating Station (BNGS) B Unit 7 as the location for the installation and operation of an Isotope Production System (IPS) to irradiate Ytterbium-176 (Yb-176) to produce Lutetium-177 (Lu-177) for the medical industry. The production of Lu-177 in a CANDU reactor is an innovative approach to isotope production, as the CANDU reactor will be able to provide a better and higher yield when compared to research reactors that are already producing Lu-177. Bruce Power will be able to provide a constant and reliable supply of Lu-177 to meet the growing demand for radiotherapy treatment of cancer.

The system that will be used to produce Lu-177 is the result of a collaboration between IsoGen and an international biotechnology and radiopharmaceutical company (name withheld due to commercial confidentiality). IsoGen is a joint venture between Kinectrics and Framatome: Kinectrics is a provider of life cycle management services for the nuclear industry with expertise in engineering, testing, inspection and certification; while Framatome is a designer and supplier of nuclear supply system and equipment, and holds the patented design for pneumatic delivery system. IsoGen is a qualified contractor under Bruce Power's approved vendor list. In other words, IsoGen has a quality management system in place that meets Bruce Power's contracting requirements. As IsoGen is a contractor, it does not need to hold a CNSC licence for the production of Lu-177. Bruce Power, as the licence holder, has the ultimate responsibility in ensuring the safe production of Lu-177.

The responsibilities of Kinectrics and Framatome are as follows:

Kinectrics

- Manages IPS project (oversees the execution of design of the IPS and safety analyses work)

Framatome

- Is the lead vendor for construction
- Will be executing the cold commissioning work (i.e., testing IPS without targets in core)
- Will be providing support to Bruce Power for hot commissioning work (i.e., testing IPS with targets in core)

The use of Lu-177 for radiation therapy has produced high response rates among men for the treatment of prostate cancer. The Lu-177 drug is used to target the cancer cell by breaking down its DNA. Clinical trials have has shown effectiveness of the drug after several treatments. There are also potential uses for Lu-177 in the treatment of other types of cancers (such as neuroendocrine tumours).

In the medical radioisotope supply chain, Bruce Power is only responsible for irradiation of the targets (see **Figure 1**), from receipt of the source material (Yb-176) through to packaging and shipment of irradiated targets (Lu-177). The shipping will be handled by an "authorized" commercial shipper as is typically done for shipment of nuclear substances. All other parts of the process (isotope enrichment, radioisotope processing, and drug manufacturing) will be handled by a licensed third party company outside of Canada, including disposal of radioactive wastes associated with the production of Lu-177. The third party is licensed in its own home country for the radioisotope enrichment, radioisotope processing and drug manufacturing.

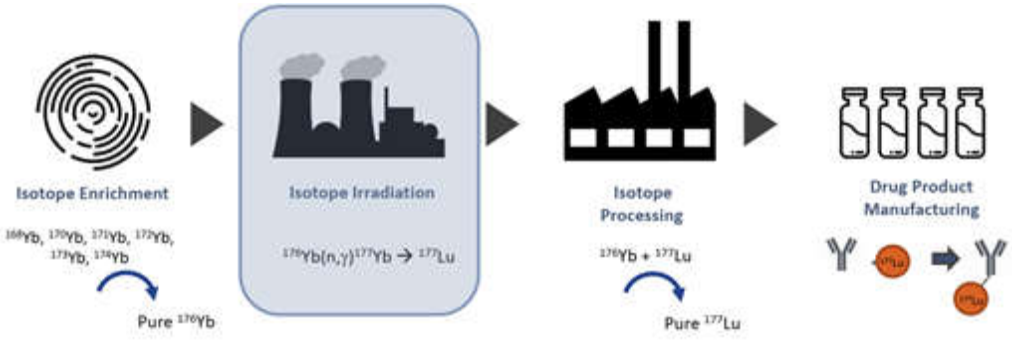


Figure 1: Supply Chain process for Lu-177 production. Bruce Power is only responsible for isotope irradiation in the highlighted box (source: Bruce Power).

The radioisotope produced at Bruce Power will be shipped out from the Bruce site and out of Canada for further processing. Bruce Power will be responsible for the packaging and shipping of the shielded transport container. Bruce Power is authorized under its licence to export the Lu-177. For shipments of nuclear substances within the nuclear facility where access to the property is controlled, Bruce Power has to meet the requirements of CNSC *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR, 2015) and the Canada's *Transportation of Dangerous Goods Regulations* (TDGR) even though the transport of the nuclear substance within Bruce Power is exempt from these requirements.

For shipment outside of the facility, Bruce Power is required to comply with CNSC's PNTSR, 2015, Canada's TDGR, and international transportation requirements and International Atomic Energy Agency (IAEA) safeguards.

Licence Amendment Application

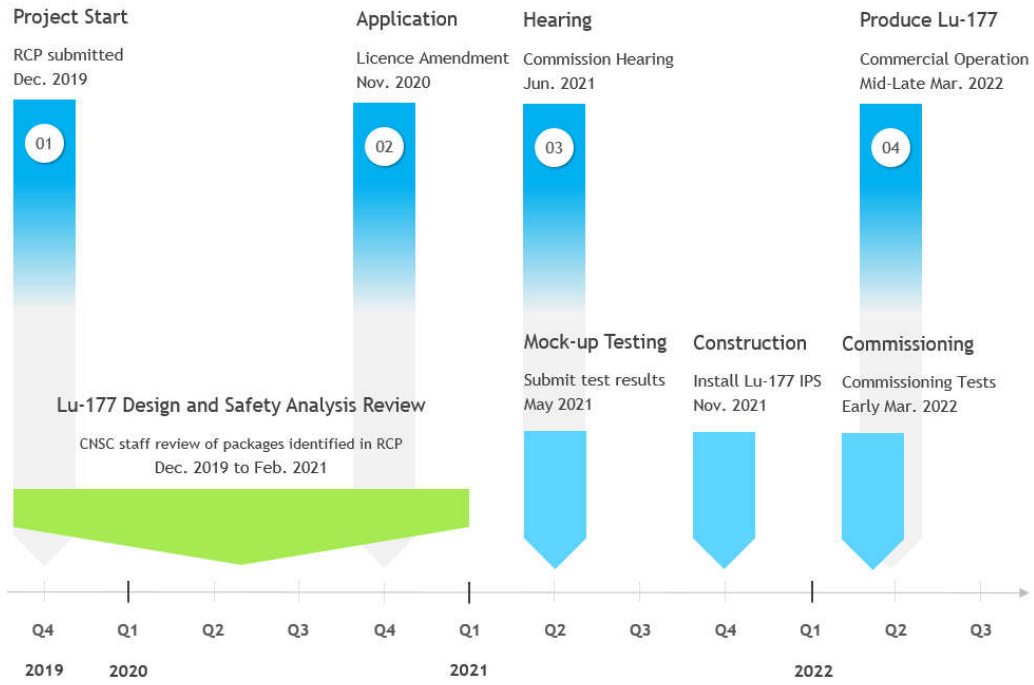
In November 2020, Bruce Power submitted to the CNSC an application [1] for the amendment of its Bruce A and B Power Reactor Operating Licence (PROL) to produce radioisotopes, specifically Lu-177 in Bruce B Unit 7. In support of the application, Bruce Power submitted safety analyses, engineering assessment results (including IPS design information), as well as pressure boundary classification information for the IPS. Prior to receiving the application, CNSC staff and Bruce Power established an administrative protocol, called a "Regulatory Communication Plan" (RCP) [2], in December 2019 which outlined in the form of a project plan the dates of the submissions and timelines for discussions with CNSC staff.

This approach enabled CNSC staff to provide feedback during the design process to help verify whether the IPS would meet existing regulatory requirements. The review also helped to identify whether there were any barriers to the installation and operation of an IPS in Bruce B Unit 7.

In February 2021, Bruce Power submitted its final integrated safety analysis report (FISAR) [3], which presented the final safety case for the Lu-177 IPS in support of the licence amendment. CNSC staff determined that the impact of the IPS to the existing Structures, Systems and Components (SSCs) is negligible. The reactivity worth of in-core components of the IPS and the targets is negligible in comparison to the total reactivity worth of the reactor core. Finally, the impact of the IPS on the quantification of Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF) is also negligible. Based on these determinations, CNSC staff concluded that production of Lu-177 is a low risk activity. Bruce Power is operating the nuclear facilities safely, and the activity associated with the production of Lu-177 will remain within the plant's existing safety envelope. CNSC staff's assessment of the design and safety analyses of the IPS is discussed in Section 3 of this CMD.

If the Commission accepts CNSC staff's recommendations and amends Bruce Power's PROL and authorize the production of Lu-177, Bruce Power intends to commence production of Lu-177 in March 2022. A timeline of the Lu-177 IPS project is presented in Figure 2.

Figure 2: Bruce Power's Lu-177 IPS project timeline



1.2 Highlights

The current PROL only allows for the production (including receipt, storage and handling) of Cobalt-60 at Bruce B. In order to produce other types of radioisotopes, Bruce Power submitted a request to the Commission to amend the PROL.

Bruce Power is utilizing a qualified external contractor (IsoGen) with experience in managing these types of projects, as well as having the knowledge and expertise with the isotope delivery system. The use of contractors for projects is not new. Bruce Power has demonstrated that it is able to maintain proper oversight of its contractors, as well as ensuring that its contractors implement Bruce Power's management system processes, through planned outages and larger projects such as Major Component Replacement or MCR (also known as refurbishment). While Bruce Power is using an external contractor for design and installation of the IPS, Bruce Power remains ultimately responsible for the safe operation of the IPS and the production of Lu-177 as it will be the licence holder (pending the Commission's decision).

Bruce Power intentionally chose an IPS design that is not overly complex nor First-of-a-Kind, as there are operating experiences with the system internationally. The IPS includes a pneumatic delivery system that will deliver and retrieve targets into and out of the reactor core. There has been extensive use of pneumatic target delivery systems in research and power reactors resulting in proven system technology (which is similar in concept to commercial systems used to transport documents).

The target material that will be used to produce Lu-177 is an Ytterbium oxide (Yb_2O_3) powder containing Ytterbium-176 (Yb-176), which is contained in sealed, leak-tested ampules that are able to withstand the temperature and radiation fields inside the reactor core. The ampules will arrive at the Bruce site inside aluminum carrier tubes; a Bruce Power worker will verify the serial numbers on the carrier tubes to confirm that the correct shipments have been received. A Bruce Power worker will then use the IPS to deliver the targets into the reactor core for irradiation. Once irradiated, a worker will use the IPS to transfer the targets into a certified shielded Transport Container (TC). The TC will be shipped outside Canada to a licensed third party for processing.

Due to the iterative nature of the design process (as the design will go through cycles of prototyping, testing, analyzing and refining) for the Lu-177 IPS project, a number of documents (for example: the final design manual, the IPS training manual and IPS operating procedures) can only be finalized closer to, but in advance of, the commissioning of the IPS. Bruce Power will also need to confirm that design and safety analyses requirements have been met through commissioning test results. These actions have been identified by Bruce Power as part of its project plan.

As such, CNSC staff have placed a regulatory hold point on Bruce Power to track the completion of these actions. The hold point is established to confirm operational readiness of the Lu-177 IPS for the staged progress through the

commissioning phase to the initial operation for the production of Lu-177. The use of hold points is a routine operational practice; CNSC staff have utilized hold points for much larger projects in the past, such as Bruce Power's MCR project. In comparison to the MCR, the risk significance of the IPS project is low. The proposed hold point details are not considered to be safety concerns; while important to be completed in advance of commissioning and startup, most are administrative in nature. CNSC staff are recommending the Commission to accept the process defined in Section 4.4 for the release of the hold point through the requested delegate of authority. Bruce Power will not be allowed to commence production of Lu-177 if it cannot meet the pre-requisites for the release of the hold point. CNSC staff will also perform compliance verification activities to confirm that the identified actions have been completed.

1.3 Overall Conclusions

The production of Lu-177 in a CANDU reactor is considered an innovative approach as the CANDU reactor will able to provide a better and higher yield when compared to research reactors that are already producing Lu-177. The IPS design is not a First-of-a-Kind as there are operating experiences with pneumatic delivery systems internationally, including in the nuclear systems. It is CNSC staff's view that this is a low risk activity; specifically, CNSC staff determined that:

- the impact of the IPS to the existing SSCs is negligible.
- the reactivity-worth of in-core components of the IPS and the targets is insignificant compared to the total reactivity-worth of the reactor core.
- the impact of the IPS on the quantification of SCDF and LRF is also negligible.

In the Lu-177 supply chain, Bruce Power is only responsible for the irradiation of the targets, from receipt of the source material through to packaging of the irradiated targets into certified shielded transport containers. All other parts of the supply chain will be handled by an third party company licensed in its own home country (name withheld due to commercial confidentiality) for radioisotope enrichment, radioisotope processing and drug manufacturing. Bruce Power will also be responsible for the packaging and shipping of the shield transport container. As Bruce Power will be the licence holder (pending the Commission's decision), it has the ultimate responsibility in ensuring the safe production of Lu-177.

Based on the review of the licence amendment application and the supporting information on the design and safety analyses of the IPS, CNSC staff determined that Bruce Power has adequate provisions in place to ensure the safe production of Lu-177. The installation and operation of the IPS will not result in significant doses to workers or members of the public, and will not result in significant releases to the environment. In addition, the existing security and safeguards program in place is sufficient for the production of Lu-177. Bruce Power continues to engage with interested Indigenous groups on this licence amendment and other ongoing activities of interest. Bruce Power will continue to protect the health and safety of the public, as well as the environment.

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.

1.4 Overall Recommendations

Due to the iterative nature of the design process for the Lu-177 IPS project (such as testing, installation, etc.), a number of documents (for example: the final design manual, the IPS training manual and IPS operating procedures) can only be finalized closer to, but in advance of, the commissioning of the IPS. CNSC staff will verify that the design and safety analyses requirements have been met through commissioning test results. These actions have been identified by Bruce Power as part of its project plan.

As such, a regulatory hold point is proposed to be placed on Bruce Power to track the completion of the identified actions. The hold point is established to confirm operational readiness of the Lu-177 IPS for the staged progress through the commissioning phase to the initial operation for the production of Lu-177. The use of hold points is a routine operational practice; CNSC staff have utilized hold points for much larger projects in past, such as Bruce Power's MCR project. In relation to the operation of the facility itself, the risk significance of the IPS project is low. The proposed hold point details are not considered to be of safety concerns; while important to be completed in advance of commissioning and startup, most are administrative in nature. CNSC staff are recommending the Commission to accept the process defined in Section 4.4 of this CMD for the release of the hold point through the requested delegate of authority. Bruce Power will not be allowed to commence production of Lu-177 if it cannot meet the pre-requisites for the release of the hold point. CNSC staff will also perform compliance verification activities to confirm that the identified actions have been completed. Finally, CNSC staff will update the Commission through the NPP status report on the status of the hold point.

The proposed LCH specifies that Bruce Power can only produce Cobalt-60 at Bruce B, and Lu-177 at Unit 7 of Bruce B. If Bruce Power plans to produce Lu-177 in other units, it must obtain concurrence from CNSC staff, demonstrate that it is a low risk activity, and that the activity will continue to remain within the plant's existing safety envelope.

In conclusion, CNSC staff recommend the Commission to accept Bruce Power's request for licence amendment to produce Lu-177, and propose the following changes to the PROL and its associated Licence Conditions Handbook (LCH):

- accepting the following amendment to the PROL licensed activities (vi), from "*produce Cobalt-60 at Bruce B*" to "*produce Cobalt-60 and Lutetium-177*"
- accepting the following amendment to the PROL licence condition 15.10, from "*The licensee shall implement and maintain a program for the receipt, storage and handling of the nuclear substance Cobalt-60 at Bruce B*" to "*The licensee shall implement and maintain a program for the production of the nuclear substances Cobalt-60 and Lutetium-177*"
- accepting the process defined in Section 4.4 of this CMD for the release of a regulatory hold point and delegate authority

The proposed PROL, as well as a draft LCH are presented in Part Two of this CMD.

2. MATTERS FOR CONSIDERATION

2.1 Environmental Assessment

CNSC staff reviewed Bruce Power's licence application in the context of the *Impact Assessment Act* (IAA). CNSC staff determined that the IAA does not apply because the proposed activities are not captured in the IAA's *Physical Activities Regulations* nor are they considered a project on federal lands.

CNSC staff conclude that the information provided by Bruce Power regarding environmental protection is adequate to meet the applicable regulatory requirements under the NSCA and associated regulations for the amendment of the Class IA Nuclear Facilities licence. More information on CNSC staff's assessment of the environmental protection safety and control area (SCA) can be found in Appendix B.9 of the CMD. CNSC staff conclude that Bruce Power will make adequate provision for the protection of the environment and the health of persons.

CNSC staff will continue to verify and ensure that, through ongoing licensing and compliance activities and reviews, the environment and the health of persons are protected and will continue to be protected over the proposed licence period.

2.2 Relevant Safety and Control Areas (SCAs)

The functional areas of any licensed facility or activity consist of a standard set of SCAs. See Appendix A, "Safety and Control Framework", for further information about SCAs.

The relevance of each SCA to this CMD is indicated in the following table. CNSC staff's comprehensive review of the 14 SCAs is provided in Appendix B of this CMD.

Functional Area	Safety and Control Area	Relevant to this CMD?
Management	Management System	Y
	Human Performance Management	Y
	Operating Performance	Y
Facility and Equipment	Safety Analysis	Y
	Physical Design	Y
	Fitness for Service	Y
Core Control Processes	Radiation Protection	Y
	Conventional Health and Safety	Y
	Environmental Protection	Y

Functional Area	Safety and Control Area	Relevant to this CMD?
	Emergency Management and Fire Protection	Y
	Waste Management	Y
	Security	Y
	Safeguards and Non-Proliferation	Y
	Packaging and Transport	Y

2.3 Other Matters of Regulatory Interest

The following table identifies other matters that are relevant to this CMD.

OTHER MATTERS OF REGULATORY INTEREST	
Area	**Relevant to this CMD?**
Indigenous Consultation	Yes
Other Consultation	No
Cost Recovery	No
Financial Guarantees	No
Improvement Plans and Significant Future Activities	No
Licensee's Public Information Program	No
Nuclear Liability Insurance	Yes

The relevant "other matters" of regulatory interest are discussed in Section 0 of this CMD.

2.4 Regulatory and Technical Basis

For this type of facility, the key requirements come directly from:

- *Nuclear Safety and Control Act* (NSCA)
- *General Nuclear Safety and Control Regulations* (GNSCR)
- *Radiation Protection Regulations* (RPR)
- *Class I Nuclear Facilities Regulations* (CINFR)
- *Packaging and Transport of Nuclear Substance Regulations*, 2015 (PTNSR 2015)
- Transport Canada's *Transport of Dangerous Goods Regulations* (TDGR)
- Bruce Power Power Reactor Operating Licence (PROL) 18.01/2028 and its associated Licence Conditions Handbook (LCH)

3. LU-177 DESIGN AND SAFETY ANALYSIS REVIEW

In December 2019, Bruce Power submitted a RCP [2] that outlined the planned submissions, meetings and interfaces for the Bruce B Lu-177 IPS project. The planned submissions include detailed design and safety analysis information related to the IPS. The purpose of the submissions is to demonstrate that the IPS will not have an impact to the existing safety case, and that Bruce Power will continue to ensure the safe operation of the nuclear facility. Specifically the submissions addressed whether:

- the design and safety analysis work associated with the IPS meets the existing regulatory requirements
- there are any barriers to the installation, commissioning and operation of an IPS in Bruce B Unit 7

The RCP was revised in November 2020 [4] to address comments raised by CNSC staff in the initial RCP, such as providing additional information to CNSC staff related to:

- operating procedures for the IPS
- commissioning plans and test report
- detailed design documents

CNSC staff performed a comprehensive review on each of the 14 SCAs to determine whether: the production of Lu-177 would have any impacts to the existing safety case, the design has addressed all current regulatory requirements, and the existing programs are sufficient to ensure the safe installation, commissioning and operation of the IPS. Subsection 3.3 of this CMD provides a summary of the review in each of the 14 SCAs; detailed review is provided in Appendix B of this CMD.

3.1 Summary of CNSC staff's design review of the IPS

This section of the CMD provides the design background, and a summary of CNSC staff's review of the design of the IPS. The chosen IPS design is not overly complex nor First-of-a-Kind as there are operating experiences (OPEX) with these types of systems internationally. Production of Lu-177 is demonstrated to be a low risk activity.

3.1.1 Design background

The target material used to produce Lu-177 is ytterbium oxide (Yb_2O_3) powder containing Ytterbium-176 (Yb-176). The ytterbium powder is contained in sealed, leak-tested ampules (see Figure 3) that are able to withstand the temperature and radiation fields inside the reactor. The ampules will arrive at the Bruce site inside aluminum carrier tubes (see Figure 4); Bruce Power staff will

verify the serial number embedded in the carrier tubes to ensure that it has received the correct shipment.

Figure 3: Ytterbium oxide contained in a quartz ampule (~60 mm in length)

Figure 4: Aluminum carrier tube

To deliver the targets into and out of the reactor vessel (or reactor core), Bruce Power will utilize a pneumatic delivery system, known as an IPS. The targets will pass through the Reactivity Mechanism Deck (RMD), by means of an existing, unused Vertifical Flux Detector (VFD) location. The targets will enter the reactor vessel via the blue path; following irradation, the targets will exit the reactor vessel via the green path (See Figure 5 for a simplified drawing of the IPS). There are no cooling requirements for the targets, as the moderator is able to provide a sufficient heat sink.

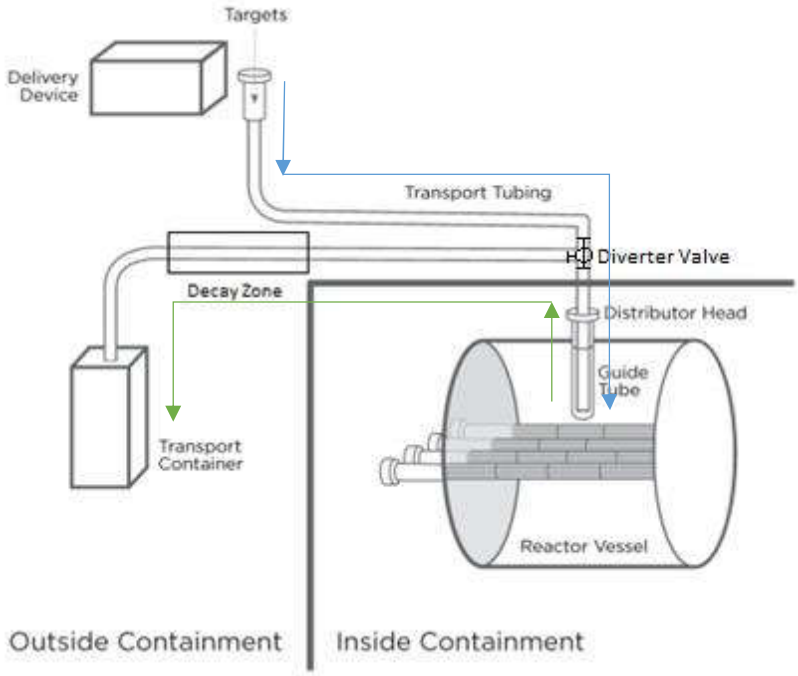


Figure 5: Simplified drawing of the IPS (source: Bruce Power's licence amendment application).

An operator will use a pnematic control panel (PCP) in the field to control and monitor the system operations; specifically, it will allow the operator to insert,

track and withdraw the targets from a centralized location. The PCP interfaces with an inert gas supply (helium) that will pneumatically insert or withdraw the targets into and out of the reactor vessel, through a metal transport tubing (target finger tube); the transport tubing is essentially a tube contained within a tube. Bruce Power will install filters between helium gas supply bottles and pressure regulators at the helium bottle station to ensure that foreign materials will not enter the system.

The control system will consist of hardwired relay logics and timers that perform automated loading and unloading sequences to drive targets in the target finger tube. The PCP will be equipped with hand switches for manual control (if required), and will provide the operator with a visual indication of the valves' positions via a mimic display of the IPS flow diagram. There will be embedded software in certain IPS components such as a gamma sensor, assaying equipment and counters used to track the number of targets in the reactor core. The human machine interface will be implemented using a programmable logic controller.

Following irradiation via neutron capture, the ampules will be pneumatically sent to a radiation shielded area (decay zone) to go through further radioactive decay and dose reduction before they are pneumatically sent to a shielded transport container.

The IPS will not require any instrumentation and control equipment in the main control room – all operation will be controlled in the field. The PCP of the IPS will be supplied from station Class IV power system. In the event that the station loses Class IV power supply during target retrieval, there is a backup system in place to allow targets to be conveyed to a shielded location. The system is designed such that, under the loss of power event, the containment boundary valves will go to the 'close' position such that the containment boundary will not be impacted.

The operation of the IPS for inserting and withdraw of the target carriers will only take place during normal operation of the reactor; IPS operation in other reactor states (such as during outages, unplanned shutdown and during unit start-up) will be restricted. The targets will spend approximately seven (7) days in the reactor core. In the event that the targets are stuck, the design of the carrier tubes is such that they are able to remain in the reactor until the unit's next outage (typically two to three years). Once the unit is safely shutdown, an operator will be able to use a manual tool to extract the stuck targets. The stuck targets will not have an impact to normal reactor operations.

The IPS design is not a First-of-a-Kind, as similar pneumatic systems are currently in use internationally at several research reactors for the transfer of targets, including the Oak Ridge National Laboratory High Flux Isotope reactor in the United States, FRM II Research reactor in Germany and HANARO research reactor in Korea. Framatome has 530 reactor-years of OPEX, as its own entity, with the target and delivery system. Irradiation of Yb-176 has also been tested in a Swiss Pressurized Water Reactor (PWR). CNSC staff performed an independent OPEX review of IAEA's databases for significant incidents

involving target delivery systems used in NPPs and found none. For research reactors, there were incidents involving rabbit pneumatic transfer systems, breakage of sample containers and an unanticipated exposure when unloading a sample. The applicable documented OPEX and the lessons learned have improved the knowledge and capabilities of designers, operators and regulators with pneumatic transfer systems and reactors. Based on the information submitted, CNSC staff determined that Bruce Power has incorporated these learned experiences for the IPS project.

The container that will be used to transport the irradiated targets was previously certified in the US in April 2016 and its certification is in the process of being renewed as per the certification renewal cycle. CNSC staff reviewed the Safety Analysis Report for Packaging (SARP) [8] associated with the shielded transport container that will be used to transport the radioisotope material to ensure that it meets Canadian requirements, and are waiting for the renewal of the US certificate prior to finalizing the certification process in Canada. This is a routine best practice followed internationally. It is CNSC staff's view that Lu-177 can be safely transported in the specified shielded transport container, and the certification process is expected to be completed in May 2021. Once the design of the shielded transport container is approved and certified for use in Canada, Bruce Power will apply to be a registered user. This activity has no impact on the installation of the IPS and the process can be done in parallel.

The IPS design is integrated into the existing station exhaust system. Emissions, from the gases used to pneumatically transport the targets within the IPS, will be routed through the contaminated stack exhaust which contains HEPA filters for removal of most particulates. Any emissions passing through the filter will be monitored and reported to the CNSC through the quarterly and annual compliance monitoring reports. The emissions for Lu-177 production will be minimal especially when compared to the Derived Release Limits (DRLs) for the site.

There are no additional security and safeguards design requirements for the IPS. The existing security and safeguards equipment in place at BNGS will ensure that the proposed activity for the production of Lu-177 will be protected and monitored.

Finally, Bruce Power built a scaled mock-up of the IPS at an offsite location to validate the design, and to provide rehearsal and training for operators (see Figure 6). This mock-up will demonstrate the functionality of the system prior to installation at the station. CNSC site staff have witnessed the initial testing and operation of the mock-up system. When the mock-up is fully completed (expected in May 2021), CNSC staff will review the functional testing results to confirm that the design requirements of the IPS are met, and that the IPS can successfully be used for the delivery of targets.

Figure 6: Photo showing a portion of the pipe run of the IPS in a mock-up facility (source: CNSC site staff inspection photo)

3.1.2 CNSC staff review of the IPS design

The purpose of the design review is to determine whether current CNSC design requirements and expectations have been met. The following information packages were submitted by Bruce Power in support of the design work:

1. A detailed engineering design plan [5], which included demonstration that the existing Bruce Power Engineering Change Control (ECC) process has been followed. The plan also included information on standard design engineering activities, as well as safety analysis, factory acceptance and installation planning work.
2. A "code classification request" of the IPS [6], [7] that is required for Bruce Power to demonstrate that pressure boundary requirements have been met.
3. An application for Canadian endorsement certificate of the transport container [8] for the Lu-177.
4. A technical Standards and Safety Authority (TSSA) design registration package for the piping systems and supports [9], [10], including the final system design flow diagram.
5. Additional supporting information on design plan [11].
6. A summary of Unit 7 IPS detailed design [4].

Bruce Power utilized its existing management system processes for the design work associated with Lu-177 IPS project, including: self-assessment and audits, problem identification and resolution, managing the design changes, and managing contractors. In addition, Bruce Power has demonstrated that lessons learned from domestic and international nuclear facilities have been applied during the design stage. CNSC staff verified that the contractors for the IPS project are qualified, and that Bruce Power has plans in place to verify and

perform oversight of the work performed by the contractors. CNSC staff conclude that Bruce Power's management system meets regulatory requirements.

As per the project plan, Bruce Power has identified a number of design documents and reports that will only be finalized closer to, but in advance of, the commissioning of the IPS. For example, Bruce Power will need to make minor design adjustments in order to address any issues that it will encounter during field installation, and update design documentation to reflect those changes in the final design manual. These minor design adjustments are not expected to have an impact to the overall design of the system.

CNSC staff have placed a regulatory hold point on Bruce Power to track the completion of the identified actions. The hold point is established to confirm operational readiness of the Lu-177 IPS for the staged progress through the commissioning phase to the initial operation for the production of Lu-177. The proposed hold point details are not considered to be safety concerns; while important to be completed in advance of commissioning and startup, most are only administrative in nature. It is CNSC staff's views that these actions will not alter the safety case presented by Bruce power. CNSC staff will perform compliance verification activities to confirm the completion of the actions. Subsection 4.4 of this CMD defines the regulatory hold point and the process for its release.

Summary of CNSC staff's IPS design review

Bruce Power provided details related to the major mechanical components used in the IPS, which include valves (such as a diverter valve, target stop valves, containment boundary valves, and a helium pressure control valve), a target finger tube and helium buffer tank. CNSC staff reviewed the information, and determined that, from a mechanical and process perspective, the IPS design will have a negligible impact on existing SSCs, including the containment boundary.

To demonstrate that pressure boundary of the IPS will be maintained, Bruce Power submitted in [6] a request for "code classification" approval of the IPS. Bruce Power demonstrated that modifications made for installation of the IPS will have a negligible impact on existing SSCs, and that the reactor containment boundary will continue to be maintained. CNSC staff reviewed and approved Bruce Power's code classification request in [7]; TSSA has also approved the design registration package in [10].

The IPS does not require any I&C equipment to be added in the main control room. In addition, the main control room will not have any annunciations and indications from the IPS components. The IPS will be controlled locally from a human-machine interface at the PCP, which will allow an operator to control and monitor the IPS, and to insert, track and retrieve the targets from a centralized location. Design change to the Reactor Regulating System (RRS) will not be required for the loading and unloading of targets into and out of the reactor core. The design analysis information submitted in [3] showed that loading and unloading targets may cause a slight change in liquid zone level; however, these changes remain within the control capability of RRS. Bruce Power determined

that operation of the IPS will have negligible impact on the RRS and its control capability. From an I&C perspective, CNSC staff conclude that the IPS design is adequate.

In the area of electrical power systems, the PCP of the IPS is supplied from the station Class IV power system. The PCP is the electrical interfacing point between the 120 VAC Class IV power system and the IPS. In the event that the station loses Class IV power supply during the retrieval of targets, the IPS design includes provision for a backup battery power supply with sufficient capacity to allow targets to be conveyed to a shielded location. Bruce Power determined that the addition of the IPS load will have a negligible impact on the existing station electrical system. CNSC staff conclude that the design of the IPS from an electrical power systems perspective is adequate.

The design of the IPS is required to meet the environmental qualification (EQ) requirements of CSA N290.13, *Environmental qualification of equipment for CANDU nuclear power plants*. The non-metallic portions of the IPS within the containment boundary is subject to evaluation as per Bruce Power's environmental qualification (EQ) governing documents. Specifically, Bruce Power is required to ensure that the containment boundary components of the IPS will maintain its integrity following Design Basis Accidents (DBAs). An EQ evaluations (EQE) will be performed on the impact of the IPS during normal and abnormal conditions. As a result of the EQE, the EQ documentation (such as room conditions manual and environmental qualification assessments) will either be updated or developed as required. The EQE will be completed prior to the procurement and installation of the components. Based on the information submitted, CNSC staff conclude that Bruce Power has considered EQ requirements in the design of the IPS. The EQ approach is aligned with the requirements defined in CSA N290.13, as well as Bruce Power's EQ governing documents. As Bruce Power is in the process of finalizing the EQE, a regulatory hold point will be established to verify the completion of the EQ document. This identified action is only administrative in nature and is not a safety concern.

Bruce Power has a seismic qualification program that meets the requirements of CSA N289.1-08, *General requirements for seismic design and qualification of CANDU nuclear power plants*. The containment boundary portions of the IPS (including distributor head, piping, supports and containment boundary valves) will be seismically qualified to the same design basis as the existing systems. CNSC staff conclude that Bruce Power has sufficiently addressed seismic qualifications requirements for the IPS project.

For civil structures design, new shielding and skid structures will need to be added as part of the IPS, which will result in an additional load (weight) to the existing structure. CNSC staff reviewed a high level results/summary of structural floor loading assessments, and determined that it was acceptable. The final structural floor loading assessment was submitted on March 31, 2021. CNSC staff are in the process of reviewing the final assessment and will be verifying it against the high level results.

In the area of human factors in design, Bruce Power is required to meet the requirements of CSA N290.12, *Human factors in design of nuclear power plants*. Guidance for considering human factors in design programs is provided in REGDOC-2.5.1, *General Design Considerations: Human Factors*. Bruce Power provided a Human Factors Engineering Program Plan (HFEPP) and interim Human Factors Engineering Summary Report (HFESR) that included preliminary information about staffing and tasks that are required to carry out the production of Lu-177. The tasks will include handling, target retrieval, craning and shipping. The interim HFESR that was submitted to date provided CNSC staff with evidence that Bruce Power has carried out preliminary human factors analysis activities in accordance with their HFEPP and the HFVVP for the IPS project. CNSC staff determined that Bruce Power has made adequate provision for human capabilities and limitations (human factors) in the design of the IPS. The final HFESR will be completed after installation of the IPS. A regulatory hold point will be established to confirm the completion of the tasks identified in the human factors analyses related to the operation of the IPS. This identified action is only administrative in nature.

The design of the IPS has taken into consideration the As Low As Reasonably Achievable (ALARA) principle to maintain worker and public doses below regulatory limits. Design and administrative measures have been put into place, such as providing radiation shielding, for the protection of workers during the operation of the IPS. Potential radiological hazards during normal operation of the IPS have been assessed and addressed through the design of the IPS. Bruce Power is currently evaluating whether additional Fixed Area Gamma Monitors (FAGMs) or active monitors are required to alert personnel of potential hazards. Bruce Power will need to determine if radiation field in the area may produce repeated nuisance alarms, and may cause the workers to develop alarm fatigue and to start ignoring them. However, portable monitoring devices (such as use of personal dosimeters) will be available for workers and therefore, is not a safety concern. A regulatory hold point is placed on Bruce Power to provide to CNSC staff the results of this determination.

Finally, in [3] and [18], Bruce Power provided the assessments on the impact of the installation of the IPS on core neutronics and determined that the effects of target insertion and retrieval on detector readings are small but observable. However, the RRS is capable in dealing with these small changes and that no manual operator actions will be required. CNSC staff determined that the assessments performed are sufficient to demonstrate that the impact of IPS installation, target insertation and retrieval activities are negligible, and that adequate provisions are in place to ensure safe production of Lu-177. Bruce Power will need to validate the assessments against commissioning results to confirm that the reactivity characteristics are consistent with the design specifications and assessments. A regulatory hold point is placed on Bruce Power to submit the commissioning results to CNSC staff.

CNSC staff conclude that Bruce Power has adequate provisions in place for the safe production of Lu-177, and that the IPS design will have negligible impact

on operations and reactor safety, and on the existing SSCs such as electrical systems, I&C, and containment.

3.2 Summary of CNSC staff's safety analysis review of the IPS

The purpose of the safety analysis review is to determine whether Lu-177 production will have an impact on the overall safety case for Bruce B. The following information packages was submitted by Bruce Power in support of the safety analysis work:

1. A safety analysis plan [2] that included the overall safety analysis scope of work
2. Code applicability documentation [12] that included an assessment on the suite of codes used in the analysis, as well as documenting code applicability and accuracy.
3. First safety analysis package [13] that documented the internal and external hazard assessments, probabilistic risk assessment, operational, and qualitative assessment on the impact of the system on existing safety analyses.
4. Additional information on safety analysis plan [14].
5. Second safety analysis package [15] that provided safety analysis performed for various events (such as in-core Loss of Coolant Accidents and failure of IPS outside of the core).
6. Additional information on code applicability assessment [11].
7. FISAR [3] that integrates the safety and operational analyses performed to demonstrate that IPS will have a negligible impact on the overall safety case.

Bruce Power performed a systematic assessment to identify the accident analyses would be impacted by the IPS. Impacts on current operational practices have also been evaluated. There were no proposed changes to the tools or methods currently used for code applicability assessment. Qualitative review was performed to evaluate the impact of IPS on Bruce B Probabilistic Safety Analysis. Bruce Power will need to ensure that any assumptions made in the safety analyses matches the final design of the IPS.

CNSC staff performed a review of the submitted safety analyses packages in the areas of:

- Deterministic safety analysis
- Operational analyses
- Code applicability assessment
- Probabilistic safety analysis
- Hazard analysis
- Severe accident analysis
- Management of safety issues, and research and development

In the area of deterministic safety analysis, Bruce Power submitted a systematic assessment in Enclosure 1 of [13] to identify which accident analyses, as documented in the Appendices of the Bruce B Safety Report, would be impacted by the IPS. Bruce Power's findings from this systematic assessment [13]

indicated that the impacts of the IPS on accident analyses identified in the safety report are either negligible or none, as the reactivity worth of in-core components of the IPS and the targets is insignificant compared to the total reactivity worth of the reactor core. Specifically, the IPS has a negligible impact on the axial power distribution in the core, and therefore on the critical channel power (CCP) and global thermalhydraulic response of the heat transport system (HTS). Based on the information provided, CNSC staff determined that the analyses performed for the IPS meet the requirements of REGDOC-2.4.1, *Deterministic Safety Analysis*, and are adequate in demonstrating that the IPS will have a negligible impact to the existing deterministic safety analysis.

In addition to performing deterministic safety analysis, Bruce Power also performed operational assessments and analyses to identify how the normal operation of Unit 7 would be affected by the IPS. Bruce Power has studied the impacts of IPS target insertation and retrieval for different core configurations. In all cases, Bruce Power indicated that the impacts of the target insertation and retrieval are well within the control capabilities of the RRS. The changes in the bundle powers and detector readings for the shutdown systems and RRS are less than 0.3%. CNSC staff determined that Bruce Power has sufficiently demonstrated that the operation of IPS will have negligible impact on current operational practices. A hold point has been established to verify the data collected during the commissioning tests. This is to confirm that the reactivity worth of Lu-177 targets has negligible impact to bundle power and channel power distribution. This identified action is not considered to be a safety concern as the reactivity worth of the targets is negligible when compared to the total reactivity worth of the reactor core.

A code applicability assessment (CAA) was performed by Bruce Power to demonstrate compliance against REGDOC-2.4.1 requirements. In general, CNSC staff reviewed the CAA report and determined that REGDOC-2.4.1 requirements have been met. For the IPS project, Bruce Power used a Commercial off the Shelf (COTS) product to determine the maximum temperature of the target capsule in the reactor core during normal operation. Bruce Power stated that the validation basis for the COTS product is considered sufficient for the purpose of analysis in support of the installation of the IPS in Bruce B. CNSC staff determined that code uncertainties will not significantly affect the safety analysis results with the installed IPS, and the identified actions is not considered to be a safety concern. However, CNSC staff expect Bruce Power to validate the COTS code through experimental or commissioning data. A regulatory hold point is established to validate the COTS code against experimental or commissioning data.

In the area of probabilistic safety analysis (PSA), Bruce Power determined that IPS has a minimal impact on the Bruce B PSA, and that the current safety goals will still be met. The impact of the IPS on the quantification of Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF) in the various PSA elements is also negligible. CNSC staff determined that analyses performed

are adequate in demonstrating that the IPS will have a negligible impact on the Bruce B PSA.

Bruce Power provided the hazard analysis and severe accident analysis for the IPS. CNSC staff determined that the installation and operation of the IPS will have a negligible impact on internal and external hazards assessment. The IPS has no impact on severe accident response and recovery, as there is a negligible impact on the severe accident source terms.

Finally, Bruce Power performed a survey of the category 2 CANDU safety issues (CSI) and determined that there is no impact to the installation and operation of the IPS. CNSC staff conclude that the existing CSI will not have an impact on the production of Lu-177.

CNSC staff reviewed the analyses in support of the IPS project in the areas of deterministic safety analysis, operational analyses, code applicability assessment, PSA, hazard analysis and severe accident management. Based on the review of the information, CNSC staff conclude that assessments performed by Bruce Power are adequate and systematic, and Bruce Power has demonstrated that Lu-177 production will have a negligible impact on the existing safety case.

3.3 Summary of application review of other 14 SCAs

In addition to the design and safety analysis review of the IPS, CNSC staff performed a comprehensive review on the other 14 SCAs (aside from the physical design and safety analyses discussions presented in subsection 3.1 and 3.2 of this CMD) to determine whether the application has addressed all current regulatory requirements, and that the existing programs are sufficient to ensure the safe commissioning and operation of the IPS. As CNSC staff consider the IPS project as low risk in nature, detailed assessments of each of the SCAs are only included as an Appendix (Appendix B) in this CMD. This section will summarize the detailed assessments of Appendix B.

Bruce Power's programs and processes are well established, and meet all of the regulatory requirements defined in the licence and the LCH. There are processes in place for self-assessment and audits, managing design changes, and managing contractors. Bruce Power identified and evaluated CANDU-specific OPEX related to reactivity mechanism deck installations, VFD performance issues, reactivity mechanism issues and radiation exposure, as well as non-CANDU-specific OPEX related to target delivery systems. The lessons learned from the OPEX evaluation has been applied during the design stages of the IPS.

Bruce Power will ensure that its workers will be trained and qualified to carry out the proposed licensed activity (i.e., the production of Lu-177).

There are no maintainability challenges associated with the IPS, as Bruce Power has chosen a design that is not novel nor First-of-a-Kind.

Bruce Power's existing radiation protection program have ensured, and will continue to ensure, the protection of workers and members of the public, and doses will be kept ALARA. There will be some expected doses to workers who will be performing installation work on the RMD. As well, it is expected that there will be some radiation hazards associated with target retrieval. However, there will be measures in place to ensure that the workers will be protected, and their doses to be kept ALARA.

Bruce Power has a well-established occupational 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.

The emissions from the production of Lu-177 will be minimal compared to the DRLs for the site; Bruce Power has a sufficient environmental management system in place to ensure the protection of the environment. As the IPS will be a pneumatic system, there will be no environmental releases to groundwater.

There are appropriate plans to deal with emergencies at the Bruce site. The waste produced from the IPS project will be minimal, and will be managed by Bruce Power's existing waste management program. The existing security and safeguards measures in place are sufficient for the IPS project.

Bruce Power will be responsible for the packaging and shipping of the shielded transport container. Shipment of Lu-177 will need to be in full compliance with the requirements of the *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR 2015) and the Canada's *Transportation of Dangerous Goods Regulations* (TDGR), as well as meeting international obligations and IAEA safeguards.

CNSC staff conclude that Bruce Power's application has sufficiently addressed all elements of the 14 SCAs, and that there are adequate provisions in place to ensure the safe production of Lu-177. Production of Lu-177 is considered a low risk activity.

3.4 Lu-177 design and safety analysis review conclusion

Bruce Power's safety analysis assessment has demonstrated that IPS design will have negligible impact on operations and reactor safety, and on the existing SSCs such as electrical systems, I&C systems, and containment. In addition, the IPS will have a negligible impact on the current safety case of Bruce B.

CNSC staff conclude that:

- existing regulatory requirements and expectations have been met in the design and safety analysis work associated with the IPS
- there are no barriers to the installation and operation of an IPS in Bruce B Unit 7
- production of Lu-177 is considered a low risk activity
- Bruce Power has adequate provisions in place to ensure that Lu-177 will be safely produced

Due to the iterative nature of the design process, a number of documents and reports can only be finalized closer to, but in advance of, the commissioning of the IPS. The outstanding matters that have been identified by Bruce Power (such as document updates, additional analyses work, additional training requirements, additional radiation protection measures that need to be taken, etc.) as part of its project plan. CNSC staff are proposing to use a hold point on Bruce Power to track the completion of these actions. The proposed hold point details are not considered to be safety concerns; while important to be completed in advance of commissioning and startup, most are only administrative in nature. CNSC staff will also perform compliance verification activities to confirm that the identified actions have been completed.

4. OTHER MATTERS OF REGULATORY INTEREST

4.1 Indigenous Engagement

The common law duty to consult with Indigenous peoples applies when the Crown contemplates actions that may adversely impact potential or established Indigenous and/or treaty rights. The CNSC ensures that all of 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.

4.1.1 Discussion

CNSC staff have identified the First Nation and Métis groups who may have an interest in the proposed licence amendment for Bruce Power's Lu-177 IPS project. 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.

These Indigenous groups were identified due to the proximity of their communities, treaty areas and/or traditional territories to the Bruce site, or due to previously expressed interest in being kept informed of CNSC licensed activities occurring in or proximal to their territories. The CNSC has signed Terms of Reference for long-term engagement with each of these Indigenous groups to facilitate ongoing relationships and meaningful engagement and consultation.

CNSC staff engagement activities

In January 2021, CNSC staff sent letters of notification to the First Nation and Métis groups who may have an interest in the Lu-177 IPS project. These letters provided information regarding the proposed licence amendment application, the availability of participant funding to facilitate participation in the regulatory process, and details on how to participate in the Commission's public hearing process. Follow-up discussions were held with each of the groups at virtual meetings in January and February 2021 to ensure they had received the letters and to answer any questions about the licence amendment application.

All of the identified Indigenous groups have been encouraged to participate in the regulatory review process and in the public hearing to advise the Commission directly of any concerns they may have in relation to this licence application. The CNSC also continues to meet with Indigenous groups to encourage and maintain productive and respectful relationships.

To date, the identified Indigenous groups have not expressed any specific concerns with regards to the licence amendment application. Should any concerns be identified, CNSC staff will provide additional information with regards to on-going engagement activities, including any concerns expressed by Indigenous groups, to the Commission and the public in a supplemental CMD.

Licensee engagement activities

CNSC REGDOC-3.2.2, *Indigenous Engagement*, published in February 2016 (updated in August 2019), sets out requirements and guidance for licensees whose proposed projects may raise the Crown's duty to consult. While the CNSC cannot delegate its obligation, it can delegate procedural aspects of the consultation process to licensees, where appropriate. The information collected and measures proposed by licensees to avoid, mitigate, or offset potential adverse impacts from the proposed licence amendment may be used by CNSC staff in meeting its consultation obligations.

Bruce Power's licence amendment application does not raise the formal requirements of REGDOC-3.2.2. However, CNSC staff recognize that Bruce Power has a well-established engagement and communications program with interested Indigenous groups and is partnering with SON on this project. As well, Bruce Power provided information on the IPS project to the Métis communities during its quarterly interactions, specifically the MNO in September 2020 and January 2021, and the HSM in October 2020 and February 2021. Bruce Power also developed documents containing frequently asked questions to support community discussions (which included feedback from HSM and MNO leadership).

CNSC staff encourage Bruce Power to continue engaging with interested Indigenous groups regarding their facilities and activities including the licence amendment application.

4.1.2 Conclusion

The proposed physical modifications associated with this licence amendment are confined to the Bruce site, and impacts (environmental and radiological) beyond the limits of the Bruce site are expected to be negligible. Bruce Power has made adequate provisions to ensure the safe production of Lu-177. Therefore, it is CNSC staff's views that this licensing decision is unlikely to have potential impacts on Indigenous and/or treaty rights.

However, the CNSC is committed to meaningful, ongoing engagement with Indigenous groups that have an interest in CNSC-regulated facilities and activities. CNSC staff engaged with all interested Indigenous groups in relation to this licence amendment application and encouraged them to identify any concerns and participate in the regulatory review process.

Bruce Power has engaged with the identified Indigenous groups and is partnering with SON on the Lu-177 radioisotope production project. CNSC staff encourage Bruce Power to continue to engage with interested Indigenous groups on this licence amendment and other ongoing activities of interest.

4.2 Participant Funding

The CNSC made available up to $50,000 through its Participant Funding Program (PFP) to Indigenous peoples, members of the public and stakeholders in providing value-added information to the Commission through informed and topic-specific

interventions. This funding was offered to review Bruce Power's application and associated documents and to prepare written submissions for the Commission's hearing in writing.

4.2.1 Discussion

The deadline for applications was February 19, 2021. A Funding Review Committee (FRC), independent from CNSC staff, reviewed the funding applications received, and made recommendations on the allocation of funding to eligible applicants. Based on recommendations from the FRC, the CNSC awarded a total of **$1,000** in funding to the following recipient, who is required to submit a written intervention to the Commission Secretariat by May 27, 2021 for the Commission's consideration:

- Anna Tilman

4.2.2 Conclusion

The CNSC continues to actively promote ongoing communication and dissemination of regulatory and scientific information through social media channels, webinars, outreach in the local communities and postings on the CNSC web site. The CNSC has various mechanisms and processes such as the PFP and mail outs to encourage the public to participate in the Commission's public hearing, as described above. The CNSC has offered assistance to interested members of the public, Indigenous groups, and other stakeholders, through the PFP, to prepare for and participate in the Commission's public hearing.

4.3 Nuclear Liability Insurance

The *Nuclear Liability and Compensation Act* (NLCA) and *Nuclear Liability and Compensation Regulations* (NLCR) establish a compensation and liability regime for Canada in the unlikely event of a nuclear accident resulting in civil injury and damages. The CNSC acts in an advisory role to the Minister of Natural Resources on the designation of nuclear installations and operators.

NRCan is responsible for assessing the limit of liability for each class of nuclear installation, which for the Bruce Nuclear Generating Stations A and B is currently assessed at $1 billion dollars, the maximum limit of liability under the NLCA. Bruce Power is meeting its obligation for nuclear liability coverage under the NLCA.

4.4 Regulatory hold point for the production of Lu-177

CNSC staff concluded that the installation and operation of the IPS will not result in significant doses to workers or members of the public, and will not result in significant releases to the environment. In addition, the existing security and safeguards program in place is sufficient for the production of Lu-177.

However, due to the iterative nature of the Lu-177 IPS project, a number of documents (such as the final design manual, training manual, program and processes documents, and operating procedures) can only be finalized closer to,

but in advance of, the commissioning of the IPS. CNSC staff will also need to verify that design and safety analyses requirements have been met through commissioning test results.

CNSC staff are proposing to use a regulatory hold point to track the completion of the identified actions. The hold point is established to confirm operational readiness of the Lu-177 IPS for the staged progress through the commissioning phase to the initial operation for the production of Lu-177. The proposed hold point details are not considered to be safety concerns; while important to be completed in advance of commissioning and startup, most are only administrative in nature. The use of hold points is a routine operational practice; CNSC staff have utilized hold point for much larger projects in past, such as Bruce Power's MCR project under Licence Condition 15.5 of the existing PROL. In comparison to the MCR, the risk significance of the IPS project is low.

The Commission may include any licence condition it considers necessary for the purposes of the NSCA. The Commission may delegate authority to CNSC staff with respect to the administration of licence conditions, or portions thereof. Licence Condition 15.5 of the existing Bruce Power PROL provides the delegation of authority prior to the removal of established regulatory hold points for MCR. CNSC staff are recommending 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 similar to Licence Condition 15.5.

4.4.1 Pre-requisites for the release of hold point

CNSC staff identified the following pre-requisites for the release of the hold point. The pre-requisites will be captured in the LCH. CNSC staff will not allow Bruce Power to produce the Lu-177 if it has not completed the pre-requisites associated with the hold point.

Pre-requisites for release of the hold point

1. All licensee commitments prior to start of the commissioning program are complete;
2. Completion of licensee's governing program and procedure documentation 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;

4.4.2 Summary of actions identified as a hold point

The following actions have been identified as a hold point in this CMD, these actions have been mapped to the pre-requisites in subsection 4.4.1.

Topic	Actions identified as hold point	Mapped to Pre-requisite
General	Submit operating procedures. Submit commissioning plan and test results.	#2 #1
Management System	Submit final irradiation program and procedures used to manage the production of Lu-177 radioisotopes.	#2
Human Performance Management	Submit an updated Human Factors Engineering Summary Report (HFESR). Submit training and qualification information for Lu-177 production.	#1
Operating Performance	Submit any fuel and physics manuals and procedures that may be impacted as a result of the IPS.	#2
Safety Analysis	Submit information related to the validation of COTS product used in code applicability assessment.	#3
Physical Design	Submit updated design manual that includes design information on seismic, electrical, instrumentation and control, etc. Submit scaled mockup testing results. Submit environmental qualification (EQ) evaluations and update of EQ document as required.	#1, #4
Fitness for Service	Submit maintenance program for IPS, including considerations of aging management strategy. Submit chemistry impact assessment.	#2
Radiation Protection	Submit information whether there is a need for the use of permanent monitors (such as FAGMs). Submit final assessment on radiological hazards to workers. Submit information related to the mitigation measures that will be put into place, as well as the protective actions to be taken to prevent unplanned exposures and keep dose to workers below regulatory limits during upset conditions. This information may be incorporated into the irradiation services program under the Management Systems SCA.	#1, #5
Environmental Protection	Submit commissioning results of the analysis of particulate filters from stack monitor to confirm that there is no impact on gaseous effluents.	#1
No actions identified for the following SCAs: Convention Health and Safety, Emergency Management and Fire Protection, Waste Management, Security, Safeguards and Non-Proliferation, and Packaging and Transport.		

4.4.3 Process for releasing the regulatory hold point

CNSC staff are recommending to the Commission to accept the following process for the release of the hold point:

1. Bruce Power submits a request to CNSC staff (including the information to demonstrate that all pre-requisites have been satisfied) for the release of the hold point.
2. CNSC staff will review the submitted information and verify Bruce Power's compliance with requirements and commitments.
3. Based on the submitted information, CNSC staff will provide a report, including recommendations, to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch whether the criteria/pre-requisites specified in the LCH have/have not been met.
4. The Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch will then consent or not consent to the removal of the regulatory hold point.
5. CNSC staff will administer the release of the hold point through a confirmation letter to Bruce Power.

5. OVERALL CONCLUSIONS AND RECOMMENDATIONS

The production of Lu-177 in a CANDU reactor is considered an innovative solution as Bruce Power will be able to provide a constant and reliable supply of Lu-177 to meet the growing demand for radiotherapy treatment of cancer. The CANDU reactor will able to provide a better and higher yield when compared to research reactors that are already producing Lu-177. The IPS design is not a First-of-a-Kind as there are OPEX with similar systems internationally. It is CNSC staff's view that this is a low risk activity and the activity will remain within the plant's existing safety envelope, specifically Bruce Power has demonstrated that:

- the impact of the IPS to the existing SSCs is negligible.
- the reactivity worth of in-core components of the IPS and the targets is insignificant compared to the total reactivity worth of the reactor core.
- the impact of the IPS on the quantification of SCDF and LRF is also negligible.

In the Lu-177 supply chain, Bruce Power is only responsible for the irradiation of the targets. All other parts of the process will be handled outside of Canada by a third party company licensed in its own home country (name withheld due to commercial confidentiality) for isotope enrichment, radioisotope processing and drug manufacturing. For packaging and transportation of Lu-177, Bruce Power will ensure all Canadian and international transportation requirements and IAEA safeguards are met.

For the IPS project, IsoGen (a joint venture between Kinectrics and Framatome) was chosen as the main contractor. IsoGen has demonstrated that it has a quality management system in place that meets Bruce Power's contracting requirements. However, as Bruce Power will be the licence holder, it has the ultimate responsibility in ensuring the safe design, installation and operation of the IPS.

Based on the review of the licence amendment application, and the supporting information on the design and safety analyses of the IPS, CNSC staff determined that Bruce Power has adequate provisions in place to ensure the safe production of Lu-177. The installation and operation of the IPS will not result in significant doses to workers or members of the public, and will not result in significant releases to the environment. In addition, the existing security and safeguards program in place is sufficient for the production of Lu-177. Bruce Power continues to engage with interested Indigenous groups on this licence amendment and other ongoing activities of interest. Finally, Bruce Power will continue to protect the health and safety of the public, as well as the environment.

CNSC staff have concluded the following with respect to paragraphs 24(4)(*a*) and (*b*) of the NSCA, in that the licensee:

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.

Due to the iterative nature of the Lu-177 IPS project (such as testing, installation, etc.), a number of documents (such as the final design manual, training manual, program and processes documents, operating procedures) can only be finalized closer to the commissioning and operation stages of the IPS. CNSC staff will also verify that the design and safety analyses requirements have been met through commissioning test results. These actions have been identified by Bruce Power as part of its project plan.

As such, CNSC staff are proposing to use a regulatory hold point to track the completion of the identified actions. The hold point identified is established to confirm operational readiness of the Lu-177 IPS for the staged progress through the commissioning phase to the initial operation for the production of Lu-177. The use of hold points is a routine operational practice; CNSC staff have utilized hold point for much larger projects in past, such as Bruce Power's MCR project. In comparison to the operation of the facility itself, the risk significance of the IPS project is low. The proposed hold point details are not considered to be of safety concerns; while important to be completed in advance of commissioning and startup, most are administrative in nature. CNSC staff will also performance compliance verification activities to confirm that the identified actions have been completed. Finally, CNSC staff will update the Commission through the NPP status report on the status of the hold point.

CNSC staff are recommending the Commission to accept the process defined in Section 4.4 for the release of the hold point through the requested delegate of authority. CNSC staff will not allowed Bruce Power to produce Lu-177 if the prerequisites for the release of the hold point cannot be met.

The Licence Conditions Handbook (LCH) will specify that Bruce Power can only produce Cobalt-60 at Bruce B, and Lu-177 at Unit 7 of Bruce B. If Bruce Power plans to produce Lu-177 in other units, it must obtain concurrence from CNSC staff, demonstrate that it is a low risk activity, and that the activity will continue to remain within the plant's existing safety envelope.

In conclusion, CNSC staff recommend the Commission to accept Bruce Power's request for licence amendment to produce Lu-177, and propose the following changes to the PROL and its associated Licence Conditions Handbook (LCH):

- accepting the following amendment to the PROL licensed activities (vi), from "*produce Cobalt-60 at Bruce B*" to "*produce Cobalt-60 and Lutetium-177*"
- accepting the following amendment to the PROL licence condition 15.10, from "*The licensee shall implement and maintain a program for the receipt, storage and handling of the nuclear substance Cobalt-60 at Bruce B*" to "*The licensee shall implement and maintain a program for the production of the nuclear substances Cobalt-60 and Lutetium-177*"
- accepting the process defined in subsection 4.4 of this CMD for the release of the regulatory hold point and delegate authority

The proposed PROL, as well as a draft LCH are presented in Part Two of this CMD.

REFERENCES

The following documents are referenced in this CMD. Note that a number of these documents are marked **Protected B(R)**, as they contain commercial confidential information related to the design of the Lu-177 IPS. Members of the public will have to follow the Access to Information and Privacy (ATIP) process in order to obtain the ***Protected B(R)*** documents listed in this CMD.

[1] 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.

[2] Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotopes Project: Submission of Regulatory Communication Plan and Safety Analysis Plan", December 19, 2019, BP-CORR-00531-00051, e-Docs 6078682. ***Protected B(R)***

[3] Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotope Project: Final Integrated Safety Analysis Report", February 1, 2021, BP-CORR-00531-01217, e-Docs 6478652. ***Protected B(R)***

[4] Letter, M. Burton to L. Sigouin, "Bruce A and B Lu-177 Isotope Project: Submission of Revised Regulatory Communication Plan and Summary of Unit 7 Detailed Design", November 26, 2020, BP-CORR-00531-01024, e-Docs 6432308. ***Protected B(R)***

[5] Letter, M. Burton to L. Sigouin, "Bruce B Unit 7: Design Plan for the Lu-177 Isotope Production System (31790B)", April 17, 2020, BP-CORR-00531-00390, e-Docs 6281239. ***Protected B(R)***

[6] Letter, M. Burton to L. Sigouin, "Bruce B Unit 7: Classification Approval for New Isotope Production System (31790B)", December 19, 2019, BP-CORR-00531-00096, e-Docs 6078684. ***protected B(R)***

[7] Letter, L. Sigouin to M. Burton, "Bruce B: Unit 7 Classification Approval for New Isotope Production System (31790B)", March 24, 2020, e-Docs 6265449. ***Protected B***

[8] Email to Forms@CNSC, "Canadian endorsement of certificate for [packaging design number] SAFKEG 3979A", April 27, 2020, e-Docs 6287277. ***Protected B(R)***

[9] Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotope Project: Submission of the Unit 7 TSSA Design Registration Package", November 16, 2020, BP-CORR-00531-01073, e-Docs 6424058. ***Protected B(R)***

[10] Letter, M. Burton to L. Sigouin, "Supplemental Information for the Application to Amend the Power Reactor Operating Licence", February 8, 2021, BP-CORR-00531-01279, e-Docs 6485460. ***Protected B(R)***

[11] Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotope Project: Additional information on the Code Applicability Assessment and Design Plan", September 29, 2020, BP-CORR-00531-00808, e-Docs 6391177. ***Protected B(R)***

[12] Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotope Project: Submission of Code Applicability Assessment", April 22, 2020, BP-CORR-00531-00385, e-Docs 6283833. ***Protected B(R)***

[13] Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotope Project: Submission of the First Safety Analysis Package", August 26, 2020, BP-CORR-00531-00709, e-Docs 6367999. ***Protected B(R)***

[14] Letter, M. Burton to L Sigouin, "Bruce B Lu-177 Isotope Project: Additional Information on the Safety Analysis Plan", September 16, 2020, BP-CORR-00531-00571, e-Docs 6381744. ***Protected B(R)***

[15] Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotope Project: Submission of the Second Safety Analysis Package", October 1, 2020, BP-CORR-00531-00819, e-Docs 6392345. ***Protected B(R)***

[16] Letter, M. Burton to L. Sigouin, "Supplemental Information for the Application to Amend the Power Reactor Operating Licence", February 19, 2021, BP-CORR-00531-01390, e-Docs 6495440. ***Protected B(R)***

[17] Letter, M. Burton to L. Sigouin, "Bruce B Lu-177 Isotope Project: Updated Detailed Design Plan and Radiation Protection Information", February 1, 2021, BP-CORR-00531-01262, e-Docs 6480311. ***Protected B(R)***

[18] Letter, L. Watt to N. Turton, "Re: Bruce Power Lutetium Project – Impact of IPS at 100% FP", August 10, 2020, NK29-31790-10AUG2020, e-Docs 6400333. ***Protected B(R)***

[19] Letter, M. Burton to L. Sigouin, "Bruce A and B Lu-177 Isotope Project – CNSC staff review of the Application for the amendment of the PROL and the revised Regulatory Communication Plan", January 8, 2021, e-Docs 6453132. ***Protected B***

[20] Letter, M. Burton to M. Leblanc, "Supplemental Information for the Application to Amend the Power Reactor Operating Licence", February 8, 2021, e-Docs 6485425.

A. SAFETY AND CONTROL AREA FRAMEWORK

A.1 Safety and Control Areas Defined

The safety and control areas comprised of specific areas of regulatory interest which vary between facility types. The following table provides a high-level definition of each SCA.

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
Management	Management System	Covers the framework which establishes the processes and programs required to ensure an organization achieves its safety objectives and continuously monitors its performance against these objectives and fostering a healthy safety culture.
	Human Performance Management	Covers activities that enable effective human performance through the development and implementation of processes that ensure that licensee staff is sufficient in number in all relevant job areas and that licensee staff have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.
	Operating Performance	This includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.
Facility and Equipment	Safety Analysis	Maintenance of the safety analysis that supports that overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards.
	Physical Design	Relates to activities that impact on the ability of systems, components and structures to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.
	Fitness for Service	Covers activities that impact on the physical condition of systems, components and structures to ensure that they remain effective

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
		over time. This includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.
Core Control Processes	Radiation Protection	Covers the implementation of a radiation protection program in accordance with the RP Regulations. This program must ensure that contamination and radiation doses received are monitored and controlled.
	Conventional Health and Safety	Covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment.
	Environmental Protection	Covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.
	Emergency Management and Fire Protection	Covers emergency plans and emergency preparedness programs which exist for emergencies and for non-routine conditions. This also includes any results of exercise participation.
	Waste Management	Covers internal waste-related programs which form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. Also covers the planning for decommissioning.
	Security	Covers the programs required to implement and support the security requirements stipulated in the regulations, in their licence, in orders, or in expectations for their facility or activity.
	Safeguards and Non-Proliferation	Covers the programs and activities required for the successful implementation of the obligations arising from the Canada/IAEA safeguards agreements as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
	Packaging and Transport	Programs that cover the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility.

A.2 Specific Areas for this Facility Type

The following table identifies the specific areas that comprise each SCA for nuclear facilities:

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
Management	Management System	▪ Management System ▪ Organization ▪ Performance Assessment, Improvement and Management Review ▪ Operating Experience (OPEX) ▪ Change Management ▪ Safety Culture ▪ Configuration Management ▪ Records Management ▪ Management of Contractors ▪ Business Continuity
	Human Performance Management	▪ Human Performance Programs ▪ Personnel Training ▪ Personnel Certification ▪ Initial Certification Examinations and Requalification Tests ▪ Work Organization and Job Design ▪ Fitness for Duty
	Operating Performance	▪ Conduct of Licensed Activity ▪ Procedures ▪ Reporting and Trending ▪ Outage Management Performance ▪ Safe Operating Envelope ▪ Severe Accident Management and Recovery ▪ Accident Management and Recovery
Facility and Equipment	Safety Analysis	▪ Deterministic Safety Analysis ▪ Hazard Analysis

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
		▪ Probabilistic Safety Analysis ▪ Criticality Safety ▪ Severe Accident Analysis ▪ Management of Safety Issues (including R&D Programs)
	Physical Design	▪ Design Governance ▪ Site Characterization ▪ Facility Design ▪ Structure Design ▪ System Design ▪ Components Design
	Fitness for Service	▪ Equipment Fitness for Service/Equipment Performance ▪ Maintenance ▪ Structural Integrity ▪ Aging Management ▪ Chemistry Control ▪ Periodic Inspection and Testing
Core Control Processes	Radiation Protection	▪ Application of ALARA ▪ Worker Dose Control ▪ Radiation Protection Program Performance ▪ Radiological Hazard Control ▪ Estimated Dose to Public
	Conventional Health and Safety	▪ Performance ▪ Practices ▪ Awareness
	Environmental Protection	▪ Effluent and Emissions Control (releases) ▪ Environmental Management System (EMS) ▪ Assessment and Monitoring ▪ Protection to the Public ▪ Environmental Risk Assessment

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
	Emergency Management and Fire Protection	▪ Conventional Emergency Preparedness and Response ▪ Nuclear Emergency Preparedness and Response ▪ Fire Emergency Preparedness and Response
	Waste Management	▪ Waste Characterization ▪ Waste Minimization ▪ Waste Management Practices ▪ Decommissioning Plans
	Security	▪ Facilities and Equipment ▪ Response Arrangements ▪ Security Practices ▪ Drills and Exercises
	Safeguards and Non-Proliferation	▪ Nuclear Material Accountancy and Control ▪ Access and Assistance to the IAEA ▪ Operational and Design Information ▪ Safeguards Equipment, Containment and Surveillance ▪ Import and Export
	Packaging and Transport	▪ Package Design and Maintenance ▪ Packaging and Transport ▪ Registration for Use

B. GENERAL ASSESSMENT OF SCAS

The specific areas that comprise the SCAs for this facility or activity type are identified in Appendix A. Due to the low risk nature of the proposed activity in comparison to the operation of the facility itself, the comprehensive review on each of the 14 SCAs is included here as an Appendix. CNSC staff performed a comprehensive review on each of the 14 SCAs to determine if the production of Lu-177 would have any impacts to the existing safety case, that the design has addressed all current regulatory requirements, and whether the existing programs are sufficient to ensure the safe commissioning and operation of the IPS. If there are any outstanding matters that have been identified by Bruce Power (such as document updates, additional analyses work, additional training requirements, additional radiation protection measures that need to be taken, etc.), CNSC staff reviewed the actions that have been taken to ensure that those matters have been addressed.

B.1 Management System

The Management System SCA covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

Discussion

Bruce Power has a management system that meets regulatory requirements stated in the LCH, specifically Canadian Standards Association (CSA) N286-12, *Management System requirements for nuclear facilities*. Bruce Power's BP-MSM-1, *Management System Manual* provides a description of how Bruce Power's business works.

Bruce Power's Lu-177 IPS project execution involves a number of management system elements, including: organizational arrangements including accountabilities and responsibilities, staff competencies, planning, qualification of suppliers, management of contractors, adequacy of documentation used engineering change control (design changes, installation, commissioning, completion assurance, turnover), oversight/verifications performed by Bruce Power of work performed by suppliers, monitoring suppliers' performance, and communication with stakeholders.

CNSC staff evaluated Bruce Power's management program for Lu-177 radioisotope production against current CNSC requirements and expectations, including but not limited to:

- CSA N286-12, *Management System requirements for nuclear facilities*
- CSA N290.14-15, *Qualification of digital hardware and software for use in instrumentation and control applications for nuclear power plants, clause 6.4.3.1 Note 2*

- CSA N286.7-16, *Quality Assurance of Analytical, Scientific and Design Computer Programs for Nuclear Power plants*

Bruce Power's management system provides the process documentation and contract requirements for execution of projects. Therefore, the Lu-177 IPS project has to adhere to those requirements, specifically to provide objective evidence of IsoGen's implementation of Bruce Power documentation (including any changes to that documentation) and contractor oversight to demonstrate that management system requirements are met.

Summary

CNSC staff reviewed the following specific areas (SpAs) in the Management System SCA:

- Management System and Organization
- Performance Assessment, Improvement and Management Review
- OPEX
- Change Management, Configuration Management and Records Management
- Management of Contractors

Management system and organization

Bruce Power is following its management system process in developing an irradiation services program that governs the production of Lu-177. CNSC staff reviewed the recent changes to the programs applicable to Lu-177 IPS project, and concluded that Bruce Power's documentation describes an acceptable management system, and continues to comply with the requirements of the LCH, specifically CSA N286-12. In addition, Bruce Power has communicated to CNSC staff the roles and responsibilities for positions involved in the Lu-177 IPS project.

Bruce Power produced a draft irradiation services program that describes at a high level the processes needed to ensure that the radioisotopes will be produced in a safe and efficient manner, as well as providing logistic support and inventory management. Bruce Power's procedure BP-PROC-01120, *Management of Lutetium-177 Production* further describes the safe processes needed at each step of the production, which include: target receiving, target loading, target retrieval, and packaging/shipping. The irradiation services program will be included in the list of Bruce Power programs in BP-MSM-1, and will specify the key activities and personnel responsibilities for the operation of the IPS. In addition, Bruce Power will perform an effectiveness review of the implementation of this new program.

CNSC staff concluded that the draft program addressed generic elements from the Bruce Power's management system. CNSC staff will verify the completion of the irradiation services program document via a regulatory hold point.

Performance assessment, improvement and management review

CNSC staff assessed Bruce Power's overall management system effectiveness program and observed active participation of senior management in the assessment of the problems for all programs.

CNSC staff determined that Bruce Power has processes in place for self-assessment and audits that meet regulatory requirements, and expect that improvements will be made as necessary for the multiple processes involved in the Lu-177 IPS project, including the future irradiation services program document.

OPEX

Bruce Power uses internal and external OPEX to identify, evaluate, and apply lessons learned to improve plant safety, reliability, and commercial performance. Bruce Power provided an OPEX review [4] for the IPS project.

For the design aspects, Bruce Power demonstrated that they have identified and implemented OPEX from sources within Bruce Power, other CANDU nuclear facilities, and international nuclear industry. It included a review of CANDU-specific OPEX related to reactivity mechanism deck installations, VFD performance issues, reactivity mechanism issues and radiation exposure, as well as non-CANDU-specific OPEX related to target delivery systems.

Bruce Power also applied OPEX in the areas of safety analyses, human factors in design, and Environment Risk Assessment. The experience gained from IsoGen's previous OPEX will be also be taken into account in the development of the operation and maintenance manual.

Bruce Power has a Condition Record process to document the problems, investigation/evaluation results and corrective actions related to people, plant, environment and processes. The process is also applicable to contractors participating in the Lu-177 IPS project.

In addition, a scaled mock-up of the anticipated design was constructed as a proof-of-concept. As there is no OPEX or experimental and operating data for an equivalent target delivery system in an operating CANDU reactor, CNSC staff emphasize the importance of the mock-up and the commissioning tests to confirm the design and operation of the IPS. However, the lack of OPEX is not a barrier to the installation of the system.

CNSC staff concluded that Bruce Power has addressed OPEX requirements.

Change management, configuration management and records management

Bruce Power's BP-PROG-16.01, *Conduct of Business* establishes the framework for change management process that ensures changes made to the processes and documents are reviewed and approved before they are implemented. In addition, Bruce Power's BP-PROG-10.01, *Configuration Management* describes the process for managing design changes (i.e., ECC process).

Based on the review of the information provided, CNSC staff concluded that Bruce Power has a sufficient change management program in place.

Management of contractors

In the area of design, Bruce Power ensures the work done by IsoGen adheres to BP-PROG-10.01, *Configuration Management* program. Bruce Power has documented and implemented specific processes to manage the high-risk design work performed by suppliers. Bruce Power also developed processes to manage the safety analysis activities performed by the suppliers.

For construction, Framatome (IsoGen) will perform the work under its own approved quality management system that meets Bruce Power's contract requirements. Bruce Power has implemented specific documentation to manage the quality of work performed by contractors and oversight activities, such as, review of Inspection and Test Plans (ITPs), independent review of records, and review of documentation used by the contractors. All these activities are specified under Bruce Power's project management and construction, and contractor management programs.

CNSC staff verified that the contractors for the IPS project are qualified, and that Bruce Power has plans in place to verify and perform oversight of the work performed by the contractors. CNSC staff concluded that Bruce Power's management of contractors and supply chain programs are adequate for the IPS project.

Conclusion

CNSC staff determined that Bruce Power has a management system that meets regulatory requirements. There are processes in place for self-assessment and audits, managing design changes, and managing contractors. OPEX was used to identify, evaluate, and apply lessons learned to improve plant safety, reliability, and commercial performance.

CNSC staff are proposing to use a regulatory hold point to track the completion of irradiation services program document (including its implementing procedures).

B.2 Human Performance Management

The Human Performance SCA covers activities that enable effective human performance through the development and implementation of processes that ensure a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

Discussion

This section of the CMD covers the following specific areas of the Human Performance Management SCA:

- Human performance program, and work organization and job design
- Personnel training

Human performance program

Bruce Power currently has a human performance program in place. REGDOC-2.2.5, *Minimum Staff Complement*, describes the CNSC's recommended approach for defining the minimum complement and sets out the key factors that CNSC staff will take into account when assessing whether the licensee has made adequate provision for ensuring the presence of a sufficient number of qualified staff.

CNSC staff evaluated Bruce Power's application to determine if production of Lu-177 will have an impact on minimum complement, and whether there are plans in place to ensure that there will be a sufficient number of trained and qualified staff for the production of Lu-177.

Personnel training

Systematic approach to training (SAT) is the framework endorsed by the CNSC for establishing and maintaining training for persons working in nuclear facilities. A SAT training system provides the basis for the analysis, design, development, implementation, evaluation, documentation and management of training for workers. It also provides a method to demonstrate that the required knowledge, skills and safety-related attributes have been attained through a performance-based assessment and that program evaluations are carried out to ensure training programs reflect the operating state of the facility.

REGDOC-2.2.2, *Personnel Training* sets out the CNSC's requirements for licensees regarding the development and implementation of SAT training system. REGDOC-2.2.2 also provides guidance on how these requirements should be met.

The licence amendment application [1] identified that Bruce Power's SAT training system will be applied to ensure workers continue to be trained and qualified to carry out their duties. Bruce Power also identified the impacted training programs will be analyzed, designed, developed, implemented, evaluated and managed in accordance with this training system.

Summary

A summary of CNSC staff's review in the Human Performance Management SCA is presented below.

Human performance program, and work organization and job design

Bruce Power provided a Human Factors Engineering Program Plan (HFEPP) and interim Human Factors Engineering Summary Report (HFESR) that included preliminary information about staffing required to carry out the production of Lu-177. The interim HFESR stated that fuel handling operators will be the primary resource for performing the tasks associated with the Lu-177 IPS. Tasks will include handling, target retrieval, craning and shipping. Bruce Power stated that headcount will remain unchanged "*based on a bridging strategy to reduce workload in dry fuel storage activities*."

CNSC staff noted that there is on-going work listed in the HFESR such as determining how long operators will be working near the RMD, analysis of tasks for the system engineer and main control room staff (such as U7 Authorized Nuclear Operator (ANO), Shift Manager and Fuel Handling Operators). The HFESR that was submitted to date provided CNSC staff with evidence that Bruce Power has carried out preliminary human factors analysis activities in accordance with their HFEPP and the Human Factors Verification and Validation Plan (HFVVP) for the Lu-177 IPS project. Bruce Power's project plan indicated that the final HFESR will be completed following initial operation for the production of Lu-177, as the final HFESR needs to align with the IPS that will be installed in the field.

CNSC staff concluded that Bruce Power has a sufficient HFEPP in place to guide human factors engineering activities during the design of the Lu-177 IPS. CNSC staff are proposing to use a regulatory hold point to track the completion of the identified tasks in the HFESR.

Personnel Training

Bruce Power has a well-established SAT-based training system (as described in Bruce Power document BP-PROG-02.02, *Worker Learning and Qualification*, BP-PROC-01071, *Systematic Approach to Training Process* and associated processes, procedures and job aids) and this training system is compliant with CNSC training requirements stipulated in REGDOC-2.2.2.

Bruce Power's documented SAT training system will be applied for the IPS to ensure workers are trained and qualified to carry out the licensed activity. Specifically, the training change management for the IPS is documented and governed by B-HBK-09500-00012, *Bruce Power Life Extension Training Work Plan* which is governed by BP-PROG-02.02.

Bruce Power identified in submission [16] that the modification training (as part of the continuing training program), which includes classroom, on-the-job and Dynamic Learning Activities (DLAs), will commence before the operation of the IPS (but after the completion of detailed design and the development of operating procedures). This is to ensure that the workers will gain hands-on experience with the installed system.

The modification training associated with IPS will be provided by IsoGen, and will be incorporated into the continuing training program for impacted workers including certified personnel. Following twenty four (24) to thirty six (36) months from the available for service date for the IPS, the IsoGen training program will be incorporated into the respective Bruce Power initial training programs. An Execution Contractor Training Assessment (ECTA) will be completed to validate that the contracted training adheres to Bruce Power's program requirements.

Bruce Power provided additional supplemental information [10] stating that the TNA-MOD-SC-P13005-00001 R001, *IPS Training Needs Analysis (TNA)* was completed. The TNA document provided details of the worker groups impacted

by the IPS activity and the resulting roles, duties and qualification requirements. TNA-MOD-SC-P13005-00001 also identified related TNAs that detail additional training and qualification requirements (e.g., supplemental staff training requirements).

CNSC staff concluded that the plans in place is sufficient to ensure workers will be trained and qualified to carry out the work associated with the production of Lu-177. Bruce Power identified future training actions that can only be finalized following commissioning of the IPS. CNSC staff are proposing to use a regulatory hold point to track the completion of those actions to ensure that the workers are qualified and trained to produce Lu-177.

Conclusion

CNSC staff concluded that the plans in place by Bruce Power are sufficient to address all human performance management aspects of the IPS project.

Human performance program

For the human performance program, the HFESR that was submitted to date provided CNSC staff with evidence that Bruce Power has carried out preliminary human factors analysis activities in accordance with their HFEPP and the HFVVP for the Lu-177 IPS project.

CNSC staff concluded that Bruce Power has a HFEPP in place to guide human factors engineering activities during the design of the Lu-177 IPS. CNSC staff are proposing to use a regulatory hold point to track the completion of the identified tasks in the HFEPP.

Personnel training

For personnel training, CNSC staff determined that Bruce Power has a well-established SAT training system that meets regulatory training requirements. Bruce Power's plans are sufficient to manage training changes, and to ensure workers will be trained and qualified to produce Lu-177.

Bruce Power's submissions identified future training actions such as the development, implementation and delivery of training and the completion of an ECTA. These training actions can only be finalized following commissioning of the IPS. CNSC staff are proposing to use a regulatory hold point to verify the completion of those actions.

B.3 Operating Performance

The Operating Performance SCA covers the conduct of the licensed activities and the activities that enable effective performance.

Discussion

As per the PROL, Bruce Power is required to implement and maintain an operations programs. These programs consist of a safe operating envelope (SOE), a set of operating policies and principles (OP&Ps), and accident management

procedures and/or guides for design-basis and beyond-design-basis accidents, including overall strategies for recovery.

In addition, CNSC staff reviewed the impact of the production of Lu-177 on fuel and physics procedures, the reactivity management program, as well as the SOE. For the SOE, CNSC staff reviewed the efficacy of core monitoring software, the impact on fuelling practices, and the impact on compliance with channel and bundle power limits.

For severe accident response and recovery, it is managed as part of BP-PROG-12.01, *Conduct of Plant Operations*. In addition, severe accident management for the Lu-177 IPS utilizes the existing concepts, structures, roles, and processes defined in Bruce Power's Nuclear Emergency Response Plan to execute the mitigating measures necessary during a severe accident.

Summary

This section of the CMD is focused on:

- Impact of the IPS on compliance with power limits
- Impact on fuel and physics manuals and procedures
- Severe accident management and recovery

Impact of IPS on compliance with power limits

CNSC staff reviewed the following impacts of IPS on compliance with power limits:

- Impact to bundle power and channel power distribution
- Verification of fuel management code capabilities

Bruce Power provided in Appendix D of [2] the evaluation of the change in reactivity worth of the Lu-177 targets and the impact on the bundle power and channel power distribution. CNSC staff determined that supporting justification and conclusion of the evaluation is adequate.

Bruce Power also verified the fuel management code capabilities, specifically the applicability of the SORO code (a steady state core tracking code) and models. To account for the installation of the IPS, Bruce Power updated the SORO model using incremental neutron cross-sections calculated with the DRAGON neutron transport code. CNSC staff find the submitted information to be supportive of the continued capability of the SORO code.

Bruce Power will need to verify, through commissioning test results, that the reactivity worth of Lu-177 targets will have negligible impact to bundle power and channel power distribution. CNSC staff are proposing to use a regulatory hold point to track the submission of the results to the CNSC.

Impact on fuel and physics manuals and procedures

Bruce Power will be preparing a full set of operating documentation, including updates to the existing operation documentation for the Lu-177 IPS. Bruce Power indicated in its project plan that these documents will be completed prior to

commissioning of the IPS. CNSC staff are proposing to use a regulatory hold point to track the submission of the fuel and physics manuals and procedures to the CNSC, as well as submitting the commissioning test results related to the reactivity worth of the Lu-177 targets.

Severe accident management and recovery

Bruce Power indicated that the production of Lu-177 will have negligible impact on the severe accident source terms. Therefore, additional mitigating measures will not be required for the IPS. CNSC staff find Bruce Power's conclusion to be acceptable.

Conclusion

CNSC staff determined that Bruce Power is following its management system process in developing fuel and physics procedures and manuals. CNSC staff are proposing to use a regulatory hold point to confirm the completion of those documents.

CNSC staff also reviewed the impact of the Lu-177 IPS on fuel and physics procedures, the reactivity management program, as well as the SOE. CNSC staff concluded that the analyses performed by Bruce Power is sufficient in demonstrating that there are negligible impacts on compliance with power limits. CNSC staff are proposing to use a regulatory hold point to track the submission of the commissioning test results related to the impact of the IPS on compliance with power limits.

Finally, CNSC staff concluded that additional mitigating measures will not be required for severe accident management and recovery as the production of Lu-177 will have negligible impact on severe accident source terms.

Overall, CNSC staff determined that the submissions supporting the Lu-177 project are aligned with the requirements for operating performance; there are no safety concerns associated with the IPS.

B.4 Safety Analysis

The Safety Analysis SCA covers maintenance of the safety analysis that supports the safety case for the production of Lu-177 at the Bruce nuclear facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards.

Discussion

In February 2021, Bruce Power submitted the Final Integrated Safety Analysis Report (FISAR) [2]. The FISAR integrates the safety and operational analyses performed to demonstrate that the IPS will have a negligible impact on the overall safety case for Bruce B, and that the operational impact of the IPS is minimal. This section covers CNSC staff's review in the following areas:

- Deterministic safety analysis

- Operational analyses
- Code applicability assessment
- Probabilistic safety analysis
- Hazard analysis
- Severe accident analysis

Deterministic Safety Analysis

Deterministic Safety Analysis requirements are defined in REGDOC-2.4.1, *Deterministic Safety Analysis*. To meet CNSC requirements, Bruce Power is required to conduct safety analyses and assessments to demonstrate that SSCs will continue to provide adequate prevention and mitigation against postulated accidents and that the plant meets safety requirements. Specifically, Bruce Power has to demonstrate that the IPS will have negligible impact on the overall safety case for the unit.

Operational Analyses

The purpose of the operational analyses is to demonstrate that the IPS will have negligible impact on the normal operation of Unit 7.

Code Applicability Assessment

The objective of code applicability assessment (CAA) is to demonstrate that codes possess adequate, validated models to simulate relevant phenomena and are therefore applicable to be used in safety analysis, design assist analysis and operational analysis in support of installation and operation of IPS.

Probabilistic Safety Analysis

Probabilistic Safety Analysis requirements are defined in REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*. For the Lu-177 IPS project, Bruce Power performed qualitative assessments on the impact of the installation and operation of the IPS equipment on each of the Bruce B PSA studies, severe accident analysis, and internal and external hazards.

Hazard Analysis

The purpose of hazard analysis is to determine whether the installation and the operation of the IPS have an impact on internal and external hazards assessments. This includes assessment on the impact to the Bruce B irradiated fuel bays (IFB) and Western Waste Management Facility (WWMF) Used Fuel Dry Storage (UFDS).

Severe accident analysis

The purpose of the severe accident analysis is to determine if the installation and operation of the IPS will have an impact on the severe accident fission products source terms and accident progression. Severe accident management requirements are defined in REGDOC-2.3.2, *Accident Management*.

Management of safety issues, and research and development

The purpose of this section is to determine if the existing safety issues have been considered, and whether they will have an impact on the installation and operation of the IPS.

Summary

This section covers CNSC staff's review in the following areas:

- Deterministic safety analysis
- Operational analyses
- Code applicability assessment
- Probabilistic safety analysis
- Hazard analysis
- Severe accident analysis
- Management of safety issues, and research and development

Deterministic Safety Analysis

Bruce Power submitted a systematic assessment in Enclosure 1 of [13] to identify which accident analyses documented in the Appendices of the Bruce B Safety Report would be impacted by the IPS. The primary criteria for assessing the potential impact of the IPS on the postulated accidents were to determine the changes:

- in the predicted radiological releases
- to any derived, or regulatory, acceptance criteria that are applicable to a particular accident category

Bruce Power's findings from this systematic assessment [13] indicated that, while the impact of the IPS on a large majority of safety report accident analyses is either negligible or none, Bruce Power needed to further assess the IPS impact on the following accidents from the safety report:

- Loss of Moderator Inventory (LOMI)
- In-Core Loss of Coolant Accident (in-LOCA)
- Slow Loss of Reactor Power Regulation (SLOR)
- Common Mode Events (CMEs)

Additional assessments were provided by Bruce Power in submission [15] to address the impacts of the accidents identified above, and their overall conclusion was that the impacts of the IPS on each postulated accident are negligible as the total reactivity worth of in-core components of the IPS is very small. CNSC staff concluded that Bruce Power has provided an adequate assessment to demonstrate that the IPS has a negligible impact on the axial power distribution in the core, and therefore on the critical channel power (CCP) and global thermalhydraulic response of the heat transport system (HTS).

In addition to the systematic assessment of the IPS impact on the accidents from the Bruce B Safety Report, Bruce Power performed an Event Identification and Classification (EIC) review as the installation of the IPS may introduce or alter

the initiating events (i.e., accidents). CNSC staff determined that the requirements of Sections 4.2.1, 4.2.2 and 4.2.3 of REGDOC-2.4.1 were met in performing the EIC review. Seven new initiating events, consisting of five design basis accidents (DBAs) and two BDBAs were identified as a result of the installation of the IPS through the EIC in Appendix B of [2]. However, the unit's safety systems are able to deal with these DBA events, and therefore the existing safety case remains valid.

CNSC staff concluded that the deterministic safety analyses performed by Bruce Power is sufficient, and that the IPS has a negligible impact on the existing analyses in the safety report.

Operational analyses

In addition to performing deterministic safety analysis, Bruce Power also performed operational assessments and analyses to identify how normal operation of Unit 7 would be affected by the IPS.

More specifically, the purpose of the operational analyses was to verify that:

- Reactor Regulating System (RRS) is capable of compensating for reactivity changes related to target insertation and retrieval operations and suppressing any potential reactivity transients
- Bundle powers following target insertation and retrieval are within acceptable operational limits and sufficient margins to licensing limits maintained
- Average Zone Level and fill levels of individual Liquid Zone Control remain within acceptable levels
- Margin to Neutron Overpower Protection (NOP) trip setpoint is not significantly reduced following target retrieval operation

Bruce Power has studied the impacts of IPS target insertation and retrieval for different core configurations. In all cases, Bruce Power indicated that the impacts of the target insertation and retrieval are well within the control capabilities of the RRS. CNSC staff concluded that the assessments performed by Bruce Power are sufficient in demonstrating that the operation of IPS will have negligible impact on current operational practices.

Code applicability assessment

Bruce Power performed code applicability assessment (CAA) to demonstrate compliance against REGDOC-2.4.1 requirements. The CAA was performed for a specific set of computer codes, accident scenarios and Figures of Merit (FOM). The assessment is to confirm that the code employs adequate models for key phenomena with proper scaling effects, numerical stability and quantification of code accuracy.

In general, CNSC staff reviewed the CAA report and determined that REGDOC-2.4.1 requirements have been met. In addition, consistent with the graded approach provided for in the N286.7 guidelines, Bruce Power's design assist analysis was performed with conservative input assumptions and demonstrated a large margin to the design limits. The CAA did not propose changes to the tools

or methods used, but did recognize a requirement to modify the core representation and material properties to account for the IPS.

For the Lu-177 IPS project, Bruce Power used a COTS product, to determine the maximum temperature of the target capsule in the reactor core during normal operation. Bruce Power stated that the validation basis for COTS product is considered sufficient for the purpose of analysis in support of the installation of the IPS in Bruce B. CNSC staff determined that code uncertainties will not significantly affect the safety analysis results with the installed IPS. However, CNSC staff expect Bruce Power to validate the COTS code through experimental or commissioning data.

CNSC staff are proposing to use a regulatory hold point to verify the accuracy of the COTS code, the updated core representation and material properties in the commissioning report.

Probabilistic safety analysis

Bruce Power performed a qualitative review of the impact of the IPS on the Bruce B PSA, including the following elements:

- Bruce B Level 1 and 2 At-Power and Outage Internal Events
- Internal Fire, Internal Flood, Seismic and High Wind

Bruce Power concluded that IPS has a minimal impact on the elements discussed above, and that the current safety goals are still met. The impact of the IPS on the quantification of Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF) in the various PSA elements is also negligible.

CNSC staff concluded that the analyses performed by Bruce Power is sufficient in demonstrating that the impact of the IPS on the Bruce B PSA is negligible.

Hazard Analysis

Bruce Power performed qualitative impact analysis of the installation and operation of the IPS on internal and external hazards assessments, as well as assessment on the impact to the Bruce B IFBs and WWMF UFDS. CNSC staff concluded that the installation and operation of the IPS will have negligible impact on internal and external hazards assessment, and that the existing assessments remain valid.

Severe accident analysis

Bruce Power performed a qualitative assessment of the impact of the installation and operation of the IPS on the severe accident fission products source terms and accident progression.

Under severe accident conditions, the IPS in-core components have the potential to meltdown and mix with the corium which can affect the accident progression. Given the addition of the IPS material to the corium, Bruce Power assessed the impact of the IPS on:

- the Bruce Power parameter file for MAAP-CANDU (a code for best estimate analyses of severe accident scenarios)

- release categorization

The analysis in enclosure 4 of [13] showed that the IPS has negligible impact on the severe accidents source terms. No changes are required to the Bruce Power MAAP-CANDU parameter file, and the IPS has no impact on the release categories assigned to different plant damage states.

Based on the information submitted, CNSC staff concluded that the Lu-177 IPS has no impact on severe accident response and recovery.

Management of safety issues, and research and development

Bruce Power performed a survey of the category 2 CANDU safety issues (CSI) and determined that the CSIs have no impacts to the installation and operation of the IPS. The analyses performed by Bruce Power demonstrated that IPS has minimal impacts on the reactor physics characteristics of the Bruce B reactor; including flux and coolant void reactivity, and reactivity worth. The analyses also demonstrated that IPS has negligible effect on the global thermal hydraulic response of the HTS.

CNSC staff concluded that Bruce Power has sufficiently evaluated category 2 CSIs for the IPS project.

Conclusion

CNSC staff concluded that the systematic assessments performed by Bruce Power is sufficient to demonstrate that:

- the IPS has a negligible impact on the axial power distribution in the core, and therefore on the CCP and global thermalhydraulic response of the HTS. the impacts of the IPS target insertation and retrieval are well within the control capabilities of the RRS
- quantification of SCDF and LRF in the various PSA elements is negligible
- the installation and operation of the IPS have negligible impact on internal and external hazards assessment
- there is negligible impact on the severe accidents source terms
- existing category 2 CSIs will not have an impact on the installation and operation of the IPS

For CAA, CNSC staff are proposing to use a regulatory hold point to verify the accuracy of the COTS code, the updated core representation and material properties in the commissioning report. This is not a safety issue as code uncertainties will not significantly affect the safety analysis results with the installed IPS.

B.5 Physical Design

The Physical Design SCA covers the activities associated with the production of Lu-177 that may have an impact the ability of SSCs to meet and maintain their design basis.

Discussion

CNSC staff performed an evaluation of the design of the Lu-177 IPS, including its impact on core neutronics and reactivity characteristics, against requirements found in the LCH, such as:

- CSA N285.0, *General Requirements for Pressure Retaining Systems and components in CANDU Nuclear Power Plants*
- CSA N289-1-08, *General requirements for seismic design and qualification of CANDU nuclear power plants*
- CSA N289.3-10, *Design procedures for seismic qualification of CANDU nuclear power plants*
- CSA N290.12, *Human factors in design of nuclear power plants*
- CSA N290.13, *Environmental qualification of equipment for CANDU nuclear power plants*
- CSA N290.14, *Qualification of pre-developed software for use in safety-related instrumentation and control applications in nuclear power plants*
- CSA N291-15, *Requirements for safety-related structures for CANDU nuclear power plants*
- CSA N289.1, *General requirements for seismic design and qualification of CANDU nuclear power plants*

As discussed in Section 3.1 of this CMD, the Lu-177 IPS is a pneumatic delivery system that will deliver the targets into and out of the reactor core (through an existing unused Vertifical Flux Detector location –VFD21). IsoGen intentionally chose a system that is not overly complex nor First-of-a-Kind.

Bruce Power provided supporting documents [2], [5], [6] and [17] to demonstrate that the Lu-177 IPS will have a negligible impact on operations and reactor safety.

Summary

This section highlights CNSC staff's review of the design of the IPS in the following areas:

- Mechanical and process system
- Pressure boundary
- Instrumentation and control
- Electrical power system
- Environmental qualification
- Seismic qualification
- Civil structure design
- Human factors in design
- Impact of IPS on core neutronics and reactivity characteristics

Bruce Power will produce a final design manual that will document the design details associated with the IPS, including the design requirements to address the areas identified above. As part of Bruce Power's project plan, the final design manual for the IPS will be completed following the initial operation for the

production of Lu-177. CNSC staff are proposing to use a regulatory hold point to verify the completeness of the design manual.

Mechanical and process system

Bruce Power provided details related to the major mechanical components used in the Lu-177 IPS. Major components of the IPS include valves (such as a diverter valve, target stop valves, containment boundary valves, and a helium pressure control valve), a target finger tube and helium buffer tank.

Bruce Power also provided details related to the helium gas used in the pneumatic system. This included information on the pressure range and purity of the helium gas. Filters between helium gas supply bottles and pressure regulators at the helium bottle station will be installed to ensure that foreign materials will not enter the system. Bruce Power also stated that there is no external cooling requirement for the IPS targets, as the moderator provides a sufficient heat sink. In the event that the station loses Class IV power supply during target retrieval, there is a backup system in place to allow targets to be conveyed to a shielded location. The system is designed such that, under the loss of power event, the containment boundary valves will go to the 'close' position such that the containment boundary will not be impacted.

CNSC staff concluded that, from a mechanical and process perspective, Bruce Power has sufficiently demonstrated that the IPS will have a negligible impact on existing SSCs, including the containment boundary.

Pressure Boundary

Bruce Power has a documented pressure boundary program that meets the requirements of CSA N285.0. There is a formal agreement in place for the Technical Standards and Safety Authority (TSSA) to act as an Authorized Inspection Agency (AIA) to provide services for the pressure boundary components.

Bruce Power submitted [6] the request for code classification approval of the IPS. Bruce Power demonstrated that modifications made for installation of the IPS will have a negligible impact on existing SSCs, and that the reactor containment boundary will continue to be maintained. CNSC staff reviewed and approved Bruce Power's code classification request [7]; TSSA has also approved the design registration package [10]. CNSC staff concluded that Bruce Power has met pressure boundary requirements.

Instrumentation and Control (I&C)

For the Lu-177 IPS, no I&C equipment will be added in the main control room. In addition, the main control room will not have any annunciations and indications from the IPS components. The IPS will be controlled from a human-machine interface at the Pneumatic Control Panel (PCP), which will allow an operator to control and monitor the IPS, and to insert, track and retrieve the targets from a centralized location.

The control system will consist of hardwired relay logics and timers that perform automated loading and unloading sequences to drive targets to the target finger tube. The PCP will provide the operator with a visual of the valves' positions via a mimic display of the IPS flow diagram, and will be equipped with hand switches for manual control (if required). System testing will verify the diverter valve's position and function, and perform a holding test to ensure that there is no gross leakage in the system.

There will be embedded software in certain IPS components such as a gamma sensor, assaying equipment and counters used to track the number of targets in the reactor core. The human machine interface will be implemented using a programmable logic controller. All digital components will be categorized and qualified in accordance with CSA N290.14-15.

Design change to the RRS will not be required for the loading and unloading of Lu-177 targets into and out of the reactor core. The design analysis information [2] showed that loading and unloading targets may cause a slight change in liquid zone level; however, these changes remain within the control capability of RRS.

Based on information submitted, CNSC staff concluded that, from an I&C perspective, Bruce Power has sufficiently demonstrated that the operation of the IPS will have negligible impact on the RRS and its control capability.

Electrical Power Systems

The PCP of the IPS is supplied from the station Class IV power system. The PCP is the electrical interfacing point between the 120 VAC Class IV power system and the IPS.

The IPS design includes provisions for a backup battery power supply with sufficient capacity to allow targets to be conveyed to a shielded location, should the station lose Class IV power supply during target retrieval.

Bruce Power performed electrical power loading, voltage drop and cable ampacity calculations to confirm that the additional loading from the IPS has negligible impact on the Class IV power system. CNSC staff reviewed the IPS cable block diagram, PCP control and electrical power load report and Class IV panel load validation for power supply to the IPS and find Bruce Power's assessment on the impact to the Class IV power system to be adequate.

Based on the information submitted, CNSC staff concluded that, from an electrical power system perspective, Bruce Power has sufficiently demonstrated that the addition of the IPS load will have negligible impact on the existing station electrical system.

Environmental Qualification

The design of the IPS is required to meet the environmental qualification (EQ) requirements of CSA N290.13. The non-metallic portions of the IPS within the containment boundary is subject to evaluation as per Bruce Power's EQ governing documents. Specifically, Bruce Power is required to ensure that the

containment boundary components of the IPS will maintain its integrity following DBAs.

A Safety Requirements Matrix (SRM) will be developed by Bruce Power for the containment boundary components of the IPS (e.g., containment boundary valves and distributor head). With the SRM, and the manufacturers' documentation for the components, Bruce Power will perform the IPS related EQ evaluations (EQE). The EQE will review the impact of the IPS on any associated EQ components during normal and abnormal conditions.

As a result of the EQE, the EQ documentation (such as room conditions manual and environmental qualification assessments) will either be updated or developed as required. The EQE will be completed prior to the procurement and installation of the components.

Based on the information submitted, CNSC staff determined that EQ requirements have been considered in the design of the IPS. The approach taken is aligned with the requirements defined in CSA N290.13, as well as Bruce Power's EQ governing documents. CNSC staff are proposing to use a regulatory hold point to track the submission of the completed EQE for the IPS, including all associated documents and reports to the CNSC.

Seismic Qualification

Bruce Power has a seismic qualification program that meets the requirements of CSA N289.1. The containment boundary portions of the IPS (including distributor head, piping, supports and containment boundary valves) will be seismically qualified to the same design basis as the existing systems.

CNSC staff concluded that seismic qualifications requirements have been sufficiently addressed by Bruce Power.

Civil Structures Design

Bruce Power stated in its application that "*the civil design of the system will be designed using the ECC implementing procedures. Structural floor loading assessments within the station will also be completed due to the significant weight of the new shielding and skid structures.*"

As part of the IPS design review, Bruce Power provided high level results/summary of structural floor loading assessments to the CNSC; CNSC staff reviewed the information and determined that it was acceptable. The final floor loading assessment was submitted on March 31, 2021. CNSC staff are in the process of reviewing the final assessment, and will verify it against the high level results.

Human factors in design

Bruce Power is required to meet the requirements of CSA N290.12, *Human factors in design of nuclear power plants*. Guidance for considering human factors in design programs is provided in REGDOC-2.5.1, *General Design Considerations: Human Factors*. REGDOC-2.5.1 states that the CNSC "*will consider whether the applicant has made adequate provision for human*

capabilities and limitations (human factors) as they relate to the safe conduct of the activity to be licensed".

As discussed in Appendix B.2 of this CMD, Bruce Power submitted an interim HFESR that provided an overview of human factors work done for the Lu-177 IPS project. The final HFESR can only be completed following initial operation for the production of Lu-177. The HFESR that was submitted to date provided CNSC staff with evidence that Bruce Power has carried out preliminary human factors analysis activities in accordance with their HFEPP and the HFVVP for the Lu-177 IPS project.

CNSC staff are proposing to use a regulatory hold point to confirm the completion of all tasks identified in: human factors analyses related to the operation of the IPS, the initiating events that have been identified in the FISAR, as well as the items previously identified in Appendix B.2 of this CMD. CNSC staff will verify the updated HFESR for its completeness.

Impact of IPS on core neutronics and reactivity characteristics

In submissions [2] and [18], Bruce Power provided the assessments on the impact of the installation of the IPS on core neutronics. The assessments included:

- qualitative and quantitative case studies to assess the impact of the IPS on normal and perturbed core states
- evaluation on the impact of reactivity characteristics due to the introduction of the IPS, including:
  - the estimated reactivity worth and uncertainties
  - changes to reactivity worth with irradiation
  - effects of target insertation and retrieval on core parameters
  - estimation of IPS incremental cross sections.

Bruce Power stated in its assessments [2] and [18] on core neutronics and reactivity characteristics that effects of target insertation and retrieval on detector readings are small but observable. However, as stated in the I&C subsection above, the RRS is capable in dealing with these small changes and that no manual operator actions will be required.

CNSC staff concluded that Bruce Power has sufficiently demonstrated that the impact of IPS installation activities is negligible based on the limited impact to bundle powers, channel powers and zone levels, and that impact of IPS target insertation and retrieval is also negligible based on the limited impact to fueling practices, NOP detector readings and local reactivity.

CNSC staff are proposing to use a regulatory hold point to track the submission of the commissioning results to confirm that the reactivity characteristics are consistent with the design specifications and assessments.

Conclusion

Based on the information submitted by Bruce Power, CNSC staff determined that the design of the IPS met regulatory requirements. CNSC staff's review was performed in the following areas:

- Mechanical and process system
- Pressure boundary
- Instrumentation and control
- Electrical power system
- Environmental qualification
- Seismic qualification
- Civil structures design
- Human factors in design
- Impact of IPS on core neutronics and reactivity characteristics

CNSC staff are proposing to use a regulatory hold point to track the completion of documents, which include the IPS interim design manual, supporting EQ and SQ documentation, floor loading assessment, and the commissioning plan, in order to verify that the final design will not impact the safety case that was presented. CNSC staff will also review the updated HFESR to confirm its completeness. Finally, CNSC staff will verify the commissioning test results to confirm that the design requirements can be met, and that the reactivity characteristics are consistent with design specifications and assessments.

B.6 Fitness for Service

The Fitness for Service SCA covers activities that impact the physical condition of SSCs to ensure that they remain effective over time. This area includes programs that ensure the IPS equipment is available to perform its intended design function when called upon to do so.

Discussion

The scope of the CNSC staff's review is focused on the specific areas of maintenance, aging management and chemistry control for the IPS project.

For the maintenance program, Bruce Power is required to meet the requirements of REGDOC-2.6.2, *Maintenance programs for Nuclear Power Plants*.

For the aging management program, Bruce Power is required to meet the requirements of REGDOC-2.6.3, *Fitness for Service: Aging Management*. Effective aging management requires the use of a systematic approach that provides an integrated framework for coordinating all supporting programs such as maintenance program and periodic inspection program. It includes the understanding, control, monitoring and mitigation of aging effects of the IPS equipment.

For chemistry control, Bruce Power is required to maintain chemistry management documents that are referenced in the LCH.

Summary

CNSC staff performed an evaluation of Bruce Power's maintenance, ageing management and chemistry control programs for the Lu-177 IPS project.

Maintenance program and aging management program

Bruce Power stated that existing station maintenance governing documents are applicable to the Lu-177 IPS. The IPS components, such as pneumatic operated valves, control relays and mimic panels, are widely used in the existing nuclear power plants; the components used in the IPS are not overly complex nor First-of-a-Kind. In addition, Bruce Power's current aging management program (AMP) meets regulatory requirements. CNSC staff concluded that the information submitted is sufficient in demonstrating that Bruce Power will not have maintainability challenges associated with the IPS components, and that that Bruce Power's existing AMP will ensure that the IPS aging effects will be addressed.

Bruce Power stated in its project plan that the required preventative maintenance program and the aging management program for the IPS can only be completed prior to the initial operation of the IPS for the production of Lu-177. CNSC staff are proposing to use a regulatory hold point to track the completion of those programs to ensure that equipment will be properly maintained, and that aging effects have been considered.

Chemistry control

As the IPS will be installed in a spare VFD that will be isolated from the moderator heavy water and auxiliary systems, there are no impacts to the moderator or cover gas chemistry under normal operation.

Bruce Power indicated to the CNSC that its chemistry staff have reviewed the design changes associated with the IPS, and if required, Bruce Power will update the chemistry procedures. Bruce Power did not identify any new or increased hazards related to chemistry control as stated in [2]. CNSC staff concluded that Bruce Power's chemistry control program is sufficient for the IPS project.

Bruce Power indicated in its project plan that a chemistry impact assessment of the IPS can only be completed closer to commissioning. The chemistry impact assessment will verify that the materials used in the IPS will not have an impact on reactor chemistry or the ability to maintain the system chemistry within its operating specifications. CNSC staff are proposing to use a regulatory hold point to track the submission of the impact assessment.

Conclusion

CNSC staff concluded that Bruce Power has met the fitness for service requirements. There are no maintainability challenges associated with the Lu-177 IPS components. Existing AMP will ensure that the IPS aging effects will be addressed. Finally, as the IPS will be isolated from the moderator heavy water and auxiliary systems, the IPS is not expected to have an impact to reactor chemistry.

Bruce Power indicated in its project plan that the required preventative maintenance program and the aging management program for the IPS can only be completed prior to the operation of the IPS. CNSC staff are proposing to use a

regulatory hold point to track the submission of those programs to confirm that equipment will be properly maintained, and that aging effects have been considered.

B.7 Radiation Protection

The Radiation Protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. The program must ensure that contamination levels and radiation doses received by individuals associated with the production of Lu-177 are monitored, controlled and maintained As Low As Reasonably Achievable (ALARA).

Discussion

The *Radiation Protection Regulations* require licensees to establish a radiation protection program to keep exposures ALARA, taking economic and social factors into account, through the implementation of a number of control programs, including:

- Management control over work practices
- Personnel qualification and training
- Control of occupational and public exposures to radiation
- Planning for unusual situations

Bruce Power's BP-PROG-12.05, *Radiation Protection Program* is designed to ensure that:

- Occupational exposures to ionizing radiation are controlled such that individual doses are kept below regulatory dose limits and unplanned exposures are avoided
- Individual and collective doses are maintaining at levels ALARA, social and economic factors being taken into account
- The movement of people and materials is done in a manner that prevents the uncontrolled release of contamination or radioactive materials from Bruce Power facilities
- High standards of radiation protection performance in accordance with industry best practices are achieved
- All applicable regulatory requirements are met

These objectives are achieved through the establishment and implementation of standards and processes for the conduct of licensed activities.

CNSC staff's evaluation of past performance in these areas indicate that Bruce Power has implemented and maintained an effective radiation protection program at Bruce A and B in accordance with regulatory requirements.

Summary

For the Lu-177 IPS project, Bruce Power will utilize its existing Radiation Protection Program (RPP) and implementing procedures to maintain worker doses

below regulatory limits and ALARA, and protect the health and safety of persons involved in the installation, operation and maintenance of the IPS.

CNSC staff assessed Bruce Power's application in the areas of:

- Application of ALARA
- Worker Dose Control
- Radiation Protection Program Performance
- Radiological Hazard Control

Application of ALARA

Bruce Power's commitment to the ALARA principle has been demonstrated through the RPP implemented at the Bruce A and Bruce B, which integrates ALARA into planning, scheduling, and work control, and establishes and monitors performance against ALARA targets for work conducted at Bruce A and Bruce B.

The day-to-day IPS activities will fall under requirements for ALARA planning and oversight as determined by Bruce Power ALARA Program. Oversight of radiological performance will be provided through established processes that include periodic self-assessments and continuous improvement initiatives. There is no performance history available regarding the implementation of ALARA for the day-to-day operation as production of Lu-177 is a new project.

CNSC staff concluded that Bruce Power has sufficiently applied the ALARA principles during the design phase of the Lu-177 IPS project. The design is in line with RP requirements set out in the existing RPP and its implementing procedures. For example, during the design stage, Bruce Power selected areas for IPS equipment that will result in minimal dose received by the workers.

Worker dose control

The RPP implemented at Bruce Power is designed to ensure that doses to workers are controlled and do not exceed regulatory limits. During the current licensing period, radiation doses to workers were maintained below the regulatory dose limits and action levels established in Bruce Power's RPP. There were no adverse trends or safety-significant unplanned exposures due to the licensed activities at Bruce A and B.

During operation and maintenance of the IPS, dose to workers will be monitored and controlled in accordance with the existing RPP procedures, including BP-RPP-00009, *Dose Limits and Exposure Control*, BP-RPP-00020, *Dosimetry and Dose Reporting*, and BP-RPP-00041, *Executing Radiological Work*.

CNSC staff determined that Bruce Power has processes in place to ensure that, doses to workers are controlled. The existing RPP and implementing procedures will be used to maintain worker doses below regulatory limits and ALARA, and to protect the health and safety of persons involved in the installation, operation and maintenance of the IPS. In addition, the IPS design includes shielding and administrative controls to keep worker exposures below dose limits and ALARA.

In the FISAR [2], Bruce Power stated that "*there are only two specific abnormal events that could cause radiological hazards to station personnel increase due to the IPS*". CNSC staff verified that potential radiological hazards during normal operation of the IPS have been assessed and addressed through the design of the IPS.

Bruce Power's project plan indicated that a number of supporting information related to worker dose control can only be completed closer to the commissioning and initial operation stages of the IPS. CNSC staff are proposing to use a regulatory hold point to track this action, specifically to confirm the effectiveness of the IPS design, and the associated safety measures in protecting workers during those events (such as DBA). This includes the mitigation measures that have been put into place, as well as the protective actions that will be taken to prevent unplanned exposures and keep dose to workers below regulatory limits during station events. However, this is not a safety concern as Bruce Power has a strong RP program.

Radiation protection program performance

Bruce Power indicated that its current expectation for activities associated with Lu-177 production will be executed "event free". For the IPS project, Bruce Power plans to apply its key radiation protection performance indicators to the IPS project to track performance and to identify areas for improvement.

CNSC staff concluded that Bruce Power's RPP is effective in protecting its workers. Bruce Power continually measures the performance of its RPP against industry-established objectives, goals and targets.

Radiological hazard control

Bruce Power's RPP ensures that there are measures in place to monitor and control radiological hazards. This includes, but is not limited to, contamination control, dose rate control, and airborne radiation monitoring and control. Radiological hazards are either eliminated (when possible), or controlled with engineered barriers and signage identifying the level and extent of hazard areas. Shielding is used to reduce radiation exposures to workers during operational and maintenance activities. In addition, work planning and the use of personal protective equipment (PPE) ensures doses to workers remain ALARA.

During normal operation of the IPS, radiological hazards will be identified, measured, and controlled in accordance with the RP procedure related to the oversight of radiological work. Work will be planned and executed in a manner that minimizes worker doses. PPE, alarming dosimeters and area radiation monitors will be used extensively, in addition to work surveys, to prevent unplanned exposures and to ensure worker doses do not exceed regulatory limits during the installation and the operation of the IPS. Monitoring, tracking and limiting the movement of radioactive material will be required for safe handling.

CNSC staff concluded that Bruce Power has sufficient measures in place to monitor and control radiological hazards to protect its workers. As indicated in its project plan, Bruce Power will need to determine if radiation field in the area may

produce repeated nuisance alarms, and may cause the workers to develop alarm fatigue and to start ignoring them. However, portable monitoring devices (such as use of personal dosimeters) will be available for workers and therefore, is not a safety concern. CNSC staff are proposing to use a regulatory hold point to confirm whether additional permanent monitoring equipment will be required.

Conclusion

CNSC staff assessed Bruce Power's documentation and analyses under the Radiation Protection SCA, and have determined that Bruce Power will utilize its existing RPP and implementing procedures to maintain worker doses below regulatory limits and ALARA, and to protect the health and safety of persons involved in the installation, operation and maintenance of the IPS.

CNSC staff concluded that Bruce Power has taken into consideration the optimization principle for the protection of workers. Design and administrative measures have been put into place, such as providing radiation shielding, for the protection of workers during the operation of the IPS. Potential radiological hazards during normal operation of the IPS have been assessed and addressed through the design of the IPS.

CNSC staff are proposing to use a regulatory hold point to confirm the effectiveness of the IPS, and the associated safety measures in protecting workers during events (such as design basis accidents), as well as whether there is a need for additional FAGMs or active monitors to alert personnel of potential hazards. These items are not a safety concern as Bruce Power has a strong RP program in place for the protection of workers.

CNSC staff will continue to assess the IPS during the commissioning phase of the project to confirm that Bruce Power effectively implements their radiation protection processes to ensure that dose to workers remain below regulatory limits and are maintained ALARA.

B.8 Conventional Health and Safety

The Conventional Health and Safety SCA covers the implementation of a program to manage workplace safety hazards and to protect workers.

Bruce Power has a well-established occupational health and safety management system in place. The conventional health and safety issues are being identified and mitigated through its ECC process for the Lu-177 project. CNSC staff will continue to monitor Bruce Power's conventional health and safety program to ensure that workers are protected from conventional hazards.

CNSC staff concluded that Bruce Power's existing occupational health and safety management system is sufficient, and that Bruce Power will ensure that the work associated with the IPS project will be conducted safely.

B.9 Environmental Protection

The Environmental Protection SCA covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment resulting from the production of Lu-177.

This section of the CMD covers the following specific areas of the Environmental Protection SCA:

- Environmental Management System
- Effluent Emissions and Control
- Assessment and Monitoring
- Estimated Public Dose
- Environmental Risk Assessment

Discussion

Bruce Power has in place BP-PROG-00.02, *Environmental Management Program* that meets the requirements of REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* and ISO 14001:2015, *Environmental management systems — Requirements with guidance for use*.

In addition, Bruce Power has implemented Effluent and Environmental monitoring programs, which comply with CSA N288.5-11, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills* and CSA N288.4-2010, *Environmental monitoring programs at nuclear facilities and uranium mines and mills* respectively.

There are established Derived Release Limits (DRLs) in place that meets the requirements of 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*. Action Levels and Internal Investigation Levels which are well below the DRLs have also been set to provide an early warning system of any actual or potential loss of control to the Environmental Protection Program.

Bruce Power continued to implement an effective environmental protection (including an environmental risk assessment (ERA)) and management program to assess, evaluate and mitigate environmental risks in accordance with CSA standard N288.6-12, *Environmental risk assessments at Class I nuclear facilities and uranium mines and mills*.

Summary

CNSC staff determined that the environment and public are, and will continue to be, protected. Bruce Power's ERA and DRLs are applicable to cover the proposed activities since the Lu-177 IPS project will only be contributing a negligible portion of the environmental releases measured and reported.

Environmental Protection

In the area of environmental protection, CNSC staff evaluated the IPS and its impact on emissions to the environment and to the public dose. Based on the information submitted [1] by Bruce Power, CNSC staff are satisfied that the emissions will be minimal especially when compared to the DRLs for the site. Emissions from the Lu-177 IPS will be routed through the contaminated stack exhaust which contains HEPA filters for removal of most particulates. Any emissions passing through the filter will be monitored and reported to the CNSC through the quarterly and annual compliance monitoring reports.

Bruce Power has indicated that during commissioning of the IPS, and for a limited period thereafter, the particulate filters from the stack monitor will be analyzed for the presence of Lu-177, Yb-175 and Yb-177 in the gaseous effluents and the results will be used to confirm that there is no impact on gaseous effluents from the facility taking place. CNSC staff will review the results of analysis of the particulate filters from the stack monitor once commercial operation commences (as part of a follow-up monitoring) to confirm that there is no impact on gaseous effluents, and whether continued monitoring will be required.

ERA Gap Analysis

Bruce Power submitted an ERA Gap Analysis for radioisotope production activities in November 2020 [1]. In response to CNSC comments identified in [19], Bruce Power submitted a revised gap analysis in [20].

CNSC staff reviewed the revised gap analysis and determined that all of CNSC staff's concerns have been addressed. Production of Lu-177 will result in contributing a portion of the environmental releases measured and reported for the Bruce site, which has been identified in the gap analysis performed by Bruce Power. However, the releases due to production of Lu-177 are minimal compared to the overall releases from the Bruce site. Therefore, CNSC staff determined that the 2017 ERA is still applicable at this time.

CSA N288.7-15, *Groundwater protection programs at Class I Nuclear Facilities and Uranium Mines and Mills* does not apply to the Lu-177 IPS proposed licensed activities as the IPS is a pneumatic system. Therefore, there are no environmental releases to groundwater. Should any of the proposed activities or facility change however, or the environmental monitoring results indicate potential impact to the groundwater, then Bruce Power will be expected to revise the groundwater protection program.

In accordance with CSA N288.6-12, Bruce Power performs an update of the ERAs every five years or more often if there is a change in operations or scientific knowledge. Specifically, Bruce Power is to include in the next version of the Bruce Power ERA the results of the calculations which verify that the magnitude of increase in Ar-41 emissions (due to potential air ingress) from Lu-177 IPS are small. The next update is planned for 2022; Bruce Power is expected to include the gap analysis results for Lu-177 radioisotope production activities and contributions in the 2022 update.

Conclusion

CNSC staff concluded that the environment and public are, and will continue to be, protected. Bruce Power's ERA and DRLs are applicable to cover the proposed activities since the Lu-177 IPS project will only be contributing a negligible portion of the environmental releases measured and reported.

CNSC staff determined that the proposed licensed activity (i.e., production of Lu-177) will continue to meet the environmental protection regulatory requirements. The 2017 Bruce Power ERA, with consideration of the production of Lu-177, continues to meet the requirements provided in CSA N288.6-12. The next ERA update is planned for 2022; Bruce Power is expected to include the gap analysis results for Lu-177 radioisotope production activities and contributions in the 2022 update.

B.10 Emergency Management and Fire Protection

The Emergency Management and Fire Protection SCA covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions associated with the production of Lu-177.

Discussion

This section of the CMD covers the specific areas of emergency management and fire protection.

Emergency management

CNSC staff evaluated Bruce Power's emergency management program for the Lu-177 project against the regulatory requirements in REGDOC-2.10.1, volume 1, *Nuclear Emergency Preparedness and Response*, which sets out the requirements and guidance related to the development of emergency measure for Class I nuclear facilities licensees.

CNSC staff also assessed Bruce Power's application against applicable CSA standards on fire response regulatory requirements, such as CSA N1600, *General requirements for nuclear emergency management programs*.

Fire protection design considerations

For the fire protection program, Bruce Power is required to meet the requirements of:

- CSA N293-12, *Fire protection for nuclear power plants*
- National Building Code of Canada (NBCC)
- National Fire Code of Canada (NFCC)

The risk to the health and safety of persons and to the environment from fire is to be minimized through appropriate fire protection system design, fire safe operation and fire prevention.

Summary

Bruce Power continues to implement and maintain an effective emergency preparedness and fire protection program at Bruce A and B that meets regulatory requirements.

There are appropriate plans in place to respond effectively to emergencies resulting from the installation and operation of the IPS. In addition, Emergency Response Team (ERT) staff will receive a presentation on the IPS at quarterly tabletop exercises to further raise their awareness of the IPS.

CNSC staff performed an evaluation in the following areas:

- Conventional emergency preparedness and response
- Nuclear emergency preparedness and response
- Fire emergency preparedness and response
- Fire protection design considerations

CNSC staff concluded that Bruce Power will continue to meet regulatory requirements in the area of emergency preparedness and fire protection with the addition of the Lu-177 IPS program.

Conventional emergency preparedness and response

Bruce Power's BP-PROG-08.01, *Emergency Management Program* ensures that the consequences of any event ("all-hazards" approach) that has the potential to impact workers, the public, the environment, and infrastructure will be managed.

The response to emergencies is led by Bruce Power's Emergency Response Organization (ERO), which includes shift, on-call, and call-in workers. On-site, 24/7 Emergency Protective Services (EPS) staff further supports emergency preparedness and response (such as fire, medical and environmental response). The ERO workers are trained and continuously assessed through quarterly drills and annual corporate-level exercises.

For the Lu-177 IPS project, Bruce Power stated that the existing conventional emergency processes and procedures are sufficient to deal with the expected increase of contractors that will be onsite during the construction/installation of the IPS. In addition, Bruce Power confirmed that the IPS does not introduce any new skills or significant modifications to the knowledge(s) that ERT staff are required to have to do their jobs and task analysis. Finally, all EPS response tasks are adequately covered by existing training from both a fire and radiological response perspective.

Bruce Power continues to meet its conventional emergency preparedness and response commitments, including making enhancements to its emergency (non-nuclear) drill program. CNSC staff concluded that the installation and operation of the IPS will not introduce additional requirements to conventional emergency preparedness and response.

Nuclear emergency preparedness and response

Bruce Power has the capability to respond effectively to nuclear emergencies. The response capability is documented in Bruce Power's consolidated emergency plan and the associated emergency preparedness program, which is demonstrated through the conduct of emergency exercises and drills. In addition, Bruce Power has emergency response facilities and equipment in place to monitor and respond to nuclear emergencies.

CNSC staff concluded that the installation and operation of the IPS will not introduce additional requirements to nuclear emergency preparedness and response.

Fire emergency preparedness and response

Bruce Power has implemented an acceptable fire protection program and continues to implement a comprehensive fire response capability that included effective procedures, training and maintenance of proficiency. The fire protection program met the requirements of CSA N293-2012 as well as key standards referenced therein such as the NBCC, NFCC and its associated National Fire Protection Association standards. There are processes in place to minimize both the probability of occurrence and the consequences of fire.

Bruce Power stated that the IPS equipment will not introduce new or unique fire hazards. As such, Bruce Power determined that the existing fire and radiological response training and enabling knowledge for the ERT staff is sufficient. Bruce Power ERT staff will be given additional training to get familiarized with the IPS equipment.

Based on the information submitted, CNSC staff concluded that Bruce Power's ERT workers will be able to respond effectively to fire emergencies at the IPS location.

Fire protection design considerations

For the Lu-177 IPS project, Bruce Power performed a fire protection assessment including code compliance review, fire hazard assessment (FHA) and fire safe shutdown analysis (FSSA). As part of the ECC process, Bruce Power confirmed that the IPS will have a negligible effect on the assumptions made in the fire protection assessment. Bruce Power determined that the installation and operation of the IPS does not add any additional requirements to the existing emergency preparedness and response plan.

CNSC staff reviewed the submitted information, and concluded that the additional IPS equipment will not pose a significant fire hazard, and that the FHA/FSSA will not be impacted. As such, a third party fire protection review report is not required. Bruce Power is expected to revise the FHA/FSSA during the next review cycle, taking into account the new Lu-177 IPS equipment.

Conclusion

Bruce Power has sufficient provisions for emergency preparedness and response capabilities that would mitigate the effects of any releases of nuclear and hazardous substances in to the environment, while protecting the health and safety of persons and national security.

CNSC staff concluded that the installation and operation of the IPS will not add additional requirements to the existing Bruce Power emergency management program, which addresses prevention, mitigation, preparedness, response, and recovery.

This existing suite of Bruce Power nuclear emergency preparedness and response documents is adequate to deal with any potential emergency event that may arise due to operation of the IPS.

In addition, CNSC staff concluded that Bruce Power's fire protection program, which includes fire response, complied with the CNSC's requirements for fire protection (CSA N293 for an industrial fire brigade) and that the fire response capability and performance of the industrial fire brigade met regulatory requirements and expectations. Bruce Power is expected to revise the FHA/FSSA during the next review cycle, taking into account the new Lu-177 IPS equipment.

B.11 Waste Management

The Waste Management SCA covers the internal waste-related programs associated with the production of Lu-177, up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.

Discussion

In accordance with the PROL, Bruce Power's waste management program shall meet the requirements of CSA N292.3, *Management of Low and Intermediate-level Radioactive Waste*. Bruce Power's waste management program is implemented and maintained through BP-PROG-12.05, *Radiation Protection Program* and BP-PROC-000878, *Radioactive Waste Management* that includes strategies for waste minimization, waste characterization and waste management practices as per CSA N292.3.

Bruce Power stated that the production of Lu-177 will only generate waste from the use of Personal Protective Equipment (PPE). The radioisotope targets arrive and leave the Bruce Power site in the same form, and the off-site processing facility will be responsible for managing its own waste.

Installation of the IPS requires work on the reactor vessel (associated with modifications to the vertical flux detector), and any waste generated, including PPE and internal reactor components removed from the reactor, will be managed through Bruce Power's existing waste management procedures. Bruce Power will be developing a specific Waste Management and Demobilization Plan (WMDP) for the IPS project.

5.1.1 Summary

Bruce Power will create a Lu-177 specific WMDP (which is essentially a checklist) to confirm that the only expected waste produced for the production of Lu-177 will be from the use of PPE. The WMDP will outline all the waste to be generated by the project and all materials, tools and equipment to be demobilized. This includes the completion of the following activities:

- filling out Bruce Power's internal FORM-11803, *Waste Minimization Plan*
- addressing the following areas in the waste management plan: packaging, labelling, demobilization and disposal

Based on the information submitted, CNSC staff agree with Bruce Power's assessment that the production of Lu-177 is only expected to have a minimal increase in waste produced from PPE from on-going operation, and one-time waste from the removal of internal reactor components; the WMDP will be completed to confirm that the waste produced will be minimal. CNSC staff concluded that Bruce Power's existing waste management program ensures that all waste produced at the site are characterized and managed. CNSC staff will confirm the completeness of WMDP, waste minimization plans and contractors waste management plans through compliance verification activities.

Conclusion

CNSC staff assessed Bruce Power's application and determined that the production of Lu-177 will generate minimal amount of radioactive waste, and the waste will be managed in accordance with Bruce Power's waste management program currently in place. CNSC staff conclude that the waste program in place is adequate and meets the requirements of CSA N292.3.

B.12 Security

The Security SCA covers the programs required to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity.

Discussion

Bruce Power continues to provide requested information and ensured that CNSC staff were kept up to date during the current licensing period. Bruce Power's security program will not need to be modified or impacted for the production of Lu-177 radioisotope.

Summary

CNSC staff determined that Bruce Power continues to implement a security program that meets the security requirements stipulated in the regulations. As previously discussed, the security program will not need to be modified for the production of Lu-177. CNSC staff performed review of the licence amendment application in the following applicable SpAs:

- General Considerations
- Prescribed Information
- Site Security Measures
- Access Control
- Site Access Clearance
- Security Arrangements with Offsite Response Force
- Physical Security
- Cybersecurity
- Nuclear Security Officer Program

General Considerations

Security considerations for this evaluation was performed as per Bruce Power's BP-PROG-08.02 R009, *Nuclear Security program*. The evaluation concluded that Bruce Power's security program will not have to be modified or changed for the production of Lu-177.

Prescribed Information

Bruce Power's BP-PROC-00110, *Information Classification, Access & Handling Requirements* governs the access to, use, storage and transmittal of prescribed and security protected information. Bruce Power staff and contractors are required to comply with the requirements of this standard. Prescribed and security sensitive information is only provided to persons with a valid security clearance and "need to know". The Lu-177 radioisotope project will not have any impact or require any changes with regards to Prescribed Information.

Site Security Measures

Security considerations with regards to the Site Security measures currently in place at Bruce Power was performed as per Bruce Power's DIV-EPS-00001 R001, *Security Operations Procedure*. CNSC staff concluded that Bruce Power's Site Security Measures will not have to be modified or changed for the production of Lu-177.

Access control

The Bruce Power site is contained within the Bruce Power controlled area. Public access to the Bruce Power's controlled area is restricted through the use of fencing, signage and access control guard houses. Bruce Power Nuclear Security Officers (NSO) patrol the controlled area on a regular continuous basis. Access Control to Bruce Power will not have to be modified or changed for the production of Lu-177.

Site access clearance

Bruce Power maintains a clearance program that is in compliance with the *Nuclear Security Regulations* and CNSC REGDOC-2.12.2, *Site Access Security Clearance*. Bruce Power procedure BP-PROC-00180 R004, *Security Clearances*, reflects the regulatory requirement. Staff and contractors requiring unescorted access to Bruce Power site, in excess of five consecutive days, will require a security clearance commensurate with the activities performed and access

required. Any staff requiring access to prescribed information require a Bruce Power site access security clearance regardless of work location. The Bruce Power Site Access Clearance program will not have to be modified or changed as a result of the Lu-177 radioisotope Project commences.

Security arrangements with offsite response force

Bruce Power has an arrangement (a Memorandum of Understanding, or MOU) with the Ontario Provincial Police (OPP) that documents arrangements with the OPP to provide an offsite response to Bruce Power facilities located on the Bruce Power sites. The agreement ensures the necessary resources are available to address design basis security events. Bruce Power conducts drills and exercises that include integrated response with the OPP offsite response force. Lessons learned from these drills and exercises are implemented within the security program. The agreement includes requirements to ensure compliance with *Nuclear Security Regulations* section 35(1). No changes to the MOU are anticipated for the production of Lu-177 radioisotope.

Physical Security

A description of Bruce Power's site existing security equipment, systems and procedures as well as a description of proposed on-site and off-site communications equipment, systems and procedures is contained in the *Bruce Power Nuclear Generating Station Security Report*.

Physical security measures for the Bruce Power site will not be impacted or affected as a result of the Lu-177 radioisotope Project. Additional security measures to comply with the *Nuclear Security Regulations* and associated regulatory documents are being used and maintained throughout the licensing period.

Cyber Security

No changes are anticipated to Bruce Power's Cyber Security program for the production of Lu-177 radioisotope.

Nuclear Security Officer (NSO) Program

Bruce Power selects, trains, and equips NSOs in accordance with the Nuclear Security Regulations and CNSC REGDOC-2.12.1 Version 2, *High Security Facilities, Volume I: Nuclear Response Force* and REGDOC-2.2.4, Fitness for Duty Volume III, *Nuclear Security Officer Medical, Physical, and Psychological Fitness*. Details relating to the selection, training, and equipment provided to both armed and unarmed NSOs is contained in the *Bruce Power Nuclear Generating Station Security Report*.

The production of Lu-177 will not require changes to be made to the structure and organization of the NSO service, including the duties, responsibilities and training of NSOs is documented in the *Bruce Power Nuclear Generating Station Security Report*.

Conclusion

CNSC staff concluded that Bruce Power continues to implement a security program that meets the security requirements stipulated in the regulations. The security program will not need to be modified for the production of Lu-177. CNSC staff will continue to monitor the production of Lu-177 in relation to the security program, including ensuring that there are adequate provisions of security prior to and during production of Lu-177.

B.13 Safeguards and Non-Proliferation

The Safeguards and Non-Proliferation SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada/IAEA safeguards agreements, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

The scope of the non-proliferation program is limited to the tracking and reporting of foreign obligations and origins of nuclear material. This tracking and reporting assists the CNSC in the implementation of Canada's bilateral Nuclear Cooperation Agreements with other countries. Finally, the import and export of controlled nuclear substances, equipment and information identified in the *Nuclear Non-proliferation Import and Export Control Regulations* require separate authorization from the CNSC, consistent with Section 3(2) of the GNSCR.

Discussion

Bruce Power continues to maintain a safeguards program that complies with its licence requirements. The program conforms to measures required by the CNSC to meet Canada's international safeguards obligations as well as other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

Pursuant to that treaty, Canada has entered into a Comprehensive Safeguards Agreement and an Additional Protocol with the IAEA (hereafter, the safeguards agreements). The objective of the safeguards agreements is for the IAEA to provide annual assurance to Canada and to the international community that all declared nuclear material is in peaceful, non-explosive uses and that there is no indication of undeclared material.

CNSC REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy* sets out requirements and guidance for safeguards programs for applicants and licensees who possess nuclear material, operate a uranium and/or thorium mine, carry out specified types of nuclear fuel-cycle related research and development work, and/or carry out specified types of nuclear-related manufacturing activities. The requirements and guidance in this document are essential to Canadian compliance with the safeguards agreements entered into with the IAEA, and are consistent with modern national and international practices.

Compliance activities include the timely provision of reports on the movement and location of nuclear material, provision of access and assistance to IAEA

inspectors for safeguards activities, support for IAEA equipment, and the submission of annual operational information, additional protocol updates as well as accurate design information.

Summary

CNSC staff performed review of the licence amendment application in the following applicable SpAs:

- Nuclear material accountancy and control
- Access and assistance to the IAEA
- Operational and design Information
- Safeguards equipment, containment and surveillance
- Import and export

Nuclear material accountancy and control

CNSC staff determined that Lu-177 is not a nuclear material that is subject to safeguards requirements pursuant to the Canada/IAEA Safeguards Agreement, and as defined in CNSC REGDOC-2.13.1.

Access and assistance to the IAEA

As Lu-177 radioisotope is not a nuclear material that is subject to safeguards requirements, routine IAEA verification is not expected. However, the Lu-177 IPS project and related activities may be subject to IAEA design information verification and complementary accesses. See next paragraph on information requirements from the IAEA.

Operational and design information

Bruce Power may be required to submit operational information to the IAEA on the production of radioisotopes, including providing the following information:

- advance information and declarations in Bruce Power's safeguards annual operational program and quarterly updates
- updates to the facility's design information questionnaire
- an update to the facility's annual submission pursuant the Additional Protocol on the site layout, buildings and functions

The IAEA will inform the CNSC when the updates will be required, and CNSC staff will contact Bruce Power to provide this information.

Safeguards equipment, containment and surveillance

The IAEA informed CNSC staff that there is no need for additional safeguards equipment for the production of Lu-177. Therefore, the Lu-177 IPS will not impact the existing safeguards equipment, containment and surveillance requirements.

Import and export

As discussed in Section 1 of this CMD, all other parts of the radioisotope process (including transportation) will be handled by a third party. The third party will

need to meet the requirements defined in *Nuclear Non-Proliferation Import and Export Control Regulations* (NNIECR) for the import and export of Lu-177 (specifically, B.1.1.19 of NNIECR).

Conclusion

CNSC staff assessed Bruce Power's licence amendment application, and concluded Bruce Power's safeguards and non-proliferation program is sufficient.

B.14 Packaging and Transport

The Packaging and Transport SCA covers the safe packaging and transport of nuclear substances associated with the production of Lu-177 to and from the licensed facility.

Discussion

Bruce Power has a packaging and transport program that meets the requirements of PTNSR 2015, and Transport Canada's TDGR. This is captured under Bruce Power's BP-PROG-12.05, *Radiation Protection Program* and BP-PROC-00188, *Radioactive Material Transportation*. The RPP requires that packaging and transport program comply with PTNSR 2015 and TDGR for all shipment of nuclear substances to and from the Bruce site

REGDOC-2.14.1, *Packaging and Transport: Information Incorporated by Reference in Canada's Packaging and Transport of Nuclear Substances Regulations, 2015, Volume I, Version 2* provides the guidance to comply with PTNSR 2015, and links provisions in the PTNSR 2015 to relevant content in the IAEA Regulations, the NSCA, other CNSC regulations, and other related information.

For shipments of nuclear substances within the nuclear facility where access to the property is controlled, Bruce Power has to meet the requirements of CNSC PTNSR 2015 and the Canada's TDGR even though the transport of the nuclear substance within Bruce Power is exempt from these requirements.

The shielded transport container that will be used to transport the irradiated targets was previously certified in the US in April 2016 and its certification is in the process of being renewed as per the certification renewal cycle. CNSC staff reviewed the design to ensure that it meets Canadian requirements, and are waiting for the renewal of the US certificate prior to finalizing the certification process in Canada. This is a routine best practice followed internationally. It is CNSC staff's view that Lu-177 can be safely transported in the specified shielded transport container, and the certification process is expected to be completed in May 2021. Once the design of the shielded transport container is approved and certified for use in Canada, Bruce Power will apply to be a registered user. This activity has no impact on the installation of the IPS and the process can be done in parallel.

Bruce Power will be responsible for the packaging and transfer of the shielded container within the site. Shipment of the shielded container outside the site will

need to comply with PTNSR 2015 and TDGR requirements, as well as IAEA safeguards.

Conclusion

CNSC staff determined that Bruce Power has a process in place to safely manage radioactive material packaging and shipments. For the IPS project, Bruce Power will need to apply to become a registered user once the shielded transport container design is certified. The design is currently undergoing the CNSC certification process and is expected to be issued in May 2021.

C. ACRONYMS

AIA	Authorized Inspection Agency
ALARA	As Low As Reasonably Achievable
AMP	Aging Management Program
ANO	Authorized Nuclear Operator
BDBA	Beyond Design Basis Accidents
BNGS	Bruce Nuclear Generating Station
CAA	Code Applicability Assessment
CCP	Critical Channel Power
CINFR	*Class I Nuclear Facilities Regulations*
CMD	Commission Member Document
COTS	Commercial Off the Shelf
CSA	Canadian Standards Association
CSI	CANDU Safety Issues
CVC	Compliance Verification Criteria
DBA	Design Basis Accidents
DLA	Dynamic Learning Activities
DRLs	Derived Release Limits
ECC	Engineering Change Control
ECTA	Execution Contractor Training Assessment
EIC	Event Identification and Classification
EPS	Emergency Protective Services
EQ	Environmental Qualification
EQE	Environmental Qualification Evaluations
ERA	Environmental Risk Assessment
ERO	Emergency Response Organization
ERT	Emergency Response Team
FAGMs	Fixed Area Gamma Monitors
FHA	Fire Hazard Assessment
FISAR	Final Integrated Safety Analysis Report
FOM	Figure of Merit
FRC	Funding Review Committee
FSSA	Fire Safe Shutdown Analysis
GNSCR	*General Nuclear Safety and Control Regulations*
HFEPP	Human Factors Engineering Program Plan
HFESR	Human Factors Engineering Summary Report
HFIR	High Flux Isotope Reactor
HFVVP	Human Factors Verification and Validation Plan
HSM	Historic Saugeen Métis
HTS	Heat Transport System
IAA	*Impact Assessment Act*
IAEA	International Atomic Energy Agency
IFB	Irradiated Fuel Bays
IPS	Isotope Production System
IRSRR	Incident Reporting Systems for Research Reactors

ITP	Inspection and Test Plan
I&C	Instrumentation and Control
LCH	Licence Conditions Handbook
LOCA	Loss of Coolant Accident
LOMI	Loss of Moderator Event
LRF	Large Release Frequency
Lu-177	Lutetium-177
MCR	Major Component Replacement
MNO	Métis Nation of Ontario
NBCC	National Building Code of Canada
NFCC	National Fire Code of Canada
NLCA	*Nuclear Liability and Compensation Act*
NLCR	*Nuclear Liability and Compensation Regulations*
NNIECR	*Nuclear Non-Proliferation Import and Export Control Regulations*
NOP	Neutron Overpower Protection
NRCAN	Natural Resources Canada
NSCA	*Nuclear Safety and Control Act*
NSO	Nuclear Security Officers
OPEX	Operational/Operating Experience
OPG	Ontario Power Generation
OPP	Ontario Provincial Police
OP&P	Operating Policies and Principles
PCP	Pneumatic Control Panel
PFP	Participant Funding Program
PPE	Personal Protective Equipment
PROL	Power Reactor Operating Licence
PTNSR	*Packaging and Transport of Nuclear Substance Regulations*
PSA	Probabilistic Safety Analysis
RMD	Reactivity Mechanism Deck
ROR	Regulatory Oversight Report
RPR	*Radiation Protection Regulations*
RPP	Radiation Protection Program
RRS	Reactor Regulating System
SAT	Systematic Approach to Training
SCA	Safety and Control Area
SCDF	Severe Core Damage Frequency
SLOR	Slow Loss of Reactor Power Regulation
SOE	Safe Operating Envelope
SON	Saugeen Ojibway Nation
SpA	Specific Area
SRM	Safety Requirements Matrix
SSCs	Structures, Systems and Components
TC	Transport Container
TDGR	*Transport of Dangerous Goods Regulations*
TFT	Target Finger Tube
TNA	Training Needs Analysis

TSSA	Technical Standards and Safety Authority
UFDS	Used Fuel Dry Storage
VFD	Vertical Flux Detector
WDMF	Waste Management and Demobilization Plan
WWMF	Western Waste Management Facility
Yb-176	Ytterbium-176

PART TWO

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

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

PROPOSED LICENCE CHANGES

Overview

The changes given in the proposed Bruce A and B Power Reactor Operating Licence (PROL) and Licence Conditions Handbook (LCH) support the implementation of a program for radioisotopes production at the Bruce Power nuclear generating stations. The additional radioisotopes which will be authorized to be produced is Lutetium-177 at Bruce B Unit 7. If there is a requirement for different radioisotopes to be produced at Bruce A and B in the future, then Commission approval will be needed.

Licence Conditions

The proposed amendment to the Bruce A and B PROL is to Part IV) Licensed Activities (vi) and to Licence Condition 15.10. The results of the amendment is that PROL 18.01/2028 will become PROL 18.02/2028, indicating the second amendment to the PROL since original issuance in October 2018. Other parts of the PROL, including the expiration date of September 30, 2028, remain unchanged.

In its application [1], Bruce Power requested that the production of the radioisotope Lutetium-177 be authorized through the isotope production system at Bruce B Unit 7.

The amendment to the Licensed Activities (vi) and Licence Condition 15.10 will change the text from production of Cobalt-60 into production of Cobalt-60 and Lutetium-177 as shown below in Table 1 and Table 2. Bruce Power is currently authorized to produce Cobalt-60. The amendment is for the activities and condition to be production of Cobalt-60 and Lutetium-177. Details of the radioisotopes to be produced will be specified in the LCH. In the future, if changes are to be made to the radioisotopes to be produced at Bruce A and B then a request will be necessary to the Commission for approval for additional radioisotopes to be produced.

Table 1: Comparison of existing and proposed licensed activities (vi)

EXISTING PROL	PROPOSED PROL	REASONS FOR CHANGE
(vi) produce Cobalt-60 at Bruce B.	(vi) produce Cobalt-60 and Lutetium-177.	To allow for the production of radioisotopes as approved by the Commission and as listed in the LCH. Through this CMD, Bruce Power is requesting that Lu-177 production at Bruce B Unit 7 be authorized. The production of Lutetium-177 would be in addition to Cobalt-60 production already authorized through LC 15.10.

Table 2: Comparison of current and proposed Licence Condition 15.10

CURRENT PROL	PROPOSED PROL	REASONS FOR CHANGE
LC 15.10 The licensee shall implement and maintain a program for the receipt, storage and handling of the nuclear substance Cobalt-60 at Bruce B.	LC 15.10 The licensee shall implement and maintain a program for the production of the nuclear substances Cobalt-60 and Lutetium-177.	To allow for the production of radioisotopes at Bruce A and B. The specific radioisotopes shall be as approved by the Commission and listed in the LCH. The manner of producing the radioisotopes shall be as approved by the Commission.

Licence Conditions Handbook

The Bruce A and B Licence Conditions Handbook (LCH) is based on CNSC staff's standard LCH template. The proposed substantive changes due to this CMD are to Section 15.10, which is currently for the production of Cobalt-60. The change would be to transform Section 15.10 to be for the production of Cobalt-60 and Lutetium-177, to align with the proposed LC 15.10. The types of radioisotopes which Bruce Power is authorized by the Commission to produce will be as given in the LCH Section 15.10. The changes to the LCH due to this CMD are shown below in Table 3.

To ensure that Bruce Power operates within the Commission-approved licensing basis, the Bruce A and B LCH contains references to program documents that are programmatic in nature or process documents only when those documents contain limits or control measures. This ensures that changes made to programs, operating limits and control measures undergo regulatory scrutiny, but allows the licensee to manage its programs within the boundaries set by its management system. Section 15.10 contain the program documents for Cobalt-60 and for Lutetium-177, the only radioisotopes which Bruce Power is authorized to produce.

Table 3: Changes to LCH Section 15.10

CURRENT SECTION 15.10	PROPOSED SECTION 15.10
Licence Condition 15.10 The licensee shall implement and maintain a program for the receipt, storage and handling of the nuclear substance Cobalt-60 at Bruce B.	**Licence Condition 15.10** The licensee shall implement and maintain a program for the production of the nuclear substances Cobalt-60 and Lutetium-177.

<table>
<tr><th>CURRENT SECTION 15.10</th><th>PROPOSED SECTION 15.10</th></tr>
<tr><td><u>Preamble:</u>
Bruce Power harvests Cobalt-60 during the removal of Cobalt adjusters from each of the Bruce B reactors. These cobalt rods are processed into cobalt bundles that are placed in sealed containers and transported to Nordion Inc. who reprocess the bundles into sealed sources. Due to decay, the Cobalt-60 sealed sources cannot be used for commercial use after many years and are shipped back to Bruce Power. The sealed sources are stored in the Secondary Irradiated Fuel Bay at Bruce B NGS and upon decommissioning; they will be placed in permanent dry storage. This LC provides adequate regulatory oversight with regards to the reporting requirements related to the licensed activity associated with Cobalt-60 sealed sources.</td><td><u>Preamble:</u>
Bruce Power has a radioisotopes production program for specific radioisotopes as specified in this section of the LCH. Bruce Power is limited to the production of the following radioisotopes:
• Cobalt-60 at Bruce B
• Lutetium-177 at Bruce B, Unit 7

Bruce Power harvests Cobalt-60 during the removal of Cobalt adjusters from each of the Bruce B reactors. These cobalt rods are processed into cobalt bundles that are placed in sealed containers and transported to Nordion Inc. who reprocess the bundles into sealed sources. Due to decay, the Cobalt-60 sealed sources cannot be used for commercial use after many years and are shipped back to Bruce Power. The sealed sources are stored in the Secondary Irradiated Fuel Bay at Bruce B NGS and upon decommissioning; they will be placed in permanent dry storage. This LC provides adequate regulatory oversight with regards to the reporting requirements related to the licensed activity associated with Cobalt-60 sealed sources.

Bruce Power has installed an Isotope Production System (IPS) in Bruce B Unit 7 for the production of Lutetium-177 (Lu-177) from Ytterbium-176 (Yb-176) oxide powder. The powder is encapsulated in a target consisting of a sealed quartz ampule and aluminum carrier. A zircaloy target finger tube (TFT) assembly has been installed via a vacant vertical flux detector guide tube assembly. Using a pneumatic system, targets in their aluminum carriers are inserted into and retrieved from the reactor through the TFT assembly. The aluminum carriers (irradiated targets) are then discharged to transport containers and shipped to processing facilities. Bruce Power is authorized to use the IPS for the production of Lu-177 at Unit 7 only.</td></tr>
<tr><td><u>Compliance Verification Criteria:</u>

<u>Licensee Documents that Require Notification of Change</u>

<table><tr><th>Document Title</th><th>Document #</th><th>Prior Notification</th></tr><tr><td>Cobalt Handling</td><td>BP-PROC-00003</td><td>Yes</td></tr></table>
The Bruce licence supports the possession of Cobalt-60 in both sealed and unsealed forms at the Bruce B nuclear facility. Bruce Power shall ensure that handling, processing and accounting of Cobalt is in accordance with Bruce Power's procedure for Cobalt Handling.

The receipt of any Cobalt-60 sealed sources shall be reported to the CNSC via the Sealed Source Tracking System and in accordance with CNSC regulatory document REGDOC-3.1.1</td><td><u>Compliance Verification Criteria:</u>

<u>Licensee Documents that Require Notification of Change</u>

<table><tr><th>Document Title</th><th>Document #</th><th>Prior Notification</th></tr><tr><td>Cobalt Handling</td><td>BP-PROC-00003</td><td>Yes</td></tr><tr><td>Irradiation Services</td><td>BP-PROG-xx.xx (number will be assigned prior to commissioning)</td><td>No</td></tr><tr><td>Management of Lutetium-177 Production</td><td>BP-PROC-01120</td><td>Yes</td></tr></table>
LC 15.10 provides the basis for regulatory oversight related to the licensed activity associated with the radioisotopes production program. The Bruce Power licence authorizes through the licensing basis the production and possession of Cobalt-60 in both sealed and unsealed forms at the Bruce B nuclear facility. Bruce Power shall ensure that handling, processing and accounting of Cobalt is in accordance with Bruce Power's procedure for Cobalt Handling.

The receipt of any Cobalt-60 sealed sources shall be reported to the CNSC via the Sealed Source Tracking System and in accordance with CNSC regulatory document REGDOC-3.1.1.

The Bruce Power licence authorizes through the licensing basis the production, possession, handling, storage, packaging, managing and transport of Lutetium-177.</td></tr>
</table>

CURRENT SECTION 15.10	PROPOSED SECTION 15.10
	Regulatory Hold Point for the Bruce B Unit 7 Lu-177 Isotope Production System A regulatory hold point has been placed on Bruce Power which must be released prior to start of the commissioning program […Insert here a statement from the Commission decision for the IPS licence amendment regarding approval of the process for the release of the hold point. Possible text for this paragraph depending upon the Commission decision could be: In the 2021 Record of Decision for Bruce A and B licence amendment, the Commission delegated the authority for this licence condition for the removal of the regulatory hold point for commissioning of the Lu-177 production system to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.] The process for the release of the regulatory hold point is as follows: 1. Bruce Power submits a request to CNSC staff (including the information to satisfy the criteria/pre-requisites) for the release of the hold point. 2. CNSC staff will review the submitted information and verify Bruce Power's compliance with requirements and commitments. 3. Based on the submitted information, CNSC staff will provide a report, including recommendations, to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch whether the criteria/pre-requisites specified in the LCH have/have not been met. 4. The Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations will then consent or not consent to the removal of the regulatory hold point. 5. CNSC staff will administer the release of the hold point through a confirmation letter to Bruce Power. <u>Pre-requisites for the Release of the Hold Point for the Bruce B Unit 7 Lu-177 IPS:</u> 1. All licensee commitments prior to start of the Commissioning program are complete; 2. Completion of licensee's governing program and procedure documentation 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; *Prohibition of Human Use* The licensee is not authorized by the licence to conduct activities related to nuclear medicine and therefore it is prohibited to use radioisotopes in or on human beings. CNSC staff will verify by whatever means available that the licensee is not using radioactive prescribed substances in or on humans.
<u>Guidance:</u> Not applicable to this LC.	**<u>Guidance:</u>** Not applicable to this LC.

Licence Format

No changes to the licence format are being proposed through this CMD.

Licence Period

There is no change requested to the licence period being made through this CMD. The proposed PROL is to expire on the same date as the current PROL, that is, September 30, 2028.

Reference

[1] Bruce Power Letter, M. Burton to M. Leblanc, "Application for the Amendment of the Power Reactor Operating Licence", November 25, 2020, BP-CORR-00531-00982, e-Doc 6430874.

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 6309625	PDF: e-docs 6462968

CURRENT LICENCE

The current licence (PROL 18.01/2028) is provided on the following pages of the document.

Word: e-docs 6113849	PDF: e-docs 6113854

Canada's Nuclear Regulator

e-Doc 6309625 (Word)

e-Doc 6462968 (PDF)

LICENCE CONDITIONS HANDBOOK

LCH-PR-18.02/2028-R003

BRUCE NUCLEAR GENERATING STATIONS A AND B
NUCLEAR POWER REACTOR OPERATING LICENCE
LICENCE # PROL 18.02/2028

DRAFT HANDBOOK

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire
Canada

This page was intentionally left blank.

Licence Conditions Handbook **Effective: Mmm, DD, 2021**

LCH-PR-18.02/2028-R003

Bruce Nuclear Generating Stations A and B

Nuclear Power Reactor Operating Licence

PROL 18.02/2028

SIGNED at OTTAWA this XXth day of Mmm, 2021

_____

Alexandre Viktorov, Ph. D.

Director General

Directorate of Power Reactor Regulation

CANADIAN NUCLEAR SAFETY COMMISSION

Revision History

Effective Date	Revision	Word e-Doc and Version	Description of the Changes	DCR List e-Doc
October 1, 2018	0	5331057 v6	Original Document (Licence Renewal)	N/A
April 1, 2019	1	5653897 v2B	See DCR	5655484
May 25, 2020	2	5863808 v4	See DCR	5863777
Mmm, DD, 2021	3	6309625	See DCR	6309683

TABLE OF CONTENT

INTRODUCTION **8**

GENERAL **10**

G. GENERAL **10**
G.1 Licensing Basis for the Licensed Activities **10**
G.2 Notification of Changes **15**
G.3 Land Use and Occupation **17**
G.4 Office for CNSC Onsite Inspectors **19**
G.5 Public Information and Disclosure **20**

1 SCA – MANAGEMENT SYSTEM **21**
1.1 Management System **21**

2 SCA – HUMAN PERFORMANCE MANAGEMENT **24**
2.1 Human Performance Program **24**
2.2 Minimum Shift Complement and Control Room Staffing **27**
2.3 Training Programs **32**
2.4 Certification Programs **34**

3 SCA – OPERATING PERFORMANCE **37**
3.1 Operations Program **37**
3.2 Approval to Restart after a Serious Process Failure **44**
3.3 Reporting Requirements **46**

4 SCA – SAFETY ANALYSIS **48**
4.1 Safety Analysis Program **48**

5 SCA – PHYSICAL DESIGN **53**
5.1 Design Program **53**
5.2 Pressure Boundary Program **58**
5.3 Equipment and Structure Qualification Program **62**

6 SCA – FITNESS FOR SERVICE **64**
6.1 Fitness for Service Program **64**

7 SCA – RADIATION PROTECTION **73**

7.1 Radiation Protection Program and Action Levels 73

8 SCA – CONVENTIONAL HEALTH AND SAFETY 78

8.1 Conventional Health and Safety Program 78

9 SCA – ENVIRONMENTAL PROTECTION 79

9.1 Environmental Protection Program 79

10 SCA – EMERGENCY MANAGEMENT AND FIRE PROTECTION 87

10.1 Emergency Preparedness Program 87

10.2 Fire Protection Program 90

11 SCA – WASTE MANAGEMENT 93

11.1 Waste Management Program 93

11.2 Decommissioning and Financial Guarantees 95

12 SCA – SECURITY 96

12.1 Nuclear Security Program 96

13 SCA – SAFEGUARDS AND NON-PROLIFERATION 100

13.1 Safeguards Program 100

14 SCA – PACKAGING AND TRANSPORT 103

14.1 Packaging and Transport Program 103

15 NUCLEAR FACILITY-SPECIFIC 104

15.1 Lease Agreement 104

15.2 Integrated Implementation Plan 106

15.3 Pressure Tube Fracture Toughness 107

15.4 Return-to-Service Plan 110

15.5 Regulatory Hold Points for Return to Service and Continued Operation 111

15.6 Periodic Safety Review 114

15.7 End of Commercial Operations 115

15.8 Booster Fuel 116

15.9 Criticality Program 117

15.10 Cobalt-60 and Lutetium-177 119

15.11 Class II Nuclear Facility 122

15.12 Nuclear Substances and Prescribed Equipment 125

APPENDIX A – Acronyms and Definitions 133

APPENDIX B – List of All Version-Controlled Documents 138

APPENDIX C – List of Documents used as Guidance 141

APPENDIX D – List of Licensee Documents Requiring Written Notification 145

INTRODUCTION

The general purpose of the Licence Conditions Handbook (LCH) is to identify and clarify the relevant parts of the licensing basis for each licence condition (LC). This will help ensure that the licensee maintains facility operation in accordance with the licensing basis for the facility and the intent of the licence. The LCH should be read in conjunction with the licence.

The LCH typically has three parts under each LC: the Preamble, Compliance Verification Criteria (CVC), and Guidance. The Preamble explains, as needed, the regulatory context, background, and/or history related to the LC. CVC are criteria used by CNSC staff to verify and oversee compliance with the LC. Guidance is non-mandatory information, including direction, on how to comply with the LC.

Most CNSC documents referenced in the LCH are available through the CNSC public website. Documents listed in the CNSC website may contain prescribed information as defined by the *General Nuclear Safety and Control Regulations*. Information in these documents will be made available only to stakeholders with appropriate security clearance on a valid need to know.

The licensee documents referenced in the LCH are not publicly available; they contain proprietary information or prescribed information as defined by the *General Nuclear Safety and Control Regulations.*

The documents referenced in the LCH by e-Access numbers are not publicly available. The links provided in the LCH are references to the internal CNSC electronic filing system, and those documents cannot be opened from outside of the CNSC network.

Throughout the licence, the statement “or consent of a person authorized by the Commission” reflects to whom the Commission may delegate certain authority (hence “consent”) to CNSC staff. Unless otherwise indicated in the CVC of specific LCs in this LCH, the delegation of authority by the Commission to act as a “person authorized by the Commission” is only applied to the incumbents of the following positions (source: “Record of Decision” for Bruce A and B licence renewal issued September 2018, e-Doc 5624480):

- Director, Bruce Regulatory Program Division
- Director General, Directorate of Power Reactor Regulation
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch

Interaction between the licensee and CNSC staff that is described in this LCH is governed by the prevailing communication protocol (e-Doc 3565860) between the two.

Current versions of the licensee documents listed in this LCH are recorded in the document “Bruce PROL - Written Notification Documents in LCH” (e-Doc 5356815), which is controlled by the Bruce Regulatory Program Division (BRPD) and is available to the licensee upon request.

The content of this LCH is an input to the compliance program for this facility.

This LCH includes appendices A to D which contain acronyms, a glossary of terms and lists of LCH-related documents.

More information on the LCH is available in the CNSC document titled *How to Write a Licence Conditions Handbook (LCH)* (e-Doc 4967591).

GENERAL

G. GENERAL

G.1 Licensing Basis for the Licensed Activities

Licence Condition G.1:

The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations;

(ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence;

(iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (CNSC, hereinafter "the Commission").

Preamble:

Licensing Basis

The licensing basis is discussed in CNSC document REGDOC-3.5.3, *Regulatory Fundamentals*, Version 2 (2021).

Licensed Activities

Paragraph 24 (1) of the Nuclear Safety and Control Act (NSCA) states "The Commission may establish classes of licences authorizing the licensee to carry on any activity described in any of paragraphs 26 (a) to (f) that is specified in the licence for the period that is specified in the licence."

Paragraph 26 (a) of the NSCA states "Subject to the regulations, no person shall, except in accordance with a licence,

(a) possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information;
(b) mine, produce, refine, convert, enrich, process, reprocess, package, transport, manage, store or dispose of a nuclear substance;
(c) produce or service prescribed equipment;
(d) operate a dosimetry service for the purposes of this Act;
(e) prepare a site for, construct, operate, modify, decommission or abandon a nuclear facility; or
(f) construct, operate, decommission or abandon a nuclear-powered vehicle or bring a nuclear-powered vehicle into Canada."

Compliance Verification Criteria:

Licensee Documents

Document Title	Document #	Prior Notification
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Application for the Renewal of the Power Reactor Operating Licence for Bruce Nuclear Generating Stations A and B", June 30, 2017, e-Doc 5291208	NK21-CORR-00531-13493	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Supplement to the Application for Renewal of the Power Reactor Operating Licence: Periodic Safety Review Reports (including revised Bruce A and B Global Assessment Report and Integrated Implementation Plan)", July 19, 2017, e-Docs 5303331, 5303343 and 5303344	NK21-CORR-00531-13543	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Supplement to the Application for the Renewal of the Power Reactor Operating Licence: Major Component Replacement Project Execution Plan and Bruce B Unit 6 Return to Service Plan", June 30, 2017, e-Doc 5292343	NK21-CORR-00531-14175	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Supplement to the Application for the Renewal of the Power Reactor Operating Licence: Updated Environmental Risk Assessment that includes Major Component Replacement", June 30, 2017, e-Doc 5291221	NK21-CORR-00531-13620	N/A
Bruce Power Letter, Frank Saunders to Ken Lafrenière, "Bruce A Environmental Assessment Follow-up Monitoring Report, 2015", November 21, 2016, e-Doc 5128322	NK21-CORR-00531-13142	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Supplement to the Application for the Renewal of the Power Reactor Operating Licence: Whitefish Research Review", June 30, 2017, e-Doc 5291210	NK21-CORR-00531-13494	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Supplement to the Application for the Renewal of the Power Reactor Operating Licence: University Research Summary", June 30, 2017, e-Doc 5291217	NK21-CORR-00531-13587	N/A

Document Title	Document #	Prior Notification
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Supplement to the Application for the Renewal of the Power Reactor Operating Licence: Security Program Description", June 30, 2017, e-Doc 5291200 **(PROTECTED)**	NK21-CORR-00531-13367 NK29-CORR-00531-13917	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Supplement to the Application for the Renewal of the Power Reactor Operating Licence: Fitness-for-Service of Pressure Tubes", October 13, 2017, e-Doc 5369131	NK21-CORR-00531-13854 NK29-CORR-00531-14517	N/A
Bruce Power Letter, F. Saunders to M. Leblanc, "Supplement to the Application for the Renewal of the Power Reactor Operating Licence: Bruce Power Indigenous Community Interest Reports for Saugeen Ojibway Nation, Historic Saugeen Metis and Metis Nation of Ontario", January 24, 2018, e-Doc 5442220 **(Protected-B-Restricted)**	NK21-CORR-00531-14156 NK29-CORR-00531-14842 NK37-CORR-00531-02912	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Bruce Power Application for the Renewal of the Power Reactor Operating Licence: Supplemental Requests", February 1, 2018, e-Doc 5451672	NK21-CORR-00531-13890	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Application for the Renewal of the Power Reactor Operating Licence: Supplemental Material", February 12, 2018, e-Doc 5458711	NK21-CORR-00531-14126 NK29-CORR-00531-14817 NK37-CORR-00531-02906	N/A
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Application for the Renewal of the Power Reactor Operating Licence: Community Interests", March 6, 2018, e-Doc 5476968	NK21-CORR-00531-14245 NK29-CORR-00531-14932 NK37-CORR-00531-02941	N/A
Bruce Power Letter, Frank Saunders to Luc Sigouin, "Bruce Power Application for the Renewal of the Power Reactor Operating Licence Supplemental Material: Probabilistic Safety Assessment", March 13, 2018, e-Doc 5484062	NK21-CORR-00531-14261 NK29-CORR-00531-14950 NK37-CORR-00531-02944	N/A
Bruce Power Letter, F. Saunders to M. Leblanc, "Application for the Renewal of the Power Reactor Operating Licence: Supplemental Material", May 16, 2018, e-Doc 5536574	NK21-CORR-00531-14285 NK29-CORR-00531-14980 NK37-CORR-00531-02956	N/A
Bruce Power Letter, F. Saunders to M. Leblanc, "Application for the Renewal of the Power Reactor	NK21-CORR-00531-14428 NK29-CORR-00531-15130	N/A

Document Title	Document #	Prior Notification
Operating Licence: Supplemental Material", May 23, 2018, e-Doc 5541447	NK37-CORR-00531-02989	
Bruce Power Letter, Maury Burton to Luc Sigouin, "Application for the Renewal of the Power Reactor Operating Licence: Licensing Basis Documents", June 29, 2018, e-Doc 5575936	NK21-CORR-00531-14288 NK29-CORR-00531-14982 NK37-CORR-00531-02957	N/A
Bruce Power 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, e-Doc 6042771	NK21-CORR-00531-15378 NK29-CORR-00531-16213	N/A
Bruce Power Letter, M. Burton to M. Leblanc, "Application for the Amendment of the Power Reactor Operating Licence", November 25, 2020, e-Doc 6430874	BP-CORR-00531-00982	N/A

Part (i) of the licensing basis includes, but is not limited to, the following:

- *Nuclear Safety and Control Act;*
- *Canadian Environmental Assessment Act;*
- *Canadian Environment Protection Act;*
- *Nuclear Liability and Compensation Act;*
- *Transportation of Dangerous Goods Act;*
- *Radiation Emitting Devices Act;*
- *Access to Information Act; and*
- *Canada/IAEA Safeguards Agreement*.

The safety and control measures mentioned in the LC under Parts (ii) and (iii) of the licensing basis include important aspects of analysis, design, operation, etc. They may be found in high-level, programmatic licensee documents but might also be found in lower-level, supporting documentation. They also include safety and control measures in licensing basis publications (e.g., CNSC regulatory documents or CSA standards) that are cited in the licence, the application, or in the licensee's supporting documentation.

Licensing basis publications are listed in tables in this LCH under the most relevant LC. All "shall" or normative statements in licensing basis publications are considered CVC unless stated otherwise. If any "should" or informative statements in licensing basis publications are also considered CVC, this is explained under the most relevant LC.

The licensee documents and relevant licensing basis publications may cite other documents that also contain safety and control measures (i.e., there may be safety and control measures in "nested" references). There is no predetermined limit to the degree of nesting at which relevant safety and control measures may be found.

LC G.1 requires the licensee to implement all the safety and control measures; however, not all details in referenced documents are necessarily considered to be safety and control measures.

- Details that are not directly relevant to safety and control measures for facilities or activities authorized by the licence are excluded from the licensing basis.
- Details that are relevant to a different safety and control area (i.e., not the one associated with the main document) are only part of the licensing basis to the extent they are consistent with the main requirements for both safety and control areas.

In the event of any perceived or real conflict or inconsistency between two elements of the licensing basis, the licensee shall consult CNSC staff to determine the approach to resolve the issue.

In case of a conflict between CSA standards, CNSC will consult with CSA Group before reaching a conclusion on the resolution.

This LC is not intended to unduly inhibit the ongoing management and operation of the facility or the licensee's ability to adapt to changing circumstances and continuously improve, in accordance with its management system. Where the licensing basis refers to specific configurations, methods, solutions, designs, etc., the licensee is free to propose alternate approaches as long as they remain, overall, in accordance with the licensing basis and have a neutral or positive impact on health, safety, the environment, security, and safeguards. However, the licensee shall assess changes to confirm that operations remain in accordance with the licensing basis.

Changes to certain licensee documents require written notification to the CNSC, even if they are in accordance with the licensing basis. Further information on this topic is provided under LC G.2.

For unapproved operation that is not in accordance with the licensing basis, the licensee shall take action as soon as practicable to return to a state consistent with the licensing basis, taking into account the risk significance of the situation.

In the event that the Commission grants approval to operate in a manner that is not in accordance with existing licensing basis, this would effectively revise the licensing basis for the facility. The appropriate changes would be reflected in the CVC of the relevant LC.

Guidance:

When the licensee becomes aware that a proposed change or activity might not be in accordance with the licensing basis, it should first seek direction from CNSC staff regarding the potential acceptability of this change or activity. The licensee should take into account that certain types of proposed changes might require significant lead times before CNSC staff can make recommendations and/or the Commission can properly consider them. Examples of these types of changes are discussed under various LCs in this LCH. Guidance for notifications to the CNSC related to licensee changes are discussed under LC G.2.

G.2 Notification of Changes

Licence Condition G.2:

> **The licensee shall give written notification of changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.**

Preamble:

CNSC staff records, in e-Doc 5356815, the version history of licensee documents that require notification of change (with the exception of security-related documents).

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Document Management	BP-PROG-03.01	No
Management of Program, Procedure and Internal Standard Documents	BP-PROC-00166	No

Written notification is a physical or electronic communication from the licensee.

In general, the changes for which the licensee shall notify the CNSC are captured as changes to specific licensee documents. The LCH identifies them under the most relevant LC (see example above). However, the licensee documents identified in the LCH only represent the minimum subset of documents that require notification of change. For any change that is not captured as a change to a document listed in the LCH, the licensee shall provide written notification (WN) of the change if the change is a significant deviation that negatively impacts designs, operating conditions, policies, programs, methods, or other elements that are integral to the licensing basis. For example, if a licensee document in the CVC refers to another document, including a third-party document, without citing the revision # of that document, if that document changes and the licensee uses the revised version, the licensee shall determine if it is necessary to notify the CNSC of the change.

The documents needed to support the licence application may include documents produced by third parties (e.g., reports prepared by third party contractors). Changes to these documents require written notification to the CNSC only if the new version continues to form part of the licensing basis. That is, if the licensee implements a new version of a document prepared by a third party, it shall inform the CNSC of the change(s), per LC G.2. On the other hand, if a third party has updated a certain document, but the licensee has not adopted the new version as part of its safety and control measures, the licensee is not required to inform the CNSC that the third party has changed the document.

Licensee documents tabulated in the CVC of the LCH are subdivided into groups having different requirements for notification of change – ones that require prior written notification of changes and those that require written notification only. For the former type, the licensee shall submit the document to the CNSC prior to implementing changes. The licensee shall allow sufficient time for the CNSC to review the

change proportionate to its complexity and the importance of the safety and control measures being affected. Typically, significant changes require submission a minimum of 30 days prior to planned implementation. For the latter type, the licensee need only submit the document at the time of implementing the change.

Written notifications shall include a summary description of the change, the rationale for the change, expected duration (if not a permanent change), and a summary explanation of how the licensee has concluded that the change remains in accordance with the licensing basis (e.g., an evaluation of the impact on health, safety, security, the environment and Canada's international obligations). A copy of the revised WN document shall accompany the notification. All written notifications shall be transmitted to CNSC per established communication protocols.

The above also applies to a notice of change that requires CNSC staff acceptance, due to some other requirement in the licensing basis.

Changes that are not clearly in the safe direction require further assessment of impact to determine if Commission approval is required in accordance with LC G.1.

The licensee shall notify the CNSC in writing when it plans to implement a new licensing basis publication, including the date by which implementation of the publication will be complete. The notice shall indicate the corresponding changes to licensee documents listed in CVC of the LCH.

Guidance:

A list of criteria that could help determine if a change would be in accordance with the licensing basis is provided in Appendix A of e-Doc 4055483. Such criteria would also be used if the change requires CNSC staff acceptance, due to some other requirement in the licensing basis.

For proposed changes that would not be in accordance with the licensing basis, the Guidance for LC G.1 applies.

G.3 Land Use and Occupation

Licence Condition G.3:

The licensee shall control the use and occupation of any land within the exclusion zone.

Preamble:

The siting guide used at the time of design of all Canadian NPPs stipulated an exclusion zone that extended at least 914 metres from the exterior of any reactor building [Reference: D.G. Hurst and F.C. Boyd, "Reactor Licensing and Safety Requirements, AECB-1059", Paper 72-CNA-102, presented at the 12th Annual Conference of the Canadian Nuclear Association, Ottawa, Canada, 11-14 June 1972, e-Doc 3000249]. The exclusion zone is an area, immediately surrounding a nuclear facility where no permanent habitation is allowed.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Site Facilities Plan of the Bruce Nuclear Power Development Lots 11 to 28 and Part of 29 and 30	NK37-DRAW-10200-10001	Yes
Bruce A Safety Report Part 1: Plant and Site Description	NK21-SR-01320-00001	Yes*
Bruce B Safety Report Part 1: Plant and Site Description	NK29-SR-01320-00001	Yes*

**The reporting requirements for updates to facility descriptions are given in REGDOC-3.1.1 (LC 3.3)*

Bruce Power shall ensure that the use and occupancy of land within the exclusion zones does not compromise the safety and control measures in the licensing basis. Specifically, the licensee shall consider emergency preparedness and ALARA with respect to land use within the exclusion zones. This applies to land that Bruce Power occupies as well as to land occupied by others.

The licensee shall not permit a permanent dwelling to be built within the exclusion zone. “Permanent dwelling” refers to housing that is meant to be fixed. The licensee may erect, for a short time without prior notification, a temporary structure (e.g., a trailer).

Bruce Power shall notify the CNSC of permanent changes to the use and occupation of any land within the exclusion zones. The notice shall be submitted prior to the change, with lead time in proportion to the expected impact of the change on the licensee’s safety and control measures.

The Bruce A nuclear facility is located on the shore of Lake Huron on parts of lots 28, 29 and 30, Lake Range, Municipality of Kincardine, County of Bruce, Province of Ontario. The Bruce B nuclear facility is located on the shore of Lake Huron on parts of lots 12, 13, 14 and 15, Lake Range, Municipality of Kincardine, County of Bruce, Province of Ontario. The location of the exclusion zones and any structures within those zones are found in Ontario Power Generation (OPG) Drawing, “Site Facilities Plan of the Bruce Nuclear Power Development Lots 11 to 28 and Part of 29 and 30”. This drawing is a plan of survey

dated May 10, 1999, prepared by Marshall Macklin Monaghan Ontario Limited, Ontario Land Surveyors, and certified by Mr. Roy C. Mayo, O.L.S.

Guidance:

Not applicable to this LC.

G.4 Office for CNSC Onsite Inspectors

Licence Condition G.4:

The licensee shall provide, at the Bruce site and at no expense to the Commission, suitable office space for employees of the Commission who customarily carry out their functions on the premises of Bruce A and B (onsite Commission staff).

Preamble:

CNSC staff requires suitable office space and equipment at the nuclear facility in order to satisfactorily carry out its regulatory activities.

Compliance Verification Criteria:

Any changes of accommodation or equipment shall be made based on discussion and subsequent agreement between the CNSC and Bruce Power.

Bruce Power shall keep the office space of onsite Commission staff separate from the remainder of the building in which it is located by walls, partitions or other suitable structures.

Guidance:

Not applicable to this LC.

G.5 Public Information and Disclosure

Licence Condition G.5:

The licensee shall implement and maintain a public information and disclosure program.

Preamble:

A Public Information and Disclosure Program (PIDP) includes a disclosure program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects of the licensed facility and its activities on the environment, health and safety of persons, thereby generating an atmosphere of openness, transparency and trust.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Stakeholder Engagement	BP-PROG-09.02	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Public Information and Disclosure	REGDOC-3.2.1	2018	August 5, 2020

CNSC regulatory document REGDOC-3.2.1, PUBLIC INFORMATION AND DISCLOSURE outlines the requirements for a public information and disclosure program.

Guidance:

Org	Document Title	Document #	Version
CNSC	Indigenous Engagement, Version 1.1	REGDOC-3.2.2	2019

It is recommended that Bruce Power submit annually to CNSC staff a report summarizing the events and developments involving the Bruce nuclear facilities for the purposes of promoting compliance verification.

1 SCA – MANAGEMENT SYSTEM

1.1 Management System

Licence Condition 1.1:

The licensee shall implement and maintain a management system.

Preamble:

Safe and reliable operation requires a commitment and adherence to a set of management system principles and, consistent with those principles, the establishment and implementation of processes that achieve the expected results. CSA standard N286 contains the requirements for a management system throughout the life cycle of a nuclear power plant and extends to all safety and control areas.

The management system must satisfy the requirements set out in the *NSCA*, regulations made pursuant to the *NSCA*, the licence and the measures necessary to ensure that safety is of paramount consideration in implementation of the management system. An adequately established and implemented management system provides the evidence that the licensing basis remains valid.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System Manual	BP-MSM-1	Yes
Conduct of Business	BP-PROG-16.01	Yes
Supply Chain	BP-PROG-05.01	No
Independent Oversight Management	BP-PROG-15.01	No
Project Management and Construction	BP-PROG-14.01	No
Contractor Management	BP-PROG-14.02	No
Organization Structure Change	BP-PROC-00001	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CSA	Management system requirements for nuclear facilities	N286	2012	Dec. 31, 2018
CNSC	Safety Culture	REGDOC-2.1.2	2018	Apr 1, 2020

Management System

The management and operation of Bruce Power are defined by the programs and their implementing documents, as described by Bruce Power's Management System Manual. Changes to the management system documents, including Bruce Power's programs and procedures listed in the LCH and the processes are to be made in accordance with the Bruce Power document "Management System (BPMS) Management".

Organization

Bruce Power shall document the organizational structure for safe and reliable conduct of licensed activities and shall include all positions with responsibilities for the management and control of the licensed activity. Any changes to the nuclear organization shall be made in accordance with Bruce Power's "Organization Structure Change".

Safety Culture

Bruce Power shall ensure that management supports the safe conduct of licensed activities at the nuclear facilities.

The Bruce nuclear facilities' operations and performance must ensure that sound nuclear safety is the overriding priority in all activities performed in support of the licensee's nuclear facilities and has clear priority over schedule, cost and production. Bruce Power's Nuclear Oversight Management and Operating Experience Program contribute to the development of a healthy safety culture throughout the oversight of Bruce Power's programs and processes by using internal and external assessments and self-assessments in order to continuously improve performance.

A safety culture self-assessment methodology has been developed by Bruce Power. It is governed by its business assessment process which promotes continuous improvement.

Configuration management

Configuration management, the process that identifies, documents changes and ensure conformance is maintained between design requirements, physical configuration and facility configuration information, is discussed in section 5.1.

Management of Contractors

Bruce Power shall implement and maintain a management of contractors program that will ensure compliance with regulatory requirements.

Business Continuity

Business continuity planning ensures that essential functions can continue to operate safely when affected by adverse physical conditions or following interruptions to normal operation. Bruce Power shall maintain contingency plans to:

- ensure minimal disruptions in the event of a labour dispute or public protest; and
- provide for essential services through a sustained period with significant employee absenteeism (e.g., influenza outbreak).

Guidance:

Org	Document Title	Document #	Version
CNSC	Management System	REGDOC-2.1.1	2019
CSA	Commentary on N286-12, Management system requirements for nuclear facilities	N286.0.1	2014

The management system should be used to promote and support a healthy safety culture. The CNSC recognizes the following characteristics that form the framework for a healthy safety culture:

- safety is a clearly recognized value;
- accountability for safety is clear;
- safety is integrated into all activities;
- a safety leadership process exists; and
- safety culture is learning-driven.

The licensee should conduct self-assessments of safety culture periodically. The assessment method should be documented and the framework should include links to the safety culture characteristics listed above.

CNSC staff encourages senior management at the Bruce nuclear facilities to continue fostering a healthy safety culture so licensee staff understands the influence that safety culture has over all other organizational processes and its role in maintaining and improving safety performance.

The management system documentation should contain sufficient directions for workers to comply with the regulatory requirements. It is recommended that when the Management System Manual is updated and the CNSC is notified, that Bruce Power also submit to the CNSC the associated sheets that provide information on program matrix, approved reference chart authorities and responsibilities, list of applicable governing Acts, Regulations, Codes and Standards, and program summaries.

2 SCA – HUMAN PERFORMANCE MANAGEMENT

2.1 Human Performance Program

Licence Condition 2.1:

The licensee shall implement and maintain a human performance program.

Preamble:

Human performance relates to reducing the likelihood of human error in work activities. It refers to the outcome of human behaviour, functions and actions in a specified environment, reflecting the ability of workers and management to meet the system's defined performance under the conditions in which the system will be employed.

Human factors are factors that influence human performance as it relates to the safety of a nuclear facility or activity over all design and operations phases. These factors may include the characteristics of the person, task, equipment, organization, environment, and training. The consideration of human factors in issues such as interface design, training, procedures, and organization and job design may affect the reliability of humans performing tasks under various conditions.

CNSC regulatory document REGDOC-2.2.1, HUMAN FACTORS, describes how the CNSC will take human factors into account during its licensing, compliance and standards-development activities.

For clarification, CNSC regulatory oversight related to hours of work is for the purpose of "nuclear safety" not for the purpose of "worker protection". Worker protection is covered under the SCA "Conventional Health and Safety" (section 8.1).

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Limits to Hours of Work	BP-PROC-00005	Yes
Conduct of Business	BP-PROG-16.01	Yes
Human Resources Management	BP-PROG-02.01	No
Fitness For Duty	BP-PROC-00610	No
Fitness for Duty Considerations for Shift Complement Staff Held Over for More than 13 Hours	GRP-OPS-00055	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Fitness for Duty: Managing Worker Fatigue	REGDOC-2.2.4	2017	Dec. 31, 2018
CNSC	Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3	REGDOC-2.2.4	2021	July 22, 2021 (except random testing) Jan. 22, 2022 (complete document)*

* See details below under *Implementation strategy for REGDOC-2.2.4, Volume II, Version 3*

In order to establish, maintain and improve human performance, Bruce Power shall monitor and control the work hours and shift schedules of nuclear workers, in accordance with BP-PROC-00005, LIMITS TO HOURS OF WORK.

Bruce Power shall also monitor and control the fitness for duty of its workers at all times as per the provisions set out in BP-PROC-00610, FITNESS FOR DUTY. Fitness for duty considerations for shift complement staff held over from their regular shift are contained in GRP-OPS-00055.

Implementation strategy for REGDOC-2.2.4, Volume II: Managing Alcohol and Drug Use, Version 3

REGDOC-2.2.4 *Fitness for Duty, Volume II: Managing Alcohol and Drug Use*, Version 3, sets out requirements and guidance for managing fitness for duty of workers in relation to alcohol and drug use and abuse. Bruce Power will implement all REGDOC-2.2.4 Vol II, Version 3 requirements, other than random alcohol and drug testing by July 22, 2021 and will implement random alcohol and drug testing by January 22, 2022.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Human Factors	REGDOC-2.2.1	2019

The program should include elements that continuously monitor human performance, identify human performance weaknesses, improve human performance, and reduce the likelihood of human performance related causes and root causes of nuclear safety events.

In addition to those listed as requirements, the human performance program should address the range of human and organizational factors that influence human performance. Moreover, the human performance program should integrate all these factors. The range of factors includes, but is not limited to, the following:

- The provision of qualified staff
    - Certification and Training

  - Staffing
  - Minimum Shift Complement
  - Fitness for duty (hours of work, fatigue management)
- The reduction of human error
  - Procedures Development
  - Procedural Compliance
  - Work protection and Work Permit Systems
  - Shift Turnover
  - Pre and Post Job Briefings
  - Safe work strategies/practices
- Organizational support for safe work activities
  - Human Actions in Safety Analysis
  - Organizational Performance and Safety Culture
- The continuous improvement of human performance

2.2 Minimum Shift Complement and Control Room Staffing

Licence Condition 2.2:

The licensee shall implement and maintain the minimum shift complement and control room staffing for Bruce A and B.

Preamble:

The minimum shift complement specifies the numbers of qualified staff that are required to operate and maintain unit(s) safely under all operating states including normal operations, anticipated operational occurrences, design-basis accidents and emergencies.

This licence condition ensures the presence of a sufficient number of qualified workers who must be present at all times to ensure safe operation of the nuclear facility, and to ensure adequate emergency response capability.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Station Shift Complement – Bruce A	DIV-OPA-00001	Yes
Station Shift Complement – Bruce B	DIV-OPB-00001	Yes

Minimum Shift Complement

Bruce Power's minimum shift complement procedures describe the minimum number of workers with specific qualifications required for the safe operation of the nuclear facilities under all operating states and the measures in place to mitigate the impact of any minimum shift complement violations until minimum complement requirements are restored.

Bruce Power shall operate the nuclear facilities in accordance with these documents and shall monitor and keep records of each shift's complement. The following tables summarize the number of workers located at Bruce A and Bruce B during one shift, as well as additional staff on site and available as call-ins.

A. Number of Workers Present at the Bruce A Nuclear Facility

DESIGNATED POSITION	# of Staff	EMERGENCY RESPONSE ORGANIZATION POSITION
Shift Manager	1	Shift Emergency Controller (SEC)
Control Room Shift Supervisor	1	Back-up SEC
Shift Assistant Technical Support	1	Emergency Shift Assistant
Field Shift Operating Supervisor	1	Out-of-Plant Coordinator for Bruce B
Authorized Nuclear Operator	6	
Supervising Nuclear Operator – Reactor Units	4	Shift Resource Coordinator
Nuclear Operator – Reactor Units	8	
Unit 0 Control Room Operator	2	
Supervising Nuclear Operator – Unit 0	1	
Nuclear Operator – Unit 0	3	
Fuel Handling Control Room Operator	1	Work Control Area Accounting Supervisor
Nuclear Operator – Fuel Handling	1	
Control Maintenance First Line Manager	1	In-plant Coordinator
Control Technician	1	
Chemistry Technician	2	Chemistry Laboratory and Supervisor
Emergency Services Maintainer First Line Manager Assistant – Bruce A	1	Emergency Response Team - Field Command (Bruce A), OSST Captain (Bruce B)
TOTAL	**35**	

B. Number of Workers Present at the Bruce B Nuclear Facility

DESIGNATED POSITION	# of Staff	EMERGENCY RESPONSE ORGANIZATION POSITION
Shift Manager	1	Shift Emergency Controller (SEC)
Control Room Shift Supervisor	1	Back-up SEC
Shift Assistant Technical Support	1	Emergency Shift Assistant
Field Shift Operating Supervisor	1	Out-of-Plant Coordinator for Bruce A
Authorized Nuclear Operator	6	
Supervising Nuclear Operator – Reactor Units	4	
Nuclear Operator – Reactor Units	8	
Unit 0 Control Room Operator	2	
Supervising Nuclear Operator – Unit 0	1	
Nuclear Operator – Unit 0	4	
Fuel Handling Control Room Operator	1	Shift Resource Coordinator
Nuclear Operator – Fuel Handling	1	Work Control Area Accounting Supervisor
Control Maintenance First Line Manager	1	In-plant Coordinator
Control Technician	1	
Mechanical Maintainer	1	
Chemistry Technician	2	Chemistry Laboratory and Supervisor
Emergency Services Maintainer First Line Manager Assistant – Bruce B	1	Emergency Response Team - Field Command (Bruce B), OSST Captain (Bruce A)
TOTAL	**37**	

C. Number of Additional Workers Present at Site in Support of the Bruce A and Bruce B Nuclear Facilities

DESIGNATED POSITION	# of Staff	EMERGENCY RESPONSE ORGANIZATION POSITION
Staff Normally Based at Bruce A		
Control Technician	1	Emergency Entry/Repair Team
Emergency Services Maintainer - Bruce A	2	Emergency Response Team
Staff Normally Based at Bruce B		
Mechanical Maintainer	1	Emergency Entry/Repair Team
Stock Keeper	1	Stores
Emergency Services Maintainer - Bruce B	2	Emergency Response Team
Additional Staff Normally Based on Site		
Shift Emergency Response Manager	1	Emergency Response Coordinator
Emergency Services Maintainer - Dispatcher	1	Dispatcher
Emergency Services Maintainer - First Line Manager(assistant) - Site	1	Emergency Response Team
Emergency Services Maintainer - Site	4	Emergency Response Team
Emergency Services Maintainer - Site	2	In-plant Survey Team
Emergency Services Maintainer - Site	2	Source Term Survey Team
TOTAL	**18**	

D. Number of Call-in Workers in Addition to Station and Site Personnel

DESIGNATED POSITION	# of Staff	EMERGENCY RESPONSE ORGANIZATION POSITION
Call-in Staff		
Security	2	Offsite Survey Team Drivers
Radiation Technician	2	Offsite Survey Team Surveyors
TOTAL	**4**	

Control Room Staffing

Bruce Power shall comply with the minimum certified worker requirements for the nuclear facilities and for the main control rooms. The certified positions are listed in LC 2.4.

In conjunction with the minimum shift complement for the facility, Bruce Power shall maintain adequate control room staffing. The licensee shall, at all times, have the following certified workers:

- at least one shift manager, six authorized nuclear operators, one control room shift supervisor and two Unit 0 control room operators at each nuclear facility (Bruce A and B);
- an authorized nuclear operator in direct attendance at the control panels of each reactor unit in the main control rooms;

- a minimum of one Unit 0 control room operator in the main control room at each nuclear facility (Bruce A and B), except for brief absences to respond to security alerts or to determine the origin of fire alarms.

"In direct attendance" means the certified person is physically in the direct line of sight and in close proximity to the control room panels to continuously monitor, recognize and differentiate panel displays, alarms and indications.

The minimum certified worker requirements for the main control rooms that this condition imposes do not apply where this minimum cannot be met due to emergency conditions that could cause an unwarranted hazard to workers in the main control rooms, in which case Bruce Power shall place the reactor(s) in a safe shutdown state and the nuclear facilities in a safe condition.

A certified person shall be in a position to rapidly respond, in accordance with his/her role, to changing unit conditions, at all times.

Bruce Power shall provide a rolling 5-year staffing profile of certified operators on an annual basis.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Minimum Staff Complement	REGDOC-2.2.5	2019
CNSC	General Design Considerations: Human Factors	REGDOC-2.5.1	2019

The adequacy of the minimum shift complement should be determined through a systematic analysis of the most resource-intensive conditions under all operating states, design-basis accidents, and emergencies. The results of the analysis should then be validated to determine the degree to which the minimum shift complement facilitates the achievement of the overall safety goals.

Guidance for the development and validation of the minimum shift complement are provided in the following CNSC guidance documents:

- REGDOC-2.2.5, MINIMUM STAFF COMPLEMENT, describes the CNSC recommended approach for defining the minimum shift complement and sets out the key factors that CNSC staff will take into account when assessing whether the licensee has made, or the applicant will make, adequate provision for ensuring the presence of a sufficient number of qualified staff.
- REGDOC-2.5.1, GENERAL DESIGN CONSIDERATIONS: HUMAN FACTORS, describes the elements of effective human factors verification and validation planning, including a suggested format for documenting these elements.

2.3 Training Programs

Licence Condition 2.3:

The licensee shall implement and maintain training programs for workers.

Preamble:

This LC provides the regulatory requirements for the development and implementation of training programs for workers.

As defined by the *General Nuclear Safety and Control Regulations* a "worker means a person who performs work that is referred to in a licence". Workers include contractors and temporary employees who perform work that is referred to in the licence. Training requirements apply equally to these types of workers as to the licensees own employees.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Worker Learning and Qualification	BP-PROG-02.02	No
Systematic Approach to Training Process	BP-PROC-01071	Yes

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Personnel Training, Version 2	REGDOC-2.2.2	2016	October 1, 2018

Given that REGDOC-2.2.2 Version 2 has no material changes to it, where REGDOC-2.2.2 (i.e., initial version) is referenced in Bruce Power governing documents, it shall be taken to mean REGDOC-2.2.2 Version 2. Bruce Power will update the references in their governance on the regular document review cycle.

Training Programs for Workers

The licensee shall implement and maintain training programs for workers in accordance with REGDOC-2.2.2, *Personnel Training*, Version 2, which defines the requirements regarding the development and implementation of a training system.

REGDOC-2.2.2 also provides the requirements necessary to support initial certification training and renewal of certification training of persons for the positions listed in LC 2.4, and as required by REGDOC-2.2.3, Vol. III, *Certifications of Persons Working at Nuclear Power Plants*.

All training programs related to workers in positions where the consequence of human error poses a risk to the environment, the health and safety of persons, or to the security of the nuclear facilities and licensed activities, are evaluated against the criteria for a systematic approach to training (SAT).

Guidance:

Not applicable to this LC.

2.4 Certification Programs

Licence Condition 2.4:

The licensee shall implement and maintain certification programs in accordance with CNSC regulatory document REGDOC-2.2.3, PERSONNEL CERTIFICATION, Volume III, CERTIFICATION OF PERSONS WORKING AT NUCLEAR POWER PLANTS.

Persons appointed to the following positions require certification:

(i) authorized health physicist;

(ii) authorized nuclear operator;

(iii) control room shift supervisor;

(iv) Unit 0 control room operator; and

(v) shift manager.

Preamble:

The licensee's documentation describes the authority and responsibilities of certified positions.

This LC provides the regulatory requirements for the initial certification, the renewal of certification and training of persons for the positions listed in the LC. It also provides the requirements regarding the program and processes necessary to support the certification and training of persons at the nuclear facility.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Bruce A Role Descriptions for Licence-Related Positions	DIV-OPA-00002	Yes
Bruce B Role Description for Licence-Related Positions	DIV-OPB-00002	Yes
Certification Training – Development and Administration of Comprehensive Written and Oral Examinations for Certification Training	BP-PROC-00568	Yes
Certification Training Examinations – Standards for Development and Administration of Closed Reference Multiple Choice Questions for Initial General Certification Written Examinations	B-HBK-09510-00012	Yes

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Certification of Persons Working at Nuclear Power Plants	REGDOC-2.2.3, Vol. III	2019	April 9, 2020

Note: Paragraph 13.1.6 of REGDOC-2.2.3, Vol. III will be amended during the next regulatory document revision to align with the written requalification test requirements in CNSC document, REQUIREMENTS FOR THE REQUALIFICATION TESTING OF CERTIFIED SHIFT PERSONNEL AT NUCLEAR POWER PLANTS, Version 2. In the interim, for REGDOC-2.2.3, Vol. III paragraph 13.1.6, CNSC staff will apply the following compliance criteria: "The person must have successfully completed written requalification tests equivalent in number to those referred to in the NPP licence that the person would have had to take during the period of absence, if the person had continued to work in the position."

Training and Certification for Staff Appointed to Certified Positions

Bruce Power shall implement and maintain a certification training and examination program in accordance with REGDOC-2.2.3, Vol. III which defines the requirements regarding certification of persons working at NPPs in positions that have a direct impact on nuclear safety.

The senior health physicist referred to in REGDOC-2.2.3, Vol. III is equivalent to the authorized health physicist position at Bruce A and B. The term authorized health physicist, referred to in Bruce Power documentation, and responsible health physicist, have the same meaning and the terms are interchangeable. The plant shift supervisor referred to in REGDOC-2.2.3, Vol. III is equivalent to the shift manager position at Bruce A and B. Any person who holds a certification as shift manager shall also be qualified to act in the control room shift supervisor position. The control room shift supervisor position may also be filled by a certified shift manager.

Note, paragraphs 25.2.6 and 26.7 of REGDOC-2.2.3, Vol. III will be amended during the next regulatory document revision. In the interim, for REGDOC-2.2.3, Vol. III paragraph 25.2.6, CNSC staff will apply the following compliance criteria: "The person must have performed the duties of the control room shift supervisor under the supervision of a **certified control room shift supervisor or a certified shift manager** for a minimum of 480 hours on shift to confirm and document that the person can perform those duties competently and safely. At least 360 of those hours must have been worked after the person has met the requirements specified in paragraphs 25.2.1 to 25.2.4". For REGDOC-2.2.3, Vol. III paragraph 26.7, CNSC staff will apply the following compliance criteria: "The person must have performed the duties of the control room shift supervisor under the supervision of a **certified control room shift supervisor or a certified shift manager** for a minimum of 480 hours on shift to confirm and document that the person can perform those duties competently and safely. At least 360 of those hours must have been worked after the person has met the requirements specified in subsections 26.2 to 26.4".

Bruce Power shall ensure persons appointed to the position of authorized health physicist, shift manager, authorized nuclear operator, control room shift supervisor and Unit 0 control room operator, at the nuclear facilities hold a certification for the position to which they have been appointed, in accordance with the requirements of the *Class I Nuclear Facilities Regulations*.

Bruce Power has a document entitled "Role Descriptions for Licence-Related Positions", which describes the authorities and responsibilities for certified positions referred to in this LC. Certified operating staff will carry out their authorities and responsibilities as per their respective role descriptions.

The authorities and responsibilities of the certified positions listed above are considered safety and control measures. Any changes to them will be reviewed by CNSC staff to confirm they remain within the licensing basis, in consultation with the designated officer to certify and decertify persons referred to in sections 9 and 12 of the *Class I Nuclear Facilities Regulations* and the Director of the Personnel Certification Division. The general criteria for reviewing changes include those described in LC G.1 and LC G.2. Any changes outside the licensing basis would require prior written approval of the Commission, per LC 1.1.

The authorities and responsibilities of an authorized health physicist, a certified position are found in the Bruce Power document BP-PROG-12.05 listed in section 7.1 as a licensee document requiring prior notification of change. Changes made to this document will be reviewed by CNSC staff including addressing the authorities and responsibilities aspects given above.

Conduct of Examinations and Tests for Certified Personnel

Currently, the following three CNSC internal documents contain the requirements for administering the certification examinations and requalification tests required by REGDOC-2.2.3, Vol. III:

- CNSC document: EXAMINATION GUIDE CNSC-EG1, REV.0: REQUIREMENTS AND GUIDELINES FOR WRITTEN AND ORAL CERTIFICATION EXAMINATIONS FOR SHIFT PERSONNEL AT NUCLEAR POWER PLANTS,
- CNSC document: EXAMINATION GUIDE CNSC-EG2, REV.0: REQUIREMENTS AND GUIDELINES FOR SIMULATOR-BASED CERTIFICATION EXAMINATIONS FOR SHIFT PERSONNEL AT NUCLEAR POWER PLANTS, and
- CNSC document: REQUIREMENTS FOR THE REQUALIFICATION TESTING OF CERTIFIED SHIFT PERSONNEL AT NUCLEAR POWER PLANTS, REVISION 2

As per the CNSC December 19, 2017 letter (e-Doc 5340379) for the General certification examinations specified in CNSC document EG1, the following CVC shall be applied. On a pilot basis, Bruce Power may choose to administer General certification examinations using a Multiple Choice Question (MCQ) format. During this pilot period, the development, conduct and marking of MCQ General certification examinations shall be in accordance with the following Bruce Power documents:

- BP-PROC-00568, and
- B-HBK-09510-00012

Guidance:

Not applicable to this LC.

3 SCA – OPERATING PERFORMANCE

3.1 Operations Program

Licence Condition 3.1:

The licensee shall implement and maintain an operations program, which includes a set of operating limits.

Preamble:

The operations program establishes safe operating practices within the nuclear facility, under all operating conditions (routine and non-routine), and provides the ability to ensure the facility is operated in such a manner that:

- applicable regulations, LCs, and standards are followed;
- the requirements of the operating policies and principles are implemented; and
- limits established in accordance with a safe operating envelope (SOE) are not exceeded.

The Operating Policies and Principles (OP&Ps):

- outline the operating rules consistent with the safety analyses and other licensing support documentation within which the station will be operated, maintained and modified, all of which should ensure nuclear safety;
- specify the authorities of the station staff positions to make decisions within the defined boundaries; and
- identify and differentiate between actions where discretion may be applied and where jurisdictional authorization is required.

The safe operating limits are derived from the safety analysis limits as well as design requirements. The SOE parameters are currently identified in various station documents, including Operational Safety Requirements (OSRs) and Instrument Uncertainty Calculations (IUCs). These limits are monitored through compliance documents such as the Impairments Manual and surveillance documentation.

Power limit specifications set limits on parameters that affect reactor core, channel, and fuel bundle powers, to ensure compliance with limits imposed by the design and safety analysis assumptions. The magnitude of the initial reactor power, channel powers and bundle powers in the reactor prior to an accident are the fundamental parameters governing whether fuel or fuel channel failure will occur during anticipated transients and the postulated Design-Basis Accidents (DBAs).

Accident management provisions address defences against radiological hazards resulting from DBAs and Beyond-Design-Basis Accidents (BDBAs). The fundamental premise underlying accident management is that overlapping measures for accident prevention and accident response are in place to:

- Prevent the escalation of the accident;
- Mitigate the consequences of the accident; and
- Achieve a long-term safe stable state after the accident.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Operating Policies and Principles – Bruce B	BP-OPP-00001	Yes
Operating Policies and Principles – Bruce A	BP-OPP-00002	Yes
Operating Policies and Principles – Central Maintenance and Laundry Facility	BP-OPP-00003	Yes
Conduct of Plant Operations	BP-PROG-12.01	No
Operational Safety Requirements for Bruce A Fuel and Reactor Physics	NK21-OSR-31000-00001	No
Operational Safety Requirements for Bruce A Moderator System	NK21-OSR-32000-00001	No
Bruce A NGS: Operational Safety Requirements for Heat Transport System	NK21-OSR-33100-00001	No
Operational Safety Requirements for Bruce A End Shield Cooling System	NK21-OSR-34110-00001	No
Operational Safety Requirements for Bruce A Containment System	NK21-OSR-34200-00004	No
Operational Safety Requirements for Bruce A Emergency Coolant Injection System	NK21-OSR-34340-00003	No
Operational Safety Requirements for Bruce A Powerhouse Emergency Venting System	NK21-OSR-34360-00001	No
Operational Safety Requirements for Bruce A Shutdown and Maintenance Cooling Systems	NK21-OSR-34700-00001	No
Operational Safety Requirements for Bruce A Annulus Gas System	NK21-OSR-34980-00001	No
Operational Safety Requirements for Bruce A Fuel Handling	NK21-OSR-35000-00001	No
Operational Safety Requirements for Bruce A Main Steam Supply System	NK21-OSR-36100-00001	No
Operational Safety Requirements for Bruce A Confinement	NK21-OSR-38330/21175-00001	No
Operational Safety Requirements for Bruce A Feedwater and Condensate System	NK21-OSR-43200-00001	No

Document Title	Document #	Prior Notification
Operational Safety Requirements for Bruce A Electrical System	NK21-OSR-53000/55000-00001	No
Operational Safety Requirements for Bruce A Qualified Power Supply System	NK21-OSR-54400-00001	No
Operational Safety Requirements for Bruce A Critical Safety Parameter Monitoring	NK21-OSR-60060-00001	No
Operational Safety Requirements for Bruce A Reactor Regulating System	NK21-OSR-63710-00001	No
Operational Safety Requirements for Bruce A Shutdown Systems	NK21-OSR-63720-63730-00001	No
Operational Safety Requirements for Bruce A Service Water Systems	NK21-OSR-71310-00001	No
Operational Safety Requirements for Bruce A Emergency Boiler Cooling System	NK21-OSR-71910-00001	No
Operational Safety Requirements for Bruce B Fuel and Reactor Physics	NK29-OSR-31000-00001	No
Operational Safety Requirements for Bruce B Moderator System	NK29-OSR-32000-00001	No
Operational Safety Requirements for Bruce B Heat Transport System	NK29-OSR-33000-00001	No
Operational Safety Requirements for Bruce B End Shield Cooling System	NK29-OSR-34110-00001	No
Operational Safety Requirements for Bruce B Containment System	NK29-OSR-34200-00001	No
Operational Safety Requirements for Bruce B Emergency Coolant Injection System	NK29-OSR-34340-00001	No
Operational Safety Requirements for Bruce B Powerhouse Emergency Venting System	NK29-OSR-34360-00001	No
Operational Safety Requirements for Bruce B Shutdown and Maintenance Cooling Systems	NK29-OSR-34700-00001	No
Operational Safety Requirements for Bruce B Annulus Gas System	NK29-OSR-34980-00001	No
Operational Safety Requirements for Bruce B Fuel Handling	NK29-OSR-35000-00001	No
Operational Safety Requirements for Bruce B Main Steam Supply System	NK29-OSR-36100-00001	No
Operational Safety Requirements for Bruce B Confinement	NK29-OSR-38330-21190-00001	No

Document Title	Document #	Prior Notification
Operational Safety Requirements for Bruce B Feedwater and Condensate System	NK29-OSR-43200-00001	No
Operational Safety Requirements for Bruce B Electrical System	NK29-OSR-53000/55000-00001	No
Operational Safety Requirements for Bruce B Emergency Power Supply System	NK29-OSR-54300-00001	No
Operational Safety Requirements for Bruce B Critical Safety Parameter Monitoring	NK29-OSR-60060-00001	No
Operational Safety Requirements for Bruce B Reactor Regulating System	NK29-OSR-63710-00001	No
Operational Safety Requirements for Bruce B Shutdown Systems	NK29-OSR-63720-63730-00001	No
Operational Safety Requirements for Bruce B Service Water Systems	NK29-OSR-71310-00001	No
Operational Safety Requirements for Bruce B Emergency Water System	NK29-OSR-71380-00001	No
Bruce Power Safeguards Site Plan 2015	NK37-CORR-00531-02784	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CSA	Requirements for the safe operating envelope for nuclear power plants	N290.15	2010 Update No. 1 (2016)	Oct. 1, 2018
CNSC	Accident Management: Severe Accident Management Programs for Nuclear Reactors	REGDOC-2.3.2	2013	Sep. 30, 2015

The licensee shall implement and maintain operations programs. These programs shall consist of, at a minimum, a safe operating envelope, a set of operating policies and principles, and accident management procedures and/or guides for design-basis and beyond-design-basis accidents, including overall strategies for recovery.

Bruce Power employs a number of programs and other governance to fulfill the objective of this LC. Operation in states not considered in, or not bounded by, the safety analyses is not permitted.

Power Limits

Bruce Power shall operate the reactor within the following limits:

Bruce A		
	Inner Flow Zone	Outer Flow Zone
Total power generated in any one fuel bundle	Shall not exceed 969 kilowatts	Shall not exceed 857 kilowatts
Total power generated in any fuel channel	Shall not exceed 6.84 megawatts under normal steady-state operating conditions	Shall not exceed 6.25 megawatts under normal steady-state operating conditions
Total thermal power from the reactor fuel	Shall not exceed 2619.6 megawatts (92.5% full power) under steady-state operating conditions	

Bruce B		
	Inner Flow Zone	Outer Flow Zone
Total power generated in any one fuel bundle	Shall not exceed 837 kilowatts under normal steady-state operating conditions	
Total power generated in any fuel channel	Shall not exceed 6.70 megawatts in the inner flow zone of the reactor core under normal steady-state operating conditions	Shall not exceed 6.23 megawatts in the outer flow zone of the reactor core under normal steady-state operating conditions
Total thermal power from the reactor fuel	Shall not exceed 2634 megawatts (93% full power) under steady-state operating conditions	

The reactor, channel and bundle power limits are considered safety and control measures. Any changes to them, or planned operations outside of these limits, would require prior written approval by the Commission, per LC G.1 and LC G.2.

Operating Policies and Principles

The OP&Ps shall provide direction for operating the nuclear facilities safely and, as a minimum, reflect the safety analyses that have been previously submitted to the Commission, or a person authorized by the Commission.

Bruce Power shall, at all times, maintain and operate the nuclear facilities within the principles of the OP&Ps and the limits of the SOE. If operation outside the operating boundaries specified by the OP&Ps and SOE is discovered, the licensee shall take immediate action to return the facility within the boundaries of safety analyses, in a safe manner as per Bruce Power procedures.

Safe Operating Envelope

CSA standard N290.15, REQUIREMENTS FOR THE SAFE OPERATING ENVELOPE FOR NUCLEAR POWER PLANTS outlines the requirements for a safe operating envelope.

Bruce Power's safe operating limits, conditions and surveillance requirements as well as their bases are documented in station and system specific Operational Safety Requirements (OSRs) documents along with any associated Instrument Uncertainty Calculations (IUCs). The limits and conditions documented in the OSRs, including any requirements for corrective or mitigating actions and action times, are specified in the applicable operations and maintenance tests, procedures and processes to ensure compliance with the SOE.

Bruce Power shall, at all times, maintain and operate the nuclear facilities within the limits of the SOE.

The SOE is considered part of the licensing basis. Changes to the SOE documentation are subject to LC G.1 and LC G.2. Changes that may reduce safety margins would require prior notification and engagement of CNSC staff.

Accident Management and Recovery

CNSC regulatory document REGDOC-2.3.2, ACCIDENT MANAGEMENT: SEVERE ACCIDENT MANAGEMENT PROGRAMS FOR NUCLEAR REACTORS outlines the requirements related to severe accident management programs, which provide additional defence against the consequences of those accidents that fall beyond the scope of events considered in the reactor design basis.

Bruce Power shall implement and maintain operational procedures for operation in all states analyzed in the design basis, including abnormal and emergency states.

Bruce Power's operational procedures ensure that the operation of the facility can be returned to a safe and controlled state should operation deviate from normal operation. Bruce Power shall ensure all abnormal operational scenarios analyzed in the design basis are accounted for in the operational procedures with the purpose of mitigating situations that may arise which cause a deviation from the expected state. These documents are conceived to return the plant to a safe and controlled state and to prevent the further escalation of the abnormal incident into a more serious deviation.

In addition to the operational guidance for abnormal and emergency states, Bruce Power shall implement and maintain a severe accident management program to address residual risks posed by severe accidents. Bruce Power shall also ensure clear instruction is provided directing operations in abnormal scenarios to the appropriate set of procedures or guides, including severe accident management guidelines (SAMGs), if a severe accident is detected.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CSA	Requirements for reactor heat removal capability during outage of nuclear power plants	N290.11	2013
CSA	Requirements for beyond design basis accidents	N290.16	2016
CNSC	Accident Management, Version 2	REGDOC-2.3.2	2015

The licensee should manage all outage heat sink work activities in accordance with CSA standard N290.11, REQUIREMENTS FOR REACTOR HEAT REMOVAL CAPABILITY DURING OUTAGE OF NUCLEAR POWER PLANTS.

The licensee should take into consideration the September 2015 version of CNSC regulatory document REGDOC-2.3.2, Version 2 on accident management.

3.2 Approval to Restart after a Serious Process Failure

Licence Condition 3.2:

The licensee shall not restart a reactor after a serious process failure without the prior written approval of the Commission, or the prior written consent of a person authorized by the Commission.

Preamble:

A serious process failure is defined in REGDOC-3.1.1 as *"A failure of a process structure, system or component that leads to a systematic fuel failure or a significant release from the nuclear power plant, or that could lead to a systematic fuel failure or a significant release in the absence of action by any special safety system."* Serious process failures are reportable in accordance with REGDOC-3.1.1.

Compliance Verification Criteria:

For the purposes of this licence condition, restart means the removal of the guaranteed shutdown state.

When an event is found to be a serious process failure or where the determination as to the cause and/or extent of condition has proved inconclusive (i.e., a serious process failure cannot be ruled out), a request for restart of the reactor shall be submitted in writing and approval to restart the reactor must be obtained from the CNSC.

If there is sufficient assurance that the cause of the serious process failure has been resolved and it is now safe to return the facility to service, a CNSC authorized person has the authority to give the consent to Bruce Power to proceed with the restart of the reactor.

The written request for restart of the reactor is to include the following information:

- a description of the event;
- the causes of the event;
- the consequences and safety significance of the event;
- a recovery plan including corrective actions, and fitness for service assessment on the systems/components impacted from the failure if applicable. This shall be completed prior to reactor restart;
- a statement regarding plant readiness to resume safe operation. This shall include any conditions that the licensee proposes to impose upon reactor restart and/or subsequent reactor operation to ensure safe operation of the nuclear facilities; and
- an extent of completion of the conditions mentioned in the statement regarding plant readiness to resume safe operation.

Guidance:

In addition to the requirements listed above, the written request to restart a reactor after a serious process failure should also include the following information:

- a statement specifying that an extent of condition has been completed;

- the documentation and communication to licensee staff (including additional training, if necessary); and
- applicable historical operating experience (OPEX) review for comparable events.

3.3 Reporting Requirements

Licence Condition 3.3:

> **The licensee shall notify and report in accordance with CNSC regulatory document REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*.**

Preamble:

CNSC regulatory document REGDOC-3.1.1 has comprehensive reporting requirements (scheduled and unscheduled) for licensees of NPPs. It describes information that the CNSC needs to evaluate the performance of the facilities it regulates. This document is complementary to the reporting requirements in the *Nuclear Safety and Control Act* and the associated regulations.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Nuclear Regulatory Affairs	BP-PROG-06.01	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Reporting Requirements for Nuclear Power Plants, Version 2	REGDOC-3.1.1	2016	April 2016
CNSC	Interpretation of REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants, Rev. 1	N/A (e-Doc 4525925)	2018	Sep. 2018

The licensee shall adjust its reporting to meet the requirements of REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants* based on the clarifications and interpretations provided in the CNSC staff interpretation document, *Interpretation of REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants.*

1. **For REGDOC-3.1.1 Section 3.1, Quarterly report on safety performance indicators:**
   Bruce Power's quarterly report on Safety Performance Indicators (SPIs) is to include contributions from the licensed support activities at Bruce Power Center of Site locations for SPI 1, Collective Radiation Exposure and SPI 5, Environmental Releases – Radiological.

2. **For REGDOC-3.1.1 Section 3.5, Annual report on environmental protection:**
   Bruce Power is to provide the reporting data with respect to sewage plant radioactivity monitoring in the annual report on environmental protection.

Guidance:

Not applicable to this LC.

4 SCA – SAFETY ANALYSIS

4.1 Safety Analysis Program

Licence Condition 4.1:

The licensee shall implement and maintain a safety analysis program.

Preamble:

A deterministic safety analysis evaluates the NPP responses to events by using predetermined rules and assumptions. The objectives of the deterministic safety analysis are stated in REGDOC-2.4.1, DETERMINISTIC SAFETY ANALYSIS.

Probabilistic safety assessment (PSA) is a comprehensive and integrated assessment of the safety of the NPP that, by considering the initial plant state and the probability, progression, and consequences of equipment failures and operator response, derives numerical estimates of a consistent measure of the safety of the design. Such assessments are most useful in assessing the relative level of safety. The objectives of the PSA are stated in REGDOC-2.4.2, PROBABILISTIC SAFETY ASSESSMENT (PSA) FOR NUCLEAR POWER PLANTS.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Bruce A Safety Report Part 2: Plant Components and Systems	NK21-SR-01320-00002, Part 2	Yes*
Bruce B Safety Report Part 2: Plant Components and Systems	NK29-SR-01320-00001, Part 2	Yes*
Bruce A Safety Report Part 3: Safety Analysis	NK21-SR-01320-00003, Part 3	Yes*
Bruce B Safety Report Part 3: Safety Analysis	NK29-SR-01320-00002, Part 3	Yes*
Severe Accident Management	BP-PROC-00659	No

**The reporting requirements for updates to safety reports are given in REGDOC-3.1.1 (LC 3.3)*

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Deterministic Safety Analysis	REGDOC-2.4.1	2014	Dec. 31, 2017

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Probabilistic Safety Assessment (PSA) for Nuclear Power Plants	REGDOC-2.4.2	2014	June 30, 2019
CSA	Quality assurance of analytical, scientific, and design computer programs	N286.7	2016	Dec 31, 2016

Deterministic Safety Analysis

CNSC regulatory document REGDOC-2.4.1 outlines the requirements related to safety analysis events, operating modes, acceptance criteria, methods, documentation and review.

COG document COG-13-9035-R00, *Derived Acceptance Criteria for Deterministic Safety Analysis* shall be used by Bruce Power when conducting deterministic safety analysis for the associated accident scenarios [Reference: CNSC letter, B. Howden to F. Saunders, "Derived Acceptance Criteria for Deterministic Safety Analysis of Slow Events and Re-categorization of the CANDU Safety Issue PF18 Fuel Bundle/Element Behaviour under Post Dryout", Apr 21, 2016, NK21-12793/NK29-3236, e-Doc 4950841].

A 3-year Safety Report Improvement (SRI) project was completed in December 2017 to align with the new REGDOC-2.4.1 framework, which also includes a new Safety Report Appendix on Common Mode Events (CME) for both the Bruce A and Bruce B Safety Reports.

CNSC staff have provided comments on the CME analyses with recommended follow-up actions. Bruce Power is expected to consider those comments and recommendations and update this new CME Safety Report section as well as other relevant sections through the Safety Report Update process.

Bruce Power shall conduct and maintain a deterministic safety analysis in accordance with applicable requirements and reflecting the actual plant design and conditions. The deterministic safety analysis shall demonstrate that the radiological consequences of the postulated initiating events involving a single process failure and events involving a single process failure in conjunction with failure of one of the special safety systems do not exceed the accident-dependent reference public dose limits specified in the siting guide [see reference in G.3] and reproduced in the following table:

	Individual Dose Limit		Population Dose Limit	
	Thyroid Dose (mSv)	Whole Body Dose (mSv)	Thyroid Dose (Person mSv)	Whole Body Dose (Person mSv)
Single Failure	30	5	10^5	10^5
Dual Failure	2500	250	10^7	10^7

Probabilistic Safety Assessment

CNSC regulatory document REGDOC-2.4.2 outlines the requirements related to PSA. REGDOC-2.4.2, which was published in 2014 includes amendments to reflect the lessons learned from the Fukushima accident.

Overall, Bruce Power has met the requirements of REGDOC-2.4.2. CNSC staff will continue monitoring the compliance of the next updates of PSA reports.

Bruce Power shall update PSA models every 5 years (the next due date is June 30, 2024) or sooner if there are significant changes in the plant design or operation.

In addition, Bruce Power shall implement internal policy to address if the PSA results are in between the safety limit and the target.

Beyond-Design-Basis Accidents/Severe Accident Analysis

REGDOC-2.4.1 provides the requirements for the performance of a safety analysis for beyond-design-basis accidents (BDBAs), including severe accidents. Severe accidents represent the set of accidents under beyond-design-basis accidents that involve significant fuel degradation, either in-core or in fuel storage.

Beyond-design-basis analysis is performed to ensure that prevention and mitigation measures are identified. The analysis can identify challenges to the plant presented by such events and identify equipment that can be included in the severe accident management guidelines.

Design and Analysis Computer Codes and Software

CSA N286.7, QUALITY ASSURANCE OF ANALYTICAL, SCIENTIFIC, AND DESIGN COMPUTER PROGRAMS provides the specific requirements related to the development, modification, maintenance and use of computer programs used in analytical, scientific and design applications.

Bruce Power shall comply with CSA N286.7 for computer programs used in design and safety analysis.

The safety and control measures are implemented through BP-PROG-10.01, “Configuration Management”, which is cited in section 5.1.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CSA	Probabilistic safety assessment for nuclear power plants	N290.17	2017
CSA	Wet storage of irradiated fuel and other radioactive materials	N292.1	2016
CSA	Interim dry storage of irradiated fuel	N292.2	2013

Detailed methodologies and derived acceptance criteria for the conduct of deterministic safety analysis are described in the following COG documents:

Document Title	Document #	Revision #
Principles & Guidelines For Deterministic Safety Analysis	COG-09-9030	Rev 3
Guidelines for Application of the Limit of the LOE/ROE Methodologies to Deterministic Safety Analysis	COG-11-9023	Rev 1

Document Title	Document #	Revision #
Guidelines for Application of the Best Estimate Analysis and Uncertainty (BEAU) Methodology to Licensing Analysis	COG-06-9012	Rev 1
Principles and Guidelines for NOP/ROP Trip Setpoint Analysis for CANDU Reactors	COG-08-2078	Rev 1
Derived Acceptance Criteria For Deterministic Safety Analysis	COG-13-9035	Rev 0

Updates to deterministic safety analysis should contain a revision summary sheet highlighting the key differences between the existing analyses and updated analysis; if the updated deterministic safety analysis has been reformatted in accordance with REGDOC-2.4.1, a mapping of new-section to old-section numbers should be considered. The revision summary should include:

- Summary of changes (key differences) such as:
  - in acceptance criteria
  - In event characterization
  - In safety analysis assumptions
  - In methodology, or in elements of a methodology
  - In plant models
  - In use of computer codes and embedded models
  - In trip coverage
- Reasons for updating the analysis and for updating models, assumptions, initial conditions or boundary conditions;
- Significance of changes, and their justification;
- Significant changes in results that may affect the conclusions of the analysis for the design; operational or emergency safety requirements for a particular situation or event; and
- Impact on operating and safety margins.

The licensee should maintain a Safety Report Basis consisting of a listing of Analysis of Record Items and auxiliary documents. The licensee should continue to provide CNSC staff with regular updates of the list indicating the submissions to be included in the next Safety Report, Part 3 update.

When the deterministic safety analysis methodology is modified as a result of improved knowledge, or to address emerging issues, the licensee should assess the impact of such a modification on the operating limits, as well as procedural and administrative rules.

The licensee should not credit results obtained with a modified safety analysis methodology to relax operating conditions and/or change safety margins until the modification of the methodology has been reviewed by CNSC staff. If CNSC staff indicate that the modified methodology is appropriate, the licensee must still fulfill any other requirements or criteria associated with the changes to the operating conditions or safety margins, as documented under other LCs such as those in Section 3.

In addition to industry standards, CNSC staff will refer to the applicable industry verification and validation process practices related to computer codes and software used to support the safe plant operation.

Beyond-Design-Basis Accidents/Severe Accident Analysis

The following can be considered as analysis of BDBA:

- Analysis of low-probability ($<10^{-5}$) dual-failure events included in the current Safety Reports;
- Recent assessments that consider the conditions beyond the plant original design basis (e.g., sensitivity cases recently performed for low-probability CME);
- MAAP-CANDU severe accident analyses as part of Level 1 and Level 2 PSA;
- MAAP-CANDU severe accident analyses to support the severe accident management technical basis; and
- BDBA/severe accident assessments (e.g., for in-vessel retention, hydrogen control and mitigation, containment performance, etc.) to address post-Fukushima questions and demonstrate the effectiveness of the design complementary features, including post-Fukushima enhancements for severe accident prevention, mitigation, and management.

Documentation of severe accident (also referred to as beyond-design-basis accident) analyses and assessments is currently not consolidated and centralized. REGDOC-2.4.1 section 4.5 provides the requirements for safety analysis documentation; however, the licensee should consider consolidating the existing and new analyses to improve the integration, maintenance, control and further updates to facilitate the regulatory review and verification.

5 SCA – PHYSICAL DESIGN

5.1 Design Program

Licence Condition 5.1:

The licensee shall implement and maintain a design program.

Preamble:

A design program ensures that the plant design is managed using a well-defined systematic approach. Implementing and maintaining a design program confirms that safety-related systems, structures and components (SSCs) and any modifications to them, continue to meet their design bases given new information arising over time and taking changes in the external environment into account. It also confirms that SSCs continue to be able to perform their safety functions under all plant states. An important cross-cutting element of a design program is design basis management.

A design program composed of sub-programs that include, but not limited to: pressure boundary design, civil structure design, seismic design, mechanical design, fuel design, core nuclear design, core thermal-hydraulic design, safety system design, fire protection design, electrical power system design, as well as instrumentation and control system design.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Configuration Management	BP-PROG-10.01	Yes

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CSA	Human factors in design for nuclear power plants	N290.12	2014	Mar. 31, 2021
CSA	Qualification of digital hardware and software for use in instrumentation and control applications for nuclear power plants	N290.14	2015	Oct. 1, 2018
CSA	Requirements for safety-related structures for CANDU nuclear power plants	N291	2015	Oct. 1, 2018

Bruce Power shall ensure that all SSCs important to safety are designed to perform their required functions under all plant states for which the system must remain available.

CSA N291-15, Requirements For Safety-Related Structures For CANDU Nuclear Power Plants

Any gaps identified with respect to N291-15 are subject to the disposition and/or corrective actions described in the Bruce A and B Global Assessment Report and Integrated Implementation Plan. Specifically, with respect to Clause 4.3(f), Ontario Power Generation (not Bruce Power) is responsible for decommissioning.

Design Basis Management

Bruce Power shall ensure that design modifications are controlled such that the plant is maintained and modified within the limits prescribed by the licensing basis. Aspects of design are considered safety and control measures if changes to them could

- invalidate the limits documented in the operating policies and principles or safe operating envelope referred to in LC 3.1;
- introduce hazards different in nature or greater in probability or consequence than those considered by the safety analyses and probabilistic safety assessment; and/or
- adversely impact other important safety and control measures, such as those related to operations, radiation protection, emergency preparedness, etc.

Bruce Power shall ensure that changes to those aspects of design remain within the licensing basis and shall notify the CNSC when such changes are planned. Changes outside the licensing basis would require prior written approval by the Commission, per LC G.1 and LC G.2.

Bruce Power shall ensure that plant design and changes to plant design are accurately reflected in the safety analysis (see section 4.1 for licensee documents that contain the facilities descriptions and the final safety analysis reports).

Design Sub-programs

See LC 5.2 for compliance verification criteria on pressure boundary design and LC 5.3 for information on equipment and structure qualification.

Bruce Power shall have sub-program elements that address the modification of the special safety systems (Shutdown System 1, Shutdown System 2, Emergency Core Cooling System and Containment). Significant changes to the special safety systems or systems connected to the special safety systems (e.g., change that would impact safety margins) would require prior notification and engagement of CNSC. Changes outside the licensing basis would require prior written approval by the Commission, per LC G.1 and LC G.2. Prior notification is not required for changes to items that serve the same functional characteristics of the originally designed item and does not result in a change to operating procedures or safety system testing.

Bruce Power shall have sub-program elements that address the design and modification of concrete containment structures and safety-related structures.

Any changes that have the potential to impact fire protection are assessed for compliance with CSA standard N293 and, if required, an external third party review shall be performed and the results submitted to the CNSC. See LC 10.2 for version control of CSA N293.

The plant electrical power system design shall include the safety classifications of the systems. Its design shall be adequate for all modes of operation under steady-state, voltage and frequency excursion, and transient conditions, as confirmed by electrical analysis. The electrical power systems shall be monitored and tested to demonstrate they comply with the design requirements and to verify the operability for AC systems and DC systems.

Bruce Power shall ensure that the plant overall instrumentation and control (I&C) system is designed to satisfy the following:

- the safety classification of the I&C system is in compliance with plant level system classification and is justified by analysis;
- I&C system meets separation requirements between the groups and channels;
- safety features for enhancing I&C system reliability and integrity are identified and implemented in the design, for example, fail-safe design, redundancy, independence and testing capability;
- I&C system is not vulnerable to common-cause failures;
- I&C of safety system meets the requirements of single-failure criteria.

Prior to making use of a new fuel bundle/fuel bundle string or fuel assembly design in the reactor, Bruce Power shall perform design verification activities, analyses and testing to demonstrate that design requirements are met. The length and complexities of those activities depend on the novelty of the design.

Bruce Power shall update and maintain the reactor core nuclear design information found in Bruce A and B Safety Reports, Part 2 (WN documents in section 4.1) and supporting design manuals. Core surveillance activities shall be implemented to ensure compliance with reactor core nuclear design and operation within the design envelope. Significant changes to core nuclear design would require prior notification and engagement of CNSC. Changes outside the reactor core nuclear design basis that would impact the licensing basis would require prior written approval by the Commission.

Modification to the design of existing safety-related structures and components shall include adequate consideration for human factors in accordance with CSA N290.12, HUMAN FACTORS IN DESIGN FOR NUCLEAR POWER PLANTS.

Bruce Power shall ensure configuration management is aligned with the design and safety analysis and incorporated into purchasing, construction, commissioning, operating and maintenance documentation. Conformance is to be maintained between design requirements, physical configuration and facility configuration information. Bruce Power shall establish a design authority function with the authority to review, verify, approve (or reject), document the design changes and maintain design configuration control.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	General Design Considerations: Human Factors	REGDOC-2.5.1	2019
CNSC	Design of Reactor Facilities: Nuclear Power Plants	REGDOC-2.5.2	2014
CSA	Configuration management for high energy reactor facilities	N286.10	2016
CSA	General requirements for concrete containment structures for CANDU nuclear power plants	N287.1	2014
CSA	Material requirements for concrete containment structures for CANDU nuclear power plants	N287.2	2008
CSA	Design requirements for concrete containment structures for CANDU nuclear power plants	N287.3	2014
CSA	Construction, fabrication, and installation requirements for concrete containment structures for CANDU nuclear power plants	N287.4	2009
CSA	Examination and testing requirements for Concrete Containment Structures for CANDU Nuclear Power Plants	N287.5	2011
CSA	Pre-operational proof and leakage rate testing requirements for concrete containment structures for CANDU nuclear power plants	N287.6	2011
CSA	General requirements for safety systems of nuclear power plants	N290.0	2011
CSA	Requirements for the shutdown systems of CANDU nuclear power plants	N290.1	2013
CSA	Requirements for emergency core cooling systems of nuclear power plants	N290.2	2011
CSA	Requirements for the containment system of nuclear power plants	N290.3	2016
CSA	Requirements for reactor control systems of nuclear power plants	N290.4	2011
CSA	Requirements for electrical power and instrument air systems of CANDU nuclear power plants	N290.5	2016
CSA	Requirements for monitoring and display of nuclear power plant safety functions in the event of an accident	N290.6	2009 (R2014)
US NRC	Unified Facilities Criteria – Structures to Resist the Effects of Accidental Explosions	UFC 3-340-02	2008

Since Bruce Power's design program spans many other programs and processes not included as a written notification document, a table or roadmap that identifies relevant design basis documents, design sub-programs and processes should be maintained by Bruce Power and made available to CNSC staff.

With regard to modifications, the design basis for the plant should be documented and maintained to reflect design changes to ensure adequate configuration management. The design basis should be maintained to reflect new information, operating experience, safety analyses, and resolution of safety

issues or correction of deficiencies. The impacts of the design changes should be fully assessed, addressed and accurately reflected in the safety analyses prior to implementation.

The licensee should demonstrate survivability of the I&C systems and component that are critical to the management of BDBAs, and the availability of power supply to necessary equipment and associated I&C for BDBAs.

For proposed modifications to the design of existing safety-related structures and components, modern requirements, that are consistent with the current licensing basis of the plant, should be applied to the extent practicable.

The design program should minimize the potential for human error and promote safe and reliable system performance through the consideration of human factors in the design of facilities, systems, and equipment. Guidance for considering human factors in design programs is provided in CNSC regulatory document REGDOC-2.5.1, GENERAL DESIGN CONSIDERATIONS: HUMAN FACTORS.

5.2 Pressure Boundary Program

Licence Condition 5.2:

The licensee shall implement and maintain a pressure boundary program and have in place a formal agreement with an Authorized Inspection Agency.

Preamble:

This LC provides regulatory oversight with regards to the licensee's implementation of a pressure boundary program and holds the licensee responsible for all aspects of pressure boundary registration and inspections.

A pressure boundary program is comprised of the many programs, processes and procedures and associated controls that are required to ensure compliance with CSA standard N285.0, GENERAL REQUIREMENTS FOR PRESSURE RETAINING SYSTEMS AND COMPONENTS IN CANDU NUCLEAR POWER PLANTS which defines the technical requirements for the design, procurement, fabrication, installation, modification, repair, replacement, testing, examination and inspection of pressure-retaining and containment systems, including their components and supports.

This LC also ensures that an Authorized Inspection Agency (AIA) will be subcontracted directly by the licensee. An AIA is an organization recognized by the CNSC as authorized to register designs and procedures, and perform inspections and other functions and activities as defined by CSA N285.0 and its applicable referenced publications (e.g., CSA standard B51 and the NATIONAL BOARD INSPECTION CODE). The AIA is accredited by the American Society of Mechanical Engineers (ASME) as stipulated by NCA-5121 of the ASME Boiler and Pressure Vessel Code.

The licensee is also responsible for all aspects of pressure boundary registration and inspections.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Pressure Boundary Quality Assurance Program	BP-PROG-00.04	No
Index to Pressure Boundary Program Elements (CSA N285.0-12 Table N.1)	B-LIST-01900-00001	No
System and Item Classification	DIV-ENG-00017	Yes
Design Registration and Reconciliation	DIV-ENG-00018	No

Licensee Documents

Document Title	Document #	Prior Notification
Bruce A and B: Authorized Inspection Agency Services Agreement for Bruce Power (May 1, 2020 - April 30, 2025), e-Doc 6297491	BP-CORR-00531-00291	N/A
Authorized Inspection Agency Services Agreement for Bruce Power L. P., (January 1, 2015 - April 30, 2020), e-Doc 4810289	NK21-CORR-00531-12247 NK29-CORR-00531-12671	N/A
Bruce A and Bruce B: Notification of Changes to the Authorized Inspection Agency Agreement, June 20, 2018, e-Doc 5573071	NK21-CORR-00531-14395 NK29-CORR-00531-15087	N/A

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CSA	General requirements for pressure-retaining systems and components in CANDU nuclear power plants	N285.0	2012 Update No. 1 (Sep. 2013) & Update No. 2 (Nov. 2014)	August 31, 2015

Note: Annex L is accepted to be used as a "Normative" Annex.

General

CSA standard N285.0 outlines the requirements for a pressure boundary program. Bruce Power shall maintain an index of the processes and procedures of the pressure boundary program (governing and implementing documents).

The licensee shall operate vessels, boilers, systems, piping, fittings, parts, components, and supports safely and keep them in a safe condition. Bruce Power shall:

- follow accepted work plans and procedures to test, maintain, or alter over-pressure protection devices;
- comply with operating limits specified in certificates, orders, designs, overpressure protection reports, and applicable codes and standards; and
- have any certified boiler or vessel that is in operation or use inspected and certified by an authorized inspector according to an accepted schedule.

Personnel conducting non-destructive examinations shall be certified in accordance with the edition of CAN/CGSB 48.9712/ISO 9712 currently adopted for use by the National Certification Body (NCB) of Natural Resources Canada for the appropriate examination method. If the NCB does not offer certification for a specific inspection method, the relevant alternate requirements of Clause 11.3 of CSA N285.0 shall apply to ensure that personnel are appropriately trained and qualified.

Classification, Registration and Reconciliation Procedures

Licensee procedures describing the classification, registration and reconciliation processes and the associated controls must form a part of the pressure boundary program. Bruce Power shall provide prior notification of any changes to these procedures.

Overpressure Protection Reports

Bruce Power shall provide written notification to CNSC staff, of new or revised overpressure protection reports after the final registration of the system.

Classification and Registration of Fire Protection Systems

Fire protection systems and associated fittings and components are to be classified at least as Code Class 6, designed to ASME B31.1 and registered, unless the exemption criteria noted below are met. The requirements of CSA standard N285.0 apply for components higher than Code Class 6.

The following fittings and components may be exempt from requiring a Canadian Registration Number provided they meet the following exemption criteria:

- fittings and components that are cUL or ULC (Underwriters Laboratory of Canada) listed, and are suitable for the expected environmental conditions and maximum pressures; or
- pressurized cylinders and tubes, such as extinguishers, inert gas and foam tanks, which bear Transport Canada approvals, and are suitable for the expected environmental conditions and maximum pressures; or
- buried fire protection piping when in compliance with NFPA-24.

Buried fire protection piping may be exempt from the ASME testing requirements if testing is performed to NFPA-24.

Formal Agreement with an Authorized Inspection Agency

The licensee shall always have in place a formal agreement with an AIA to provide services for the pressure boundaries of the nuclear facilities as defined by CSA N285.0 and its applicable referenced publications.

Design registration services for pressure boundary shall be provided by an AIA legally entitled under the provincial boilers and pressure vessels acts and regulations to register designs. Registration of piping systems shall be done by the Technical Standards and Safety Authority, who is legally entitled to register designs in Ontario.

A copy of the signed agreement shall be provided to the CNSC. During the licence period, Bruce Power shall notify the CNSC in writing of any change to the terms and conditions of the agreement, including termination of the agreement. This correspondence shall be addressed to the Director of the Bruce Regulatory Program Division.

The licensee shall arrange for the AIA inspectors to have access to all areas of the facility and records, and to the facilities and records of the licensee's pressure boundary contractors and material organizations, as necessary for the purposes of performing inspections and other activities required by the standards.

Inspectors of the AIA shall be provided with information, reasonably in advance with notice and time necessary to plan and perform inspections and other activities required by the standards.

For a variance or deviation from the requirements of CSA N285.0, except as noted below, the licensee must first submit the proposed resolution to the AIA for evaluation, and then to the CNSC for consent. The licensee must demonstrate that meeting the code requirement is impracticable and the proposed resolution will provide adequate safety. Per the agreement with the AIA, the evaluated resolution shall not be implemented without the prior written consent of CNSC staff. A variance or deviation related to Code Edition, Code Classification, and Legacy Registration issues may be submitted directly to the CNSC without prior AIA evaluation. General criteria for obtaining prior written consent/approval for a proposed resolution from the CNSC can be found in LC G.1 and LC G.2.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
ASME	Boiler and Pressure Vessel Code – Code Cases	N/A	2010 Edition with 2011 Addendum
ASME	Power Piping	B31.1	2010
ASME	Process Piping	B31.3	2010
ASME	Refrigeration Piping and Heat Transfer Components	B31.5	2010
CSA	Boiler, Pressure Vessel and Piping Code	B51	2014
CSA	General requirements for pressure-retaining systems and components in CANDU nuclear power plants	N285.0	2017

Note: Where these standards/codes or portions thereof are required for compliance with a governing standard referenced in the CVC of the LCH, compliance to the referenced standards/codes or portions thereof is required for compliance with the governing standard and the LC.

The AIA, and its authorized inspectors, should be familiar with and capable of applying the CSA N285.0 provisions to perform their activities as defined by the standard.

5.3 Equipment and Structure Qualification Program

Licence Condition 5.3:

The licensee shall implement and maintain an equipment and structure qualification program.

Preamble:

Environmental qualification (EQ) ensures that all required equipment in a nuclear facility is qualified to perform its safety functions if exposed to harsh environmental conditions resulting from credited Design-Basis Accidents (DBAs) and that this capability is preserved for the life of the plant.

Seismic qualification (SQ) ensures that all seismically credited safety-related SSCs in a nuclear power plant are designed, installed and maintained to perform their safety function during and/or after (as needed and pre-defined) a design basis earthquake or site design earthquake and also ensures an adequate margin against review level earthquakes.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Environmental Qualification	BP-PROC-00261	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CSA	General requirements for seismic design and qualification of CANDU nuclear power plants	N289.1	2008	October 1, 2018
CSA	Ground motion determination for seismic qualification of CANDU nuclear power plants	N289.2	2010	October 1, 2018
CSA	Design procedures for seismic qualification of CANDU nuclear power plants	N289.3	2010	October 1, 2018
CSA	Testing procedures for seismic qualification of nuclear power plant structures, systems, and components	N289.4	2012	October 1, 2018
CSA	Seismic instrumentation requirements for nuclear power plants and nuclear facilities	N289.5	2012	October 1, 2018
CSA	Environmental qualification of equipment for CANDU nuclear power plants	N290.13	2005 Reaffirmed 2015	October 1, 2018

Any gaps identified with respect to N289.1-08, N289.2-10, N289.3-10, N289.4-12, and N289.5-12 are subject to the disposition and/or corrective actions described in the Bruce A and B Global Assessment

Report and Integrated Implementation Plan. Specifically with respect to Clause 4.1.1.3 of N289.5-12, Bruce Power is not required to install an onsite seismic instrumentation system and Bruce Power complies with the intent of Clause 6.5.2(c) of N289.1-08 through offsite monitoring within 20 km of the Bruce site.

CSA standard N290.13, ENVIRONMENTAL QUALIFICATION OF EQUIPMENT FOR CANDU NUCLEAR POWER PLANTS outlines the requirements for an EQ program.

In addition to the criteria set out in CSA N290.13, Bruce Power's EQ program shall include a monitoring program consisting of condition monitoring and environmental monitoring, to measure degradation and failures of qualified equipment, including cables.

Guidance:

The processes and procedures related to the EQ program should meet the requirements of recognized industrial standards.

6 SCA – FITNESS FOR SERVICE

6.1 Fitness for Service Program

Licence Condition 6.1:

The licensee shall implement and maintain a fitness for service program.

Preamble:

A fitness for service program includes the following elements:

- An effective control of plant chemistry to ensure critical plant equipment performs safely and reliably;
- aging management activities to ensure the availability of required safety functions of structures, systems and components (SSCs);
- periodic and in-service inspection programs to ensure that pressure-boundary components, containment structures and components, continue to meet their design requirements;
- in-service inspection of balance of plant to ensure safety significant pressure retaining systems, components and safety-related structures are monitored for degradation; and
- proper reliability program and implementation to ensure that SSCs important to safety continue to meet their performance requirements.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title		Document #	Prior Notification
Plant Maintenance		BP-PROG-11.04	No
Equipment Reliability		BP-PROG-11.01	No
N287.7	CSA N287.7-08 Periodic Inspection Program for Bruce NGS A Concrete Containment Structures and Appurtenances (Excluding Vacuum Building)	NK21-PIP-21100-00001	Yes
	CSA N287.7-08 Periodic Inspection Program for Bruce NGS A Vacuum Building	NK21-PIP-25100-00001	Yes
	CSA N287.7-08 Periodic Inspection Program for Bruce NGS B Concrete Containment Structures and Appurtenances (Excluding Vacuum Building)	NK29-PIP-21100-00001	Yes
	CSA N287.7-08 Periodic Inspection Program for Bruce NGS B Vacuum Building	NK29-PIP-25100-00001	Yes
	Visual Inspection of Containment Boundary Components	BP-PROC-00815	Yes
N285.4	Bruce A Periodic Inspection Plan Units 1, 2, 3 and 4	NK21-PIP-03641.2-00001	Yes

Document Title		Document #	Prior Notification
	Bruce B Periodic Inspection Plan Units 5, 6, 7 and 8	NK29-PIP-03641.2-00001	Yes
	Bruce Nuclear Generating Station Fuel Channel Periodic Inspection Program	B-PIP-31100-00002	Yes
N285.5	Bruce A NGS N285.5 Periodic Inspection Plan for Unit 0 and Units 1 to 4 Containment Components	NK21-PIP-03642-00001	Yes
	Bruce B Periodic Inspection Plan for Unit 0 and Units 5 to 8 Containment Components	NK29-PIP-03642-00001	Yes
Life Cycle Management Plan for Safety Related Civil Structures		B-LCM-20000-00001	Yes
Fuel Channel Life Cycle Management Plan		B-LCM-31100-00001	Yes
Steam Generator and Preheater Periodic Inspection Plan		B-PIP-33110-00001	Yes
PHT Feeder Piping Periodic Inspection Plan		B-PIP-33126-00001	Yes
On-Line Work Management Program		BP-PROG-11.02	No
Outage Work Management		BP-PROG-11.03	No
Chemistry Management		BP-PROG-12.02	No

Licensee Documents

Document Title	Document #	Prior Notification
Systems Important to Safety List, e-Doc 6028118	B-REP-09034-00002	N/A

The Systems Important to Safety List, B-REP-09034-00002, was revised based on S-294, Probabilistic Safety Assessment compliant models on June 1, 2018.

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Reliability Programs for Nuclear Power Plants	REGDOC-2.6.1	2017	Oct. 1, 2018
CNSC	Maintenance Programs for Nuclear Power Plants	REGDOC-2.6.2	2017	Oct. 1, 2018
CNSC	Aging Management	REGDOC-2.6.3	2014	Dec. 31, 2016
CSA	Periodic inspection of CANDU nuclear power plant components (see Note)	N285.4	2014	Aug. 17, 2020
CSA	Periodic inspection of CANDU nuclear power plant containment components	N285.5	2008	Jun. 1, 2015
CSA	Periodic inspection of CANDU nuclear power plant containment components	N285.5	2018	Jan. 1, 2023

Org	Document Title	Document #	Revision #	Effective Date
CSA	Periodic inspection of CANDU nuclear power plant balance of plant systems and components	N285.7	2015	Program documents to be submitted for CNSC staff acceptance by Oct. 1, 2028
CSA	Technical requirements for in-service evaluation of zirconium alloy pressure tubes in CANDU reactors (see Note)	N285.8	2015 Update 1 (Oct. 2019)	Sep. 1, 2020
CSA	In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plants	N287.7	2008	Jun. 1, 2015
CSA	Requirements for safety-related structures for CANDU nuclear power plants	N291	2015	Oct. 1, 2018

Note: Where N285.4 refers to N285.8, Bruce Power shall comply with the CNSC-accepted Bruce Power Compliance Plan for N285.8-15 Update 1.

References:
[1] CNSC letter, "Bruce A and B: Compliance Plan to CSA N285.8", May 29, 2020, BP-CORR-00531-00607, e-Doc 6307648.
[2] Bruce Power letter, "Bruce A and B: Compliance Plan to CSA N285.8", June 26, 2019, NK21-CORR-00531-15154/NK29-CORR-00531-15925, e-Doc 5936135.

CSA N291-15, Requirements For Safety-related Structures for CANDU Nuclear Power Plants

Any gaps identified with respect to N291-15 are subject to the disposition and/or corrective actions described in the Bruce A and B Global Assessment Report and Integrated Implementation Plan. Specifically, with respect to Clause 4.3(f), Ontario Power Generation (not Bruce Power) is responsible for decommissioning.

Reliability of Systems Important to Safety

REGDOC-2.6.1, Reliability Program for Nuclear Power Plants outlines the requirements for a reliability program. This document has replaced RD/GD-98 in the regulatory framework in 2017.

Given that REGDOC-2.6.1 has no material changes to it, where RD/GD-98 is referenced in Bruce Power governing documents, it shall be taken to mean REGDOC-2.6.1. Bruce Power will update the references in their governance on the regular document review cycle.

Maintenance

A NPP maintenance program consists of policies, processes and procedures that provide direction for maintaining SSCs of the plant. The intent of a maintenance program is to ensure that the SSCs remain capable of performing their function as described in the safety analysis. A maintenance program uses organized activities, both administrative and technical, to keep SSCs in good operating condition, and to ensure that they function as per design.

CNSC regulatory document REGDOC-2.6.2, MAINTENANCE PROGRAMS FOR NUCLEAR POWER PLANTS outlines the requirements for a maintenance program. This document has replaced RD/GD-210 in the regulatory framework in 2017.

Given that REGDOC-2.6.2 has no material changes to it, where RD/GD-210 is referenced in Bruce Power governing documents, it shall be taken to mean REGDOC-2.6.2. Bruce Power will update the references in their governance on the regular document review cycle.

Management of Planned Outages

The maintenance program shall include provisions for the management of planned outages. Bruce Power's program related to management of planned outages is documented in the licensee's procedure BP-PROC-00342, "Planned Outage Management".

Accordingly, Bruce Power shall make outage-related information (including Levels 1 and 2 Outage Plans, detailing all major work on safety related SSCs to be carried out during the planned outage) available to CNSC staff. Levels 1 and 2 outage plans are defined in Appendix A – Acronyms and Definitions.

Planned outages represent a key activity that has a high regulatory significance. Therefore a review is required to ensure proper scoping (of safety-related commitments), planning and execution of the commitments (e.g., for heat sinks, dose control, etc.).

Chemistry Control

The chemistry control program shall specify processes, specifications, overall requirements, parameter monitoring, data trending and evaluation to ensure effective control of plant chemistry during operational and lay-up conditions. Bruce Power shall maintain the implementing documents referenced in their chemistry management program that describe the design basis for chemistry control.

Aging Management

CNSC regulatory document REGDOC-2.6.3, AGING MANAGEMENT outlines the requirements related to aging management. SSC-specific aging management programs (also, in some cases, referred to as Life Cycle Management Plans (LCMPs)), shall be implemented in accordance with the overall integrated aging management program framework, and address the attributes of an effective aging management program as listed in REGDOC-2.6.3. The SSC-specific aging management programs (AMPs) or LCMPs are to include structured, forward looking inspection and maintenance schedules, requirements to monitor and trend aging effects, and any preventative actions necessary to minimize and control aging degradation of the SSCs.

Pressure tube fracture toughness assessments

Bruce Power submits assessments for fuel channel components to support safe operation and satisfy compliance verification criteria in CSA N285.4-14 and CSA N285.8-15 Update 1. These assessments rely on models that conservatively represent the current and future conditions of fuel channel components. Fracture toughness models are used to assess risk of pressure tube failure from postulated flaws in uninspected pressure tubes. The current model for fracture toughness in CSA N285.8-15 Update 1, that is,

Revision 1 of the Cohesive Zone Model, has an upper bound for hydrogen equivalent concentration [H_{eq}] in pressure tubes of 120 ppm.

In support of the continued use of Revision 1 of the Cohesive Zone Model in Fracture Toughness assessments, Bruce Power submitted on November 30, 2020, for CNSC staff acceptance, a quantitative assessment of uncertainties in Revision 1 of the Cohesive Zone Model. CNSC staff reviewed the assessment and requested additional information from Bruce Power, which has been provided and is currently under review.

Additionally, Bruce Power shall submit an impact assessment for CSA N285.8-15 Update 1 Clause 7 evaluations whenever a fracture toughness test result challenges the model's lower prediction bound, and where the model is applied in the Clause 7 evaluation(s).

Periodic Inspection and Testing

CSA standards N285.4, PERIODIC INSPECTION OF CANDU NUCLEAR POWER PLANT COMPONENTS and N285.5, PERIODIC INSPECTION OF CANDU NUCLEAR POWER PLANT CONTAINMENT COMPONENTS outline the requirements related to periodic inspections for nuclear pressure retaining and containment systems and components. CSA standard N287.7, IN-SERVICE EXAMINATION AND TESTING REQUIREMENTS FOR CONCRETE CONTAINMENT STRUCTURES FOR CANDU NUCLEAR POWER PLANTS outlines the requirements for in-service examination and testing.

Bruce Power shall carry out the periodic inspections in accordance with the accepted PIP documents. If a deviation from the accepted PIP program is anticipated during inspection planning activities, the licensee shall obtain CNSC acceptance prior to conducting the affected inspections. However, for any findings, discoveries or deviations from the accepted PIP that are identified during an inspection, Bruce Power shall follow organizational governance to provide justification to CNSC in the inspection report submission, based on OPEX and Best Industry Practices. For permanently required exemptions to the requirements of CSA PIP standards, the licensee shall document these exemptions in a revised PIP document and submit to the CNSC for acceptance.

When the hydrogen equivalent concentration at a point along the length of a pressure tube is measured or predicted to exceed the limits specified in Clause 8.2(a) of CSA N285.8-15 Update 1 during the evaluation period, the periodic inspection program shall include a selection of pressure tubes with the highest expected [H_{eq}] and highest potential for crack initiation due to service induced flaws for volumetric examination and hydrogen measurement. Inspection of the selected tubes should include locations where [H_{eq}] has exceeded or is expected to exceed the specified limits during the evaluation period. The justification for the selection of tubes and the scope and schedule of the inspections shall be submitted to CNSC staff for acceptance.

When PIP requirements are addressed exclusively within an aging management or LCMP document, only those elements of the document which directly address the PIP requirements of the governing CSA standard require acceptance from CNSC staff prior to implementation.

As indicated in the Bruce Design Manuals, the fuel channels were designed to meet the intent of section III of ASME Boiler and Pressure Vessel Code. As a planning assumption, the fuel channels were designed and assembled to satisfy function and economic life requirements for at least the equivalent of 210,000 hours of full power operation (i.e., 30 years at a capacity factor of 80%). Demonstration that fuel channels continue to meet the intent of section III of ASME Boiler and Pressure Vessel Code is part of

the design basis, which in turn is part of the licensing basis. For operation beyond 210,000 equivalent full power hours (EFPH), the licensee shall provide evidence to demonstrate that the predicted condition of pressure tubes continues to be sufficient to support safe operation. Bruce Power provided this evidence as part of the 2015 licence renewal and requested operation of Bruce NGS A and B up to 247,000 EFPH. In 2015, the Commission approved operation of Bruce NGS A and B up to a maximum of 247,000 EFPH.

In 2017, Bruce Power requested in its licence renewal application operation of Bruce NGS A and B up to 300,000 EFPH. As a result of the 2018 licence renewal hearing proceedings, the Commission authorized operation of Bruce NGS A and B up to a maximum of 300,000 EFPH as stated in the CNSC's *Record of Decision*, in the matter of "Bruce Power Inc.: Application to Renew the Power Reactor Operating Licence for Bruce A and Bruce B Nuclear Generating Stations", September 27, 2018. Operation of Bruce NGS A and B beyond 300,000 EFPH is not permitted unless approved by the Commission in accordance with LC G.1.

Specific requirements related to the validation of fracture toughness models to support fuel channel evaluations can be found in section 15.3.

With respect to CSA N285.4 Clause 12.2.5.1.3, CNSC staff have reviewed and accepted (e-Doc 6307648) Bruce Power's Compliance Plan (e-Doc 5936135) for the use of CSA N285.8-15 Update 1 to evaluate inspection results.

With respect to CSA N285.4 Clause 8.2.1(d) and Clause 13.2.5.1.3, CNSC staff have accepted Bruce Power's request to use COG report COG-JP-4107-V06-R03, "Fitness-for-Service Guidelines for Feeders in CANDU Reactors" (e-Docs 4050031, 4103896 and 3922170).

With respect to CSA N285.4 Clause 14.2.5.1.3, CNSC staff have accepted the use of Bruce Power Procedure B-REP-33110-00001 R00, "Fitness-for-Service Guidelines for Steam Generators and Preheaters Tubes in CANDU Nuclear Power Plants" (e-Docs 5245670 and 5414771).

Personnel conducting non-destructive examinations shall be certified in accordance with the edition of CAN/CGSB 48.9712/ISO 9712 currently adopted for use by the National Certification Body (NCB) of Natural Resources Canada for the appropriate examination method. For Steam Generator tube inspection, the use of personnel certified according to ASNT CP-189 for eddy current inspections is permitted provided they have received additional training, evaluation and qualification, in accordance with CNSC letter from J.D. Harvie to G.C. Andognini, "Use of ASNT Certified Eddy Current Inspection Personnel for OHN Steam Generator Inspections", February 12, 1999, N-CORR-00531-00263, e-Docs 404126. The final review and reporting of all significant indications is provided by CGSB certified personnel. Otherwise, if the NCB does not offer certification for a specific inspection method, the relevant alternate requirements of Clause 5 of CSA N285.4 or Clause 6 of CSA N285.5 shall apply to ensure that personnel are appropriately trained and qualified.

Fuel channel annulus spacer surveillance

For the purposes of Clause 12.5 of CSA N285.4-14, Bruce Power is not required to remove fuel channels for specific purposes of fuel channel annulus space surveillance. Bruce Power shall recover spacers for material surveillance anytime a single fuel channel is replaced for pressure tube material surveillance in accordance with Clause 12.4 of CSA N285.4-14. If fuel channels are replaced for any other reason, Bruce Power should make reasonable effort to recover spacers for material surveillance.

Inspection of Balance of Plant

Bruce Power shall have adequate knowledge of the current state of balance-of-plant (BOP) pressure retaining systems, components and safety-related structures to ensure that they are capable of operating within their design intent and perform required safety functions if called upon. Bruce Power shall implement and maintain inspection program(s) and LCMPs for these systems in keeping with industry best practices.

Specifically, Bruce Power shall develop:

a) an inspection program and LCMPs for safety-significant BOP pressure retaining systems and components; and
b) an inspection program and LCMPs for BOP safety-related structures.

Implementation plan for CSA N285.7

CNSC staff accepted Bruce Power's March 28, 2019 Implementation Plan for CSA standard N285.7, PERIODIC INSPECTION OF CANDU NUCLEAR POWER PLANT BALANCE OF PLANT SYSTEMS AND COMPONENTS (e-Doc 5868019). This standard will become effective on October 1, 2028. The next status update on the implementation plan will be submitted by March 31, 2022.

Implementation plan for CSA N285.5-18

CNSC staff have accepted Bruce Power's April 8, 2019 Implementation Plan for CSA N285.5-18 (e-Doc 5877488). Bruce Power plans to start implementing the updated program in compliance with N285.5-18 at the beginning of the next 10-year cycle in January 2023. Milestones dates for the implementation of N285.5-18 can be found in the Bruce Power Implementation Plan.

Station Containment Outage and Vacuum Building Outage

Under the licensee's periodic inspection program for CSA N287.7, Bruce Power shall either:
(a) carry out a test to measure the leakage rate at full design pressure of the Vacuum Building (VB) and inspect the VB concrete structure and components once every twelve (12) years; or
(b) develop and carry out the test in accordance with a CNSC-accepted performance-based methodology.

Bruce Power submitted an industry performance-based methodology, developed by Bruce Power and Ontario Power Generation, in July 2010 (attachment 2 of NK21-CORR-00531-07994/NK29-CORR-00531-08849). CNSC staff reviewed and subsequently accepted the proposed methodology (NK-21-00531-09426).

Bruce Power is to carry out a test to measure the leakage rate at full design pressure of station containment and inspect the associated concrete structures and components once every six (6) years.

The previous Station Containment Outage (SCO) for Bruce A was in May 2016 and for Bruce B was in April 2015. Additionally, the previous Vacuum Building Outage (VBO) for Bruce A was in September 2009 and for Bruce B was in April 2015. All previous SCOs and VBOs included positive pressure tests.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CSA	Aging management for concrete containment structures for nuclear power plants	N287.8	2015
CSA	Reliability and maintenance programs for nuclear power plants	N290.9	2019
COG	Interim Implementation Guidelines for CANDU Nuclear Plant Reliability Programs	COG-05-9011	2006
COG	Fuel Channel Life Management – Third Party Review of Probabilistic Fracture Protection Evaluation Methodology Acceptance Criteria	COG-JP-4491-V197	2017

Reliability of Systems Important to Safety

The licensee should consider CSA N290.9, *Reliability and maintenance programs for nuclear power plants* for guidance when updating B-REP-09034-00002, "Systems Important to Safety List" or when issuing a subsequent report.

Outage Management

The outage program should have designated criteria that the licensee will follow to confirm that planned and discovery work has been satisfactorily completed during the planned outage, and that all safety-significant SSCs are available to ensure the continued safe operation of the facilities.

CNSC staff located at licensees' site offices should be invited to the restart meetings in order to verify that all appropriate sign-offs for restart of the reactor have occurred.

Aging Management

Bruce Power should maintain a roadmap outlining the programs and procedures that ensure a well-documented overall integrated aging management framework exists.

The licensee should have an adequate knowledge of the current state of the SSCs and should document the knowledge in the SSC-specific AMP or LCMPs. The AMPs and/or LCMPs may include in-service inspections and preventative actions to minimize and limit the effects of aging on the operational reliability and the fitness for service of the SSCs and to effectively manage and maintain the SSCs to meet its intended design function until the end of life.

Whenever a revision to the AMP, SSC-specific AMP or LCMP is submitted to CNSC for review, the licensee should identify whether the revision(s), affects the previously planned inspection and maintenance activities, with supporting technical basis for the change.

The quantitative assessment of uncertainties in Revision 1 of the Cohesive Zone Model should utilize the approach in sections A.1, A.2 and A.5 of Appendix A to COG-JP-4491-V197, "Fuel Channel Life Management: Third Party Review of Probabilistic Fracture Protection Evaluation Methodology and Acceptance Criteria".

Periodic Inspection and Testing

To satisfy the compliance verification criteria for the inclusion of high [H_{eq}] pressure tubes in the periodic inspection program it may be necessary to increase the number of pressure tubes selected for inspection in the current periodic inspection program accepted by CNSC staff. Any substitutions of high [H_{eq}] tubes for tubes previously selected for inspection during the periodic inspection interval will require technical justification. The inclusion of volumetric inspections for high [H_{eq}] tubes in the periodic inspection program will not preclude the requirement to disposition the results of [H_{eq}] measurements in accordance with the requirements of Clause 12.3.5 of CSA N285.4.

Inspection Programs for Balance of Plant

The licensee may document the inspection requirements for the safety-significant BOP pressure-retaining components and safety-related structures within AMPs or LCMPs, linking inspection requirements to potential degradation mechanisms of concern. For SSCs that do not have AMPs or LCMPs the licensee may develop SSC specific or degradation mechanism specific inspection programs. The licensee should apply a systematic and integrated approach to establish, implement and improve programs in keeping with industry best practices until full implementation of CSA N285.7 and CSA N291 programs is achieved.

7 SCA – RADIATION PROTECTION

7.1 Radiation Protection Program and Action Levels

Licence Condition 7.1:

The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

Preamble:

The *Radiation Protection Regulations* require that the licensee implement a radiation protection program and also ascertain and record doses for each person who perform any duties in connection with any activity that is authorized by the NSCA or is present at a place where that activity is carried on. This program must ensure that doses to workers do not exceed prescribed dose limits and are kept As Low As Reasonably Achievable (the ALARA principle), social and economic factors being taken into account. Also, the program shall ensure that occupational exposures are ascertained and recorded in accordance with the *Radiation Protection Regulations* through the establishment of dosimetry requirements.

Note that the regulatory dose limits to workers and the general public are explicitly provided in the *Radiation Protection Regulations*.

Action Levels (ALs) relate to the parameters of dose to workers and surface contamination levels. ALs are designed to alert licensees before regulatory dose limits are reached. By definition, if an AL referred to in a licence is reached, a loss of control of some part of the associated radiation protection program may have occurred, and specific action is required, as defined in the *Radiation Protection Regulations* and the licence. ALs are not intended to be static and are to reflect operating conditions in the station.

Administrative Dose Limits (ADLs) are the licensee's internal dose limits designed to ensure individuals do not exceed regulatory dose limits. ADLs that are exceeded without prior approval from the designated licensee authority are reported as AL exceedances in accordance with the *Radiation Protection Regulations*.

The *Radiation Protection Regulations* specify the requirements related to ALs and indicate that the licence will be used to identify their notification timeframes. For this licence, the ALs are provided in the CVC below.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Radiation Protection Program	BP-PROG-12.05*	Yes
ALARA Program	BP-RPP-00044	No

Document Title	Document #	Prior Notification
Dosimetry Requirements	BP-PROC-00280	Yes
Dose Limits and Exposure Control	BP-RPP-00009	Yes

* As this document provides the authorities and responsibilities for an authorized health physicist, a certified position, as stated in section 2.4, any change to the authorities and responsibilities of the authorized health physicist will be reviewed by CNSC staff to confirm they remain within the licensing basis, in consultation with the designated officer to certify and decertify persons referred to in sections 9 and 12 of the *Class I Nuclear Facilities Regulations* and the Director of the Personnel Certification Division.

The current ALs and ADLs for Bruce A and B (including the Central Storage Facility (CSF) and Central Maintenance and Laundry Facility (CMLF)) are summarized in the tables below for convenience.

The ALs shown in table 7.1 are taken from the "Actions Levels" appendix of Bruce Power's document "Radiation Protection Program":

Table 7.1: Bruce Power Action Levels

Description	Bruce A and B	CSF	CMLF and Class II Nuclear Facility	Nuclear Substances and Radiation Devices	Notes
Unplanned External Exposure	2 mSv (200 mrem) or more above planned dose	0.5 mSv (50 mrem) or more above planned dose	250µSv (25 mrem) or more above planned dose	2 mSv (200 mrem) or more above planned dose	Unplanned external exposure is per shift and above the value of the Dose Control Device back-out level. For an individual that is not working on a Radiation Exposure Permit (i.e., a back-out limit has not been established), the back-out level is considered to be 0 millisievert (0 millirem).
Unplanned Internal Exposure – Tritium	Unplanned committed effective dose* of 2 mSv (200 mrem) or more	Unplanned committed effective dose* of 0.5 mSv (50 mrem) or more	N/A	N/A	Unplanned internal exposure from Tritium is per shift and above the planned tritium dose level. For an individual that is not working on a Radiation Exposure Permit, the planned dose level is considered to be 0 millisievert (0 millirem).
Unplanned Internal Exposure – Non-Tritium	Unplanned committed effective dose* of 2 mSv (200 mrem) or more	Unplanned committed effective dose* of 0.5 mSv (50 mrem) or more	N/A	N/A	Internal exposure - Non-Tritium encompasses all other nuclear substances (e.g., fission products, activation products, transuranics) taken into the body that result in committed effective doses above the recordable level.

					Unplanned internal exposure - Non-Tritium is the total dose above an approved planned level during a 1 year dosimetry period. If a planned dose is not established in an approved Radiation Exposure Permit then the back-out level is considered to be 0 millisievert (0 millirem). Both unplanned acute and unplanned chronic low level uptakes that exceed 2 mSv/y (0.5mSv/y for CSF) above an approved planned level are considered AL exceedances (e.g., four unplanned exceedances within a calendar year with a committed effective dose assignment 0.5 mSv/each would be considered an AL exceedance).
Accumulated Dose	Exceeding an ADL without prior approval				Accumulated doses that are to be compared with the ADLs include doses received at all places of employment during the dose period as defined in the table below. ADLs are defined in the Bruce Power document BP-RPP-00009, Dose Limits and Exposure Control.
Beta-Gamma surface Contamination in Zone 1	Total: Greater than 3.7 Bq/cm^2		N/A	N/A	Beta-gamma contamination that exceeds 3.7 Bq/cm^2 normally calculated over a 100 cm^2 reference area on any surface in those areas deemed equivalent to the public domain (e.g., Zone 1) within the licensed facility.
Beta–Gamma Discrete Radioactive Particle in Public Domain	Greater than 100 nCi (3700 Bq)		N/A	N/A	Detected by portal monitors with alarm setpoint $\leq$ 100 nCi (3700 Bq) Cs-137 Action Level for Discrete Radioactive Particles (DRP) are defined in B-REP-0907171-1APR2019 (e-Doc 6242072).
Alpha Surface Contamination in Zone 1	Total: Greater than 0.05 Bq/cm^2		N/A	N/A	Alpha contamination that exceeds 0.05 Bq/cm^2 (300 dpm/100 cm^2) normally calculated over a 100 cm^2 reference area on any surface in

				those areas deemed equivalent to the public domain (e.g., Zone 1) within the licensed facility.

**Committed Effective Dose is calculated from the time of intake.*

The ADLs shown in table 7.2 are taken from the Bruce Power document BP-RPP-00009, Dose Limits and Exposure Control.

Table 7.2: Administrative Dose Limits (ADLs)

Category of Worker	Dose Period	Employees	Contractors
Nuclear Energy Worker (NEW)	One-year dosimetry period	20 mSv	40 mSv
	Five-year dosimetry period	50 mSv	90 mSv
Pregnant NEW	Balance of pregnancy	0.5 mSv	0.5 mSv
Non-NEW	One calendar year	0.5 mSv	0.5 mSv

Estimated Dose to the Public

The *Radiation Protection Regulations* prescribe the radiation dose limits for the general public of 1 mSv per calendar year. The licensee reports the estimated dose to the public from the Bruce site annually, in accordance with REGDOC-3.1.1, REPORTING REQUIREMENTS FOR NUCLEAR POWER PLANTS (See LC 3.3), in the Environmental Protection report.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)"	G-129	2004
CNSC	Developing and Using Action Levels	G-228	2001

CNSC guidance document G-129, KEEPING RADIATION EXPOSURES AND DOSES "AS LOW AS REASONABLY ACHIEVABLE (ALARA)" provides the licensee guidance for developing, implementing and maintaining a radiation protection program to ensure that exposures will be ALARA.

CNSC guidance document G-228, DEVELOPING AND USING ACTION LEVELS provides the licensees guidance for developing ALs in accordance with the *General Nuclear Safety and Control Regulations* and section 6 of the *Radiation Protection Regulations*.

NOTE: If REGDOC-2.7.1, *Radiation Protection* is published prior to the issuance of Bruce A and B LCH R003 then the table and two paragraphs above will be deleted and replaced by:

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Radiation Protection	REGDOC-2.7.1	2021

The licensee should conduct a documented review and, if necessary, revise the ALs specified above at least once per licence period in order to validate their effectiveness. The results of such reviews should be provided to CNSC staff.

8 SCA – CONVENTIONAL HEALTH AND SAFETY

8.1 Conventional Health and Safety Program

Licence Condition 8.1:

The licensee shall implement and maintain a conventional health and safety program.

Preamble:

The conventional health and safety program is used to manage workplace safety hazards and protect personnel and environment.

NPPs in Ontario are regulated by the *Ontario Occupational Health and Safety Act* and the *Labour Relations Act*.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Health and Safety Management	BP-PROG-00.06	No

Bruce Power's "Health and Safety Management Program", a licensee document listed in the notification of change table, describes the occupational health and safety practices at the Bruce site. The *Ontario Occupational Health and Safety Act* contains the detailed regulatory requirements for workplace health and safety in Ontario.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Conventional Health and Safety	REGDOC-2.8.1	2019

Regulatory document REGDOC-2.8.1, Conventional Health and Safety, sets out information regarding conventional health and safety (CHS) and the implementation and maintenance of a CHS program. This document applies to all CNSC-licensed activities. This document does not include any requirements, but is a source of CHS-related information for all applicants and licensees.

9 SCA – ENVIRONMENTAL PROTECTION

9.1 Environmental Protection Program

Licence Condition 9.1:

The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

Preamble:

The *Radiation Protection Regulations* prescribe radiation dose limits for the general public of 1 mSv per calendar year.

Derived Release Limits (DRLs) are calculated or derived using environmental transfer modeling that describes transfer of radioactive materials through environmental pathways to humans. DRLs are required for the purpose of protecting members of the public from unreasonable risk resulting from releases of radionuclides into the environment from the normal operation of the licensed facility.

Licensees set Environmental Action Levels (EALs) and related parameters, so as to provide early warnings of any actual or potential losses of control of the Environmental Protection Program. EALs are precautionary levels and are set far below the actual DRLs. EALs are designed to alert licensees before DRLs are reached. They are required by regulations to be specific doses of radiation or other parameter that, if reached, may indicate a loss of control of the licensee's Environmental Protection Program.

The *Radiation Protection Regulations* specify requirements related to "Action Levels" and indicate that the licence will be used to identify the action levels and the notification timeframes.

The release of hazardous substances is regulated by both the Ministry of Environment, Conservation and Parks (MECP) and Environment Canada and Climate Change (ECCC) through various acts and regulations, as well as the CNSC.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Environmental Management	BP-PROG-00.02	Yes
Derived Release Limits and Environmental Action Levels for Bruce Nuclear Generating Station A	NK21-REP-03482-00002	Yes
Derived Release Limits and Environmental Action Levels for Bruce Nuclear Generating Station B	NK29-REP-03482-00003	Yes

Document Title	Document #	Prior Notification
Derived Release Limits and Environmental Action Levels for Central Maintenance and Laundry Facility	NK37-REP-03482-00001	Yes
Derived Release Limits and Environmental Action Levels for Central Storage Facility (CSF)	NK37-REP-03482-00002	Yes
Radiological Emissions	BP-PROC-00171	Yes

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Environmental Protection: Environmental Principles, Assessments and Protection Measures, Version 1.2	REGDOC-2.9.1	2020	Apr. 1, 2021
CSA	Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	N288.1	2008 Update No.1 (2011)	June 1, 2015
CSA	Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	N288.1	2014 Updates No.1 (May 2017), No. 2 (Nov. 2017) and No. 3 (Jun. 2018)	Dec. 31, 2021
CSA	Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills	N288.4	2010	Dec. 31, 2018
CSA	Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills	N288.5	2011	Dec. 31, 2018
CSA	Environmental risk assessment at Class I nuclear facilities and uranium mines and mills	N288.6	2012	Dec. 31, 2018
CSA	Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	N288.7	2015	Dec. 31, 2020
CSA	Establishing and implementing action levels for releases to the environment from nuclear facilities	N288.8	2017	Dec. 31, 2021

Environmental Management System (EMS)

The objective of the environmental protection policies, programs and procedures is to establish adequate provision for protection of the environment at Class I nuclear facilities and uranium mines and mills. This shall be accomplished through an integrated set of documented activities that are typical of an environmental management system (EMS).

Bruce Power has established and implemented an environmental management program to assess environmental risks associated with its nuclear activities, and to ensure these activities are conducted in such a way that adverse environmental effects are prevented or mitigated.

CNSC regulatory document REGDOC-2.9.1, ENVIRONMENTAL PROTECTION: ENVIRONMENTAL PRINCIPLES, ASSESSMENTS AND PROTECTIVE MEASURES outlines the requirements related for an environmental protection program. Bruce Power's governing document "Environmental Management" is the key document of the environmental protection program.

Bruce Power is in compliance with all requirements of REGDOC-2.9.1, Version 1.2.

Assessment and Monitoring

CSA standard N288.4, ENVIRONMENTAL MONITORING PROGRAMS AT CLASS I NUCLEAR FACILITIES AND URANIUM MINES AND MILLS outlines the requirements for an environmental monitoring program. This document was revised in May 2010 to include radioactive and hazardous substances, physical stressors, potential biological effects, and pathways for both human and non-human biota. Note: CSA guidance N288.9, GUIDELINE FOR DESIGN OF FISH IMPINGEMENT AND ENTRAINMENT PROGRAMS AT NUCLEAR FACILITIES was issued in May 2018 and provides guidance for monitoring and assessment of fish impingement and entrainment which is a physical stressor.

An Environmental Monitoring Program (EMP) consists of a risk-informed set of integrated and documented activities to sample, measure, analyze, interpret, and report the following:

- the concentration of hazardous and/or nuclear substances in environmental media to assess one or both of
  - exposure of receptors to those substances; and
  - the potential effects on human health, safety, and the environment;
- the intensity of physical stressors and/or their potential effect on human health and the environment; and
- the physical, chemical, and biological parameters of the environment normally considered in design of the EMP.

CSA standard N288.7, GROUNDWATER PROTECTION PROGRAMS AT CLASS I NUCLEAR FACILITIES AND URANIUM MINES AND MILLS provides requirements and guidance which facilitate groundwater protection at Class I nuclear facilities and uranium mines and mills. Compliance with N288.7 will allow facilities to demonstrate that they will not pose an unreasonable risk to the environment or the health and safety of humans and non-human biota from groundwater. N288.7 addresses the design, implementation, and management of a groundwater protection program that incorporates best practices in Canada and internationally.

Effluent and Emissions Control (Releases)

The licensee shall ensure effluent monitoring for nuclear and hazardous substances is designed, implemented and managed to respect applicable laws and to incorporate best practices. The effluent monitoring program shall incorporate airborne and waterborne effluents.

CSA standard N288.5, EFFLUENT MONITORING PROGRAMS AT CLASS I NUCLEAR FACILITIES AND URANIUM MINES AND MILLS outlines the requirements for an effluent monitoring program. Bruce Power shall ensure effluent monitoring sub-program for nuclear and hazardous substances is designed, implemented and managed to respect applicable laws and to incorporate best practices. The effluent monitoring program shall incorporate airborne and waterborne effluents. Effluent monitoring is a risk-informed activity that is to quantify or estimate the nuclear and hazardous substances being released into the environment.

Bruce Power's Effluent Monitoring Program shall ensure compliance with CSA N288.5 in accordance with the implementation plan below.

Nuclear Substances – Derived Release Limits (DRLs)

Bruce Power shall control radiological emissions to ALARA, within the Derived Release Limits (DRLs), and take action to investigate cause(s) and correct the cause(s) of increased emissions.

CSA standard N288.1, GUIDELINES FOR CALCULATING DERIVED RELEASE LIMITS FOR RADIOACTIVE MATERIAL IN AIRBORNE AND LIQUID EFFLUENTS FOR NORMAL OPERATION OF NUCLEAR FACILITIES outlines the requirements related to DRLs. Bruce Power shall ensure compliance with CSA N288.1 in accordance with the implementation plan below.

Implementation strategy for CSA N288.1

Bruce Power will be in full compliance with CSA N288.1 (2014, Updates No. 1, May 2017, No. 2, Nov. 2017, and No. 3, Jun. 2018) by December 31, 2021.

The DRLs are considered part of the licensing basis. Changes to these limits are subject to LC G.1 and LC G.2. The DRLs for Bruce A and Bruce B nuclear facilities, the Central Maintenance and Laundry Facility (CMLF) and the Central Storage Facility (CSF) once N288.1-14 Update No. 3 is implemented are summarized in table 9.1a. During the transition period until December 31, 2021, the DRLs are summarized in table 9.1. In the event of a discrepancy between tables 9.1a and 9.1 and the licensee documentation upon which it is based, the licensee documentation shall be considered the authoritative source (assuming that the licensee has followed its own change control process).

Table 9.1a: New Derived Release Limits

		Bruce A	Bruce B	CMLF	CSF
Release Category	Radionuclide/Radionuclide Group[1]	DRL (Becquerel/year)			
Air	Tritium	3.34E+17	7.84E+17	3.05E+17	4.22E+17
	Carbon-14	2.26E+15	4.09E+15	N/A	2.20E+15
	Iodine (mixed fission products)	3.50E+12	3.87E+12	1.96E+12	N/A
	Noble Gases[2]	1.54E+17	3.77E+17	N/A	N/A
	Particulate (Alpha)	2.60E+11	7.12E+11	3.49E+11	4.11E+11
	Particulate (Beta/Gamma)	6.45E+11	1.37E+12	7.51E+11	9.03E+11
Water	Tritium	8.57E+17	7.50E+17	N/A	N/A
	Carbon-14	1.00E+14	2.12E+14	N/A	N/A
	Gross Alpha	1.55E+12	3.29E+12	N/A	N/A
	Gross Beta/Gamma	2.94E+12	6.38E+12	N/A	N/A

Notes:
[1] Individual DRLs are calculated for about 102 radionuclides and isotopes. Only the significant radionuclide groups which are given in the table are monitored and reported to the CNSC.
[2] The unit for Noble Gases DRLs is Bq-MeV/year.

Table 9.1: Transition Derived Release Limits

		Bruce A	Bruce B	CMLF	CSF
Release Category	Radionuclide/Radionuclide Group[1]	DRL (Becquerel/year)			
Air	Tritium	1.98E+17	3.16E+17	2.45E+17	4.22E+17
	Carbon-14	6.34E+14	7.56E+14	N/A	2.20E+15
	Iodine (mixed fission products)	1.14E+12	1.35E+12	1.31E+12	N/A
	Noble Gases[2]	1.12E+17	2.17E+17	N/A	N/A
	Particulate (Alpha)	2.96E+11	5.77E+11	4.40E+11	4.11E+11
	Particulate (Beta/Gamma)	1.73E+12	3.61E+12	3.03E+12	9.03E+11
Water[3, 4]	Tritium	2.30E+18	1.84E+18	N/A	N/A
	Carbon-14	1.03E+15	1.16E+15	N/A	N/A
	Gross Alpha	1.12E+14	1.21E+14	N/A	N/A
	Gross Beta/Gamma	4.58E+13	5.17E+13	N/A	N/A

Notes:
[1] Individual DRLs are calculated for about 118 radionuclides and isotopes. Only the significant radionuclide groups which are given in the table are monitored and reported to the CNSC.
[2] The unit for Noble Gases DRLs is Bq-MeV/year.
[3] The Bruce A waterborne DRLs are based on the flow rate of 156 m^3/s condenser cooling water (CCW).

[4] The Bruce B waterborne DRLs are based on the flow rate of 168 m^3/s CCW, representing 12 pump design flow.

These DRLs for radionuclides and radionuclide groups account for the most significant releases and are the focus of monitoring and reporting requirements.

Hazardous Substances

Bruce Power shall control hazardous substances releases according to the limits defined in the licensing basis in accordance with the applicable environmental compliance approvals and take action to investigate and correct the cause(s) of increased emissions. Under the jurisdiction of MECP and ECCC, Bruce Power prepares routine environmental reports at different frequencies.

Environmental Action Levels

Environmental Action Levels (EALs) are considered part of the licensing basis. Changes to these limits are subject to LC G.1 and LC G.2.

Implementation strategy for CSA N288.8

Bruce Power will be in full compliance with CSA N288.8 (2017) by December 31, 2021.

The EALs for Bruce A and Bruce B nuclear facilities, the Central Maintenance and Laundry Facility (CMLF) and the Central Storage Facility (CSF) once N288.8-17 is implemented are summarized in table 9.2a. During the transition period until December 31, 2021, the EALs are summarized in table 9.2. In the event of a discrepancy between tables 9.2a and 9.2 and the licensee documentation upon which it is based, the licensee documentation shall be considered the authoritative source.

Table 9.2a: New Environmental Action Levels (EALs)

Facility	Release Category	**Radionuclide/ Radionuclide Group**	**Monitoring Points[1]**	**EAL (Bq/Week)[2,3]**
Bruce A	Air	Tritium	CSA	1.97E+13
			U1-4 C	7.74E+13
			ASB	1.21E+13
			U1-4 NC	2.22E+13
		Carbon-14	CSA	1.45E+11
			U1-4 C	2.30E+11
		Iodine	CSA	1.00E+08
			U1-4 C	1.15E+06
		Noble Gases[2]	CSA	4.73E+12
			U1-4 C	5.23E+12
			U1-4 NC	5.83E+12
		Gamma	U1-4 C	1.59E+05
			ASB	1.38E+05
			CRB	1.64E+05
	Water[3]	Carbon-14	ALW	2.80E+09
Bruce B	Air	Tritium	CSA	2.01E+13
			U5-8 C	7.58E+13

			ASB	1.00E+13
			U5-8 NC	2.21E+13
		Carbon-14	CSA	8.51E+10
			U5-8 C	1.18E+11
		Iodine	CSA	4.76E+06
			U5-8 C	6.45E+05
		Noble Gases[2]	CSA	1.17E+12
			U5-8 C	3.19E+12
		Gamma	U5-8 C	1.67E+05
	Water[3]	Carbon-14	ALW	1.35E+10
CSF	Air	Beta-Gamma	Exhaust Stack	2.21E+05

Notes:

1. EALs are only presented for those radionuclide monitoring pairs that require an EAL based on the methodology in NK21-REP-03482-00002, NK29-REP-03482-00003, NK37-REP-03482-00001 and NK37-REP-03482-00002, which is based on CSA Standard N288.8-17. The following are acronyms for monitoring points:

    - CSA: Central Services Area Contaminated Exhaust Stack
    - U1-4 C: Unit 1 to Unit 4 Contaminated Exhaust Stack
    - U1-4 NC: Unit 1 to Unit 4 Non Contaminated Exhaust Stack
    - U5-8 C: Unit 5 to Unit 8 Contaminated Exhaust Stack
    - U5-8 NC: Unit 5 to Unit 8 Non Contaminated Exhaust Stack
    - ASB: Ancillary Services Building Contaminated Exhaust Stack
    - CRB: Construction Re Tube Building Contaminated Exhaust Stack
    - ALW: Active Liquid Waste
    - CSF: Central Storage Facility

2. The unit for Noble Gases EALs is Bq-MeV/week.
3. The unit for waterborne EALs is Bq/month.

Table 9.2: Transition Environmental Action Levels (EALs)

Release Category	Radionuclide	**Bruce A Gaseous** releases (Becquerel/week)	**Bruce B Gaseous** releases (Becquerel/week)	**CMLF Gaseous** releases (Becquerel/week)	**CSF Gaseous** releases (Becquerel/week)
Air	Tritium (HTO)	3.97E+14	6.32E+14	4.89E+14	N/A
	Iodine (mfp)	2.27E+09	2.71E+09	2.62E+09	N/A
	Carbon-14	1.27E+12	1.51E+12	N/A	N/A
	Noble Gases*	2.23E+14	4.34E+14	N/A	N/A
	Particulate – Gross Beta – Gamma	3.46E+09	7.22E+09	6.06E+09	2.21E+05
	Particulate – Gross Alpha	5.92E+08	1.15E+09	8.81E+08	N/A
Release Category	Radionuclide	**Liquid** releases (Becquerel/month per kg/month of CCW)	**Liquid** releases (Becquerel/month per kg/month of CCW)	**Liquid** releases (Becquerel/month per kg/month of CCW)	**Liquid** releases (Becquerel/month per kg/month of CCW)
Water	Tritium (HTO)	4.48E+04	3.33E+04	N/A	N/A
	Carbon-14	2.01E+01	2.10E+01	N/A	N/A
	Gross Alpha	2.18E+00	2.19E+00	N/A	N/A
	Gross Beta-Gamma	8.94E-01	9.37E-01	N/A	N/A

**The unit for Noble Gases EALs is Bq-MeV/week.*

Environmental Risk Assessment

CSA standard N288.6, ENVIRONMENTAL RISK ASSESSMENT AT CLASS I NUCLEAR FACILITIES AND URANIUM MINES AND MILLS outlines the requirements for an environmental risk assessment. This specific area provides assessment of environmental risks associated with contaminants and physical stressors in the environment relevant to nuclear facilities, and to the short-term and long-term safety of human health and the environment.

The ERA provides the basis for the environmental monitoring program (CSA standard N288.4) and also the effluent monitoring program (CSA standard N288.5), including Radiological Environmental Monitoring Programs. The ERA shall be updated periodically with the results from the environmental and effluent monitoring programs in order to confirm the effectiveness of any additional mitigation measures needed.

Bruce Power submitted an Environmental Risk Assessment (ERA) in 2017 as a supplement to its licence application, followed by assessments conducted in 2018 and 2019 in compliance with the requirements of CSA N288.6. Bruce Power then used the ERA findings to develop and implement compliance plans for CSA N288.4 and N288.5.

Bruce Power submitted an ERA gap analysis *Environmental Risk Assessment Gap Analysis for Isotope Production Activities* in 2021, which confirmed that the Lutetium-177 Isotope Production System project (section 15.10) does not change the conclusions of risk to the public or the environment as determined by the 2017 ERA.

Protection of the Public

See LCH Section 7.1, Radiation Protection under the sub-title Estimated Dose to the Public.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CSA	Performance testing of nuclear air-cleaning systems at nuclear facilities	N288.3.4	2013
CSA	Guideline for design of fish impingement and entrainment programs at nuclear facilities	N288.9	2018

10 SCA – EMERGENCY MANAGEMENT AND FIRE PROTECTION

10.1 Emergency Preparedness Program

Licence Condition 10.1:

The licensee shall implement and maintain an emergency preparedness program.

Preamble:

Emergency preparedness allows preparation and management of resources for responding to emergencies, with the aim to reduce the harmful effects of emergency. Specific provisions for dealing with emergencies are required because normal processes are disrupted and a different set of resources is needed to respond to and recover from the disruption.

In addition to the nuclear emergency plan, the licensee maintains a set of emergency operating procedures and abnormal plant operating procedures. This aspect is covered under LC 3.1.

A security response to malevolent acts is governed by a separate plan under the licensee's Nuclear Security program (LC 12.1) but provisions of the licensee's site security report apply to any associated potential threat of release of radioactive material - for example, the need for offsite notification, situation updates and confirmation of any radioactive releases.

Liquid emission response and radioactive materials transportation emergency response are also governed by separate plans (LCs 9.1 and 14.1).

CNSC regulatory document REGDOC-2.10.1, NUCLEAR EMERGENCY PREPAREDNESS AND RESPONSE replaced CNSC regulatory document RD-353, TESTING AND IMPLEMENTATION OF EMERGENCY MEASURES and CNSC regulatory guide G-225, EMERGENCY PLANNING AT CLASS I NUCLEAR FACILITIES AND URANIUM MINES in October 2014.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Bruce Power Nuclear Emergency Response Plan	BP-PLAN-00001	Yes
Radioactive Material Transportation Emergency Response Plan	BP-PLAN-00005	No
Emergency Management Program	BP-PROG-08.01	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Nuclear Emergency Preparedness and Response	REGDOC-2.10.1	2014	Feb. 28, 2019

CNSC regulatory document REGDOC-2.10.1 outlines the requirements for an emergency preparedness program.

Clause 2.2.6(4) of REGDOC-2.10.1 is satisfied by the current location of Bruce Power's Emergency Management Centre with supporting procedures on security and communications arrangements as described in the clause.

The emergency preparedness program is documented in Bruce Power's Nuclear Emergency Response Plan. Bruce Power shall maintain equipment, procedures and staff to support offsite response activities for an accidental release. Infrastructures defined within may be used in planning and response to virtually all emergencies. Bruce Power's Nuclear Emergency Response Plan also represents a basis for controlling changes and modifications to the emergency preparedness program.

In accordance with section 2.3.3 of REGDOC-2.10.1, the licensee shall test all requirements listed in this regulatory document over a five-year period, with a full-scale integrated emergency testing exercise at least once every three years involving, at a minimum, regional and provincial offsite authorities. To meet this requirement, Bruce Power shall conduct emergency exercises and drills as described in their Nuclear Emergency Response Plan. In most areas, drills and/or exercises are required at least annually. A corporate exercise is held annually at either the Bruce A or B nuclear facility. A "site evacuation" is held every three years and alternates between the two nuclear facilities. Annual exercises are also conducted at other facilities, such as hospitals and offsite centres by mutual agreement. Participation by municipal and provincial emergency response groups is also scheduled by mutual agreement.

In accordance with section 2.1 of REGDOC-2.10.1, the licensee is required to provide regional and provincial offsite authorities with the necessary information to allow for effective emergency planning policies and procedures to be established and modified, if needed or on a periodic basis. This information to include an estimate of the associated radiological consequences, including isotopic release quantities (source term), possible release start time and duration and the geographical area potentially affected. See LCH Section 4.1 for more information on severe accident analysis.

The CNSC will inform federal authorities of updates to the licensee's Emergency Planning Technical Basis.

NPP Automatic Data Transfer
In order to align with international best practices, CNSC staff have determined that it is vital to have automated data sharing during a nuclear emergency. CNSC plans to incorporate these requirements in the next revision of REGDOC-2.10.1. Based on this a GNSCR 12(2) letter [1] was issued to Bruce Power requesting implementation plans, noting that this would become part of the future licensing basis.

The Bruce Power solution is an application accessible remotely by the CNSC EOC which delivers the required plant parameter data with trending and graphs available. The system is described in [2] and was implemented by the end of 2019. CNSC staff have accepted this solution [3].

Bruce Power continues to investigate and implement improvements to the solution, and provides quarterly updates to the CNSC.

References:
[1] CNSC letter, "Request pursuant to subsection 12(2) of the *General Nuclear Safety and Control Regulations*: Bruce NGS - Nuclear Power Plant (NPP) Automatic Data Sharing Requirement during a Nuclear Emergency", January 26, 2017, e-Doc 5240682.
[2] Bruce Power letter, "Nuclear Power Plant Automatic Data Sharing during a Nuclear Emergency", NK21-CORR-00531-15108 | NK29-CORR-00531-15869, August 1, 2019, e-Doc 5963671.
[3] CNSC letter, L. Sigouin to M. Burton, "Automatic Data Sharing During Nuclear Emergencies", December 9, 2019, e-Doc 6066527.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Accident Management, Version 2	REGDOC-2.3.2	2015
CSA	General requirements for nuclear emergency management programs	N1600	2016

Org	Document Title	Document #	Implementation Plan Submission Date	Version
CNSC	Nuclear Emergency Preparedness and Response, Version 2	REGDOC-2.10.1	September 24, 2021	2016

The licensee should provide emergency communications outlining what surrounding community residents need to know and do before, during and after a nuclear emergency. Information should be in plain language, readily accessible and include the following:

- how the public is notified of an emergency;
- what protective actions may be required during an emergency;
- what the public is expected to do, and why, when directed to take protective actions;
- what the public can do now to be better prepared for an emergency;
- where can the public get more information on emergency plans.

10.2 Fire Protection Program

Licence Condition 10.2:

The licensee shall implement and maintain a fire protection program.

Preamble:

Licensees require a comprehensive fire protection program (the set of planned, coordinated, controlled and documented activities) to ensure the licensed activities do not result in unreasonable risk to the health and safety of persons and to the environment due to fire, and to ensure that the licensee is able to efficiently and effectively respond to emergency fire situations.

Fire protection provisions are applicable to all work related to the design, construction, operation, and maintenance of the nuclear facility, including systems, structures and components (SSCs) that directly support the plant and the protected area. External events such as an aircraft crash or threats are dealt under LC 12.1.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Fire Safety Management	BP-PLAN-00008	No
Conventional Emergency Plan	BP-PLAN-00006	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CSA	Fire protection for nuclear power plants	N293	2012	June 1, 2015

CSA standard N293, FIRE PROTECTION FOR NUCLEAR POWER PLANTS outlines the requirements for a fire protection program.

An implementation strategy for CSA N293-12 is not required since Bruce Power is compliant with the programmatic and operational requirements of CSA N293-12. The requirements for a revised Code Compliance Review, Fire Hazard Assessment and Fire Safety Shutdown Analysis did not change from CSA N293-07 to N293-12; N293-12 simply provided additional clarification on the requirements.

Due to the date of construction of the Bruce facilities versus the date of issuance of the codes (1970's vs. 2012) a number of historical design related non-conformances were identified. Bruce Power has submitted a revised Code Compliance Review, Fire Hazard Assessment and Fire Safety Shutdown Analysis to the CNSC, as well as implementation dates for the remaining plant upgrades to address these

design non-conformances. The implementation plan to complete this work was submitted to CNSC staff in October 2014 and has been accepted by CNSC staff.

CNSC staff have accepted Bruce Power's Integrated Implementation Project (IIP), which includes details of the Fire Protection Capital Project. Updates to the Fire Protection Capital Project will be provided as a part of IIP communication.

Bruce Power shall arrange for third party audits of one industrial fire brigade fire drill once every two years, alternating between stations on an annual cycle. The purpose of a Third Party Audit is to provide an in-depth analysis of the Industrial Fire Brigade's (IFB) fire response performance against applicable regulatory criteria. A fire response is a planned, coordinated and controlled activity to provide emergency response to a fire. The audit is to analyze and ensure competencies of the IFB against CSA standard N293. The resulting audit report shall be submitted to CNSC staff for review.

An independent third party auditor is required to be an expert in their discipline, normally fire-fighting and qualified through specific education and relevant experience. The third party auditor is required to be independent or at "arm's length" from the facility to ensure total impartiality. The review shall be of sufficient depth and detail that the reviewer can attest with reasonable confidence on the competencies of the IFB at the facility.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
NEI	Guidance for Post Fire Safe Shutdown Circuit Analysis	NEI 00-01	Rev. 2 (2009)

Org	Document Title	Document #	Implementation Plan Submission Date	Version
CSA	Fire protection for nuclear power plants	N293	September 24. 2021	2012 (R2017)

The Nuclear Energy Institute NEI 00-01, GUIDANCE FOR POST FIRE SAFE SHUTDOWN CIRCUIT ANALYSIS is used by CNSC staff to help determine the adequacy of safe shutdown electrical circuit analysis.

Expectation for the Third Party Audit Report

The results of the audits will typically consist of reports that compare the requirements of the applicable codes and standards with the implementation of the Fire Protection Program and the Fire Response exercised. The report should identify any non-compliance and formulate a conclusion if the licensee's program and IFB meet the requirements of the standards referenced in the facilities licence. The format of the submission is not specified and can be tailored to the facility. However, as a guideline the following suggestions for the content and format of the written report are provided as follows:

1. Cover page with the name of the facility, date and signature of the authors;
2. Name, address, phone number, of the preparing agency or organization;
3. Names of review team members, including brief descriptions of experience and education;
4. Name, address, and phone number of licensee;

5. Title of report, date, and document number;
6. Introduction briefly describing the area of interest that is audited;
7. Statement of review scope specifically listing any exclusions;
8. Objectives of the review;
9. A list of applicable codes and standards;
10. Summary of the review methodology, including areas and documents reviewed;
11. Detailed observations with relation to standard requirements against the observed response;
12. Conclusions, including a statement that the program or the IFB response meet the requirements of the applicable standards, achieves their objectives, and a summary of any non-compliances;
13. Recommendations (if any); and
14. An issues tracking table.

11 SCA – WASTE MANAGEMENT

11.1 Waste Management Program

Licence Condition 11.1:

The licensee shall implement and maintain a waste management program.

Preamble:

This LC covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. Topics include waste management, waste characterization, waste minimization and waste management practices.

CNSC Regulatory Document REGDOC-2.11 *Framework for Radioactive Waste Management and Decommissioning in Canada* defines radioactive waste as any material (liquid, gaseous or solid) that contains a radioactive nuclear substance, as defined in section 2 of the *Nuclear Safety and Control Act*, and which the owner has declared to be waste. In addition to containing nuclear substances, radioactive waste may also contain non-radioactive hazardous substances, as defined in section 1 of the *General Nuclear Safety and Control Regulations*.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Nuclear Fuel Management	BP-PROG-12.03	No
Radiation Protection Program	BP-PROG-12.05	Yes

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CSA	Management of low- and intermediate-level radioactive waste	N292.3	2014	October 1, 2018

The licensee shall implement and maintain a program for waste management that includes strategies for waste minimization, waste characterization and waste management practices. Low- and intermediate-level waste shall be managed in accordance with CSA N292.3, *Management of Low and Intermediate-Level Radioactive Waste*.

Bruce Power shall:

- characterize its waste streams and minimize the production of all wastes taking into consideration the health and safety of workers and the environment;

- integrate waste management programs as a key element of the facility's safety culture; and
- audit on a regular basis its program to maximize its effectiveness and per the governance given in BP-PROG-15.01, *Independent Oversight Management*.

In its 2018 licence renewal decision for Bruce A and B, the Commission directed that Bruce Power make available for public review in a single document all the information regarding the anticipated volume of waste that will be produced during the MCR outages of the six units at Bruce A and B.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CSA	General principles for the management of radioactive waste and irradiated fuel	N292.0	2014
CSA	Wet storage of irradiated fuel and other radioactive materials	N292.1	2016
CSA	Interim dry storage of irradiated fuel	N292.2	2013
CSA	Guideline for the exemption of clearance from regulatory control of materials that contain, or potentially contain, nuclear substances	N292.5	2011

With respect to the storage and management of spent nuclear fuel, it should reflect the fundamental safety concerns related to criticality, exposure, heat control, containment and retrievability. Namely, the systems that are designed and operated should assure subcriticality, control of radiation exposure, assure heat removal, assure containment and allow retrievability.

11.2 Decommissioning and Financial Guarantees

Licence Condition 11.2:

The licensee shall notify the Commission of any changes regarding the obligations of decommissioning and financial guarantees under the Lease Agreement with Ontario Power Generation Inc. as described in 15.1.

Preamble:

The decommissioning plan includes strategies for the management of low and intermediate level waste, reactor and waste storage facility decommissioning, and the used fuel arising from the operation of the nuclear facility.

Financial guarantees for decommissioning show that sufficient financial resources are available to fund all approved decommissioning activities.

Compliance Verification Criteria:

Ontario Power Generation Inc. (OPG) is responsible for the decommissioning plan and strategies of the Bruce nuclear facilities; however, Bruce Power shall provide a status update with the licence renewal application.

OPG is also responsible for all costs of decommissioning of the Bruce nuclear facilities. All such costs are included in the Decommissioning Cost Estimates and are covered by OPG's consolidated financial guarantee for decommissioning.

In terms of operational financial guarantees, Bruce Power Limited Partnership maintains an Investment Grade Credit Rating for the operation of the Bruce nuclear facilities. Bruce Power shall inform CNSC staff in writing **within forty-five days** of any changes to this credit rating.

Guidance:

Not applicable to this LC.

12 SCA – SECURITY

12.1 Nuclear Security Program

Licence Condition 12.1:

The licensee shall implement and maintain a security program.

Preamble:

The *Nuclear Security Regulations* require that a licence application contain specific information related to nuclear security, stipulates the requirements for high-security sites, and contains specific requirements pertaining to the transportation of Category I, II or III nuclear material.

The *Nuclear Security Regulations* require that a licensee of a high security site:

- maintain at all times a qualified onsite nuclear response force;
- obtain the applicable certifications, before issuing an authorization to a nuclear security officer;
- prevent and detect unauthorized entry into a protected area or inner area; and
- prevent unauthorized entry of weapons and explosive substances into a protected area or inner area.

The *Nuclear Security Regulations* require every licensee to: conduct, at least once every 12 months, a threat and risk assessment specific to a facility where it carries on licensed activities in order to determine the adequacy of its physical protection system; make modifications to its physical protection system, as necessary, to counter any credible threat identified as a result of the threat and risk assessment; keep a written record of each threat and risk assessment that it conducts and provide a copy of the written record, together with a statement of actions taken as a result of the threat and risk assessment, to the Commission upon request (within 60 days) after completion of the assessment.

CNSC regulatory document REGDOC-2.12.1 (Vol. I) describes how, when required by a CNSC licence or order, a trained and equipped onsite nuclear response force shall be established and deployed at a nuclear facility.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Nuclear Security	BP-PROG-08.02	Yes
Cyber Security	BP-PROC-00784	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	High-Security Facilities, Vol. I: Nuclear Response Force, Version 2	REGDOC-2.12.1	2018	July 1, 2020
CNSC	High-Security Facilities, Vol. II: Criteria for Nuclear Security Systems and Devices	REGDOC-2.12.1	2018	Sep. 1, 2018
CNSC	Site Access Security Clearance	REGDOC-2.12.2	2013	June 1, 2015
CNSC	Security of Nuclear Substances: Sealed Sources	REGDOC-2.12.3	2013	Oct. 1, 2018
CNSC	Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, and Psychological Fitness	REGDOC-2.2.4	2018	July 1, 2020
CSA	Cyber security for nuclear power plants and small reactor facilities	N290.7	2014	Dec. 31, 2020

Nuclear Security Program

CNSC regulatory documents REGDOC-2.12.1 (Vol. I), REGDOC-2.12.1 (Vol. II) and REGDOC-2.2.4 (Vol. III) outline the requirements related to a nuclear security program.

Bruce Power shall ensure the identified vital areas within the nuclear facilities are protected against design basis threats and any other credible threat identified in their Threat and Risk Assessment documentation. The prime functions that must be maintained to prevent unacceptable radiological consequences are those of control, cool, and contain.

Bruce Power shall maintain the operation, design and analysis provisions credited in the above assessments required to ensure adequate engineered safety barriers for the protection against malevolent acts. The provisions for the protection against malevolent acts shall be documented as part of a managed program or process within the management system. Bruce Power shall summarize changes in design, analysis or operational procedures which are credited for the protection against malevolent acts in the annual threat and risk assessment, and submit a copy to the Commission 60 days after completion of the assessment.

Bruce Power shall implement measures for the purpose of preventing and detecting unauthorized entry into a protected area or inner area at a high-security site, including:

- vehicle barriers and vehicle access control points;
- intrusion detection systems and devices;
- closed-circuit video systems/devices for applications in a protected area or inner area;
- the design and functioning of security monitoring rooms; and
- the security monitoring room systems and devices.

CNSC staff will assess the changes to the site security program to determine if a recommendation to update the Station Security Reports would be required.

The licensee shall meet the security measures for sealed sources as set out in Regulatory Document REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*. CNSC staff expect for high-security nuclear sites that the licensee would provide the required details as to how they meet the applicable requirements of this regulatory document within the protected area. CNSC staff accepted the Bruce Power Site Security Plan, dated January 30, 2018 (e-Doc 5449717) and found that it meets the requirements of REGDOC-2.12.3.
Reference: CNSC letter, M. Beaudette to N. Contartese, "Technical Assessment of Bruce Power Inc. Site Security Plan", Mar. 22, 2018, e-Doc 5483719.

Cyber Security Program

Bruce Power's cyber security program shall be implemented and maintained to protect the cyber-essential assets for nuclear safety, physical protection, emergency preparedness and safeguards functions from cyber-attacks. CSA standard N290.7, CYBER SECURITY FOR NUCLEAR POWER PLANTS AND SMALL REACTOR FACILITIES outlines the requirements for a cyber security program.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Security Programs for Category I or II Nuclear Material or Certain Nuclear Facilities	G-274	2003
CNSC	Transportation Security Plans for Category I, II or III Nuclear Material	G-208	2003
CNSC	Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, Version 2.1	REGDOC-2.12.3	2020
Treasury Board of Canada Secretariat (TBS)	TBS Standard on Security Screening	N/A	2014
IAEA	Engineering Safety Aspects of the Protection of Nuclear Power Plants Against Sabotage	IAEA Nuclear Security Series No. 4 Technical Guidance	2007
IAEA	Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5)	IAEA Nuclear Security Series No. 13	2011
IAEA	Computer Security at Nuclear Facilities	IAEA Nuclear Security Series No. 17 Technical Guidance	2011
IAEA	Computer Security of Instrumentation and Control Systems at Nuclear Facilities	IAEA Nuclear Security Series No 33-T Technical Guidance	2018

CNSC guidance document G-274, SECURITY PROGRAMS FOR CATEGORY I OR II NUCLEAR MATERIAL OR CERTAIN NUCLEAR FACILITIES provides guidance for preparing, submitting and revising the Station Security Report. CNSC guidance document G-208, TRANSPORTATION SECURITY PLANS FOR

CATEGORIES I, II, OR III NUCLEAR MATERIAL provides guidance to licensee on how to prepare and submit a "written transportation security plan".

Guidance may be obtained in the IAEA Nuclear Security Series No. 4, Technical Guidance "Engineering Safety Aspects of the Protection of Nuclear Power Plants Against Sabotage" and IAEA Nuclear Security Series No. 13 "Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5)" for developing and maintaining a security program.

Guidance may be obtained in the IAEA Nuclear Security Series No. 17, Technical Guidance "Computer Security at Nuclear Facilities" for developing and maintaining a cyber security program.

Guidance may be obtained in the IAEA Nuclear Security Series No. 33-T, Technical Guidance, "Computer Security of Instrumentation and Control Systems at Nuclear Facilities" for developing and maintaining a cyber security program.

13 SCA – SAFEGUARDS AND NON-PROLIFERATION

13.1 Safeguards Program

Licence Condition 13.1:

The licensee shall implement and maintain a safeguards program.

Preamble:

Safeguards is a system of inspection and other verification activities undertaken by the International Atomic Energy Agency (IAEA) in order to evaluate a Member State's compliance with its obligations pursuant to its safeguards agreements with the IAEA.

Canada has entered into a Safeguards Agreement and an Additional Protocol (hereinafter referred to as "safeguards agreements") with the IAEA pursuant to its obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons* (INFCIRC/140). The objective of the Canada-IAEA Safeguards Agreement is for the IAEA to provide assurance on an annual basis to Canada and to the international community that all declared nuclear materials are in peaceful, non-explosive uses and that there is no indication of undeclared nuclear materials or activities. This conclusion confirms that Canada is in compliance with its obligations under the following Canada-IAEA safeguards agreements:

- *Agreement Between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons; and*
- *Protocol Additional to the Agreement Between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons*.

These are reproduced in information circulars INFCIRC/164, and INFCIRC/164/Add. 1.

The scope of the non-proliferation program for the PROL is limited to the tracking and reporting of foreign obligations and origins of nuclear material. In addition, the import and export of controlled nuclear substances, equipment and information identified in the *Nuclear Non-proliferation Import and Export Control Regulations* require separate authorization from the CNSC, consistent with section 3(2) of the *General Nuclear Safety and Control Regulations*.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Safeguards Operating Manual (Bruce A) U0 F/H	NK21-OM-35370	No
Safeguards Operating Manual (Bruce B) U0 F/H	NK29-OM-35370	No

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Safeguards and Nuclear Material Accountancy	REGDOC-2.13.1	2018	December 31, 2019

CNSC regulatory document REGDOC-2.13.1 sets out CNSC requirements and guidance for the establishment and maintenance of a safeguards program.

To avoid a potential non-compliance with REGDOC-2.13.1, section 8.1.1, when the Nuclear Material Accountancy Reporting (NMAR) e-business system is not available, Bruce Power is to contact the CNSC International Safeguards Division (cnsc.sg.official.ccsn@canada.ca) to inform them of the issue and to seek guidance on how to fulfill reporting requirements. When Bruce Power inventory change documents and physical-key measurement point inventory summaries are submitted using an alternative method, Bruce Power will still be required to re-submit using the NMAR e-business system once the NMAR system becomes available. For additional information see CNSC letter [1].

Reference
[1] CNSC letter, G. Frappier to M. Burton, "Submission of Nuclear Material Accountancy Reports Using the CNSC NMAR e-Business System", November 28, 2019, e-Doc 6032599.

Bruce Power shall not make changes to operation, equipment or procedures that would affect the implementation of safeguards measures, except with the prior written approval of the Commission or CNSC staff as follows:

- Director, International Safeguards Division
- Director General, Directorate of Security and Safeguards
- Vice-President, Technical Support Branch

With respect to the implementation of safeguards measures, changes made by the licensee to the operation, equipment or procedures as a result of the agreement between Bruce Power, the CNSC and the IAEA are considered routine.

If a requested change would adversely impact Canada's compliance with the agreement, CNSC staff do not have the authority to give the approval, as this would violate the obligations arising from the Canada-IAEA safeguards agreement.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Import and Export, Version 2	REGDOC-2.13.2	2018

14 SCA – PACKAGING AND TRANSPORT

14.1 Packaging and Transport Program

Licence Condition 14.1:

The licensee shall implement and maintain a packaging and transport program.

Preamble:

Every person who transports radioactive material, or requires it to be transported, shall act in accordance with the requirements of the *Transportation of Dangerous Goods Regulations* (TDGR) and the *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR 2015).

The TDGR and PTNSR 2015 provide specific requirements for the design of transport packages, the packaging, marking and labeling of packages and the handling and transport of nuclear substances.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Radioactive Material Transportation	BP-PROC-00188	No

Bruce Power shall implement and maintain a packaging and transport program that will ensure compliance with the requirements set out in the TDGR and PTNSR 2015 for all shipments of nuclear substances to and from the Bruce site. Shipments of nuclear substances within the nuclear facility where access to the property is controlled are exempted from the application of TDGR and PTNSR 2015.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Packaging and Transport: Information Incorporated by Reference in Canada's *Packaging and Transport of Nuclear Substances Regulations*, 2015, Volume I, Version 2	REGDOC-2.14.1	2021

15 NUCLEAR FACILITY-SPECIFIC

15.1 Lease Agreement

Licence Condition 15.1:

The licensee shall inform the Commission in writing of any amendments to the Amended and Restated Lease Agreement between Ontario Power Generation Inc., Bruce Power L.P., OPG-Huron A Inc./OPG-Huron B Inc./OPG-Huron Common Facilities Inc., British Energy PLC, Cameco Corporation, TransCanada Pipelines Limited, BPC Generation Infrastructure Trust and Ontario Municipal Employees Retirement Board dated February 14, 2003.

Preamble:

Bruce Power leases the Bruce A and B nuclear facilities from Ontario Power Generation Inc. (OPG).

Compliance Verification Criteria:

Licensee Documents

Document Title	Document #	Prior Notification
Second Amended and Restated Bruce Lease between Ontario Power Generation Inc., Bruce Power L.P., OPG-Huron A Inc./OPG-Huron B Inc./OPG-Huron Common Facilities Inc., TransCanada Pipelines Ltd and Omers Administration Corporation, October 11, 2016 **Note:** For the period Oct. 16, 2016 to Dec. 31, 2018 with option to renew the Lease for additional consecutive renewal periods for up to 46 years (until Dec. 31, 2064).	NK21-CORR-00531-13144 NK29-CORR-00531-13629 NK37-CORR-00531-02633 e-Doc 5109064 Lease dated October 11, 2016	N/A
Initial Renewal Notice for the first renewal period of one year under the Amended and Restated Lease Agreement relating to the lease of those portions of the Bruce Nuclear Power Development defined therein as the Leased Premises dated as of May 12, 2001, originally between Ontario Power Generation Inc. ("OPG"), certain subsidiaries of OPG, Bruce Power L.P. ("Bruce Power") and British Energy plc (as amended, the "Lease") **Note:** Renewal for the one-year period, Jan. 1, 2019 to Dec. 31, 2019.	NK21-CORR-00531-12301 NK29-CORR-00531-12731 NK37-CORR-00531-02459 e-Doc 4829250 Notice dated August 18, 2015	N/A

Document Title	Document #	Prior Notification
Renewal Notice for a renewal period of two years under the Second Amended and Restated Lease Agreement dated as of October 11, 2016, between Ontario Power Generation Inc. ("OPG"), certain subsidiaries of OPG, Bruce Power L.P. ("Bruce Power"), TransCanada Pipelines Limited and OMERS Administration Corporation (the "Lease") relating to the lease of those portions of the Bruce Nuclear Power Development defined therein as the Leased Premises **Note:** Renewal for the two- year period, Jan. 1, 2020 to Dec. 31, 2021 [1]. Renewal for the two- year period, Jan. 1, 2022 to Dec. 31, 2023 [2].	NK21-CORR-00531-14826 NK29-CORR-00531-15544 NK37-CORR-00531-03112 [1] e-Doc 5746948 Notice dated May 29, 2018 [2] e-Doc 6284385 Notice dated April 22, 2020	N/A
First Amendment to Second Amended and Restated Bruce Lease	BP-CORR-00531-01533 e-Doc 6528570 Document dated March 31, 2021	N/A

Bruce Power is responsible for informing the Commission of any change in the lease agreement with OPG. Bruce Power shall inform the Commission in writing no **later than 30 days** after the execution of any such amendments.

Bruce Power and OPG have consolidated and superseded all prior amendments to the lease into a Second Amended (February 14, 2003) and Restated Lease Agreement dated October 11, 2016.

Guidance:

Not applicable to this LC.

15.2 Integrated Implementation Plan

Licence Condition 15.2:

The licensee shall implement the Integrated Implementation Plan.

Preamble:

The Integrated Implementation Plan (IIP) contains commitments, including the timeframes for implementation, from the Bruce A and B Periodic Safety Reviews (PSRs).

Compliance Verification Criteria:

Licensee Documents

Document Title	Document #	Prior Notification
Bruce A and B Global Assessment Report and Integrated Implementation Plan	B-GAR-09701-00001 R002 e-Doc 5303331	N/A
Bruce A and B Integrated Implementation Plan Management	NK21-CORR-00531-14012 | NK29-CORR-00531-14693 e-Doc 5435884	N/A

In implementing the commitments identified in the IIP (Bruce A and B Global Assessment Report and Integrated Implementation Plan, B-GAR-09701-00001 R002, e-Doc 5303331), Bruce Power committed to submitting to CNSC staff formal progress reports on the status of all IIP commitments on an annual basis by March 31st of each year during the licence period. All changes to the IIP will be managed in accordance with the IIP Communications Plan (Bruce Power Letter, F. Saunders to L. Sigouin, "Bruce A and B Integrated Implementation Plan Management", January 18, 2018, e-Doc 5435884, NK21-CORR-00531-14012 / NK29-CORR-00531-14693).

Guidance:

Not applicable to this LC.

15.3 Pressure Tube Fracture Toughness

Licence Condition 15.3:

Before hydrogen equivalent concentrations exceed 120 ppm, the licensee shall demonstrate that pressure tube fracture toughness will be sufficient for safe operation beyond 120 ppm.

Preamble:

Bruce Power submits assessments for fuel channel components to support safe operation and satisfy compliance verification criteria in CSA N285.4-14 and CSA N285.8-15 Update 1 as outlined in Section 6.1. These assessments rely on models intended to conservatively predict the current and future conditions of fuel channel components. Fracture toughness models are used to assess risk of pressure tube failure from postulated flaws in uninspected pressure tubes. The current model for fracture toughness in CSA N285.8-15 Update 1 has an upper bound for hydrogen equivalent concentration, [H_{eq}], in pressure tubes of 120 parts per million (ppm). To reach Major Component Replacement target dates, Bruce Power currently predicts that some pressure tubes will operate with [H_{eq}] in excess of 120 ppm and has proposed the development and validation of a new fracture toughness model in support of satisfying this licence condition. To meet compliance verification criteria for pressure tubes with [H_{eq}] greater than 120 ppm: i) a new fracture toughness model (hereafter referred to as the Fracture Toughness Model) needs to be developed and accepted by CNSC staff prior to use; and ii) the licensee must periodically demonstrate that fracture protection and Leak-Before-Break assessments of Bruce Power pressure tubes (using predictions of the Pressure Tube Fracture Toughness) satisfy CSA N285.8-15 Update 1 acceptance criteria.

Compliance Verification Criteria:

1. For continued operation of units containing pressure tubes with a [H_{eq}] exceeding 120 ppm between the inlet and outlet burnish marks:
   a. Bruce Power shall obtain approval from the Commission before operating any pressure tube with a measured [H_{eq}] greater than 120 ppm, or beyond the time any pressure tube is predicted to have a [H_{eq}] greater than 120 ppm,
      i. Predictions of maximum [H_{eq}] shall be determined utilizing the hydrogen prediction model applied to the unit in the most recent report submitted to the CNSC under CSA N285.4, Clause 12.3.6.2. Revisions to the hydrogen prediction model used in the most recent report shall be accepted by the CNSC.
   b. Bruce Power shall submit annual reports by July 1 of each year indicating when each unit is predicted to reach a maximum [H_{eq}] of 120 ppm.

2. Criteria for the development of the Fracture Toughness Model:

   Bruce Power submitted to CNSC on September 22, 2020 a technical basis document for the Fracture Toughness Model including a schedule for any remaining activities to complete model development and validation. The documents are currently being reviewed by CNSC staff.

   Until the Fracture Toughness Model is accepted for use, Bruce Power shall report, on a semi-annual basis, the following:

   a. status updates on the validation of the Fracture Toughness Model,
   b. a quantitative assessment of uncertainties for the Fracture Toughness Model as new test data is added; and
   c. updates to the test plan, which includes:
      i. status of findings and outcomes from previous fracture toughness tests;
      ii. additions and changes to the test plan i.e., schedule of fracture toughness tests;
      iii. changes to the Test Strategy; and
      iv. results of fracture toughness tests including, as a minimum, material tested, test conditions, the results, whether the test objective has been met, and the tests planned for the next six months.

3. Criteria for demonstration of sufficient pressure tube fracture toughness:

   Bruce Power shall submit assessments of fracture protection and Leak-Before-Break, using the new fracture toughness model, to the CNSC prior to the predicted [H_{eq}] exceeding 120 ppm in one or more pressure tubes in any unit. The assessments shall be submitted for each unit no earlier than 1 year and no later than 6 months prior to the date that the [H_{eq}] for a pressure tube in the given unit is predicted to exceed 120 ppm.

   Fracture protection assessments shall address the requirements of CSA N285.8-15 Update 1 Clauses 7.2.1 and 7.2.2, unless an assessment methodology/acceptance criteria for probabilistic fracture protection has received prior acceptance by CNSC.

Guidance for performing Leak-Before-Break assessments is offered below.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
COG	Fuel Channel Life Management – Third Party Review of Probabilistic Fracture Protection Evaluation Methodology Acceptance Criteria	COG-JP-4491-V197	2017
COG	Theory Manual for the Evaluation Module of Probabilistic Core Assessment Computer Code, SCEPTR V1.2e	COG-JP-4452-V119	2015
Bruce Power	Letter - F. Saunders to K. Lafrenière related to fitness-for-service of pressure tubes to support licence renewal application	NK21-CORR-00531-13981/ NK29-CORR-00531-14657 (e-Doc 5412860)	Dec. 8, 2017

Attributes of an acceptable fracture toughness model

To support the licensing application of the updated model(s), the licensee should demonstrate that the model can:

i. explicitly account for actual hydride orientation;
ii. account for the variation in hydride morphology from pressure tube inlet to outlet;
iii. predict hydride fracture, as a function of hydride length and temperature;
iv. predict the transition-to-upper shelf temperature;
v. account for hydride length and orientation (using improved fracture path and ligament rupture models);
vi. explicitly model the fissures initiating at zirconium-chlorine-carbon precipitates; and
vii. make use of the conventional traction-separation rule applied to finite-element cohesive-zone analyses.

Acceptable demonstration of Leak-Before-Break

To satisfy LC 15.3, the licensee should perform a Method 2 probabilistic assessment of Leak-Before-Break (PLBB) in accordance with procedures detailed in COG-JP-4452-V119-R0. In conducting these assessments, Bruce Power should:

- Determine the toughness of (hypothetical) pressure tubes using either the Fracture Toughness Model or, pending CNSC acceptance of the Model, using Bruce Power's contingency plan (ref. December 8, 2017 BP letter to CNSC).
- Incorporate, where appropriate, mutually-agreed upon improvements to the Method 2 PLBB methodology arising from on-going discussions with CNSC.
- Incorporate, where appropriate, any changes to the Method 2 PLBB methodology recommended by industry's planned "Final Report", documenting resolution of the Probabilistic Core Assessment (PCA) flaw removal issue (ref. Attachment 1 to e-Doc 5384059).

Uncertainty Analysis

To support the licensing application of the Fracture Toughness Model, a quantitative assessment of uncertainties should be conducted. The assessment should utilize the approach in sections A.1, A.2 and A.5 of Appendix A to COG-JP-4491-V197, "Fuel Channel Life Management: Third Party Review of Probabilistic Fracture Protection Evaluation Methodology and Acceptance Criteria", e-Doc 5230291.

Predicted maximum hydrogen equivalent concentration

The predicted [H_{eq}] at the inlet and outlet burnish marks at the end of the evaluation period should be determined through a station or unit-specific model. The initial hydrogen concentration should be from off-cut measurements and be channel-specific, the unit-specific bounding value, or the station-specific bounding value. Operating conditions such as temperature and fast flux, where applicable to the model or its components, should be channel-specific, the unit-specific bounding combination, or the station-specific bounding combination. If any inputs are sampled from a distribution, the inputs as well as their percentiles should be justified. For a probabilistic Monte Carlo approach, the upper-bound percentile for the [H_{eq}] prediction at the end of the evaluation period should be justified. In accordance with Clauses 12.3.4.6 and 12.4.4.6 of CSA N285.4, Bruce Power should report all of the parametric data used in the determination and prediction of the [H_{eq}] values.

15.4 Return-to-Service Plan

Licence Condition 15.4:

The licensee shall implement a return-to-service plan for Major Component Replacement.

Preamble:

Return to service (RTS) involves returning the reactor and associated nuclear and non-nuclear systems to commercial operation. The licensee must demonstrate that all regulatory requirements have been met and that the associated work has been done to the satisfaction of the CNSC.

Compliance Verification Criteria:

Licensee Documents

Document Title	Document #	Prior Notification
Bruce Power Letter, Frank Saunders to Marc Leblanc, "Supplement to the Application for the Renewal of the Power Reactor Operating Licence: Major Component Replacement Project Execution Plan and Bruce B Unit 6 Return to Service Plan", June 30, 2017, e-Doc 5292343	NK21-CORR-00531-14175	N/A

Bruce Power has notified CNSC of its intention to extend the operational lives of Bruce A Units 3 and 4 and Bruce B Units 5-8 including the replacement of major components.

Bruce Power shall develop and implement a project execution plan and a return-to-service plan for any refurbishment activities.

Guidance:

Not applicable to this LC.

15.5 Regulatory Hold Points for Return to Service and Continued Operation

Licence Condition 15.5:

The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.

Preamble:

CNSC have identified four (4) regulatory hold points for the return to service of each unit undergoing a Major Component Replacement (MCR) outage for which CNSC approval will be sought prior to proceeding to the subsequent commissioning phase. These hold points require regulatory verification to confirm operational readiness of the plant safety systems to satisfy regulatory requirements for staged progress through the commissioning phases up to full power operation. These regulatory hold points are consistent with the regulatory approach described in REGDOC-2.3.1, CONDUCT OF LICENSED ACTIVITY: CONSTRUCTION AND COMMISSIONING PROGRAMS.

Compliance Verification Criteria:

The licensee shall seek approval of the Commission or consent of a person authorized by the Commission prior to the removal of the following regulatory hold points for the return to service of each unit. The regulatory hold points that mark the completion of the commissioning phases are as follows:

1. Prior to **Fuel Load - Phase A**
2. Prior to removal of **Guaranteed Shutdown State - Phase B**
3. Prior to exceeding **1% Full Power - Phase C**
4. Prior to exceeding **35% Full Power - Phase D**

In its 2018 Record of Decision for Bruce A and B licence renewal, the Commission delegated the authority for this licence condition for the removal of regulatory hold points for the return to service of each unit undergoing a MCR outage to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

For each of the regulatory hold points, the licensee shall submit Completion Assurance Documents (CADs). In addition to these CADs, the licensee shall submit CADs following sustained operation at 100% full rated power that will specify activities that were completed between 35% and 100% full rated power. Each CAD shall present evidence that all pre-established conditions for removal have been met.

Prior to GSS removal, all plant personnel who work on the reactor that has undergone major component replacement shall have completed update training appropriate to the knowledge and skill requirements of the applicable position covering the changes to facility systems, equipment and procedures made during the Major Component Replacement outages.

For each ANO, CRSS and SM this includes, at a minimum:

- Principles of reactor operation with a pre-equilibrium core;
- Principles of nuclear safety relevant to the operation of the reactor unit with a pre-equilibrium core;

- Operating constraints and limits associated with the operation of the reactor unit with a pre-equilibrium core;
- The initial approach to criticality and power increase until control by the reactor regulating system is established, including the systems and equipment required and their operation; and
- Changes in fuel composition and core reactivity until reaching equilibrium fuel conditions.

This training shall include formal knowledge and performance evaluations that confirm and document that, at the time of GSS removal, the person has the required knowledge and skills to perform the duties of the applicable position.

Low power testing (Phase C) shall be carried out at the lowest possible power level, with a maximum of 1% of full power.

Prior to release of a regulatory hold point, CNSC staff will verify compliance of the licensee to the pre-requisites for release of a hold point and provide a report to the Commission or person authorized by the Commission. Based on the results of the review of this report, the CNSC's Regulatory Operations Branch will issue a record of decision.

Pre-requisites for Release of Hold Points:

Pre-requisites for Fuel Load

1. All IIP commitments required prior to fuel load are complete;
2. All SSCs required for safe operation beyond fuel load are available for service;
3. Staffing levels to safely operate the unit are adequate;
4. Specified operating procedures for fuel load have been formally validated;
5. Specified training for fuel load is complete and staff qualified;
6. Specified SSCs meet the quality and completion requirements of CSA N286;
7. All non-conformances and open items identified as a pre-requisite to fuel load are addressed; and
8. Verification by CNSC staff that all construction, commissioning, re-start, and available for service activities required prior to fuel load have been successfully completed.

With respect to pre-requisite #3: Staffing levels refers to a sufficient number of qualified workers present at all times to ensure the safe operation of the nuclear facility and to ensure adequate emergency response capability. The licensee should have adequate staff available such that absences due to vacation, sick leave and training do not cause violations of the minimum shift complement levels.

Pre-requisites for GSS Removal

1. All IIP commitments required prior to GSS removal are complete;
2. All SSCs required for safe operation beyond GSS removal are available for service;
3. Specified operating procedures for GSS removal have been formally validated;
4. Specified training for GSS removal is complete and staff qualified;
5. All non-conformances and open items identified as a pre-requisite to GSS removal are addressed;
6. Specified SSCs meet the quality and completion requirements of CSA N286; and
7. Verification by CNSC staff that all construction, commissioning, re-start, and available for service activities required prior to GSS removal have been successfully completed.

Pre-requisites for Reactor Power Increases Prior to exceeding 1% Full Power

1. All IIP commitments required prior to increasing reactor power are complete;
2. All SSCs required for safe operation are available for service;
3. Specified operating procedures have been formally validated;
4. Specified training is complete and staff qualified;
5. All non-conformances and open items identified as a pre-requisite to reactor power increases above 1% power are addressed;
6. Specified SSCs meet the quality and completion requirements of CSA N286; and
7. Verification by CNSC staff that all construction, commissioning, re-start, and available for service activities required prior to increasing reactor power have been successfully completed.

Pre-requisites for Reactor Power Increases Prior to exceeding 35% Full Power

1. All IIP commitments required prior to normal operation are complete;
2. All SSCs required for safe operation are available for service;
3. Specified operating procedures have been formally validated;
4. Specified training is complete and staff qualified;
5. All non-conformances and open items identified as a pre-requisite to reactor power increases above 35% power are addressed;
6. Specified SSCs meet the quality and completion requirements of CSA N286; and
7. Verification by CNSC staff that all construction, commissioning, re-start, and available for service activities required prior to increasing reactor power have been successfully completed.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Conduct of Licensed Activity: Construction and Commissioning Programs	REGDOC-2.3.1	2016
IAEA	Commissioning for Nuclear Power Plants	Specific Safety Guide Series No. SSG-28	2014
IAEA	Safety of Nuclear Power Plants: Commissioning and Operation	Specific Safety Requirements Series No. SSR-2/2	2011

Bruce Power should apply the concepts described in REGDOC-2.3.1, CONDUCT OF LICENSED ACTIVITY: CONSTRUCTION AND COMMISSIONING PROGRAMS, to the extent practicable, when commissioning and returning SSCs to service, as part of the MCR. CNSC staff will consider pertinent sections of REGDOC-2.3.1 when evaluating Bruce Power's commissioning and return to service activities related to MCR.

15.6 Periodic Safety Review

Licence Condition 15.6:

The licensee shall conduct and implement a periodic safety review.

Preamble:

A periodic safety review (PSR) is a comprehensive evaluation of the design, condition and operation of a nuclear power plant. It is an effective way to obtain an overall view of actual plant safety and the quality of the safety documentation, and to determine reasonable and practical improvements to ensure safety until the next PSR or, where appropriate, until the end of commercial operation.

This licence condition pertains to the next PSR that Bruce Power shall submit during the licence period.

Compliance Verification Criteria:

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Periodic Safety Reviews	REGDOC-2.3.3	2015	June 1, 2015

The licensee shall conduct a PSR to obtain an overall view of actual plant safety and the quality of safety documentation and to determine reasonable and practical improvements to ensure safety. The PSR shall be conducted in accordance with CNSC regulatory document REGDOC-2.3.3, PERIODIC SAFETY REVIEWS.

Bruce Power shall submit the next PSR to CNSC staff for review approximately 18 months prior to the next licence application.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CSA	Periodic safety review for nuclear power plants	N290.18	2017
IAEA	Periodic Safety Review for Nuclear Power Plants	Specific Safety Guide No. SSG-25	2013

15.7 End of Commercial Operations

Licence Condition 15.7:

The licensee shall inform the Commission of any reactor to be removed from commercial operation at Bruce A and B, and shall provide a plan describing the activities and timeline for transitioning from operations to safe storage.

Preamble:

Given that Bruce Power leases the Bruce A and Bruce B facilities, there is a need to ensure that when Bruce Power plans to take a reactor unit out of commercial service that there are adequate plans to ensure the safe transition from an operating unit into safe storage and the eventual transfer of the facility back to Ontario Power Generation.

Compliance Verification Criteria:

For any reactor that is to be removed from commercial operation, Bruce Power shall produce a strategy and plan of activities to manage and execute a safe process for removal from commercial service of a reactor unit at the nuclear facility. This plan shall cover:

- safe operation until end of commercial operation;
- transition to safe storage;
- staffing profiles;
- any required changes to Bruce Power programs covered in the operating licence;
- transition of the facility back to the owner for decommissioning.

Guidance:

The licensee should consider all units at a facility when developing the required plan. This is to take into consideration that units are likely to be removed from commercial service in a staggered approach such that the plan may need to cover several years.

15.8 Booster Fuel

Licence Condition 15.8:

The licensee shall store and manage booster fuel assemblies at Bruce A in a manner that ensures their physical security.

Preamble:

This LC is required for Bruce A due to the booster fuel assemblies.

Compliance Verification Criteria:

Bruce Power shall ensure the inner areas within the nuclear facility at Bruce A are protected in accordance with section 14 of the *Nuclear Security Regulations* against design basis threats and any other credible threat identified in the Threat and Risk Assessment documentation.

Guidance:

Not applicable to this LC.

15.9 Criticality Program

Licence Condition 15.9:

The licensee shall implement and maintain a nuclear criticality safety program.

Preamble:

This LC is required for Bruce A due to the booster fuel assemblies and for Bruce B due to the Low Void Reactivity Fuel (LVRF) Demonstration Irradiation. The booster fuel assemblies and LVRF bundles are currently in storage and only relevant sections of RD-327, NUCLEAR CRITICALITY SAFETY are applicable. The other sections would apply only if Bruce Power proposes a change to the storage conditions.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Nuclear Criticality Safety Management	BP-PROC-00324	Yes

Licensing Basis Publications

Org	Document Title	Document #	Revision #	Effective Date
CNSC	Nuclear Criticality Safety	RD-327	2010	May 31, 2016

Bruce Power is to maintain their nuclear criticality safety program in accordance with certain sections of CNSC regulatory document RD-327. Due to the presence of fissionable materials (as defined in section 2.3.1.3 of RD-327) in the booster fuel assemblies at Bruce A and the LVRF bundles at Bruce B, several of the requirements listed in RD-327 have been assessed as being applicable. The applicable requirements are:

Subject	Section
Nuclear criticality safety program relative to categorization	2.3.1.3, 2.3.1.4 , 12.8
Responsibilities	2.3.2.1, 12.3.1, 12.3.2, 12.3.3
Quality Management program and procedures	2.3.2.3, 2.3.2.6
Materials control	2.3.2.4 , 12.6
Operational control	2.3.2.7
Emergency procedures	2.3.2.9, 12.7
Nuclear criticality safety in the storage of fissile materials	6.0
Nuclear criticality safety training	13.0

Bruce Power is to maintain their nuclear criticality safety program in accordance with the Nuclear Criticality Safety Management procedure such that Upper Subcritical Limits established by the program

will not be exceeded under both normal and credible abnormal conditions of operations with fissionable materials outside the reactors.

BP-PROC-00324 has been updated to meet the requirements of CSA standard N286-12.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Guidance for Nuclear Criticality Safety	GD-327	2010
CNSC	Nuclear Criticality Safety, Version 1.1	REGDOC-2.4.3	2020

15.10 Cobalt-60 and Lutetium-177

Licence Condition 15.10:

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

Preamble:

Bruce Power is limited to nuclear substances production at the following locations:

- Cobalt-60 at Bruce B
- Lutetium-177 at Bruce B, Unit 7

Bruce Power harvests Cobalt-60 during the removal of Cobalt adjusters from each of the Bruce B reactors. These cobalt rods are processed into cobalt bundles that are placed in sealed containers and transported to Nordion Inc. who reprocess the bundles into sealed sources. Due to decay, the Cobalt-60 sealed sources cannot be used for commercial use after many years and are shipped back to Bruce Power. The sealed sources are stored in the Secondary Irradiated Fuel Bay at Bruce B NGS and upon decommissioning; they will be placed in permanent dry storage.

Bruce Power has installed an Isotope Production System (IPS) in Bruce B Unit 7 for the production of Lutetium-177 (Lu-177) from Ytterbium-176 (Yb-176) oxide powder. The powder is encapsulated in a target consisting of a sealed quartz ampule and aluminum carrier. A zircaloy target finger tube (TFT) assembly has been installed via a vacant vertical flux detector guide tube assembly. Using a pneumatic system, targets in their aluminum carriers are inserted into and retrieved from the reactor through the TFT assembly. The aluminum carriers (irradiated targets) are then discharged to transport containers and shipped to processing facilities. Bruce Power is authorized to use the IPS for the production of Lu-177 at Unit 7 only.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Cobalt Handling	BP-PROC-00003	Yes
Irradiation Services	BP-PROG-xx.xx (number will be assigned prior to IPS commissioning)	No
Management of Lutetium-177 Production	BP-PROC-01120	No

LC 15.10 provides the basis for regulatory oversight related to the licensed activity associated with the radioisotopes production program. The Bruce Power licence authorizes through the licensing basis the production and possession of Cobalt-60 in both sealed and unsealed forms at the Bruce B nuclear facility. Bruce Power shall ensure that handling, processing and accounting of Cobalt is in accordance with Bruce Power's procedure for Cobalt Handling.

The receipt of any Cobalt-60 sealed sources shall be reported to the CNSC via the Sealed Source Tracking System and in accordance with CNSC regulatory document REGDOC-3.1.1.

The Bruce Power licence authorizes through the licensing basis the production, possession, handling, storage, packaging, managing and transport of Lutetium-177.

Bruce Power has only presented the safety case for production of Cobalt-60 and Lutetium-177. Bruce Power will need to request the Commission's approval if it plans to produce radioisotopes other than Cobalt-60 and Lutetium-177.

Regulatory Hold Point for the Bruce B Unit 7 Lu-177 Isotope Production System:

A regulatory hold point has been placed on Bruce Power which must be released prior to start of the Commissioning program.

[*…Insert here a statement from the Commission decision for the IPS licence amendment regarding approval of the process for the release of the hold point. Possible text for this paragraph depending upon the Commission decision could be:*

In the 2021 Record of Decision for Bruce A and B licence amendment, the Commission delegated the authority for this licence condition for the removal of the regulatory hold point for commissioning of the Lu-177 production system to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.]

The process for the release of the regulatory hold point is as follows:
1. Bruce Power submits a request to CNSC staff (including the information to satisfy the criteria/pre-requisites) for the release of the hold point.
2. CNSC staff will review the submitted information and verify Bruce Power's compliance with requirements and commitments.
3. Based on the submitted information, CNSC staff will provide a report, including recommendations, to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch whether the criteria/pre-requisites specified in the LCH have/have not been met.
4. The Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch will then consent or not consent to the release of the regulatory hold point.
5. CNSC staff will administer the release of the hold point through a confirmation letter to Bruce Power.

Pre-requisites for the Release of the Hold Point for the Bruce B Unit 7 Lu-177 IPS:

1. All licensee commitments prior to start of the Commissioning program are complete;
2. Completion of licensee's governing program and procedure documentation 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

Prohibition of Human Use
The licensee is not authorized by the licence to conduct activities related to nuclear medicine and therefore it is prohibited to use nuclear substances in or on human beings.

CNSC staff will verify by whatever means available that the licensee is not using radioactive prescribed substances in or on humans.

Guidance:
Not applicable to this LC.

15.11 Class II Nuclear Facility

Licence Condition 15.11:

The licensee shall implement and maintain a program for the operation of the Class II nuclear facility.

Preamble:

Bruce Power possesses Class II prescribed equipment and associated nuclear substances for the Class II nuclear facility as listed in B-LIST-67874-00001.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management of Class II Nuclear Facilities	BP-PROC-00817	No
Leak Testing	BP-PROC-00143	No
Radiation Calibration Facility Safety Interlock Checks and Operation	NK29-CMP-67880-00001	No
Radiation Calibration Facility General Arrangement Drawing	NK29-DRAW-67880-10001	No
Radiation Calibration Facility Cable Block Diagram	NK29-DRAW-67880-10003	No
Nuclear Substances and Prescribed Equipment List	B-LIST-67874-00001	Yes

Licensee Documents

Document Title	Document #	Prior Notification
Plans and Design of the Calibration Facility	NK29-CORR-00531-01343	N/A
Shielding Calculations for the Calibration Facility	NK29-CORR-00531-04839	N/A

Sealed Source Tracking
Unless otherwise permitted by the prior written approval of the Commission or a person authorized by the Commission the licensee shall, in respect of a radioactive nuclear substance set out:

1) in table 15.11.1 column 1, report in writing to the Commission or a person authorized by the Commission any transfer, receipt, export, or import of a sealed source whose corresponding activity is equal to or greater than the value set out in column 2; or
2) in B-LIST-67874-00001 section 4.0, report in writing to the Commission or a person authorized by the Commission any transfer, receipt, import or export of any sealed source:
   (a) at least 24 hours before any transfer within Canada;
   (b) at least 7 days before any export; and
   (c) within 48 hours of any receipt of a transfer or import.

Table 15.11.1: Activity Limits

Column 1 Nuclear Substance	Column 2 (TBq)
Americium 241	0.6
Americium 241/Beryllium	0.6
Californium 252	0.2
Curium 244	0.5
Cobalt 60	0.3
Cesium 137	1
Gadolinium 153	10
Iridium 192	0.8
Promethium 147	400
Plutonium 238	0.6
Plutonium 239/Beryllium	0.6
Radium 226	0.4
Selenium 75	2
Strontium 90 (Yttrium 90)	10
Thulium 170	200
Ytterbium 169	3

The written report shall be in a form acceptable to the Commission that includes:

1) on transfer or export of a sealed source(s),
   (a) the date of transfer or export,
   (b) the export licence number (where applicable),
   (c) the name of the recipient and licence number or the name of the importer,
   (d) the address of the recipient's or importer's authorized location,
   (e) the nuclear substance (radionuclide),
   (f) activity (radioactivity) (Bq) per sealed source on the reference date,
   (g) the reference date,
   (h) the number of sealed source(s),
   (i) the aggregate activity (Bq),
   (j) the sealed source unique identifiers (if available), and
   (k) where the sealed source is incorporated in a prescribed equipment,
      i. the name and model number of the equipment, and
      ii. the equipment serial number (if available)

2) on receipt or import of a sealed source(s),
   (a) the date of receipt of a transfer or import,
   (b) the name of the shipper and licence number or the name of the exporter,
   (c) the address of the shipper's or exporter's authorized location,
   (d) the nuclear substance (radionuclide),
   (e) activity (radioactivity) (Bq) per sealed source on the reference date,
   (f) the reference date,
   (g) the number of sealed source(s),
   (h) the aggregate activity (Bq),
   (i) sealed source unique identifiers (if available), and
   (j) where the sealed source is incorporated in a prescribed equipment,
      i. the name and model number of the equipment, and
      ii. the equipment serial number (if available)

Annual Compliance Report for a Class II Nuclear Facility
The licensee is required to submit to the Commission the annual compliance report by March 31 of each year. The report shall include activities covering the nuclear substances and prescribed equipment of the Class II nuclear facility as listed in this section of the LCH.

The report shall include:

- information on the activities conducted during the previous year, including a summary of workload;
- the current inventory of radiation devices, sealed sources, and unsealed sources; and
- information on any transfers or disposals.

Guidance:

Not applicable to this LC.

15.12 Nuclear Substances and Prescribed Equipment

Licence Condition 15.12:

The licensee shall implement and maintain a program for nuclear substances and prescribed equipment.

Preamble:

Bruce Power has been authorized to use the types of nuclear substances and prescribed equipment listed in B-LIST-67874-00001 and B-LIST-67874-00002.

Compliance Verification Criteria:

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management of Nuclear Substances and Radiation Generating Equipment	BP-RPP-00043	No
Hopewell Designs BX-3-Box Calibrator Pre-Use Operational and Safety Interlock Checks	NK21-CMP-67870-00002	No
Hopewell Designs Inc. Model BX3 Gamma Irradiator Operations & Maintenance Manual (Version 1)	N/A	No
Hopewell Designs, Inc. Stand-Alone Irradiator Calibrator 3347-R2 User Manual	N/A	No
Instructions for the Removal/Replacement of Kinectrics KIN-FLS400 Sealed Source Assembly	N/A	No
Conduct of Radiography	BP-PROC-00036	No
Radiography Emergency Procedures	BP-PROC-00798	No
Leak Testing	BP-PROC-00143	No
Nuclear Substances and Prescribed Equipment List	B-LIST-67874-00001	Yes
Security Protected Nuclear Substances and Prescribed Equipment List	B-LIST-67874-00002	Yes

The licensee shall implement and maintain a nuclear substances and prescribed equipment program.

The licensee main support process document which describes the program for nuclear substances and prescribed equipment is BP-RPP-00043, *Management of Nuclear Substances and Radiation Generating Equipment*.

Nuclear substances and prescribed equipment are used throughout the Bruce site, subject to the requirements of the program for nuclear substances and prescribed equipment.

The licensee is authorized to conduct licensed activities with the nuclear substances and the prescribed equipment listed in B-LIST-67874-00001 and B-LIST-67874-00002 throughout the Bruce site. This includes use of the nuclear substances and the prescribed equipment to support dosimetry services authorized by CNSC licence 13152-6-27.5 and any subsequent amendments or renewals.

Prohibition of Human Use
The licensee is not authorized by the licence to conduct activities related to nuclear medicine and therefore it is prohibited to use nuclear substances in or on human beings.

CNSC staff will verify by whatever means available that the licensee is not using radioactive prescribed substances in or on humans.

List of areas, rooms and enclosures
The licensee shall maintain a list of all areas, rooms and enclosures in which more than one exemption quantity of a nuclear substance is used or stored. The allowable maximum quantities of radionuclides are found in B-LIST-67874-00001 sections 1.0 and 2.0 and B-LIST-67874-00002.

Posting of Safety Posters
The licensee shall post and keep posted, in a readily visible location in the areas, rooms or enclosures where nuclear substances are handled, a radioisotope safety poster approved by the Commission or a person authorized by the Commission, which corresponds to the classification of the area, room or enclosure.

Storage
The licensee shall:
- ensure that when in storage radioactive nuclear substances or radiation devices are accessible only to persons authorized by the licensee;
- ensure that the dose rate at any occupied location outside the storage area, room or enclosure resulting from the substances or devices in storage does not exceed 2.5 microSv/h; and
- have measures in place that the dose limits in the *Radiation Protection Regulations* are not exceeded as a result of the substances or devices in storage.

Area Classification
The licensee shall classify each room, area or enclosure where more than one exemption quantity of an unsealed nuclear substance is used at a single time as:
- basic-level if the quantity does not exceed 5 Annual Limit on Intake (ALI);
- intermediate-level if the quantity used does not exceed 50 ALI;
- high-level if the quantity does not exceed 500 ALI; or
- containment-level if the quantity exceeds 500 ALI;

Except for the basic-level classification, the licensee shall not use unsealed nuclear substances in these rooms, areas or enclosures without written approval of the Commission or a person authorized by the Commission.

Contamination Meter Requirements
The licensee shall make available to workers at all times at the site of the licensed activity a properly functioning portable contamination meter.

Survey Meter Requirements
The licensee shall provide at all times where nuclear substances, except for Hydrogen-3 and Nickel-63, are handled or stored a radiation survey meter.

Contamination Criteria
The licensee shall ensure that for nuclear substances listed in table 15.12.1, Classes of Radionuclides, given below:

1) non-fixed contamination in all areas, rooms or enclosures where unsealed nuclear substances are used or stored does not exceed:
   a) 3 becquerels per square centimetre for all Class A radionuclides;
   b) 30 becquerels per square centimetre for all Class B radionuclides;
   c) 300 becquerels per square centimetre for all Class C radionuclides; averaged over an area not exceeding 100 square centimetres;

and

2) non-fixed contamination in all other areas does not exceed:
   a) 0.3 becquerels per square centimetre for all Class A radionuclides;
   b) 3 becquerels per square centimetre for all Class B radionuclides;
   c) 30 becquerels per square centimetre for all Class C radionuclides; averaged over an area not exceeding 100 square centimetres.

The most commonly licensed radionuclides have been grouped into Class A, Class B and Class C, based upon their radiological properties as shown in the table below.

Table 15.12.1: Classes of Radionuclides

Class	Radionuclide				
Class A	All alpha emitters and their daughter isotopes				
	Ag-110m	Bi-210	Co-56	Co-60	Cs-134
	Cs-137	I-124	Lu-177m	Mn-52	Na-22
	Po-210	Pu-238	Pu-239	Pu-240	Sb-124
	Sc-46	Sr-82	U-234	U-235	U-238
	V-48	Zn-65			
Class B	Au-198	Ba-133	Br-82	Ce-143	Co-58
	Cu-67	Fe-59	Hg-194	Hg-203	I-131
	Ir-192	La-140	Mo-99	Nb-95	Pa-233
	Ra-223	Re-186	Re-188	Ru-103	Sb-122
	Sm-153	Sr-90	Xe-127	Y-86	Y-90
	Yb-169	Zr-89	Zr-95		
Class C	C-11	C-14	Ca-45	Cd-109	Ce-141
	Cl-36	Co-57	Cr-51	Cu-60	Cu-61
	Cu-64	F-18	Fe-55	Ga-67	Ga-68
	Ge-68	H-3	I-123	I-125	In-111
	In-113m	In-114	K-42	Kr-85	Lu-177
	Mn-52m	Mn-56	N-13	Na-24	Nb-98
	Ni-63	O-15	P-32	P-33	Pd-103
	Pr-144	Pu-241	Rh-106	S-35	Sc-44
	Sn-113	Sr-89	Tc-94m	Tc-99	Tc-99m
	Te-127	Tl-201	V-49	W-181	W-188
	Xe-133	Zn-63			

When using more than one radionuclide in a room, the radionuclide with the lowest contamination limit must be used to determine the limit, Class A, Class B or Class C that applies to the room.

Extremity Dosimetry – Beta Emitters
The licensee shall ensure that any person who handles a container which contains more than 50 MBq of phosphorus 32, strontium 89, yttrium 90, samarium 153 or rhenium 186 wears an extremity dosimeter, such as, a ring dosimeter, a Thermoluminescent Dosimeter (TLD) chip taped to the middle finger or other acceptable dosimetry methods that may be developed in the future. The dosimeters must be supplied and read by a dosimetry service licensed by the Commission.

Internal Authorization
The licensee shall ensure that:

- internal authorizations are issued in accordance with the licensee's internal authorization policies and procedures approved by the Commission or a person authorized by the Commission;
- internal authorization forms are posted in a readily visible location in or near each room, area or enclosure where nuclear substances and radiation devices are used or stored; and
- the licensed activity is conducted in accordance with the terms and conditions of the internal authorization.

Project Approval
The licensee shall obtain written approval from the Commission or a person authorized by the Commission before starting any work requiring the use of more than 10,000 exemption quantities of a nuclear substance at a single time.

Disposal (General)
When disposing of unsealed nuclear substances set out in table 15.12.2 column 1, Disposal Limits to municipal waste, to sewer systems or to atmosphere, the licensee shall ensure that the concentration limit set out for each nuclear substance is not exceeded:

a) The concentration limits set out in column 2 apply to quantities of solid waste of less than three tonnes per building per year. Nuclear substances released to the municipal garbage system must be in solid form and uniformly distributed in the waste with a concentration that is less than the limits in column 2. Where more than one nuclear substance is disposed of at one time, the sum of the quotients obtained by dividing the quantity of each substance by its corresponding limit in column 2 shall not exceed one.
b) The limits set out in column 3 apply to the water soluble liquid form of each nuclear substance which may be disposed of per building per year. Where more than one nuclear substance is disposed of at one time, the sum of the quotients obtained by dividing the quantity of each substance by its corresponding limit in column 3 shall not exceed one.
c) The concentration limits set out in column 4 may be averaged over a one-week period and apply to releases of less than 3 million cubic metres per year. Where more than one nuclear substance is disposed of at one time, the sum of the quotients obtained by dividing the quantity of each substance by its corresponding limit in column 4 shall not exceed one.

Table 15.12.2: Disposal Limits

Column 1 Nuclear Substance	Column 2 Solids to Municipal Garbage System (Qty per kg)	Column 3 Liquids (Water Soluble) to Municipal Sewer System (Qty per year)	Column 4 Gases to Atmosphere (Qty per cubic metre)
Americium 241	0.001 MBq	10 MBq	0.03 Bq
Antimony 124	0.37 MBq	0.1 MBq	N/A
Barium 133	0.037 MBq	1 MBq	N/A
Cadmium 109	0.37 MBq	10 MBq	N/A
Carbon 14	3.7 MBq	10000 MBq	N/A
Cerium 139	0.1 MBq	1 MBq	30 Bq
Cesium 134	0.01 MBq	0.1 MBq	N/A
Cesium 137	0.01 MBq	1 MBq	N/A
Chlorine 36	0.37 MBq	10000 MBq	N/A
Cobalt 57	0.37 MBq	1000 MBq	N/A
Cobalt 60	0.01 MBq	0.1 MBq	0.3 Bq
Hydrogen 3	37 MBq	1 TBq	37 kBq
Iron 55	3.7 MBq	10000 MBq	N/A
Mercury 203	0.1 MBq	10 MBq	N/A
Natural Uranium	0.01 MBq	1.4 kg	N/A
Nickel 63	0.1 MBq	10000 MBq	N/A
Niobium 95	0.01 MBq	N/A	N/A
Strontium 85	0.1 MBq	1 MBq	N/A
Strontium 90	0.1 MBq	1 MBq	0.3 Bq
Tin 113	1 MBq	N/A	N/A
Yttrium 88	0.01 MBq	0.1 MBq	3 Bq

Decommissioning

The licensee shall ensure that prior to decommissioning any area, room or enclosure where the licensed activity has been conducted:

1) the non-fixed contamination for nuclear substances listed in the licence application guide table titled "Classification of Radionuclides" does not exceed:
   a) 0.3 becquerels per square centimetre for all Class A radionuclides;
   b) 3 becquerels per square centimetre for all Class B radionuclides;
   c) 30 becquerels per square centimetre for all Class C radionuclides; averaged over an area not exceeding 100 square centimetres;
2) the release of any area, room or enclosure containing fixed contamination, is approved in writing by the Commission or person authorized by the Commission;
3) all nuclear substances and radiation devices have been transferred in accordance with the conditions of this licence; and
4) all radiation warning signs have been removed or defaced.

Sealed Source Tracking

Unless otherwise permitted by the prior written approval of the Commission or a person authorized by the Commission the licensee shall, in respect of a radioactive nuclear substance set out:

1) in table 15.12.3 column 1, report in writing to the Commission or a person authorized by the Commission any transfer, receipt, export, or import of a sealed source whose corresponding activity is equal to or greater than the value set out in column 2; or

2) in B-LIST-67874-00001 section 3.0 or B-LIST-67874-00002, report in writing to the Commission or a person authorized by the Commission any transfer, receipt, import or export of any sealed source:
   a) at least 24 hours before any transfer within Canada;
   b) at least 7 days before any export; and
   c) within 48 hours of any receipt of a transfer or import.

Table 15.12.3: Activity Limits

Column 1 Nuclear Substance	Column 2 (TBq)
Americium 241	0.6
Americium 241/Beryllium	0.6
Californium 252	0.2
Curium 244	0.5
Cobalt 60	0.3
Cesium 137	1
Gadolinium 153	10
Iridium 192	0.8
Promethium 147	400
Plutonium 238	0.6
Plutonium 239/Beryllium	0.6
Radium 226	0.4
Selenium 75	2
Strontium 90 (Yttrium 90)	10
Thulium 170	200
Ytterbium 169	3

The written report shall be in a form acceptable to the Commission that includes:
1) on transfer or export of a sealed source(s),
   a) the date of transfer or export,
   b) the export licence number (where applicable),
   c) the name of the recipient and licence number or the name of the importer,
   d) the address of the recipient's or importer's authorized location,
   e) the nuclear substance (radionuclide),
   f) activity (radioactivity) (Bq) per sealed source on the reference date,
   g) the reference date,
   h) the number of sealed source(s),
   i) the aggregate activity (Bq),
   j) the sealed source unique identifiers (if available), and
   k) where the sealed source is incorporated in a prescribed equipment,
      i. the name and model number of the equipment, and
      ii. the equipment serial number (if available)

2) on receipt or import of a sealed source(s),
   a) the date of receipt of a transfer or import,
   b) the name of the shipper and licence number or the name of the exporter,
   c) the address of the shipper's or exporter's authorized location,
   d) the nuclear substance (radionuclide),
   e) activity (radioactivity) (Bq) per sealed source on the reference date,

f) the reference date,
g) the number of sealed source(s),
h) the aggregate activity (Bq),
i) sealed source unique identifiers (if available), and
j) where the sealed source is incorporated in a prescribed equipment,
    i. the name and model number of the equipment, and
    ii. the equipment serial number (if available)

Annual Compliance Report for Nuclear Substances and Prescribed Equipment
The licensee is required to submit to the Commission the annual compliance report by March 31 of each year. The report shall include activities covering the nuclear substances and prescribed equipment listed in this section of the LCH.

The report shall include:

- information on the activities conducted during the previous year,
- the current inventory of radiation devices, sealed sources, and unsealed sources, and
- information on any transfers or disposals.

Import and Export Restrictions
The licensee shall not import or export any items described in the schedule, Parts A and B, to the *Nuclear Non-proliferation Import and Export Control Regulations*, without a valid import/export licence issued by the CNSC.

The import or export licence issued by the CNSC includes licence conditions to verify compliance with the *Nuclear Non-proliferation Import and Export Control Regulations*. CNSC inspectors can verify compliance by reviewing shipping documents pertaining to imports and exports.

Export Limitations – Sealed Sources
The licence does not authorize the licensee, in respect of a radioactive nuclear substance set out in table 15.12.4 column 1, to export a sealed source whose corresponding activity is equal to or greater than the value set out in column 2.

Table 15.12.4: Export Limitations

Column 1 Nuclear Substance	Column 2 (TBq)
Americium 241	0.6
Americium 241/Beryllium	0.6
Californium 252	0.2
Curium 244	0.5
Cobalt 60	0.3
Cesium 137	1
Gadolinium 153	10
Iridium 192	0.8
Promethium 147	400
Plutonium 238	0.6
Plutonium 239/Beryllium	0.6
Radium 226	0.4
Selenium 75	2
Strontium 90 (Yttrium 90)	10

Thulium 170	200
Ytterbium 169	3

Import and Export of Nuclear Substances as Contamination on Equipment
The licensee is authorized to import and export nuclear substances present as contamination on equipment, subject to activity limits per package provided in table 15.12.5. It is not necessary to notify the CNSC of shipments, including destination.

Table 15.12.5: Authorized import and export of nuclear substances present as contamination

Unsealed Nuclear Substance	Maximum activity per package
Iron 55	400 GBq
Cobalt 60	40 GBq
Niobium 95	40 GBq
Antimony 124	40 GBq
Zirconium 95	40 GBq
Carbon 14	4 TBq
Natural Uranium	1 MBq
Activated materials	10 GBq
Fission products	10 GBq

Location Notification
The licensee shall, for any site where licensed activities are to be conducted for more than 90 consecutive days, notify the Commission in writing of the site within 7 days of starting to conduct the activities at the site. The licensee shall notify the Commission in writing within 7 days of the discontinuance of licensed activities at any site. The continuity of consecutive days is not broken during offsite use or offsite temporary storage.

Maintenance Limitations
The licence authorizes the cleaning and lubrication of the radiation devices listed in this section, in accordance with the manufacturer's operating manual.

Guidance:

Guidance Publications

Org	Document Title	Document #	Version
CNSC	Import and Export, Version 2	REGDOC-2.13.2	2018

APPENDIX A – Acronyms and Definitions

A.1 Acronyms

The following is the list of acronyms used in the LCH:

ADL	Administrative Dose Limits
AIA	Authorized Inspection Agency
AL	Action Levels
ALARA	As Low As Reasonably Achievable
AMP	Aging Management Plan
ASME	American Society of Mechanical Engineers
BDBA	Beyond-Design-Basis Accident
BEAU	Best Estimate Analysis and Uncertainty
BOP	Balance of Plant
BPMS	Bruce Power Management System
BRPD	Bruce Regulatory Program Division
CANDU	Canadian Deuterium Uranium
CCW	Condenser Cooling Water
CNSC	Canadian Nuclear Safety Commission
CSA	Canadian Standards Association
cUL/ULC	Underwriters Laboratory of Canada
CVC	Compliance Verification Criteria
DBA	Design-Basis Accident
DCR	Document Change Request
DG	Director General
DPRR	Directorate of Power Reactor Regulation
DRL	Derived Release Limits
EAL	Environmental Action Levels
ECCC	Environment and Climate Change Canada
EFPH	Equivalent Full Power Hours
EMS	Environmental Management System
EQ	Environmental Qualification
ERA	Environmental Risk Assessment
FFSG	Fitness for Service Guidelines
$[H_{eq}]$	Hydrogen Equivalent Concentration
HTO	Hydrogenated Tritium Oxide (Tritium)
I&C	Instrumentation and control
IAEA	International Atomic Energy Agency
IFB	Industrial Fire Brigade
IIP	Integrated Implementation Plan
IUCs	Instrument Uncertainty Calculations
LC	Licence Condition
LCH	Licence Conditions Handbook
LCMP	Life Cycle Management Plans
LOE	Limit of Operating Envelope
LVRF	Low Void Reactivity Fuel
mfp	Mixed Fission Products
MECP	Ministry of Environment, Conservation and Parks

NCB	National Certification Body
NDE	Non-destructive Examination
NEW	Nuclear Energy Worker
NFPA	National Fire Protection Association
NGS	Nuclear Generating Station
NMAR	Nuclear Material Accountancy Reporting
NOP/ROP	Neutron Overpower Protection/Regional Overpower Protection
NPP	Nuclear Power Plant
NSCA	*Nuclear Safety and Control Act*
OP&P	Operating Policies and Principles
OPEX	Operating Experience
OPG	Ontario Power Generation Inc.
OSRs	Operational Safety Requirements
ppm	Parts per million
PBQA	Pressure Boundary Quality Assurance
PIDP	Public Information and Disclosure Program
PIP	Periodic Inspection Program
PROL	Nuclear Power Reactor Operating Licence
PSA	Probabilistic Safety Assessment
PSR	Periodic Safety Review
ROE	Realistic Operating Envelope
RPD	Regulatory Program Division
SAMGs	Severe Accident Management Guidelines
SAT	Systematic Approach to Training
SCA	Safety and Control Area
SCO	Station Containment Outage
SOE	Safe Operating Envelope
SPOC	Single Point of Contact
SQ	Seismic Qualification
SSCs	Structures, systems and components
VB	Vacuum Building
WN	Written Notification [document]

A.2 Definitions

The following is a list of definitions of words or expressions used in the LCH that may need clarification. Unless a reference source is provided in parenthesis, the words or expressions have been defined for the purpose of the LCH. Additional definitions could be found in REGDOC-3.6, GLOSSARY OF CNSC TERMINOLOGY.

Accept/ed/able/ance

Meet regulatory requirements, which mean it is in compliance with regulatory documents or technical standards referenced in the licence.

Approval

Commission's permission to proceed, for situations or changes where the licensee would be:

- not compliant with a regulatory requirements set out in applicable laws and regulations; or
- not compliant with a licence condition; or
- not in the safe direction but the objective of the licensing basis is met.

Boundary conditions (context differs from REGDOC-3.6)

Procedural, administrative rules and operating limits for ensuring safe operation of the facility based on safety analysis. It also includes any applicable regulatory requirements.

Certified staff

Trained licensee staff, certified by the Commission to be competent in completing tasks identified in their respective roles.

Compliance verification criteria

Criteria used by CNSC staff to verify compliance with a licence condition. CVC provides the licensee and CNSC staff with detailed information to clarify regulatory requirements for compliance purposes.

Consent

Written permission to proceed, given by CNSC delegated authority, for situations or changes where the licensee would:

- comply with a regulatory requirements set out in applicable laws and regulations;
- comply with a licence condition; and
- not adversely impact the licensing basis.

Effective date

The date that a given document becomes incorporated into the licensing basis within the licensing period.

Extent of condition

Means an evaluation to determine if an issue has potential or actual applicability to other activities, processes, equipment, programs, facilities, operations or organizations.

Graduated enforcement

A process for escalating enforcement action. If initial enforcement action does not result in timely

compliance, gradually more severe enforcement actions may need to be used. It takes into account such things as:

- the risk significance of the non-compliance with respect to health, safety, security, the environment and international obligations;
- the circumstances that lead to the non-compliance (including acts of willfulness);
- previous compliance record; and
- operational and legal constraints (for example, Directive on the Health of Canadians)
- industry specific strategies.

Levels 1 and 2 Outage Plans

A level 1 outage plan is a schedule which identifies the key components of the finalized critical path, major projects and programs. A level 2 outage plan is a schedule which identifies the system windows with durations.

Program(s)

A documented group of planned activities, procedures, processes, standards and instructions coordinated to meet a specific purpose.

Qualified staff

Trained licensee staff, deemed competent and qualified to carry out tasks associated to their respective positions.

Guidance

These are non-mandatory suggestions on how to comply with the licence condition. Guidance may include regulatory advice and/or recommended industry best practices to guide the licensee towards a higher level of safety and/or fully satisfactory performance/implementation of its programs.

Safe direction

Means changes in plant safety levels which would not result in:

- a reduction in safety margins,
- a breakdown of barrier,
- an increase (in certain parameters) above accepted limits,
- an increase in risk,
- impairment(s) of special safety systems,
- an increase in the risk of radioactive releases or spills of hazardous substances,
- injuries to workers or members of the public,
- introduction of a new hazard,
- reduction of the defense-in-depth provisions,
- reducing the capability to control, cool and contain the reactor while retaining the adequacy thereof, and
- causing hazards or risks different in nature or greater in probability or magnitude than those stated in the safety analysis of the nuclear facility.

Safety and control measures

Criteria used in assessing the compliance of a licence application with regulatory requirements. These measures or provisions demonstrate that the applicant:

(i) is qualified to carry on the licensed activities, and

(ii) has made adequate provision for the protection of the environment, the health and safety of persons, the maintenance of national security and any measures required to implement international obligations to which Canada has agreed.

Shall

Is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the licence.

Written Notification

A physical or electronic communication that follows established communication protocols.

APPENDIX B – List of All Version-Controlled Documents

B.1 – All Canadian Standards Association (CSA) documents

Document #	Document Title	Issue Date	L.C.
N286	Management system requirements for nuclear facilities	2012	1.1
N290.15	Requirements for the safe operating envelope for nuclear power plants	2010 Update 1 (2016)	3.1
N286.7	Quality assurance of analytical, scientific, and design computer programs	2016	4.1
N290.12	Human factors in design for nuclear power plants	2014	5.1
N290.14	Qualification of digital hardware and software for use in instrumentation and control applications for nuclear power plants	2015	5.1
N291	Requirements for safety-related structures for CANDU nuclear power plants (2015)	2015	5.1, 6.1
N285.0	General requirements for pressure-retaining systems and components in CANDU nuclear power plants	2012 Update No. 1 (Sep. 2013) & Update No. 2 (Nov. 2014)	5.2
N289.1	General requirements for seismic design and qualification of CANDU nuclear power plants	2008	5.3
N289.2	Ground motion determination for seismic qualification of CANDU nuclear power plants	2010	5.3
N289.3	Design procedures for seismic qualification of CANDU nuclear power plants	2010	5.3
N289.4	Testing procedures for seismic qualification of nuclear power plant structures, systems, and components	2012	5.3
N289.5	Seismic instrumentation requirements for nuclear power plants and nuclear facilities	2012	5.3
N290.13	Environmental qualification of equipment for CANDU nuclear power plants	Reaffirmed 2015	5.3
N285.4	Periodic inspection of CANDU nuclear power plant components	2014	6.1
N285.5	Periodic inspection of CANDU nuclear power plant containment components	2008	6.1
N285.5	Periodic inspection of CANDU nuclear power plant containment components	2018	6.1
N285.7	Periodic inspection of CANDU nuclear power plant balance of plant systems and components	2015	6.1
N285.8	Technical requirements for in-service evaluation of zirconium alloy pressure tubes in CANDU reactors	2015 Update 1 (Oct. 2019)	6.1
N287.7	In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plant components	2008	6.1

Document #	Document Title	Issue Date	L.C.
N288.1	Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	2008 Update No.1 (2011)	9.1
N288.1	Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	2014 Updates No. 1 (May 2017), No. 2 (Nov. 2017), and No. 3 (Jun. 2018)	9.1
N288.4	Environmental monitoring program at Class I nuclear facilities and uranium mines and mills	2010	9.1
N288.5	Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills	2011	9.1
N288.6	Environmental risk assessments at Class I nuclear facilities and uranium mines and mills	2012	9.1
N288.7	Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	2015	9.1
N288.8	Establishing and implementing action levels for releases to the environment from nuclear facilities	2017	9.1
N292.3	Management of low- and intermediate-level radioactive waste	2014	11.1
N290.7	Cyber security for nuclear power plants and small reactor facilities	2014	12.1
N293	Fire protection for nuclear power plants	2012	10.2

CSA standards are the proprietary of the Canadian Standards Association (CSA Group) and are covered by copyright law. The CNSC has an online subscription (licence agreement) with the CSA Group for CNSC staff to access the nuclear standards ("my subscription"). The public has read-only access through the following platform:

https://community.csagroup.org/community/nuclear

CNSC staff may access standards and codes via e-Access – folder #4021465 – maintained by the Regulatory Framework Division.

B.2 – All Canadian Nuclear Safety Commission (CNSC) documents

Document #	Document Title	Issue Date	L.C.
REGDOC-3.2.1	Public Information and Disclosure	May 2018	G.5
REGDOC-2.1.2	Safety Culture	April 2018	1.1
REGDOC-2.2.4	Fitness for Duty: Managing Worker Fatigue	March 2017	2.1
REGDOC-2.2.4	Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3	January 2021	2.1
REGDOC-2.2.2	Personnel Training, Version 2	Dec. 2016	2.3
REGDOC-2.2.3	Personnel Certification, Volume III: Certifications of Persons Working at Nuclear Power Plants	Sep. 2019	2.4
REGDOC-2.3.2	Accident Management: Severe Accident Management Programs for Nuclear Reactors	Sep. 2013	3.1
REGDOC-3.1.1	Reporting Requirements: Nuclear Power Plants, Version 2	April 2016	3.3

Document #	Document Title	Issue Date	L.C.
N/A	Interpretation of REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants, Revision 1	September 2018	3.3
REGDOC-2.4.1	Deterministic Safety Analysis	May 2014	4.1
REGDOC- 2.4.2	Probabilistic Safety Assessment (PSA) For Nuclear Power Plants	May 2014	4.1
REGDOC-2.6.1	Reliability Programs for Nuclear Power Plants	August 2017	6.1
REGDOC-2.6.2	Maintenance Programs for Nuclear Power Plants	August 2017	6.1
REGDOC-2.6.3	Aging Management	March 2014	6.1
REGDOC- 2.9.1	Environmental Protection: Environmental Principles, Assessments and Protection Measures, Version 1.2	Sep. 2020	9.1
REGDOC-2.10.1	Nuclear Emergency Preparedness and Response	Oct. 2014	10.1
REGDOC-2.12.1	High-Security Facilities, Vol. I: Nuclear Response Force, Version 2	Sep. 2018	12.1
REGDOC-2.12.1	High-Security Facilities, Vol. II: Criteria for Nuclear Security Systems and Devices	Sep. 2018	12.1
REGDOC- 2.12.2	Site Access Security Clearance	April 2013	12.1
REGDOC-2.12.3	Security of Nuclear Substances: Sealed Sources	May 2013	12.1
REGDOC-2.2.4	Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, and Psychological Fitness	Sep. 2018	12.1
REGDOC-2.13.1	Safeguards and Nuclear Material Accounting	February 2018	13.1
REGDOC-2.3.3	Periodic Safety Reviews	April 2015	15.6
RD-327	Nuclear Criticality Safety	Dec. 2010	15.9

ALL CNSC REGULATORY DOCUMENTS CAN BE FOUND ON THE CNSC WEBSITE:
http://www.nuclearsafety.gc.ca

Any superseded regulatory document may be requested through the email account:
cnsc.consultation.ccsn@canada.ca

In addition, the following documents are referenced in the LCH under CVC:

Document #	Document Title	Date	L.C.	e-Docs
EG1	Requirements and Guidelines for Written and Oral Certification Examinations for Shift Personnel at Nuclear Power Plants	July 2005	2.3	3402702
EG2	Requirements and Guidelines for Simulator-based Certification Examinations for Shift Personnel at Nuclear Power Plants	June 2004	2.3	3402705
N/A	Requirements for the Requalification Testing of Certified Shift Personnel at Nuclear Power Plants	May 2009	2.3	3436327

APPENDIX C – List of Documents used as Guidance

C.1 – Other Codes or Standards to be used as guidance

Document #	Document Title	L.C.
CSA N286.0.1	Commentary on N286-12, Management system requirements for nuclear facilities (2014)	1.1
CSA N290.11	Requirements for heat removal capability during outage of nuclear power plants (2013)	3.1
CSA N290.16	Requirements for beyond design basis accidents (2016)	3.1
CSA N290.17	Probabilistic safety assessment for nuclear power plants (2017)	4.1
CSA N292.1	Wet storage of irradiated fuel and other radioactive materials (2016)	4.1
CSA N292.2	Interim dry storage of irradiated fuel (2013)	4.1
COG-09-9030	Principles & Guidelines For Deterministic Safety Analysis	4.1
COG-11-9023	Guidelines for Application of the LOE/ROE Methodologies to Deterministic Safety Analysis	4.1
COG-06-9012	Guidelines for Application of the Best Estimate Analysis and Uncertainty (BEAU) Methodology to Licensing Analysis	4.1
COG-08-2078	Principles and Guidelines for NOP/ROP Trip Setpoint Analysis for CANDU Reactors	4.1
COG-13-9035	Derived Acceptance Criteria For Deterministic Safety Analysis	4.1
CSA N286.10	Configuration management for high energy reactor facilities (2016)	5.1
CSA N287.1	General requirements for concrete containment structures for CANDU nuclear power plants (2014)	5.1
CSA N287.2	Material requirements for concrete containment structures for CANDU nuclear power plants (2008)	5.1
CSA N287.3	Design requirements for concrete containment structures for CANDU nuclear power plants (2014)	5.1
CSA N287.4	Construction, fabrication, and installation requirements for concrete containment structures for CANDU nuclear power plants (2009)	5.1
CSA N287.5	Examination and testing requirements for concrete containment structures for CANDU nuclear power plants (2011)	5.1
CSA N287.6	Pre-operational proof and leakage rate testing requirements for concrete containment structures for CANDU nuclear power plants (2011)	5.1
CSA N290.0	General requirements for safety systems of nuclear power plants (2011)	5.1
CSA N290.1	Requirements for the shutdown systems of CANDU nuclear power plants (2013)	5.1
CSA N290.2	Requirements for emergency core cooling systems of nuclear power plants (2011)	5.1
CSA N290.3	Requirements for the containment system of nuclear power plants (2016)	5.1
CSA N290.4	Requirements for reactor control systems of nuclear power plants (2011)	5.1
CSA N290.5	Requirements for electrical power and instrument air systems of CANDU nuclear power plants (2016)	5.1
CSA N290.6	Requirements for monitoring and display of nuclear power plant safety functions in the event of an accident (2009, R2014)	5.1
(USNRC) UFC-3-340-02	Unified Facilities Criteria – Structures to Resist the Effects of Accidental Explosions	5.1

Document #	Document Title	L.C.
ASME B31.1	Power Piping	5.2
ASME B31.3	Process Piping	5.2
ASME B31.5	Refrigeration Piping and Heat Transfer Components	5.2
ASME	Boiler and Pressure Vessel Code – Code Cases	5.2
CSA B51	Boiler, Pressure Vessel and Piping Code	5.2
CSA N285.0	General requirements for pressure-retaining systems and components in CANDU nuclear power plants (2017)	5.2
COG-05-9011	Interim Implementation Guidelines for CANDU Nuclear Plant Reliability Programs	6.1
CSA N285.4	Construction, fabrication, and installation requirements for concrete containment structures for CANDU nuclear power plants (2014)	6.1
CSA N287.8	Aging management for concrete containment structures for nuclear power plants (2015)	6.1
CSA N290.9	Reliability and maintenance programs for nuclear power plants (2019)	6.1
CSA N288.3.4	Performance testing of nuclear air-cleaning systems at nuclear facilities (2013)	9.1
CSA N288.9	Guideline for design of fish impingement and entrainment programs at nuclear facilities (2018)	9.1
CSA N1600	General requirements for nuclear emergency management programs (2016)	10.1
NEI 00-01	Guidance for Post Fire Safe Shutdown Circuit Analysis	10.2
CSA N293-12 (R2017)	Fire protection for nuclear power plants (2012 R2017)	10.2
CSA N292.0	General principles for the management of radioactive waste and irradiated fuel (2014)	11.1
CSA N292.1	Wet storage of irradiated fuel and other radioactive materials (2016)	11.1
CSA N292.2	Interim dry storage of irradiated fuel	11.1
N/A	TBS Standard on Security Screening	12.1
CSA N292.5	Guideline for the exemption of clearance from regulatory control of materials that contain, or potentially contain, nuclear substances (2011)	11.1
IAEA	IAEA Nuclear Security Series No. 4 Technical Guidance: Engineering Safety Aspects of the Protection of Nuclear Power Plants Against Sabotage	12.1
IAEA	IAEA Nuclear Security Series No. 13 Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5)	12.1
IAEA	IAEA Nuclear Security Series No. 17 Technical Guidance: Computer Security at Nuclear Facilities	12.1
IAEA	IAEA Nuclear Security Series No 33-T Technical Guidance: Computer Security of Instrumentation and Control Systems at Nuclear Facilities	12.1
COG JP-4491-V197	Fuel Channel Life Management – Third Party Review of Probabilistic Fracture Protection Evaluation Methodology Acceptance Criteria (2017)	15.3
IAEA	Specific Safety Guide Series No. SSG-28 Commissioning for Nuclear Power Plants	15.5
IAEA	Specific Safety Requirements Series No. SSR-2/2 Safety of Nuclear Power Plants: Commissioning and Operation	15.5
CSA N290.18	Periodic safety review for nuclear power plants (2017)	15.6

Document #	Document Title	L.C.
IAEA	Specific Safety Guide No. SSG-25 Periodic Safety Review for Nuclear Power Plants	15.6

Canadian standards/codes and international documents can be found on the internet under the organization's website. CNSC staff may access standards and codes via e-Access folder #4021465 – maintained by the Regulatory Framework Division.

C.2 – Other CNSC documents referenced in the LCH

Document #	Document Title	L.C.
REGDOC-3.5.3	Regulatory Fundaments, Version 2	G.1
REGDOC-3.2.1	Public Information and Disclosure (2018)	G.5
REGDOC-3.2.2	Indigenous Engagement, Version 1.1 (2019)	G.5
REGDOC-2.1.1	Management System (2019)	1.1
REGDOC-2.2.1	Human Factors (2019)	2.1
REGDOC-2.2.5	Minimum Shift Complement (2019)	2.2
REGDOC-2.5.1	General Design Considerations: Human Factors	2.2, 5.1
REGDOC-2.3.2	Accident Management, Version 2 (2015)	3.1, 10.1
REGDOC-2.5.2	Design of Reactor Facilities: Nuclear Power Plants (2014)	5.1
G-129	Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA)" (2004)	7.1
G-228	Developing and Using Action Levels (2001)	7.1
REGDOC-2.8.1	Conventional Health and Safety (2019)	8.1
REGDOC-2.10.1	Nuclear Emergency Preparedness and Response, Version 2 (2016)	10.1
G-274	Security Programs for Category I or II Nuclear Material or Certain Nuclear Facilities (2003)	12.1
G-208	Transportation Security Plans for Category I, II or III Nuclear Material (2003)	12.1
REGDOC-2.12.1	High-Security Facilities, Volume II: Criteria for Nuclear Security Systems and Devices (2018)	12.1
REGDOC-2.12.3	Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, Version 2.1 (2020)	12.1
REGDOC-2.13.2	Import and Export, Version 2 (2018)	13.1 15.12
REGDOC-2.14.1	Packaging and Transport: Information Incorporated by Reference in Canada's *Packaging and Transport of Nuclear Substances Regulations*, 2015, Volume I, Version 2 (2021)	14.1
REGDOC-2.3.1	Conduct of Licensed Activity: Construction and Commissioning Programs (2016)	15.5
GD-327	Guidance for Nuclear Criticality Safety (2010)	15.9
REGDOC-2.4.3	Nuclear Criticality Safety, Version 1.1 (2020)	15.9

ALL CNSC REGULATORY DOCUMENTS CAN BE FOUND ON THE CNSC WEBSITE:
http://www.nuclearsafety.gc.ca

APPENDIX D – List of Licensee Documents Requiring Written Notification

Document #	Document Title	Notification Requirements	L.C.
GENERAL			
BP-PROG-03.01	Document Management	At Implementation	G.2
BP-PROC-00166	Management of Program, Procedure and Internal Standard Documents	At Implementation	G.2
NK37-DRAW-10200-10001	Site Facilities Plan of the Bruce Nuclear Power Development Lots 11 to 28 and Part of 29 and 30	Prior to Implementation	G.3
NK21-SR-01320-00001	Bruce A Safety Report Part 1: Plant and Site Description	Prior to Implementation	G.3
NK29-SR-01320-00001	Bruce B Safety Report Part 1: Plant and Site Description	Prior to Implementation	G.3
BP-PROG-09.02	Stakeholder Engagement	At Implementation	G.5
MANAGEMENT SYSTEM			
BP-MSM-1	Management System Manual	Prior to Implementation	1.1
BP-PROG-16.01	Conduct of Business	Prior to Implementation	1.1
BP-PROG-05.01	Supply Chain	At Implementation	1.1
BP-PROG-15.01	Independent Oversight Management	At Implementation	1.1
BP-PROG-14.01	Project Management and Construction	At Implementation	1.1
BP-PROG-14.02	Contractor Management	At Implementation	1.1
BP-PROC-00001	Organization Structure Change	At Implementation	1.1
HUMAN PERFORMANCE MANAGEMENT			
BP-PROC-00005	Limits to Hours of Work	Prior to Implementation	2.1
BP-PROG-16.01	Conduct of Business	Prior to Implementation	2.1
BP-PROC-00610	Fitness For Duty	At Implementation	2.1
GRP-OPS-00055	Fitness for Duty Considerations for Shift Complement Staff Held Over for More than 13 Hours	At Implementation	2.1
DIV-OPA-00001	Station Shift Complement – Bruce A	Prior to Implementation	2.2
DIV-OPB-00001	Station Shift Complement – Bruce B	Prior to Implementation	2.2
BP-PROG-02.01	Human Resources Management	At Implementation	2.1
BP-PROG-02.02	Worker Learning and Qualification	At Implementation	2.3
BP-PROC-01071	Systematic Approach to Training Process	Prior to Implementation	2.3

Document #	Document Title	Notification Requirements	L.C.
DIV-OPA-00002	Bruce A Role Descriptions for Licence-Related Positions	Prior to Implementation	2.4
DIV-OPB-00002	Bruce B Role Description for Licence-Related Positions	Prior to Implementation	2.4
BP-PROC-00568	Certification Training – Development and Administration of Comprehensive Written and Oral Examinations for Certification Training	Prior to Implementation	2.4
B-HBK-09510-00012	Certification Training Examinations – Standards for Development and Administration of Closed Reference Multiple Choice Questions for Initial General Certification Written Examinations	Prior to Implementation	2.4
OPERATING PERFORMANCE			
BP-OPP-00001	Operating Policies and Principles – Bruce B	Prior to Implementation	3.1
BP-OPP-00002	Operating Policies and Principles – Bruce A	Prior to Implementation	3.1
BP-OPP-00003	Operating Policies and Principles – Central Maintenance and Laundry Facility	Prior to Implementation	3.1
BP-PROG-12.01	Conduct of Plant Operations	At Implementation	3.1
NK21-OSR-31000-00001	Operational Safety Requirements for Bruce A Fuel and Reactor Physics	At Implementation	3.1
NK21-OSR-32000-00001	Operational Safety Requirements for Bruce A Moderator System	At Implementation	3.1
NK21-OSR-33100-00001	Bruce A NGS: Operational Safety Requirements for Heat Transport System	At Implementation	3.1
NK21-OSR-34110-00001	Operational Safety Requirements for Bruce A End Shield Cooling System	At Implementation	3.1
NK21-OSR-34200-00004	Operational Safety Requirements for Bruce A Containment System	At Implementation	3.1
NK21-OSR-34340-00003	Operational Safety Requirements for Bruce A Emergency Coolant Injection System	At Implementation	3.1
NK21-OSR-34360-00001	Operational Safety Requirements for Bruce A Powerhouse Emergency Venting System	At Implementation	3.1
NK21-OSR-34700-00001	Operational Safety Requirements for Bruce A Shutdown and Maintenance Cooling Systems	At Implementation	3.1
NK21-OSR-34980-00001	Operational Safety Requirements for Bruce A Annulus Gas System	At Implementation	3.1
NK21-OSR-35000-00001	Operational Safety Requirements for Bruce A Fuel Handling	At Implementation	3.1

Document #	Document Title	Notification Requirements	L.C.
NK21-OSR-36100-00001	Operational Safety Requirements for Bruce A Main Steam Supply System	At Implementation	3.1
NK21-OSR-38330/21175-00001	Operational Safety Requirements for Bruce A Confinement	At Implementation	3.1
NK21-OSR-43200-00001	Operational Safety Requirements for Bruce A Feedwater and Condensate System	At Implementation	3.1
NK21-OSR-53000/55000-00001	Operational Safety Requirements for Bruce A Electrical System	At Implementation	3.1
NK21-OSR-54400-00001	Operational Safety Requirements for Bruce A Qualified Power Supply System	At Implementation	3.1
NK21-OSR-60060-00001	Operational Safety Requirements for Bruce A Critical Safety Parameter Monitoring	At Implementation	3.1
NK21-OSR-63710-00001	Operational Safety Requirements for Bruce A Reactor Regulating System	At Implementation	3.1
NK21-OSR-63720-63730-00001	Operational Safety Requirements for Bruce A Shutdown Systems	At Implementation	3.1
NK21-OSR-71310-00001	Operational Safety Requirements for Bruce A Service Water Systems	At Implementation	3.1
NK21-OSR-71910-00001	Operational Safety Requirements for Bruce A Emergency Boiler Cooling System	At Implementation	3.1
NK29-OSR-31000-00001	Operational Safety Requirements for Bruce B Fuel and Reactor Physics	At Implementation	3.1
NK29-OSR-32000-00001	Operational Safety Requirements for Bruce B Moderator System	At Implementation	3.1
NK29-OSR-33000-00001	Operational Safety Requirements for Bruce B Heat Transport System	At Implementation	3.1
NK29-OSR-34110-00001	Operational Safety Requirements for Bruce B End Shield Cooling System	At Implementation	3.1
NK29-OSR-34200-00001	Operational Safety Requirements for Bruce B Containment System	At Implementation	3.1
NK29-OSR-34340-00001	Operational Safety Requirements for Bruce B Emergency Coolant Injection System	At Implementation	3.1
NK29-OSR-34360-00001	Operational Safety Requirements for Bruce B Powerhouse Emergency Venting System	At Implementation	3.1
NK29-OSR-34700-00001	Operational Safety Requirements for Bruce B Shutdown and Maintenance Cooling Systems	At Implementation	3.1
NK29-OSR-34980-00001	Operational Safety Requirements for Bruce B Annulus Gas System	At Implementation	3.1
NK29-OSR-35000-00001	Operational Safety Requirements for Bruce B Fuel Handling	At Implementation	3.1

Document #	Document Title	Notification Requirements	L.C.
NK29-OSR-36100-00001	Operational Safety Requirements for Bruce B Main Steam Supply System	At Implementation	3.1
NK29-OSR-38330-21190-00001	Operational Safety Requirements for Bruce B Confinement	At Implementation	3.1
NK29-OSR-43200-00001	Operational Safety Requirements for Bruce B Feedwater and Condensate System	At Implementation	3.1
NK29-OSR-53000/55000-00001	Operational Safety Requirements for Bruce B Electrical System	At Implementation	3.1
NK29-OSR-54300-00001	Operational Safety Requirements for Bruce B Emergency Power Supply System	At Implementation	3.1
NK29-OSR-60060-00001	Operational Safety Requirements for Bruce B Critical Safety Parameter Monitoring	At Implementation	3.1
NK29-OSR-63710-00001	Operational Safety Requirements for Bruce B Reactor Regulating System	At Implementation	3.1
NK29-OSR-63720-63730-00001	Operational Safety Requirements for Bruce B Shutdown Systems	At Implementation	3.1
NK29-OSR-71310-00001	Operational Safety Requirements for Bruce B Service Water Systems	At Implementation	3.1
NK29-OSR-71380-00001	Operational Safety Requirements for Bruce B Emergency Water System	At Implementation	3.1
NK37-CORR-00531-02784	Bruce Power Safeguards Site Plan 2015	At Implementation	3.1
BP-PROG-06.01	Nuclear Regulatory Affairs	At Implementation	3.3
SAFETY ANALYSIS			
NK21-SR-01320-00002, Part 2	Bruce A Safety Report Part 2: Plant Components and Systems	Prior to Implementation	4.1
NK29-SR-01320-00001, Part 2	Bruce B Safety Report Part 2: Plant Components and Systems	Prior to Implementation	4.1
NK21-SR-01320-00003, Part 3	Bruce A Safety Report Part 3: Safety Analysis	Prior to Implementation	4.1
NK29-SR-01320-00002, Part 3	Bruce B Safety Report Part 3: Safety Analysis	Prior to Implementation	4.1
BP-PROC-00659	Severe Accident Management	At Implementation	4.1
PHYSICAL DESIGN			
BP-PROG-10.01	Configuration Management	Prior to Implementation	5.1
BP-PROG-00.04	Pressure Boundary Quality Assurance Program	At Implementation	5.2
B-LIST-01900-00001	Index to Pressure Boundary Program Elements (CSA N285.0-12 Table N.1)	At Implementation	5.2
DIV-ENG-00017	System and Item Classification	Prior to Implementation	5.2
DIV-ENG-00018	Design Registration and Reconciliation	At Implementation	5.2

Document #	Document Title		Notification Requirements	L.C.
BP-PROC-00261	Environmental Qualification		At Implementation	5.3
FITNESS FOR SERVICE				
BP-PROG-11.04	Plant Maintenance		At Implementation	6.1
BP-PROG-11.01	Equipment Reliability		At Implementation	6.1
NK21-PIP-21100-00001	N287.7	CSA N287.7-08 Periodic Inspection Program for Bruce NGS A Concrete Containment Structures and Appurtenances (Excluding Vacuum Building)	Prior to Implementation	6.1
NK21-PIP-25100-00001		CSA N287.7-08 Periodic Inspection Program for Bruce NGS A Vacuum Building	Prior to Implementation	6.1
NK29-PIP-21100-00001		CSA N287.7-08 Periodic Inspection Program for Bruce NGS B Concrete Containment Structures and Appurtenances (Excluding Vacuum Building)	Prior to Implementation	6.1
NK29-PIP-25100-00001		CSA N287.7-08 Periodic Inspection Program for Bruce NGS B Vacuum Building	Prior to Implementation	6.1
BP-PROC-00815		Visual Inspection of Containment Boundary Components	Prior to Implementation	6.1
NK21-PIP-03641.2-00001	N285.4	Bruce A Periodic Inspection Plan Units 1, 2, 3 and 4	Prior to Implementation	6.1
NK29-PIP-03641.2-00001		Bruce B Periodic Inspection Plan Units 5, 6, 7 and 8	Prior to Implementation	6.1
B-PIP-31100-00002		Bruce Nuclear Generating Station Fuel Channel Periodic Inspection Program	Prior to Implementation	6.1
NK21-PIP-03642-00001	N285.5	Bruce A NGS N285.5 Periodic Inspection Plan for Unit 0 and Units 1 to 4 Containment Components	Prior to Implementation	6.1
NK29-PIP-03642-00001		Bruce B Periodic Inspection Plan for Unit 0 and Units 5 to 8 Containment Components	Prior to Implementation	6.1
B-LCM-20000-00001	Life Cycle Management Plan for Safety Related Civil Structures		Prior to Implementation	6.1
B-LCM-31100-00001	Fuel Channel Life Cycle Management Plan		Prior to Implementation	6.1

Document #	Document Title	Notification Requirements	L.C.
B-PIP-33110-00001	Steam Generator and Preheater Periodic Inspection Plan	Prior to Implementation	6.1
B-PIP-33126-00001	PHT Feeder Piping Periodic Inspection Plan	Prior to Implementation	6.1
BP-PROG-11.02	On-Line Work Management Program	At Implementation	6.1
BP-PROG-11.03	Outage Work Management	At Implementation	6.1
BP-PROG-12.02	Chemistry Management	At Implementation	6.1
RADIATION PROTECTION			
BP-PROG-12.05	Radiation Protection Program	Prior to Implementation	7.1, 11.1
BP-RPP-00044	ALARA Program	At Implementation	7.1
BP-PROC-00280	Dosimetry Requirements	Prior to Implementation	7.1
BP-RPP-00009	Dose Limits and Exposure Control	Prior to Implementation	7.1
CONVENTIONAL HEALTH AND SAFETY			
BP-PROG-00.06	Health and Safety Management	At Implementation	8.1
ENVIRONMENTAL PROTECTION			
BP-PROG-00.02	Environmental Management	Prior to Implementation	9.1
NK21-REP-03482-00002	Derived Release Limits and Environmental Action Levels for Bruce Nuclear Generating Station A	Prior to Implementation	9.1
NK29-REP-03482-00003	Derived Release Limits and Environmental Action Levels for Bruce Nuclear Generating Station B	Prior to Implementation	9.1
NK37-REP-03482-00001	Derived Release Limits and Environmental Action Levels for Central Maintenance and Laundry Facility	Prior to Implementation	9.1
NK37-REP-03482-00002	Derived Release Limits and Environmental Action Levels for Central Storage Facility (CSF)	Prior to Implementation	9.1
BP-PROC-00171	Radiological Emissions	Prior to Implementation	9.1
EMERGENCY MANAGEMENT AND FIRE PROTECTION			
BP-PLAN-00001	Bruce Power Nuclear Emergency Response Plan	Prior to Implementation	10.1
BP-PLAN-00005	Radioactive Material Transportation Emergency Response Plan	At Implementation	10.1
BP-PROG-08.01	Emergency Management Program	At Implementation	10.1
BP-PLAN-00008	Fire Safety Management	At Implementation	10.2
BP-PLAN-00006	Conventional Emergency Plan	At Implementation	10.2
WASTE MANAGEMENT			

Document #	Document Title	Notification Requirements	L.C.
BP-PROG-12.03	Nuclear Fuel Management	At Implementation	11.1
BP-PROG-12.05	Radiation Protection Program	Prior to Implementation	7.1, 11.1
SECURITY			
BP-PROG-08.02	Nuclear Security	Prior to Implementation	12.1
BP-PROC-00784	Cyber Security	At Implementation	12.1
SAFEGUARDS			
NK21-OM-35370	Safeguards Operating Manual (Bruce A) U0 F/H	At Implementation	13.1
NK29-OM-35370	Safeguards Operating Manual (Bruce B) U0 F/H	At Implementation	13.1
PACKAGING AND TRANSPORT			
BP-PROC-00188	Radioactive Material Transportation	At Implementation	14.1
NUCLEAR FACILITY-SPECIFIC			
BP-PROC-00324	Nuclear Criticality Safety Management	Prior to Implementation	15.9
BP-PROC-00003	Cobalt Handling	Prior to Implementation	15.10
BP-PROG-xx.xx (number will be assigned prior to IPS commissioning)	Irradiation Services	At Implementation	15.10
BP-PROC-01120	Management of Lutetium-177 Production	At Implementation	15.10
BP-PROC-00817	Management of Class II Nuclear Facilities	At Implementation	15.11
BP-PROC-00143	Leak Testing	At Implementation	15.11, 15.12
NK29-CMP-67880-00001	Radiation Calibration Facility Safety Interlock Checks and Operation	At Implementation	15.11
NK29-DRAW-67880-10001	Radiation Calibration Facility General Arrangement Drawing	At Implementation	15.11
NK29-DRAW-67880-10003	Radiation Calibration Facility General Arrangement Drawing	At Implementation	15.11
B-LIST-67874-00001	Nuclear Substances and Prescribed Equipment List	Prior to Implementation	15.11, 15.12
BP-RPP-00043	Management of Nuclear Substances and Radiation Generating Equipment	At Implementation	15.12
NK21-CMP-67870-00002	Hopewell Designs BX-3-Box Calibrator Pre-Use Operational and Safety Interlock Checks	At Implementation	15.12
BP-PROC-00036	Conduct of Radiography	At Implementation	15.12
BP-PROC-00798	Radiography Emergency Procedures	At Implementation	15.12

APPENDIX D - LIST OF LICENSEE DOCUMENTS REQUIRING WRITTEN NOTIFICATION

Document #	Document Title	Notification Requirements	L.C.
B-LIST-67874-00002	Security Protected Nuclear Substances and Prescribed Equipment List	Prior to Implementation	15.12

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

PDF Ref.: e-Doc 6113854
Word Ref.: e-Doc 6113849
File / Dossier: 2.01

NUCLEAR POWER REACTOR OPERATING LICENCE

BRUCE NUCLEAR GENERATING STATIONS A AND B

I) LICENCE NUMBER: **PROL 18.01/2028**

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act* this licence is issued to:

Bruce Power Inc.
P.O. Box 1540, R.R. #2
Building B10, 177 Tie Road
Municipality of Kincardine
Tiverton, Ontario
N0G 2T0

III) LICENCE PERIOD: This licence is valid from October 1, 2018 to September 30, 2028, unless suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(i) operate the Bruce Nuclear Generating Stations A and B (hereinafter "Bruce A and B") comprised of reactor units 1 to 4 and 5 to 8 respectively, at the Bruce site located in the County of Bruce in the regional municipality of Kincardine, Province of Ontario; and,

(1) possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities described in (i), except for booster fuel assemblies;

(2) possess, transfer and use prescribed equipment that is required for, associated with, or arises from the activities described in (i);

(3) possess and use prescribed information that is required for, associated with, or arises from the activities described in (i);

(ii) operate a Class II nuclear facility at the Bruce site; and,

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

(2) possess, transfer and use prescribed equipment that is required for, associated with, or arises from the activities described in (ii);

(iii) possess, transfer, use, manage and store nuclear substances and prescribed equipment to perform industrial radiography throughout the Bruce site;

(iv) import and export nuclear substances and prescribed equipment, except controlled nuclear substances and controlled nuclear equipment, that are required for, associated with, or arise from the activities described in (i), (ii) and (iii);

(v) possess, manage and store booster fuel assemblies at Bruce A; and

(vi) produce Cobalt-60 at Bruce B.

V) EXPLANATORY NOTES:

(i) Nothing in this licence shall be construed to authorize non-compliance with any other applicable legal obligation or restriction.

(ii) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* and associated Regulations.

(iii) The BRUCE NGS A AND B LICENCE CONDITIONS HANDBOOK (LCH) provides compliance verification criteria including the Canadian standards and regulatory documents used to verify compliance with the conditions in the licence. The LCH also provides information regarding delegation of authority, applicable versions of documents and non-mandatory recommendations and guidance on how to achieve compliance.

VI) CONDITIONS:

G. General

G.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations;

(ii) the conditions and safety control measures described in the facilities' licence and the documents directly referenced in that licence;

(iii) the safety and control measures described in the licence applications and the documents needed to support those licence applications;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (CNSC) (hereinafter "the Commission").

G.2 The licensee shall give written notification of changes to the facilities or their operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.

G.3 The licensee shall control the use and occupation of any land within the exclusion zones.

G.4 The licensee shall provide, at the Bruce site and at no expense to the Commission, office space for employees of the Commission who customarily carry out their functions on the premises of Bruce A and B (onsite Commission staff).

G.5 The licensee shall implement and maintain a public information and disclosure program.

1. Management System

1.1 The licensee shall implement and maintain a management system.

2. Human Performance Management

2.1 The licensee shall implement and maintain a human performance program.

2.2 The licensee shall implement and maintain the minimum shift complement and control room staffing for Bruce A and B.

2.3 The licensee shall implement and maintain training programs for workers.

2.4 The licensee shall implement and maintain certification programs in accordance with CNSC [Amended regulatory document REGDOC-2.2.3, PERSONNEL CERTIFICATION, VOLUME III: CERTIFICATION 2020-03] OF PERSONS WORKING AT NUCLEAR POWER PLANTS.

Persons appointed to the following positions require certification:

(i) authorized health physicist;
(ii) authorized nuclear operator;
(iii) control room shift supervisor; (iv) Unit 0 control room operator; and (v) shift manager.

3. Operating Performance

3.1 The licensee shall implement and maintain an operations program, which includes a set of operating limits.

3.2 The licensee shall not restart a reactor after a serious process failure without the prior written approval of the Commission, or prior written consent of a person authorized by the Commission.

3.3 The licensee shall notify and report in accordance with CNSC regulatory document REGDOC-3.1.1 REPORTING REQUIREMENTS FOR NUCLEAR POWER PLANTS.

4. Safety Analysis

4.1 The licensee shall implement and maintain a safety analysis program.

5. Physical Design

5.1 The licensee shall implement and maintain a design program.

5.2 The licensee shall implement and maintain a pressure boundary program and have in place a formal agreement with an Authorized Inspection Agency.

5.3 The licensee shall implement and maintain an equipment and structure qualification program.

6. Fitness for Service

6.1 The licensee shall implement and maintain a fitness for service program.

7. Radiation Protection

7.1 The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

8. Conventional Health and Safety

8.1 The licensee shall implement and maintain a conventional health and safety program.

9. Environmental Protection

9.1 The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

10. Emergency Management and Fire Protection

10.1 The licensee shall implement and maintain an emergency preparedness program.

10.2 The licensee shall implement and maintain a fire protection program.

11. Waste Management

11.1 The licensee shall implement and maintain a waste management program.

11.2 The licensee shall notify the Commission of any changes regarding the obligations of decommissioning and financial guarantees under the Lease Agreement with Ontario Power Generation Inc., as described in 15.1.

12. Security

12.1 The licensee shall implement and maintain a nuclear security program.

13. Safeguards and Non-Proliferation

13.1 The licensee shall implement and maintain a safeguards program.

14. Packaging and Transport

14.1 The licensee shall implement and maintain a packaging and transport program.

15. Nuclear Facility-Specific

15.1 The licensee shall inform the Commission in writing of any amendments to the Amended and Restated Lease Agreement between Ontario Power Generation Inc., Bruce Power L.P., OPG-Huron A Inc./OPG-Huron B Inc./OPG-Huron Common Facilities Inc., British Energy PLC, Cameco Corporation, TransCanada Pipelines Limited, BPC Generation Infrastructure Trust and Ontario Municipal Employees Retirement Board dated February 14, 2003.

15.2 The licensee shall implement the Integrated Implementation Plan.

15.3 Before hydrogen equivalent concentrations exceed 120 ppm, the licensee shall demonstrate that pressure tube fracture toughness will be sufficient for safe operation beyond 120 ppm.

15.4 The licensee shall implement a return-to-service plan for Major Component Replacement.

15.5 The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.

15.6 The licensee shall conduct and implement a periodic safety review.

15.7 The licensee shall inform the Commission of any reactor to be removed from commercial operations at Bruce A and B, and shall provide a plan describing the activities and timeline for transitioning from operations to safe storage.

15.8 The licensee shall store and manage booster fuel assemblies at Bruce A in a manner that ensures their physical security.

15.9 The licensee shall implement and maintain a nuclear criticality safety program.

15.10 The licensee shall implement and maintain a program for the receipt, storage and handling of the nuclear substance Cobalt-60 at Bruce B.

15.11 The licensee shall implement and maintain a program for the operation of the Class II nuclear facility.

15.12 The licensee shall implement and maintain a program for nuclear substances and prescribed equipment.

SIGNED at OTTAWA April 9, 2020

Rumina Velshi
President
CANADIAN NUCLEAR SAFETY COMMISSION

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

DRAFT PROL 18.02/2028

PDF Ref.: e-Doc 6462573
Word Ref.: e-Doc 6411221
File / Dossier: 2.01

NUCLEAR POWER REACTOR OPERATING LICENCE

BRUCE NUCLEAR GENERATING STATIONS A AND B

I) LICENCE NUMBER: **PROL 18.02/2028**

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act* this licence is issued to:

Bruce Power Inc.
P.O. Box 1540, R.R. #2
Building B10, 177 Tie Road
Municipality of Kincardine
Tiverton, Ontario
N0G 2T0

III) LICENCE PERIOD: This licence is valid from October 1, 2018 to September 30, 2028, unless suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(i) operate the Bruce Nuclear Generating Stations A and B (hereinafter "Bruce A and B") comprised of reactor units 1 to 4 and 5 to 8 respectively, at the Bruce site located in the County of Bruce in the regional municipality of Kincardine, Province of Ontario; and,

(1) possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities described in (i), except for booster fuel assemblies;

(2) possess, transfer and use prescribed equipment that is required for, associated with, or arises from the activities described in (i);

(3) possess and use prescribed information that is required for, associated with, or arises from the activities described in (i);

(ii) operate a Class II nuclear facility at the Bruce site; and,

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

(2) possess, transfer and use prescribed equipment that is required for, associated with, or arises from the activities described in (ii);

(iii) possess, transfer, use, manage and store nuclear substances and prescribed equipment to perform industrial radiography throughout the Bruce site;

(iv) import and export nuclear substances and prescribed equipment, except controlled nuclear substances and controlled nuclear equipment, that are required for, associated with, or arise from the activities described in (i), (ii) and (iii);

(v) possess, manage and store booster fuel assemblies at Bruce A; and

(vi) produce Cobalt-60 and Lutetium-177. [Amended 2021-##]

V) EXPLANATORY NOTES:

(i) Nothing in this licence shall be construed to authorize non-compliance with any other applicable legal obligation or restriction.

(ii) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* and associated Regulations.

(iii) The BRUCE NGS A AND B LICENCE CONDITIONS HANDBOOK (LCH) provides compliance verification criteria including the Canadian standards and regulatory documents used to verify compliance with the conditions in the licence. The LCH also provides information regarding delegation of authority, applicable versions of documents and non-mandatory recommendations and guidance on how to achieve compliance.

VI) CONDITIONS:

G. **General**

G.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations;

(ii) the conditions and safety control measures described in the facilities' licence and the documents directly referenced in that licence;

(iii) the safety and control measures described in the licence applications and the documents needed to support those licence applications;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (CNSC) (hereinafter "the Commission").

G.2 The licensee shall give written notification of changes to the facilities or their operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.

G.3 The licensee shall control the use and occupation of any land within the exclusion zones.

G.4 The licensee shall provide, at the Bruce site and at no expense to the Commission, office space for employees of the Commission who customarily carry out their functions on the premises of Bruce A and B (onsite Commission staff).

G.5 The licensee shall implement and maintain a public information and disclosure program.

1. Management System

1.1 The licensee shall implement and maintain a management system.

2. Human Performance Management

2.1 The licensee shall implement and maintain a human performance program.

2.2 The licensee shall implement and maintain the minimum shift complement and control room staffing for Bruce A and B.

2.3 The licensee shall implement and maintain training programs for workers.

2.4 The licensee shall implement and maintain certification programs in accordance with CNSC [Amended regulatory document REGDOC-2.2.3, Personnel Certification, Volume III: Certification 2020-03] of Persons Working at Nuclear Power Plants.

Persons appointed to the following positions require certification:

(i) authorized health physicist;
(ii) authorized nuclear operator;
(iii) control room shift supervisor;
(iv) Unit 0 control room operator; and
(v) shift manager.

3. Operating Performance

3.1 The licensee shall implement and maintain an operations program, which includes a set of operating limits.

3.2 The licensee shall not restart a reactor after a serious process failure without the prior written approval of the Commission, or prior written consent of a person authorized by the Commission.

3.3 The licensee shall notify and report in accordance with CNSC regulatory document REGDOC-3.1.1 Reporting Requirements for Nuclear Power Plants.

4. Safety Analysis

4.1 The licensee shall implement and maintain a safety analysis program.

5. Physical Design

5.1 The licensee shall implement and maintain a design program.

5.2 The licensee shall implement and maintain a pressure boundary program and have in place a formal agreement with an Authorized Inspection Agency.

5.3 The licensee shall implement and maintain an equipment and structure qualification program.

6. Fitness for Service

6.1 The licensee shall implement and maintain a fitness for service program.

7. Radiation Protection

7.1 The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

8. Conventional Health and Safety

8.1 The licensee shall implement and maintain a conventional health and safety program.

9. Environmental Protection

9.1 The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

10. Emergency Management and Fire Protection

10.1 The licensee shall implement and maintain an emergency preparedness program.

10.2 The licensee shall implement and maintain a fire protection program.

11. Waste Management

11.1 The licensee shall implement and maintain a waste management program.

11.2 The licensee shall notify the Commission of any changes regarding the obligations of decommissioning and financial guarantees under the Lease Agreement with Ontario Power Generation Inc., as described in 15.1.

12. Security

12.1 The licensee shall implement and maintain a nuclear security program.

13. Safeguards and Non-Proliferation

13.1 The licensee shall implement and maintain a safeguards program.

14. Packaging and Transport

14.1 The licensee shall implement and maintain a packaging and transport program.

15. Nuclear Facility-Specific

15.1 The licensee shall inform the Commission in writing of any amendments to the Amended and Restated Lease Agreement between Ontario Power Generation Inc., Bruce Power L.P., OPG-Huron A Inc./OPG-Huron B Inc./OPG-Huron Common Facilities Inc., British Energy PLC, Cameco Corporation, TransCanada Pipelines Limited, BPC Generation Infrastructure Trust and Ontario Municipal Employees Retirement Board dated February 14, 2003.

15.2 The licensee shall implement the Integrated Implementation Plan.

15.3 Before hydrogen equivalent concentrations exceed 120 ppm, the licensee shall demonstrate that pressure tube fracture toughness will be sufficient for safe operation beyond 120 ppm.

15.4 The licensee shall implement a return-to-service plan for Major Component Replacement.

15.5 The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.

15.6 The licensee shall conduct and implement a periodic safety review.

15.7 The licensee shall inform the Commission of any reactor to be removed from commercial operations at Bruce A and B, and shall provide a plan describing the activities and timeline for transitioning from operations to safe storage.

15.8 The licensee shall store and manage booster fuel assemblies at Bruce A in a manner that ensures their physical security.

15.9 The licensee shall implement and maintain a nuclear criticality safety program.

15.10 The licensee shall implement and maintain a program for the production of the nuclear substances Cobalt-60 and Lutetium-177. [Amended 2021-xx]

15.11 The licensee shall implement and maintain a program for the operation of the Class II nuclear facility.

15.12 The licensee shall implement and maintain a program for nuclear substances and prescribed equipment.

SIGNED at OTTAWA _____

_____

Rumina Velshi
President
CANADIAN NUCLEAR SAFETY COMMISSION