BrucePower
Innovation at work

November 25, 2020

BP-CORR-00531-00982

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

Dear Mr. Leblanc:

Application for the Amendment of the Power Reactor Operating Licence

The purpose of this letter is:

- to request an amendment to the Power Reactor Operating Licence PROL 18.01/2028, pursuant to the Nuclear Safety and Control Act, Section 24(2), and the General Nuclear Safety and Control Regulations, Section 6; and,
- to request a panel hearing and decision by September 21, 2021.

In order to meet the expanding global supply need for radioisotopes used to treat cancer, Bruce Power plans to equip the Bruce site reactors with an Isotope Production System (IPS).

Medical isotope production represents one of the key ways in which nuclear science positively impacts Canadians, providing transformative and alternative cancer treatments while also generating sustainable economic and societal benefits. The clearest and widest-reaching benefits come from the enabling of life-saving medical treatments by providing medical isotopes for patient use.

Nuclear reactors have long been used to produce longer-lived radioactive isotopes such as Cobalt-60, where the targets are inserted and harvested while the reactor is off-line for servicing in an outage. They have, to date, not been used for short-lived medical isotope production as this would require targets to be introduced and removed while the reactor is operating.

In this project the IPS will be developed and installed in one of Bruce Power's reactors. The IPS will be a game changer in the global medical isotope supply chain, providing unprecedented capacity for the production of some medical isotopes with the existing Bruce Power infrastructure.

The IPS will first be used to produce Lutetium-177, which is currently used to treat neuroendocrine tumors, and has additional applications for prostate treatments.

Bruce Power Maury Burton, Chief Regulatory Officer
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However, once operational, the IPS will have the capacity to produce a wide variety of isotopes and will open the door to large-scale research and development opportunities.

Most importantly, the proposed IPS will not materially change the overall safety case for the Bruce site.

Additionally, Bruce Power has entered into an agreement with the Saugeen Ojibway Nation (SON) in which the SON has the option to become an investor and partner in the project. By working together on this medical isotope project, Bruce Power and SON will engage on marketing and collaboration while working jointly with the Ontario and federal governments to leverage this historic opportunity and create sustainable economic benefits.

Retaining a secure supply of isotopes and infrastructure in Canada will allow us to maintain a leadership position in the development of new nuclear medicine technologies, and support the economy through creating good jobs here in Ontario.

This submission includes the following:

- Attachment A: Licence Amendment Application,
- Attachment B: Performance Review, and,
- Enclosure 1: Environmental Risk Assessment Gap Analysis for Isotope Production Activities.

In order to progress with planning and subsequent installation of the Isotope Production System, Bruce Power requests a panel hearing and decision by September 21, 2021. This request was previously made in Reference 1.

If you require further information or have any questions regarding this submission, please contact Mr. Jeroen Thompson, Regulatory Issues Specialist, Operations Regulatory Affairs, at 519-385-2433, or jeroen.thompson@brucepower.com.

Yours truly,

Maury Burton
Bruce Power
2020.11.25 13:43:30
-05'00'

Maury Burton
Chief Regulatory Officer
Bruce Power

cc: CNSC Bruce Site Office
L. Sigouin – Ottawa

Attach.

<u>Enclosure:</u>

1. B-REP-03443-19NOV2020, Environmental Risk Assessment Gap Analysis for Isotope Production Activities

<u>Reference:</u>

1. Letter, M. Burton to M. Leblanc, "Bruce A and B: Notice of Intent to Amend the Power Reactor Operating Licence", August 26, 2020, BP-CORR-00531-00719.

Attachment A

APPLICATION FOR AMENDMENT OF PROL 18.01/2028

December 2020

APPLICANT AUTHORITY

Mr. ☑ Dr. ☐ Mrs. ☐ Ms. ☐

Name: Michael Rencheck

Title: President and Chief Executive Officer

Telephone: 519-361-2673

Email: michael.rencheck@brucepower.com

Applicant: Bruce Power Inc.

Address: PO Box 1540
Building B10, 177 Tie Road
Municipality of Kincardine,
Tiverton, ON
N0G 2T0

I, Michael Rencheck, have been designated by Bruce Power (Reference A1) as having signing authority for this application, pursuant to the General Nuclear Safety and Control Regulations, Section 15(b).

Signature: Michael W. Rencheck

Date: 2020 / 11 / 25
YYYY/ MM/ DD

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1.0 INTRODUCTION

This document addresses the regulatory requirements for an application to amend a power reactor operating licence, pursuant to the *General Nuclear Safety and Control Regulations* (GNSCR).

A supplementary Performance Review provides a high-level discussion of Bruce Power programs, processes, and performance with respect to CNSC Safety and Control Areas.

2.0 DESCRIPTION OF THE AMENDMENT

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

Bruce Power requests the following amendments to PROL 18.01/2028:

- Section IV, activity (vi), “produce Cobalt-60 at Bruce B” is to be amended to “produce nuclear substances at Bruce A and B”; and,
- Section VI, 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” is to be amended to “the licensee shall implement and maintain a program for the production of nuclear substances”.

Initially, Bruce Power plans to produce Lu-177 in Unit 7. Accordingly, Bruce Power requests revisions to Section 15.10 of LCH-PR-18.01/2028-R002:

- Production of nuclear substances is to be limited to Cobalt-60 (Bruce B) and Lutetium-177 (Unit 7).
- CNSC expectations with respect to production of Lutetium-177 are to be included. Bruce Power expects to discuss the relevant Compliance Verification Criteria with CNSC staff.
- No change to CNSC expectations with respect to Cobalt-60, including sealed source tracking.

However, the proposed amendment is intended to address production of various nuclear substances in all eight Bruce site units. As the isotope production business expands, Bruce Power will request appropriate revisions to the LCH, subject to acceptance by CNSC staff.

3.0 STATEMENT IDENTIFYING CHANGES

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

The most recent application for a renewal (Reference A2, Attachment A) and the most recent application for an amendment (Reference A3) were reviewed. However, no changes material to this proposed amendment were identified.

Note that the licensing basis is maintained pursuant to the licence conditions of PROL 18.01/2028, including Licence Conditions G.1 and G.2. As such, LCH-PR-18.01/2028-R002 documents the routine evolution of the licensing basis since the most recent application for a renewal. That evolution includes changes to programs and procedures, as well as environmental action levels and derived release limits. Additionally, the most current list of authorized delegates and responsible persons was submitted in Reference A4.

4.0 DESCRIPTION OF AFFECTED NUCLEAR SUBSTANCES

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

Bruce Power plans to install an isotope production system to permit in-core neutron irradiations. A target finger tube assembly is to be installed via a vacant vertical flux detector guide tube assembly. Targets are to be contained within protective carriers and are to be inserted and retrieved by a pneumatic system. Irradiated targets are to be discharged to transport containers.

Initially, the isotope production system is to be installed in Unit 7 for the production of Lutetium-177 from Ytterbium-176 powder. The same (or very similar) isotope production system may be installed in other units. Additional isotopes or non-medical irradiation applications may also be considered in the future, subject to global health demands and innovation, and as consistent with the safety case.

5.0 PROPOSED STARTING AND COMPLETION DATE OF MODIFICATIONS

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

Installation of the isotope production system in Unit 7 is currently planned to begin in 2021 Q4, with production beginning in 2022 Q1.

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

6.0 CONCLUSION

The information provided in this application and supplementary Performance Review demonstrates the following:

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

7.0 REFERENCES

A1. Letter, M. Burton to L. Sigouin, C. Purvis, M. Broeders, C. Pike, "Bruce Power Authorized Delegates and Responsible Persons", September 11, 2020, BP-CORR-00531-00857.

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

A3. Letter, M. Burton to M. Leblanc, "Request for Amendment of the Nuclear Power Reactor Operating Licence Bruce Nuclear Generating Stations A and B – PROL 18.00/2028", November 11, 2019, NK21-CORR-00531-15378 / NK29-CORR-00531-16213.

A4. Letter, M. Burton to L. Sigouin, "Bruce Power Authorized Delegates and Responsible Persons", June 1, 2020, BP-CORR-00531-00560.

Attachment B

PERFORMANCE REVIEW OF BRUCE A AND BRUCE B

December 2020

Executive Summary

For more than 60 years, Canada has been a global leader in the research, development and production of medical isotopes and radiopharmaceuticals used in the fight against cancer and keeping our hospitals clean and safe.

The landscape of medical isotope production in Canada is diverse, due in part to long-standing, world-class research into nuclear science and particle acceleration. Canada is a leader in reactor construction and applications for the production of medical isotopes that have been used globally for the past several decades. Canada relies on both domestic production and the global supply chain to provide medical isotopes to our hospitals.

Medical isotope production represents one of the key ways in which nuclear science positively impacts Canadians, providing transformative and alternative cancer treatments while also generating clear economic and societal benefits. The clearest and widest-reaching benefits come from the enabling of life-saving medical treatments by providing medical isotopes for patient use.

The demand for medical isotopes is projected to increase in the coming years as a result of new and emerging treatments, aging populations, and the modernization of health-care facilities. Although the demand for isotopes is increasing, research reactors that have traditionally supplied isotopes are nearing end of life or have already been decommissioned.

2018 marked the end of an era for medical isotope production in Canada, as the National Research Universal (NRU) reactor in Chalk River was taken out of service after six decades of supplying medical isotopes to the world. Nevertheless, Canada continues to play an important role on the global stage as a large-scale producer and exporter of several key medical isotopes including Cobalt-60 and Iodine-125.

With this decrease in supply capacity, there is a need for other reactors with irradiation capacity to step up and support the medical community. This gap also presents an important opportunity to strengthen Canada's long-term supply of reactor-produced isotopes for domestic and international use, while also retaining our global leadership by using the existing power reactors at Bruce Power.

Recently, Bruce Power updated its vision to "We Power the Future". This change expanded how we as a company view our impact on the community, province, country, and beyond. As part of the vision change, our business focus became more holistic, focusing on how our CANDU reactors can deliver products our communities need. Medical isotopes, although something Bruce Power is already producing in our reactors, is an additional way we can continue to support our communities, and use our existing infrastructure to provide additional benefits at home and globally.

As part of this, Bruce Power has engaged in various initiatives. We have partnered with various community groups, engaged in strategic partnerships with our local communities and businesses, connected with industry experts in Ontario and with the medical community, established the Bruce Power Medical Isotope Advisory Council, and participate as an active member of the Canadian Nuclear Isotope Council.

Bruce Power launched its Medical Isotope Advisory Panel in June 2020. The panel consists of experts and medical professionals from across Canada, and is intended to provide the company with an external perspective in the development of its isotope program by taking into account emerging trends, treatments and solutions for a range of global health challenges.

The Medical Advisory Panel communicates with the public through Bruce Power-directed events and webinars, helping to educate the broader nuclear supply chain on emerging opportunities with isotopes, while at the same time utilizing the expertise of the panel to best understand the need of patients now and into the future.

Bruce Power was also the catalyst for the creation of the Canadian Nuclear Isotope Council (CNIC) in April 2018. The CNIC serves as a voice to safeguard the continued availability of isotopes by ensuring that our public policies in this arena are risk-informed, science-based, and foster the health and well-being of Canadians. Leveraging Canada's existing physical and knowledge infrastructure to revitalize the domestic isotope supply chain will lead to new and innovative patient treatments, and maintain Canada's role as a global leader in nuclear science and technology.

The culture of isotope production is not new to Bruce Power. Our CANDU reactors have been used to produce longer lived radioactive isotopes such as Cobalt-60 as these can be inserted and harvested while the reactor is off-line for servicing during unit outages. Bruce Power has been a critical supplier of Cobalt-60 for three decades. Cobalt-60 is used around the world, in the sterilization of single-use medical equipment, food irradiation and even to combat deadly diseases like the Zika virus through insect sterilizations. Bruce Power's supply of Cobalt-60 helps to sterilize 40 per cent of the world's single-use medical devices, including sutures, syringes, masks, gloves and more. Since 2019, Bruce Power has also been producing medical-grade Cobalt-60 which can be used to deliver life-saving brain cancer treatments.

CANDU reactors like those at Bruce Power have, to date, not been used for short-lived medical isotope production as this would require targets to be introduced and removed while the reactor is online. However, the design and operating characteristics of the CANDU reactor enables access to the high neutron zones of the reactor while at power, and so creates the possibility of online target loading and unloading.

Bruce Power, with its partner IsoGen (a joint venture between Framatome and Kinectrics), has begun work on a made-in-Ontario, Isotope Production System (IPS). This will help ensure that Canada remains at the forefront of nuclear medicine, providing isotopes for medical diagnostics and therapeutics which improve our quality of life and strengthen our economy. Bruce Power and IsoGen have entered into a supply agreement with Isotopen Technologien Munchen (ITM), a global leader in radiopharmaceutical production, which guarantees a customer for the product and sustainable demand for Lutetium-177 production once the IPS is installed. Given the growing market opportunity for this medical isotope, multiple Canadian suppliers will ensure the availability of Lutetium-177 in order to reach global and Canadian patients.

As a further community engagement initiative, Bruce Power has entered into an agreement with the Saugeen Ojibway Nation (SON) in which the SON has the option to become an investor and partner in the project. The Anishinaabemowin project name, "Gamzook'aamin aakoziwin" translates to "We are teaming up on the sickness". This name and the project logo were designed by SON community leaders and members as a part of the ongoing community engagement which has been done through the course of the partnership.

The SON and Bruce Power believe this partnership is the first step in a new relationship that will create mutually shared benefits. The project will contribute resources to the world's health-care system. It is a project that the people of SON support. It is a project that would benefit Canadians through its contributions to the health-care system, the creation of jobs, advancing innovation, and giving a boost to the economy. The revenue-sharing program with the SON will provide economic benefits to the SON community from their return on this investment, enabling them to take a self-directed approach to managing social and economic conditions within their community. This revenue stream will provide a great opportunity to address wealth creation and improve well-being for the SON community. The project will deliver benefits beyond the local community, including the reduction of barriers to economic self-sufficiency, improving the socioeconomic circumstances of SON members, as well as having a positive impact globally on treating cancer.

The SON is also a member of the CNIC. Its membership is an effort to advance reconciliation in a way that engages a First Nations community in securing critical infrastructure key to Canada's economic and strategic strength in the isotope sector. By working together on this project, Bruce Power and SON will engage together on marketing and collaboration, while working jointly with the Ontario and federal governments to leverage this historic opportunity and create sustainable economic benefits.

The IPS will be a game changer in the global medical isotope supply chain, providing unprecedented capacity for the production of some medical isotopes with the existing Bruce Power infrastructure. It will provide both redundancy and a scalable supply of isotopes to the worldwide market, and will make Canada a first mover in large-scale production of certain medical isotopes. The successful implementation of this project will create new technology and modernization, established through Canadian research and development, and is an example of innovation that will distinguish Canada and reinforce its role as a nuclear leader.

Bruce Power's ability to contribute to the supply chain of Lutetium-177 will become increasingly important for Canadians and patients around the world. Its unique properties emit sufficient gamma radiation for imaging, while its beta radiation allows for the therapeutic treatment of tumours, helping to save thousands of lives.

Lutetium-177 is a therapeutic medical isotope that can be used to provide targeted therapy for advanced prostate cancer and neuroendocrine tumours. The radioactive Lutetium-177 atoms are linked to targeting molecules, which are administered in the body and selectively accumulate at the disease site(s). The Lutetium-177 atoms then emit beta particles which destroy the cancer cells while leaving healthy cells unaffected. In Canada, Lutetium-177 is currently being used to treat neuroendocrine tumours in the form of the approved radiopharmaceutical Lutathera. With current trials in Canada and the United States, it is expected that an additional Lutetium-177 radiopharmaceutical will be approved to treat prostate cancer in the next few years.

In the Canadian therapeutic market, Lutetium-177 accounts for 16 per cent of the beta emitters. Due to ongoing medical developments, demand for Lutetium-177 is projected to grow at a compound annual growth rate (CAGR) of 11 per cent from 2018-2023, translating into a tremendous opportunity for Canada.

To produce Lutetium-177, the IPS will interface with a Bruce Power's reactors. Lutetium-177 is generated through the irradiation of Ytterbium-176. The IPS will use an inert carrier gas to pneumatically insert targets into the reactor and then retrieve them after the required irradiation period. A delivery device outside of containment will be the main operator interface. It will be used to add and remove targets and control system operations. The delivery device, the gas supply, and the reactor penetration will be connected by tubing. To ensure no contact between the IPS and D_2O moderator, the guide tube serves as the pressure boundary between the IPS and moderator.

The isotope project will follow Bruce Power's number one value of Safety First. Conventional safety for the isotope project is being evaluated during the Engineering Change Control process by Bruce Power staff. A mock-up facility has been created to allow for acceptance testing of the IPS design. During the ECC process, Bruce Power operations staff utilized the mock-up facility to evaluate the safety and efficacy of the design. From this evaluation, observations and suggestions are being provided for improvements to further minimize potential risk to workers. Once the design is finalized, the mock-up facility will be modified as necessary and will become a training facility for all required personnel.

In addition to conventional safety, radiation protection principles have been applied to this project. Applications of As Low as Reasonably Achievable (ALARA) are being utilized during the design phase. For example, determining locations of reduced background radiation dose for equipment installation and incorporating shielding into the design to minimize dose received by the workers. A shielded transport container is currently undergoing certification with the Canadian Nuclear Safety Commission (CNSC). Once the container is certified, Bruce Power will apply to become a registered user.

The planned IPS has been reviewed and is not expected to have an impact on the environment. In the unlikely event of a failure and the generation of activation products, emissions would be directed to the exhaust stack and be contained by the high-efficient particulate air (HEPA) filters. Releases through the stack are detected via continuous monitoring. The 2022 Environmental Risk Assessment (ERA) will include assessment of impacts as a result of any relevant changes to operations, including isotope production.

Additionally, the operation of the IPS is not expected to generate any additional nuclear waste.

By using nuclear reactors and expanding the production of radioisotopes, Bruce Power will continue to keep the country at the forefront of innovations that save lives, improve quality of life and invest in our economy. We all play a role in fighting cancer. We are united in the fight against cancer. By all of us doing our part, we can and will make a difference.

Bruce Power is applying for an amendment to its Power Reactor Operating Licence (PROL) to expand its isotope production business line, beginning with the production of Lutetium-177. Once operational, the IPS will have the capacity to produce a wide variety of isotopes and will open the door to large-scale research and development opportunities. As such, this project will become a key part of the Canadian Medical Isotope Ecosystem, providing a new approach to isotope production.

The Isotope Production System will be designed, installed and operated in accordance with Bruce Power's Management System and associated business programs. At this time (November 2020), the project is in the detailed design phase of the engineering change control process. Technical discussions with CNSC staff are ongoing in alignment with design activities.

This Performance Review provides a high-level overview of Bruce Power's management of the Safety and Control areas, as applicable to isotope production. This document demonstrates that Bruce Power is fully qualified to carry on the licensed activities, and that Bruce Power will make adequate provision for the protection of the environment, the health and safety of people, and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

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0.0 INTRODUCTION

Bruce Power

The Bruce Power site is located in rural southwestern Ontario and has the unique benefit of a remote location, while at the same time enjoying well-established infrastructure to support the world's largest operating nuclear facility.

Formed in 2001, Bruce Power is Canada's first private nuclear generator, and provides 30 per cent of Ontario's power at 30 per cent less than the average cost to produce residential power to families and businesses across the province and life-saving medical isotopes around the globe. We produce low-cost, emissions-free electricity, while also driving the economy through significant infrastructure investments and a commitment to the protection of our environment.

Our Life-Extension Program which will enable our site to operate safely to 2064 is also recapitalizing the Ontario nuclear supply chain with 95 per cent of the entire program spending occurring in Ontario. That will help to support more than 22,000 jobs across the province and generate over $4 billion in economic activity annually.

Bruce Power is a limited liability partnership between the TC energy, OMERS Infrastructure, the Power Workers' Union, and The Society of United Professionals, making it one of the largest P3 partnerships in the world. Bruce Power employs more than 4,000 people, and over the past 15 years has been one of the largest investors in Ontario's electricity infrastructure, providing billions in private dollars to the Bruce Power site — which continues to be owned by the province.

Figure 1: Power Line Infrastructure Connecting Bruce Power to the Electricity Grid

The site is leased from the Province of Ontario under a long-term arrangement in which all of the assets remain publicly owned, while the company is responsible for operating and investing in the units, including refurbishment and maintenance costs. Bruce Power is also responsible for waste management costs while contributing to fund the decommissioning of the facilities at their end of life.

Home to a naturally diverse environment on the shores of Lake Huron, Bruce Power recognizes the importance of our natural surroundings and is committed to minimizing the environmental footprint in addition to supporting healthy habitats and waterways.

Figure 2: Bruce Generating Station seen from Lake Huron

Canadian Isotope Leadership

Today, more than 10,000 hospitals around the world use medical isotopes for sterilization, diagnostic imaging and for various treatments. Canada's nuclear isotope program pioneered a number of medical applications which are used widely, and much of that work has been focused on the diagnosis and treatment of cancer.

Medical isotopes also provide a pathway for health-care professionals to improve lives through targeted imaging and therapy that will deliver a specific medical diagnosis and treatment to an individual. They provide the foundation with the tools to advance research for improved drug discovery and development.

The use of these applications is rapidly increasing, however. Research reactors that supplied medical isotopes are nearing end of life or already decommissioned, such as NRU in Chalk River. A gap has been created with the limited supply of reliable, domestic medical isotopes to provide Canadians and people around the world with life-saving nuclear medicine scans and treatments.

This gap in our national infrastructure needs to be addressed in order for Canada to retain a strategic and economic advantage in this innovative field. By using the existing power reactors at Bruce Power, there is an extraordinary opportunity to strengthen Canada’s long-term supply of reactor-produced isotopes for domestic and international use, while also retaining our global leadership. This will help ensure that Canada remains at the forefront of nuclear medicine, providing diagnostics and therapeutics that improve our quality of life and strengthen our economy.

Bruce Power changed its vision to “We Power the Future”, which expanded how we as a company view our impact on the community, province, country, and beyond. As part of the vision change, our business focus became more holistic, focusing on how our CANDU reactors can deliver products our communities need. Although isotopes are something Bruce Power has been producing in our reactors for decades, there is an opportunity to continue to support our communities and use our existing infrastructure to provide additional benefits both at home and around the world.

As part of this, Bruce Power has engaged in various initiatives. We have partnered with various community groups, engaged in strategic partnerships with our local communities and businesses, connected with industry experts in Ontario and with the medical community, established the Bruce Power Medical Isotope Advisory Council, and become an active member of the Canadian Nuclear Isotope Council.

In 2018, Bruce Power was the catalyst for the formation of the Canadian Nuclear Isotope Council (CNIC). The CNIC is an independent organization consisting of representatives from various levels within the Canadian health sector, nuclear industry and research bodies, convened specifically to advocate for our country’s role in the production of the world’s isotope supply.

The CNIC serves as a voice to safeguard the continued availability of isotopes by ensuring that our public policies in this arena are risk informed and science based, and foster the health and well-being of Canadians. Leveraging Canada’s existing physical and knowledge infrastructure to revitalize the domestic isotope supply chain will lead to new and innovative patient treatments, and maintain Canada’s role as a global leader in nuclear science and technology.

In its 2019 report, “Isotopes, Global Importance and Opportunities for Canada”, the CNIC highlighted the need for strong Canadian leadership to ensure a domestic and international supply of medical isotopes. The report makes it clear that Canada must enable investment in its isotope infrastructure and ensure the building blocks are in place for this sector to remain a global leader. Such investments would exhibit a commitment to Canada’s role as a leader in nuclear medicine, and dramatically bolster the country’s capacity to innovate while delivering substantial economic and societal benefits to both Canadians and patients around the globe.

As a founding member of the CNIC, Bruce Power is well positioned to help Canada capitalize on this opportunity for medical isotope production, which will deliver tangible impact to Canadians generating clear economic and societal benefits.

Isotope Production

Bruce Power positively impacts millions of people. Aside from providing carbon-free electricity, it also benefits the world's health-care system through the production of isotopes.

Isotopes are essential components of modern health care, natural resource development, and infrastructure management. Isotopes are used to characterize human disease, detect contraband at international borders, sterilize medical equipment, and power batteries for space exploration. Isotopes also enable research in agriculture, astronomy, biology, chemistry, materials science, medicine, and nuclear safety. Canada has historically been a world leader in isotope production, and has the physical and knowledge infrastructure necessary to make a major contribution to this important field on the international stage.

For more than 30 years, the four reactors at Bruce Power's Bruce B generating station have been a reliable Cobalt-60 supply for Nordion, an Ottawa-based company. Cobalt-60 is used around the world in the sterilization of single-use medical equipment, food irradiation and even to combat deadly diseases like the Zika virus through insect sterilizations. Bruce Power's supply of Cobalt-60 helps to sterilize 40 per cent of the world's single-use medical devices, including sutures, syringes, masks, gloves and more. Since 2019, Bruce Power has also been producing medical-grade Cobalt-60 which can be used to deliver life-saving brain cancer treatments.

To date, Bruce Power's reactors have not been used to produce short-lived medical isotopes, as this would require targets to be introduced and removed while the reactor is on power. However, the design and operating characteristics of the CANDU reactor enables access to the high neutron zones of the reactor, and so creates the possibility of target loading and unloading while the reactor is producing power.

Bruce Power, with its partner IsoGen (a joint venture between Framatome and Kinectrics), has begun work on a made-in-Ontario, Isotope Production System (IPS). Framatome holds the patented design for the delivery and retrieval of targets from the reactor core, while Kinectrics is responsible for project management, design, and safety analysis. In turn, Bruce Power is responsible for operation of the IPS and packaging of the irradiated targets for shipment.

This partnership will help ensure that Canada remains at the forefront of nuclear medicine, providing diagnostics and therapeutics that improve our quality of life and strengthen our economy. Bruce Power and IsoGen have entered into a supply agreement with ITM which guarantees a customer for the product and sustainability of Lutetium-177 production once the IPS is installed. Given the growing market opportunity for this medical isotope, multiple Canadian suppliers will ensure the availability of Lu-177 in order to reach patients both at home and across the world.

The IPS will be a game changer in the global medical isotope supply chain, providing unprecedented capacity for the production of some medical isotopes within the existing Bruce Power infrastructure. It will provide both redundancy and a scalable supply of isotopes to the worldwide market, and will make Canada a first mover in large-scale production of certain medical isotopes. The successful implementation of this project will create new technology and modernization, established through Canadian research and development, and is an example of innovation that will distinguish Canada and reinforce its role as a nuclear leader.

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Lutetium-177 is a therapeutic medical isotope that can be used to provide targeted therapy for advanced prostate cancer and neuroendocrine tumours. The radioactive Lutetium-177 atoms are linked to targeting molecules, which are administered in the body and selectively accumulate at the disease site(s). The Lutetium-177 atoms then emit beta particles which destroy the cancer cells while leaving healthy cells unaffected. In Canada, Lutetium-177 is currently being used to treat neuroendocrine tumours in the form of the approved radiopharmaceutical Lutathera. With current trials in Canada and the United States, it is expected that an additional Lutetium-177 radiopharmaceutical will be approved to treat prostate cancer in the next few years.

In the Canadian therapeutic market, Lutetium-177 accounts for 16 per cent of the beta emitters. Due to ongoing medical developments, demand for Lutetium-177 is projected to grow at a compound annual growth rate (CAGR) of 11 per cent from 2018-2023, translating into a tremendous opportunity for Canada.

In Bruce Power's reactors, Lutetium-177 is generated through the irradiation of Ytterbium-176. The system will use an inert carrier gas to pneumatically insert targets into the reactor then retrieve them after the required irradiation period. A delivery device outside of containment will be the main operator interface. It will be used to add and remove targets and control system operations. The delivery device, the gas supply, and the reactor penetration will be connected by tubing. To ensure no contact between the IPS and D_2O moderator, the guide tube serves as the pressure boundary between the IPS and moderator.

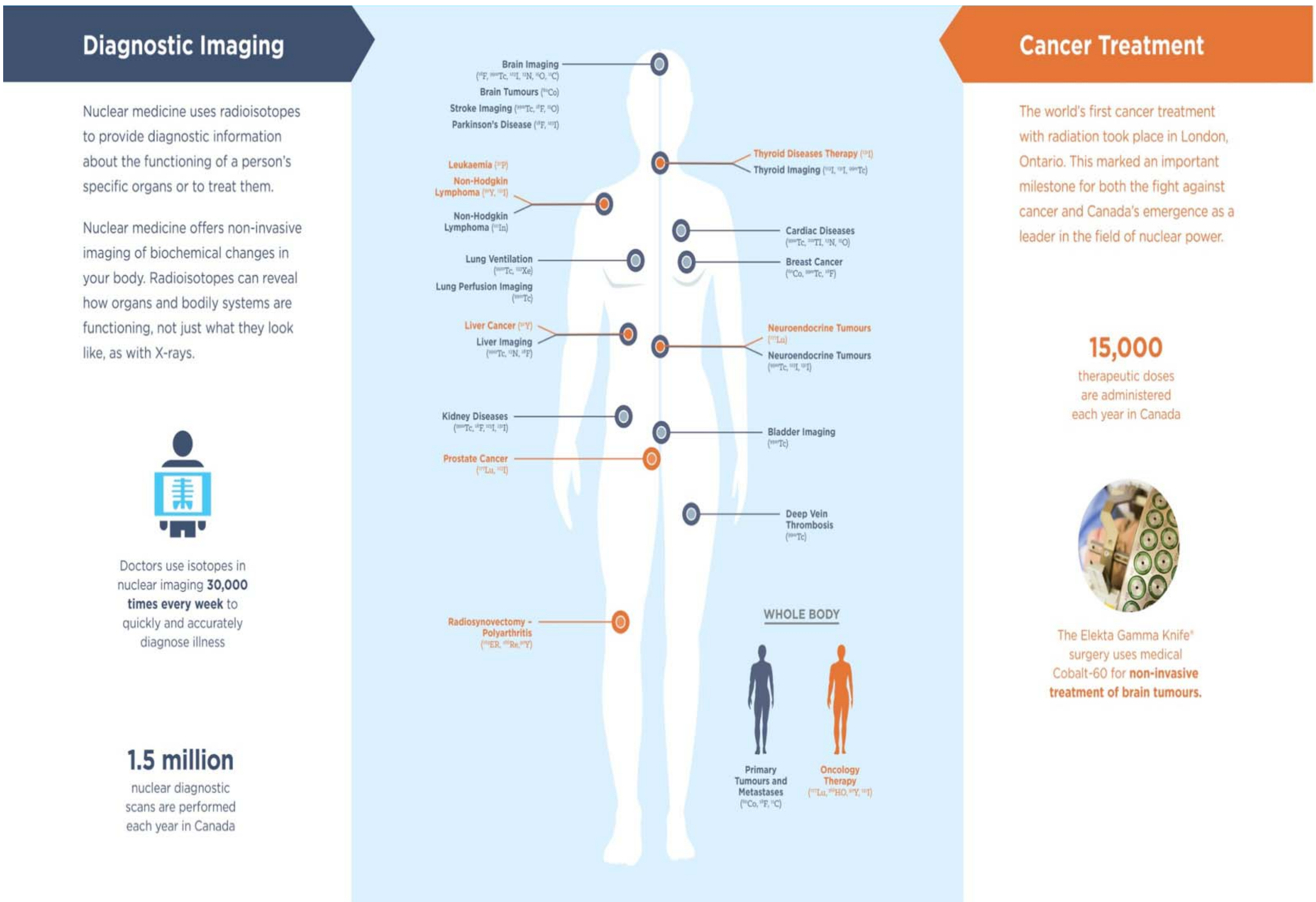

Figure 3: Diagnostic and Therapeutic Isotope Uses

Community Engagement

Bruce Power is located within the traditional territory of the Anishinaabe people of the Saugeen Ojibway Nation (SON), including the Chippewas of Nawash (Neyaashiinigmiing) and the Chippewas of Saugeen First Nation. Bruce Power is committed to honouring Indigenous history and culture as well as moving forward in the spirit of reconciliation and respect with Indigenous communities.

We are dedicated to fostering meaningful relationships with the Saugeen Ojibway Nation (SON), including the Chippewas of Nawash (Neyaashiinigmiing) and the Chippewas of Saugeen First Nation, Métis Nation of Ontario (MNO) Region 7 and the Historic Saugeen Métis (HSM) while increasing local First Nations and Métis employment through targeted education and training programs.

The Saugeen Ojibway Nation (SON) and Bruce Power have entered into an agreement to jointly market new isotopes in support of the global fight against cancer while also working together on creating new economic opportunities within the SON territory by establishing new isotope infrastructure. Bruce Power and SON have agreed to collaborate in the development of this infrastructure project not only as a means of building trust, but towards enhancing SON's ability to generate an ongoing revenue stream that will benefit the SON communities.

SON and Bruce Power have been working together over the past few years on a number of initiatives including environmental protection and stewardship, employment, education, training and contracting. Bruce Power and SON have created a number of forums for these interactions to take place, and they have recently resulted in stronger collaboration. Progress on these initiatives has created confidence in the ability to work together, committed to continuing to build a strong and positive relationship. The foundation of this progress is recognition of the importance of meaningful and reciprocal dialogue towards creating opportunities to work together.

The Anishinaabemowin project name, "Gamzook'aamin aakoziwin" translates to "We are teaming up on the sickness". This name, along with the project logo, was designed by SON community leaders and members as a part of the ongoing community engagement which has been done through the course of the partnership.

This partnership is the first step in a new relationship that will create mutually shared benefits. The project will contribute resources to the world's health-care system. It is a project that the people of Saugeen Ojibway Nation (SON) support. It is a project that would benefit Canadians through its contributions to the health-care system, the creation of jobs, advancing innovation, and providing a boost to the economy.

HSM and MNO were engaged early in the isotope project, allowing open dialogue amongst everyone. Presentations were made to each Indigenous community to increase their understanding of the isotope project and explain the importance that isotopes have worldwide. During these presentations comments and questions were encouraged. Regular ongoing meetings with our Indigenous communities include updates on the isotope project.

In August 2019, Bruce Power invited the public to a free breakfast to learn about medical isotopes and Bruce Power's contributions to health care, not only at home but around the world. The "Up and Atom" sessions were delivered by Bruce Power personnel in Southampton on August 15, in Walkerton on August 20 and in Kincardine on August 27. The presentations covered our history of producing Cobalt-60, introduced Lutetium-177, and explained the production process and shared details around the SON partnership. At the end of the presentation, Bruce Power led a Q&A session with participants and directed them to our website for further details on the project.

Health and Safety

Bruce Power's number one value of Safety First is fundamental to its success and essential to achieving its long-term business goals. Safety is the primary consideration guiding decisions and actions.

Conventional safety for the isotope project is being evaluated during the Engineering Change Control process by Bruce Power staff. A mock-up facility has been created to allow for acceptance testing of the IPS design. During the ECC process, Bruce Power operations staff utilized the mock-up facility to evaluate the safety and efficacy of the design. From this evaluation, observations and suggestions are being provided for improvements to further minimize potential risk to workers. Once the design is finalized and the mock-up facility has been modified as necessary, it will become a training facility for all required personnel.

In addition to conventional safety, radiation protection principles have been applied to this project. Applications of As Low As Reasonably Achievable (ALARA) are being utilized during the design phase. For example, determining locations of reduced background radiation dose for equipment installation and incorporating shielding into the design to minimize dose received by the workers. A shielded transport container is currently undergoing certification with the Canadian Nuclear Safety Commission (CNSC). Once the container is certified, Bruce Power will apply to become a registered user.

Environmental Stewardship

Nuclear power generation is among the most environmentally-conscious industries in the world, offering low emissions as well as capture and/or responsible management of waste streams.

As such, environmental stewardship is central to Bruce Power's daily operations. Bruce Power is committed to meeting or exceeding the high standards of environmental performance set by federal and provincial regulators, and to continually assessing the implications that the day-to-day actions have on the land, water and air which surround the site.

Bruce Power's Environmental Monitoring Program confirms that the site is operating well within the established, safe environmental standards required by federal and provincial regulators. In addition to routine updates set out by each governing body over the course of the year, effluent and environmental monitoring program results are compiled and communicated annually through the Environmental Program Report.

In addition, Bruce Power goes beyond compliance to the strict regulatory requirements and continuously seeks additional opportunities to ensure and enhance environmental protection.

To promote the environment and sustainability, Bruce Power partners with local environmental organizations across Grey, Bruce and Huron counties to deliver key on-the-ground projects and initiatives. Since 2015, Bruce Power has provided more than $2 million in funding towards environment and sustainability initiatives, in addition to pro-bono environmental expertise and resources. Supported initiatives focus on key areas of the environment that our business interacts with, and ensure enhanced preservation, restoration, conservation, and education. The cumulative impact of this program includes, but is not limited to:

- The offset of 150,000 tons of CO_2 equivalent via tree planting through conservation authorities and local non-governmental organizations;
- Improvement of water quality through restoration of 13 hectares of land in the Pine River watershed;
- Improvement of water quality and fish habitat with the installation of 5 kilometers of cattle exclusion fencing along tributaries running into Georgian Bay;
- Habitat preservation via the protection of 150 acres of ecologically-diverse land through partnerships with various land trust organizations; and,
- Habitat restoration through removal of over 830 tonnes of the invasive species Phragmites along the shores of Lake Huron.

In 2020, Bruce Power provided support and funding to local organizations in line with the environmental stewardship goals. Bruce Power continues to prioritize these sustainability and environmental protection initiatives and is working on better ways to measure our impacts in these areas.

Bruce Power maintains ISO 14001 certification as required by REGDOC-2.9.1, Environmental Principles, Assessments and Protection Measures. This regulatory document specifies requirements for an environmental management system that an organization can use to enhance its environmental performance to ensure compliance with the regulatory requirements, and improve efficiency and effectiveness to earn and retain regulatory and community trust.

In regards to the isotope project, the planned IPS is not expected to have an impact on the environment. In the unlikely event of a failure and the generation of activation products, emissions would be directed to the exhaust stack and be contained by the high-efficiency particulate air (HEPA) filters. Releases through the stack are detected via continuous monitoring. The 2022 Environmental Risk Assessment (ERA) will include assessment of impacts as a result of any relevant changes to operations, including isotope production.

Additionally, the operation of the IPS is not expected to generate any additional nuclear waste.

Figure 4: Members of the Bruce Power Team conducting Environmental Studies

Business Plan

Using the eight reactors at Bruce Power, this project is focused on closing the critical gap we have in Canada's isotope infrastructure. It presents an outstanding opportunity to strengthen Canada's long-term supply of reactor isotopes for domestic and international use while also retaining our global leadership and ecosystem.

Bruce Power expects to seamlessly transition to the operation of the IPS through leveraging the extensive experience and knowledge Bruce Power personnel have in reactor operations, radiation and conventional safety. In addition, Bruce Power will also be able to use their experience in production, harvesting, and transportation of Cobalt-60 to establish a world-class isotope delivery model.

Initially, operation of the IPS is planned for a single unit, producing a single isotope, Lutetium-177. To do this, Bruce Power is applying for an amendment to its Power Reactor Operating Licence (PROL) to expand its isotope production business line, beginning with the production of Lutetium-177. Once operational, however, the IPS will have the capacity to produce a wide variety of isotopes and will open the door to large-scale research and development opportunities. As such, this project will become a key part of the Canadian Medical Isotope Ecosystem and provide a new approach to isotope production.

The same or very similar systems may be installed on other units, and the Isotope Production System(s) may be used to produce additional nuclear substances in the future, in accordance with global health demands. This installation is planned for the Unit 7 outage of 2021 with production beginning in Q1 of 2022. This timing is important as it coincides with the planned FDA approval of Lutetium-177 for prostate cancer treatment, which is expected to increase the demand for Lu-177.

Bruce Power plans to invest $100 million into the development, installation, and operation of the IPS. In addition, the Saugeen Ojibway Nation (SON) will contribute as an equity partner in this investment, which will generate a revenue stream for the SON to use for healthy-living initiatives in their communities.

In addition, Bruce Power continues to progress with its Life-Extension Program. Key elements of Bruce Power's plans for the future include:

- Investing in site infrastructure and life extension to ensure there is a reliable supply of electricity for Ontario;
- Implementing strong project oversight and to safely deliver projects with high quality, on time and on budget;
- Implementing robust succession planning and leadership development programs;
- Fostering strong support from the region around the site, including Indigenous communities, through a range of programs related to corporate social responsibility, economic development, and community outreach;
- Promoting innovation and collaboration with the community, suppliers, unions, and industry partners in order to find new ways to improve operations; and,
- Working in partnership with Ontario Power Generation, allowing both organizations the opportunity to leverage experience in operations, isotope production, and advocacy.

Summary

This document - the Performance Review - addresses each of the CNSC Safety and Control areas through a high-level summary of relevant aspects of the Bruce Power Management System (BPMS - generally, business programs), which governs the entirely of Bruce Power's operations. At this time (November 2020), the project is in the detailed design phase of the engineering change control process. Technical discussions with CNSC staff are ongoing in alignment with design activities.

For each of the specific areas within each Safety and Control Area, this Performance Review addresses the following:

- Relevance and Management: the relevance of the Specific Area with respect to isotope production, and the overall approach by which Bruce Power manages that specific area.
- Past performance: performance since the 2018 PROL renewal, as applicable to isotope production.
- Future plans: specific future plans with respect to that Specific Area as applicable to isotope production. General statements of planned improvement have not been made, as continuous improvement is expected for all areas of the BPMS.

The Performance Review demonstrates that Bruce Power is fully qualified to carry on the licensed activities, and that Bruce Power will make adequate provision for the protection of the environment, the health and safety of people, the maintenance of national security, and measures required to implement international obligations to which Canada has agreed.

1.0 MANAGEMENT SYSTEM

Covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against those objectives, and fosters a healthy safety culture.

1.1 Management System

1.1.1 Relevance and Management

The Bruce Power Management System (BPMS) describes the structure of Bruce Power as well as its key processes and expectations. It defines how all aspects of the business fit together in an integrated manner and drives Bruce Power towards excellence. The BPMS supports the enhancement and improvement of safety culture, excellence in worker performance, and the achievement of nuclear safety, security, and, business results.

The BPMS is documented in a Management System Manual (BP-MSM-1) and a suite of business programs, which are the second tier of documents in the BPMS. Each business program is in turn a suite of related procedures and processes that are managed collectively. The governance provided by the BPMS controls changes to the interdependent processes, organizational structure, and document structures that are essential to managing business.

Bruce Power conducts its business in accordance with the Governance, Oversight, Support, and Perform (GOSP) model. The business is divided into functional areas that are made up of one or more business programs that collectively represent related, interdependent work activities. Program Leads are responsible for Governance and Oversight for the relevant business programs, while Perform Leads are responsible for Support and Perform functions (i.e., execution).

By design, the BPMS contributes to the establishment of a healthy culture for nuclear safety and security. The BPMS assures the "Four Pillars" of nuclear safety (reactor, environmental, industrial, and radiological safety) and nuclear security are met during normal operations as well as during extreme events.

The BPMS complies with N286-12, Management System Requirements for Nuclear Facilities. N286-12 is based on generic management system principles, as well as specific requirements for various facilities (including high-energy reactor facilities such as the Bruce nuclear generating stations). The general principles and specific requirements are satisfied through the BPMS suite of business programs and implementing procedures.

A graded approach is used throughout the BPMS. The degree to which management system requirements are applied reflects the importance of the activity to safety, health, environmental, security, quality, economic, or other business requirements. Where a graded approach is adopted, the grading process is documented, with safety being the paramount consideration guiding decisions and actions.

Addition or obsolescence of a business program requires the approval by the applicable program owner, the executive team, and the CEO. This review and approval process ensures that new business programs meet the requirements of the BPMS in order to define:

- Program Tier: an assigned grading that reflects safety significance and defines the level of oversight;
- Program Owner: Bruce Power senior leadership team member with accountability to ensure that governance and oversight are established and meet requirements;
- Program Lead: competent individual that is responsible for establishing the governance and providing oversight to their program and procedures that implement it;
- How the program will meet regulatory and statutory requirements including the generic and specific requirements of CSA N286-12;
- Implementing procedures and internal standards;
- Program Health Assessment Frequency: amount of times per year required for a full programmatic review to determine if regulatory, statutory business and document requirements are still current and valid;
- Relationship to interdependent programs;
- Organizational structure; and,
- Program governance structure.

1.1.2 Past Performance

Not applicable

1.1.3 Future Plans

Bruce Power plans to develop and approve a business program, Irradiation Services, to manage isotope production. This business program is planned to be in place prior to the operation of the IPS.

1.2 Organization

1.2.1 Relevance and Management

The clear definition of roles, authorities, and responsibilities is critical to achieving excellence in nuclear safety and Bruce Power's business goals.

An organizational hierarchy, defining lines of authority and responsibility, is established and maintained from the highest level of management through to individual contributors. Changes to the organizational structure are documented and approved according to a risk-based, graded approach. Responsibilities and interfaces exist in process documents and those who are involved understand these details.

1.2.2 Past Performance

Not applicable

1.2.3 Future Plans

The organization structure is being updated to reflect work associated with isotopes, ensuring roles and responsibilities are updated. Once complete, all organizational changes are reported to the CNSC as per the Quarterly Report on Nuclear Power Plant Personnel.

1.3 Performance Assessment, Improvement and Management Review

1.3.1 Relevance and Management

The Conduct of Business, BP-PROG-16.01, establishes the processes that implement the GOSP model at Bruce Power and establishes processes and internal standards to support the organization with improving performance. This program has established the Performance Monitoring process (BP-PROC-14998), Peer Group Standard (BP-STND-00007), Program Health Assessment (BP-PROC-00016) and Performance Review Meetings – Standards, Cadence and Metrics (BP-STND-00008). These documents ensure high levels of performance are obtained through measurement of behaviour, key performance indicators (KPIs), and continuous improvement.

Bruce Power utilizes a corrective action process which is governed by BP-PROC-00060, Station Condition Record Process. This process is used to document adverse conditions, drive investigations and evaluations, and apply corrective actions in a timely manner. It supports Bruce Power’s commitment to ensure that safety is the paramount consideration guiding decisions.

In addition to the formal corrective action process, line management undertakes continuous in-process performance assessment through day-to-day activities such as observations at work, use and sharing of operating experience, lessons learned in project activities, monitoring metrics and supervisory oversight of workers.

1.3.2 Past Performance

Not applicable

1.3.3 Future Plans

Bruce Power plans to develop KPIs to monitor the performance of the IPS. These KPIs will be proposed, approved, and - as necessary - modified in line with the business processes defined by the BPMS. See Section 1.1.3.

1.4 Operating Experience

1.4.1 Relevance and Management

Bruce Power systemically identifies, evaluates, and applies lessons learned from within Bruce Power and from the international nuclear industry. Internal and external operating experience (OPEX) is considered and appropriately dispositioned; relevant items are communicated within Bruce Power so that risks and lessons learned are fully understood.

By applying OPEX, Bruce Power ensures safety is the primary consideration guiding decisions and actions. The use of OPEX improves plant safety, equipment reliability and commercial performance by improving design, training, processes, and procedures.

1.4.2 Past Performance

The IPS is a modification of existing technology for application to CANDU reactors. Accordingly, the design process has considered OPEX from a variety of sources including Bruce Power's Station and Condition Reports, CANDU Owners Group (COG), World Association of Nuclear Operators (WANO) and international reactors. The OPEX from these different sources were documented in the conceptual engineering report.

1.4.3 Future Plans

As noted in the introduction, Bruce Power plans to install IPSs in additional units. Although it is expected that any subsequent IPS will be substantially identical to the initial IPS, the design process includes review of OPEX. If necessary, design adjustments will be made for any subsequent IPS.

1.5 Change Management

1.5.1 Relevance and Management

BP-PROC-00166, Management of Program, Procedure and Internal Standards Documents, establishes the change management framework for business programs, and general procedures. BP-PROC-00166 ensures that changes to governance are identified, justified, reviewed by stakeholders, approved, and implemented. Changes are controlled to ensure that safety and regulatory requirements continue to be met or exceeded and to ensure that changes reflect Bruce Power's number one value of Safety First.

1.5.2 Past Performance

Not applicable

1.5.3 Future Plans

Not applicable

1.6 Safety Culture

1.6.1 Relevance and Management

As discussed in Section 1.1.3, Bruce Power plans to develop a new business program for governing irradiation services. As part of the BPMS, this future business program will contribute to Bruce Power's commitment to ensure that safety is the paramount consideration guiding decisions and actions by establishing a healthy culture for nuclear safety and security. The BPMS ensures that the four pillars of nuclear safety (reactor, environment, industrial, and radiological safety), and security are met, during normal operations as well as during off-normal operation events.

1.6.2 Past Performance

Not applicable

1.6.3 Future Plans

Not applicable

1.7 Configuration Management

1.7.1 Relevance and Management

The physical design of the Bruce site facilities is managed through Plant Design Basis Management, Engineering Change Control (ECC) and Configuration Management business programs. These programs provide a disciplined approach to the control of the physical configuration, design requirements and facility configuration such that structures, systems, and components are fully functional, and support safe, reliable plant operation.

The configuration management information such as a design drawing that requires updates with the addition of the IPS will be identified in accordance with the ECC process.

1.7.2 Past Performance

Not applicable

1.7.3 Future Plans

Not applicable

1.8 Records Management

1.8.1 Relevance and Management

Bruce Power’s document management business program defines the fundamental business need, constituent elements, functional requirements, implementing approaches and key responsibilities associated with the management of controlled documents and records.

The document management process maintains and manages documents during their life cycles in a manner that ensures integrity, security, accessibility, disclosure and preservation, while satisfying applicable legal and regulatory requirements. Vital records essential to the continued operations of Bruce Power are managed in support of business continuity to ensure recovery from possible disaster.

1.8.2 Past Performance

Not applicable

1.8.3 Future Plans

New records generated by the isotope project will be kept in Content Server at Bruce Power.

1.9 Management of Contractors

1.9.1 Relevance and Management

Bruce Power retains responsibility for its statutory and licensing requirements when contracting out any work and when receiving any item, product, or service. Bruce Power identifies the requirements that each supplier must meet, and—regardless of the approach used by a supplier to meet the requirements—Bruce Power is ultimately responsible for ensuring the requirements are met.

Bruce Power executes these responsibilities:

- By developing and specifying scope of work (SOW) requirements to suppliers and ensuring these requirements are understood;
- By evaluating and selecting suppliers based on their abilities to meet requirements; and,
- By planning and conducting oversight to ensure compliance with requirements and accepted processes.

These processes include provisions for defining the boundaries of the supplier's Quality Assurance (QA) program.

These processes are collectively described in BP-PROG-05.01, Supply Chain, and BP-PROG-14.02, Contractor Management. Regular performance summaries and program health assessments are conducted and reviewed by senior management to identify and address performance and governance gaps.

The scope of BP-PROG-14.02 covers all Bruce Power contractors and field work execution. Work execution models are implemented, and qualifications and scope specifications (including safety, quality, cost, and schedule requirements) are defined and communicated to suppliers. The qualifications and ability of suppliers to meet requirements are assessed, and subsequently, oversight of field work is conducted via deployment of qualified Contract Supervisors.

As per BPMS requirements, the performance and health of BP-PROG-14.02 is assessed on a quarterly basis. Standard programmatic metrics and contractor metrics (including safety and quality measures for key, high-value contractors) are reviewed to gauge the level of compliance with of BP-PROG-14.02 and to identify adverse trends which trigger corrective actions to governance or program implementation.

BP-PROG-14.02 has well-defined interfaces with other business programs such as Supply Chain, Engineering, Construction, and Quality, and governance changes based on performance and user feedback continue to be assessed to accommodate new strategies.

1.9.2 Past Performance

Bruce Power's Independent Oversight organization conducted an audit in Q4 2019 to assess completeness and effective implementation of BP-PROG-14.02. Governance was found to be generally established, and improvements were noted in implementing procedures from previous audit findings.

Recent (2020) program health assessments have noted that Bruce Power's strategic contracting needs are evolving as the volume and use of contract resources grows in a variety of work execution situations. This evolution requires the implementation of enhanced contracting models for work execution that span a continuum moving away from brokered resources toward acceptance and application of contractor QA Programs and supporting work plans and practices. This enhanced approach is described in detailed in Section 1.9.3 and is being used to execute the Isotope Project.

1.9.3 Future Plans

Application of BP-PROG-14.02 to the IPS involves the following standard contractor management process activities:

- Identification of field work execution model and conduct of contract planning: Quality assurance program requirements are specified for the work, and scoping checklists are referenced to support the SOW. Requirements are developed based on the execution model. This documents whether the supplier QA program will apply and outlines supplier responsibilities and points of interface with Bruce Power;

- Development of SOW based on execution model: The SOW documents supplier requirements and deliverables. This includes specification of the execution documentation and other information to be produced for Bruce Power review and acceptance;

- Procurement process;

- Conduct supplier documentation review: Bruce Power reviews the supplier's plans and procedures for scope execution;

- Conduct field work oversight: Bruce Power assigns and deploys qualified contract supervisors (or other quality oversight individuals) to conduct oversight of field work against the defined requirements and accepted work processes. Construction oversight reports are prepared;

- Take corrective action: Bruce Power identifies adverse conditions and non-conformances. Subsequently, corrective actions are implementation and/or overseen. See Section 1.3.

1.10 Business Continuity

1.10.1 Relevance and Management

BP-PROC-00239, Business Continuity, is used to identify risk, threats, and vulnerabilities that could impact Bruce Power's continued operations. Additionally, the business continuity process provides a framework for building organizational resilience and the capability for an effective business recovery in the event of a business interruption.

The business continuity process is an element of Bruce Power's Emergency Management business program (see Section 10.0). The process is based on the PLAN-DO-CHECK-ACT cycle, as follows:

- PLAN: identification of business functions which are critical to the existence of Bruce Power, and determination of the time at which those functions must be operational following a business interruption;

- DO: implementation of business continuity controls, processes, strategies, and plans;

- CHECK: validation, monitoring, and review of performance with reporting to the Business Continuity Governance Committee; and,

- ACT: improvement of the process through preventative and corrective actions, based on the results of the reviews and drills.

As part of the business continuity process, Bruce Power has defined a Business Continuity and Recovery Plan. The plan includes a set of activities to guide the recovery director in formulating the incident-specific recovery plan to continue or recover critical functions with the goal of minimizing loss or harm to Bruce Power.

In addition to the overall Business Continuity and Recovery Plan, Bruce Power has subsidiary plans for each individual functional area. As discussed in Section 1.1.1, functional areas are made up of one or more business programs that collectively represent related, interdependent work activities.

The functional area business continuity plans document all activities to continue or recover the critical functions and the resources (tools, material, staff, and information) required to operate the critical functions at a minimally acceptable level, within a specific recovery time that ranges from zero (0) hours to three (3) months. The plans are written in a manner that enables repeatable recovery performance by any knowledgeable worker assigned to lead or perform the recovery activities.

1.10.2 Past Performance

Bruce Power's business continuity management process has evolved considerably since the 2018 PROL renewal. Several improvements have been made to the process; level of executive oversight, quality of the functional area business continuity plans, integration with emergency response, testing of the plans, and increased training for key business continuity roles.

In late 2018, an internal audit was performed of the business continuity process, with the following strengths identified:

- Cross-functional governance of the Business Continuity program;

- Strong coordination between the program coordinator and the program leads;

- Clearly defined and documented processes and procedures;

- Good review processes for the review of the critical functions, and;

- Well-executed 2018 corporate business continuity exercise.

Some low-risk findings were identified with all corrective actions complete by April 2020.

Improvements to Governance Committee oversight consisted of an enhanced scorecard to measure conformance to the Business Continuity Management process and level of completeness of the Functional Area Business Continuity plans. Daily reporting of Business Continuity actions are included on the management report, and senior leadership approval for drill and event reports is required.

Cross-functional exercises were performed in 2016, 2018, and 2019 (These exercises were in addition to the annual requirement to test the Functional Area Business Continuity Plan). Lessons learned for all exercises, drills, and events are documented in a drill or event report and managed through the Bruce Power corrective action processes.

Prior to the World Health Organization's declaration of a global pandemic for the novel coronavirus, the functional-area Business Continuity leads leveraged their Business Continuity plans to assess the impact of a staff shortage on critical functions.

Subsequently, the staff shortage assessments and Business Continuity plans informed the development of Severity Level 1 and Severity Level 2 plans which focus on the safe continuation of high-priority work with limited staff on site, and the majority of staff supporting remotely. Bruce Power executed these plans as the pandemic spread.

1.10.3 Future Plans

The continued focus of business continuity management is on ensuring continuous improvement through the CHECK and ACT elements of the process, applying lessons learned, and through implementing OPEX.

The operation of the IPS will be integrated into the business continuity plans as needed. Specifically, for the IPS, once the design is complete, a business impact analysis (BIA) will be conducted to identify critical functions for the IPS as per BP-PROC-00239. The output of the BIA will determine the required next steps.

2.0 HUMAN PERFORMANCE MANAGEMENT

Covers activities that enable 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.

2.1 Human Performance Program

2.1.1 Relevance and Management

Bruce Power's standards for human performance are directed by BP-PROG-16.01, Conduct of Business, which describes a system of interrelated inputs with the purpose of protecting the individual from causing errors through managing defences.

The standard details the hierarchy of defences that include engineered, administrative, cultural, and oversight controls. As a last line of defence, the standard describes the various human-performance tools which are used to anticipate, prevent and detect errors before they cause harm to people, plant, property or the environment.

The standard also outlines the key set of human performance indicators and supporting indicators that are used as common measurements to determine site effectiveness in the prevention of events.

The goal of human factors engineering work is to analyze and evaluate the elements that impact human performance, system usability, and to make recommendations where possible to improve the elements in compliance with N290.12-14, Human Factors in Design for Nuclear Power Plants and in accordance with DPT-PDE-00013, Human Factors Engineering Program Plan.

2.1.2 Past Performance

Not applicable

2.1.3 Future Plans

With respect to the IPS specifically, the interim Human Factors Engineering Summary Report has been submitted to the CNSC. Human Factors have followed the Engineering Change Control (ECC) process, adding recommendations throughout the design process. A final report will be completed after detailed design is finished.

A mock-up facility has been created to allow for acceptance testing of the IPS design. During the ECC process, Bruce Power operations staff utilized the mock-up facility to evaluate the safety and efficacy of the design. From this evaluation, observations and suggestions are being provided for improvements to further minimize potential risk to workers.

2.2 Personnel Training

2.2.1 Relevance and Management

The Training Change Management process is documented and governed in the Bruce Power Life Extension Training Work Plan (B-HBK-09500-00012), governed by BP-PROG-02.02, Worker Learning and Qualification. The work plan was developed to meet the requirements of CNSC REGDOC-2.2.2, Personnel Training.

With respect to the IPS, a Training Needs Analysis (TNA) has been developed. Preparation of the TNA utilized internal and external OPEX as well as task analyses for trades, engineering, chemistry technicians, operations, control maintenance, mechanical maintenance, health physics, and radiation protection. The training required for each impacted group is documented in the TNA.

Bruce Power's Systematic Approach to Training (SAT) ensures identified training needs are analyzed and appropriate performance-based training is designed, developed, implemented and evaluated. As part of the SAT, the Analysis, Design, Development, Implementation, Evaluation (ADDIE) model ensures training programs are evaluated, and these evaluations are fed back into the training developments to improve the quality and/or content of the training.

To validate that the vendors working on the Bruce Power site provide personnel which are adequately trained, Bruce Power uses an Execution Contractor Training Assessment (ECTA). The ECTAs assess the contractor's training program against criteria specified in the TNA. If the training programs are found to be unsatisfactory, the execution contractor will develop a training recovery plan to address the unsatisfactory areas, and provide any gap training that is required.

At Bruce Power, training of trades' personnel is performed at three levels:

- Level 1: training required for site access;
- Level 2: training specific to the project; and,
- Level 3: training provided by Execution Contractor (EC), specific to the work tasks of the project as determined by the TNA.

From the above levels, level 1 and level 2 training are covered within the Worker Learning and Qualification, BP-PROG-02.02. Level 3 training is governed by the EC training programs.

Figures 5&6: These images depict and demonstrate the IPS mock-up which is assembled to validate working principles of the system. After detailed design is completed, changes will be made to the mock-up to accurately represent the system that will be installed at Bruce Power. This Isogen Facility will provide hands on training for the required personnel.

2.2.2 Past Performance

Not applicable

2.2.3 Future Plans

After detailed design is complete, training aids will be prepared by IsoGen and Bruce Power stakeholders.

IsoGen plans to provide training for installation and operation of the IPS, including both classroom and hands-on learning. This training is planned to begin in 2021, after the completion of detailed design and development of operating procedures. As discussed in Section 2.3.3. Bruce Power plans to incorporate the operation of the IPS into continuing training for certified personnel and other required personnel.

The operation of the IPS will be performed by non-certified operators who will receive both classroom and dynamic training at the full-scale mock-up.

2.3 Personnel Certification

2.3.1 Relevance and Management

Bruce Power manages control room personnel certification as an element of the Worker Learning and Qualification program. The Worker Learning and Qualification program enables personnel to competently and safely operate, maintain, and improve the performance of the Bruce A and Bruce B stations.

2.3.2 Past Performance

A second full-scope simulator for Bruce B, which replicates Unit 7 and Unit 0, entered service in 2020.

2.3.3 Future Plans

Required training, as documented in the TNA, will be delivered as part of the certification continuing training program for Bruce B.

Authorized Nuclear Operators (who are certified by the CNSC) will receive classroom training for the addition of the IPS and the operations and maintenance requirements.

2.4 Initial Certification Examination and Requalification Tests

2.4.1 Relevance and Management

Bruce Power manages initial certification examinations and requalification tests as a subset of the BP-PROG-02.02. This business program enables personnel to competently and safely operate, maintain, and improve the performance of Bruce A and Bruce B.

2.4.2 Past performance

Not applicable

2.4.3 Future Plans

The IPS is expected to become a testable topic for both initial and requalification certification testing, subject to the standard topic sampling, selection, and testing guidance.

2.5 Work Organization and Job Design

2.5.1 Relevance and Management

Bruce Power manages the workforce through the workforce planning process, which is reviewed annually. A staffing verification by station senior management was completed to verify required headcount prior to operation of the IPS on Unit 7. It has been determined that the headcount will remain unchanged.

The roles and responsibilities required to support the production of isotopes at Bruce Power has been reviewed against existing job descriptions, and no gaps have been identified. Therefore, existing job descriptions will encompass the operation of the IPS.

However, a job and task analysis has been completed, and new operating procedures are planned to detail the step-by-step instructions to operate the IPS and to define the responsibilities of all relevant personnel.

2.5.2 Past Performance

Not applicable

2.5.3 Future Plans

Not applicable

2.6 Fitness for Duty

2.6.1 Relevance and Management

The fitness-for-duty process is an important part of work done by managers, with support and oversight from Employee Wellness. The fitness-for-duty process encompasses all aspects of a worker’s fitness to perform work, including fatigue, physical health and mental health. Bruce Power is committed to assisting workers achieve optimum functioning by providing support and resources. A computer-based training module, ensuring people are fit for duty, is required training for Bruce Power managers.

Severe weather demonstrates the need for a fitness-for-duty process. In some cases, longer shifts are required for minimum complement staff if the next shift is unable to safely travel to the Bruce site.

2.6.2 Past Performance

Bruce Power revised GRP-OPS-00055, Fitness for Duty Considerations for Shift Complement Staff Held over for more than 13 hours, to include reference to FORM-12987, Fitness for Duty Checklist, and FORM-13981, Fitness for Duty Checklist, Fatigue Assessment.

2.6.3 Future Plans

BP-PROC-00610, Fitness for Duty, will continue to apply to workers who are installing or operating the IPS.

Bruce Power will always emphasize the importance of supervisors' observations of fitness for duty since Bruce Power cannot control a worker's actions during off-work hours, which may impact that worker's ability to arrive well-rested for work.

3.0 OPERATING PERFORMANCE

Includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

3.1 Conduct of Licensed Activities

3.1.1 Relevance and Management

Bruce Power conducts licensed activities in a manner that complies with legal requirements ensuring the protection of workers, the public, and the environment. As Bruce Power's business is integrated within the overall management system, this entire Performance Review is relevant to the conduct of licensed activities and the overall Operating Performance Safety and Control Area (SCA).

With respect to the operation of Bruce A and Bruce B specifically (i.e., not considering supporting activities or areas addressed elsewhere in this review), Bruce Power manages the conduct of licensed activities through maintenance of Operating Policies & Principles (OP&Ps) and the Conduct of Plant Operations business program, BP-PROG-12.01. The OP&Ps are policy-level documents within the Bruce Power Management System (BPMS) and which define operating requirements and parameters consistent with relevant safety analyses and licensing requirements.

BP-PROG-12.01 defines the requirements and responsibilities of operations workers. The overall objective of the program is to put in place the governance to safely and reliably operate the station systems within the design basis and licensing basis. Operations conducted in accordance with the standards and expectations defined in this program provide strong support for the four pillars of nuclear safety: reactor safety, industrial safety, radiation safety, and environmental safety.

A key element of oversight for licensed activities is the Nuclear Safety Review Board (NSRB). The NSRB is a subcommittee of the Bruce Power Board of Directors and reports to the Board of Directors on the extent to which Bruce Power conducts its business in a manner that promotes safety. The NSRB emphasizes the long-term effort required to make permanent improvements in safety culture, including changing management behaviours and demonstrating leadership.

At least three appointed members of the NSRB are required to be expert in matters of nuclear operations and safety. Each of the members is independent of Bruce Power and is required to be experienced in matters of operational safety including: industrial safety, nuclear safety and/or environmental compliance. The NSRB also includes up to 10 ex-officio, non-voting members, including the President and CEO, and the Chief Nuclear Officer.

The NSRB reports directly to the Board of Directors on safety issues, performance, and culture. The NSRB reviews management safety reports, CNSC inspection reports, and internal audit reports, receives briefings from staff and management, reviews significant events, reviews industry reports, and conducts plant tours, observations, and investigations.

3.1.2 Past Performance

World Association of Nuclear Operators (WANO) evaluations for both Bruce A and B were completed recently (2018 and 2019 respectively). These evaluations identified areas of strength that can be shared with other operators around the world, and areas where we can learn from others to improve on our own performance.

Major Component Replacement for Unit 6 is in progress. Additionally, Bruce Power recently implemented a new enterprise asset management system (Maximo) which will help drive sustainable improvements for long-term operations.

In 2020, Bruce Power introduced its new Excellence Model serving as a foundation for the Management System (BP-MSM-1). The Excellence Model provides the full picture of organizational effectiveness, illustrating how we achieve excellence as a company and deliver business results.

3.1.3 Future Plans

To further improve operations, Bruce Power uses continuous improvement processes such as the corrective action program, internal assessments, and documented improvement plans.

Additionally, capital projects, outage maintenance, and online work management processes continue to improve the overall health of Bruce A and Bruce B station equipment.

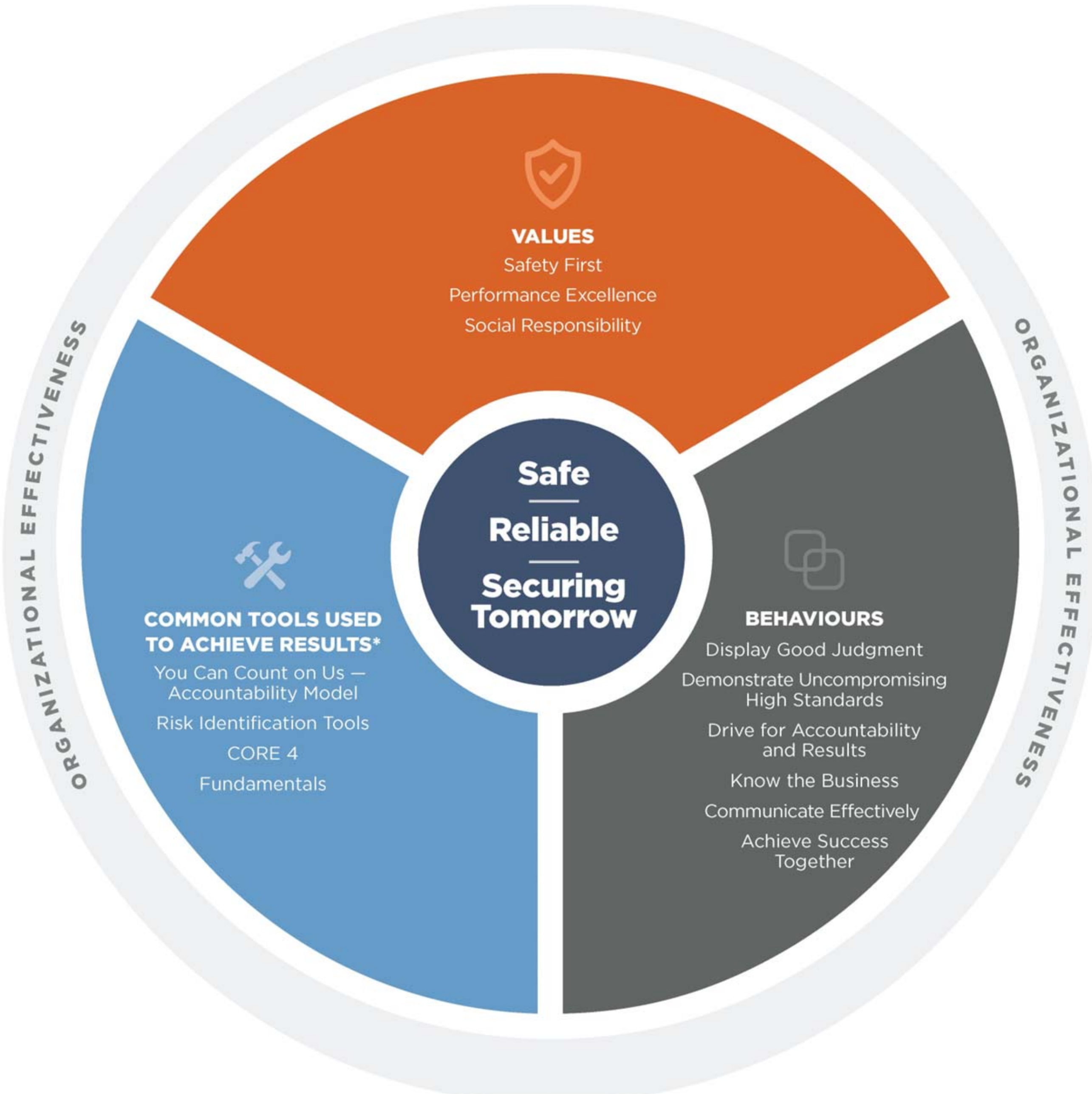

Figure 7: Bruce Power Excellence Model

3.2 Procedures

3.2.1 Relevance and Management

Bruce Power maintains OP&Ps for Bruce A and Bruce B. The OP&Ps clearly outline the operating boundaries within which the station is safely operated, maintained, and modified. The OP&Ps also specify the authorities of station staff - in particular, the Senior Operations Authority, the Shift Manager, and the Chief Engineer - to make decisions within defined boundaries. The OP&Ps identify actions for which discretion may be applied and for which appropriate jurisdictional authorization is required.

The OP&Ps are a combination of principle statements and policies, as well as operating limits and conditions which reflect the Safe Operating Envelope (SOE). The principles provide context for the more detailed requirements, while the policies provide direction for establishing, maintaining, and restoring safe operation. The limits and conditions define the specific requirements which must be met in order to determine if a station is in an accepted safe state.

Within the boundaries of the OP&Ps, detailed operating procedures are written to clearly define operating requirements for normal, abnormal, and emergency conditions. As operating experience accumulates, these detailed procedures are occasionally revised to improve the quality, simplicity and efficiency of station operation.

3.2.2 Past Performance

Not applicable

3.2.3 Future Plans

Operating procedures are currently being developed for the IPS.

3.3 Reporting and Trending

3.3.1 Relevance and Management

Pursuant to the Power Reactor Operating Licence, Bruce Power provides scheduled and unscheduled reports in accordance with REGDOC-3.1.1. Operation of the IPS will therefore be subject to the requirements of REGDOC-3.1.1.

3.3.2 Past Performance

Not applicable

3.3.3 Future Plans

Not applicable

3.4 Outage Management Performance

3.4.1 Relevance and Management

Bruce Power manages outages through the business program, Outage Work Management, BP-PROG-11.03, which provides the controls associated when planning, implementing, assessing and continuously improving work performance on a shutdown reactor unit. BP-PROG-11.03 ensures that work activities are identified and that the requirements for the work are understood.

3.4.2 Past Performance

Not applicable

3.4.3 Future Plans

The outage team was engaged early on to create a schedule that would lead to a successful installation of the IPS, utilizing BP-PROG-11.03. Installation of the IPS is planned to occur during a Unit 7 outage in late 2021.

3.5 Safe Operating Envelope

3.5.1 Relevance and Management

Bruce Power manages the SOE through the Plant Design Basis Management, BP-PROG-10.01, as well as the Engineering Change Control, BP-PROG-10.02, in accordance with CSA N290.15-10, Requirements for the Safe Operating Envelope for Nuclear Power Plants. This standard provides requirements for the definition, implementation and maintenance of the SOE.

The nuclear generating stations must be designed, analyzed, operated, and maintained within the defined SOE.

Safe operating limits, conditions, and surveillance requirements, as well as their bases with respect to the current safety analyses, are documented in station- and system-specific Operational Safety Requirements (OSRs) along with any associated instrumentation uncertainty calculations.

Operations and maintenance procedures, processes, and tests are required to comply with the OSRs, including any corrective or mitigating actions and action times. Changes to station design, maintenance, or operation require that compliance is maintained.

A deterministic safety assessment for the operation of the IPS was performed through a systematic review of the Bruce B Safety Report supported by specific assessments which demonstrate there is no material change in accident analysis results or event progression. Analysis has also shown negligible change associated with nominal reactor operation.

The results of the deterministic safety assessment were provided to the CNSC. The assessment demonstrated that the impact of the IPS on the Bruce B Safety Report is negligible and thus the impact on the SOE, as defined in CSA N290.15, is also negligible.

3.5.2 Past Performance

An internal audit was completed in 2015 to verify compliance to CSA N290.15. All findings from the audit have been addressed.

3.5.3 Future Plans

Not applicable

3.6 Severe Accident Management and Recovery

3.6.1 Relevance and Management

Severe accident response and recovery is managed as part of BP-PROG-12.01. Additionally, severe accident management at Bruce Power 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.

To the maximum extent practicable, Bruce Power has adopted the COG Industry recommendations for Severe Accident Management Guidelines (SAMG). These recommendations are summarized in a technical support group user's guide. The user's guide is a field-level reference and training document that describes the overall structure of SAMG, the rules of SAMG usage, and additional practical aspects associated with Technical Support Group (TSG) performance of evaluations and development of recommended mitigating strategies and recovery actions. It is intended to support TSG member training by providing a concise high-level summary of the key points associated with use of the SAMG package.

A qualitative impact analysis of the installation and operation of the IPS on the severe accident fission product source terms was performed. The results of the severe accident assessment were provided to the CNSC. The assessment documents there are no impact on the severe accident source terms due to the installation of the IPS equipment and/or operation of the IPS. It was also concluded that no changes are required to the Bruce Power MAAP-CANDU parameter file due to the IPS, and the IPS has no impact on the release categories assigned to different plant damage states. Therefore Lutetium-177 production has been deemed to have no impact on severe accident response and recovery.

3.6.2 Past Performance

As a result of the incident at Fukushima Daiichi Nuclear Power Plant, COG established an industry joint project to review SAMG in use at Canadian nuclear power plants. The COG review identified several gaps in the pre-Fukushima SAMG, including:

- Lack of guidance to address shutdown units or low-power operation;
- Lack of guidance for multi-unit events;
- Lack of guidance for irradiated fuel bay severe accidents;
- A need to develop a methodology for evaluating instrumentation and equipment survivability during a severe accident; and,
- A need to develop a process to determine plant habitability during a severe accident.

As a result of this review, the Bruce Power SAMG Technical Basis Document was revised to address these gaps, along with the revision of station-specific guidelines.

Bruce Power has completed validation of the SAMGs. New SAMG-enabling instructions were created for new toolkits that have been installed in the stations for temporary water makeup connections to the Primary Heat Transport System and to the Moderator System.

3.6.3 Future Plans

Not applicable

3.7 Accident Management and Recovery

3.7.1 Relevance and Management

The Bruce Power operations program establishes safe, uniform, and efficient practices under all operating conditions (routine and non-routine), ensuring that legal requirements are met and the requirements of the OP&Ps are implemented. Operating limits are established in accordance with a SOE.

The measures in place to address accident management and recovery include the following:

- Abnormal Incident Manuals (AIMs): These manuals provide responses or direction to address unit upsets within the design basis. While the use of AIMs is rare, their use prevents any OP&P limits from being exceeded;
- Emergency Field Operation procedures (EFOs);
- Severe Accident Management procedures: These procedures provide a framework for identifying appropriate mitigating actions for events that fall into the severe accident category;
- Sufficient number of qualified staff during accidents: At all times, Bruce Power staffs Bruce B with the required number of workers who are qualified to fill minimum complement positions, and;
- Emergency Response Organization: Bruce Power's Emergency Management Program, BP-PROG-08.01, and emergency response organization are described further in Section 10.1.

An impact assessment for the operation of the IPS was performed through a systematic review of the Bruce B Safety Report supported by specific assessments which demonstrate there is no material change in accident analysis results or event progression. Analysis has also shown negligible change associated with nominal reactor operation.

The results of the deterministic safety assessment were provided to the CNSC. The assessment demonstrated that the impact of the IPS on the Bruce B Safety Report is negligible, and thus the impact on accident management and recovery is also negligible.

3.7.2 Past Performance

On an annual frequency, each nuclear operator and authorized nuclear operator who holds a minimum complement position receives training on EFOs and AIMs.

Bruce Power's “all hazards” approach to emergency management has been tested and assessed through quarterly drills and annual corporate-level exercises. The drills and exercises are used to verify that the integrated emergency response processes, command structure, equipment, systems, and personnel are capable of responding to and mitigating the effects of design basis accidents.

3.7.3 Future Plans

Not applicable

4.0 SAFETY ANALYSIS

Covers maintenance of the safety analysis that supports the 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.

4.1 Deterministic Safety Analysis

4.1.1 Relevance and Management

Bruce Power integrates deterministic safety analysis (DSA) and probabilistic safety assessment (PSA) (also known as probabilistic risk assessment) to ensure nuclear safety requirements are defined for issues that may impact the station's design basis or safety analysis basis.

Safety analysis is performed in accordance with REGDOC-2.4.1, Deterministic Safety Analysis, and REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants, to verify that regulatory requirements (such as dose limits) are met, to assist in defining the Safe Operating Envelope (SOE), and to verify that special safety systems and safety-related systems can perform their mitigating role for design basis accidents.

An impact assessment for the operation of the IPS was performed through a systematic review of the Bruce B Safety Report, supported by specific assessments which demonstrate there is no material change in accident analysis results or event progression. Analysis has also shown negligible change associated with nominal reactor operation.

The results of the deterministic safety assessment were provided to the CNSC. The assessment demonstrated that the impact of the IPS on the Bruce B Safety Report is negligible.

The safety analysis that was performed and discussed in this document is specific to the initial IPS and the isotope Lutetium-177.

4.1.2 Past Performance

The Bruce A and Bruce B Safety Reports were updated in 2017.

4.1.3 Future Plan

Bruce Power Safety Report is updated every five (5) years. The next update for Bruce Power is planned for 2022, which will include the IPS.

Prior to installation of any additional IPSs or the production of isotopes other than Lutetium-177, additional safety analysis is planned to be performed to ensure the system and/or isotope production can be safely introduced into the Bruce site units.

4.2 Hazard Analysis

4.2.1 Relevance and Management

The CSA N289 series of standards includes general requirements for seismic hazard evaluation, seismic design and qualification, and testing and monitoring, as applicable for the seismic qualification of those nuclear power plant structures, systems, and components necessary for safe shutdown, fuel cooling, the containment of potential releases of radioactive material, and the monitoring and control of essential safety-related functions in the event of an earthquake.

Bruce B was originally designed with a design basis earthquake. Modifications to Bruce B are qualified to the Bruce B design basis earthquake. The containment boundary portions of the IPS (distributor head, piping, supports, containment boundary valves) will be seismically qualified to the same design basis as applicable to seismically qualified systems within containment. Other portions of the system outside the containment boundary that could impact seismically qualified Structures, Systems, Components, and Tools (SSCTs) are also being seismically assessed for their interaction with the neighbouring seismically qualified components. The assessment basis is planned to be the same as of the target component.

The fire protection assessment—including code compliance review, fire hazard assessment, and fire safe shutdown analysis—is completed and updated in accordance with CSA N293,Fire Protection for Nuclear Power Plants. Changes to the facility (engineering changes) are assessed to determine whether the change adversely affects assumptions in the fire protection assessment. The detailed engineering review process provides the Bruce Power fire protection specialist with the details needed to determine the level of independent review required and when it will be included in the fire hazard assessment. For the IPS, the assessment is planned to be part of the electrical/instrumentation design change notice.

Bruce Power has a robust process for the PSA in order to evaluate the safe operation of the stations against defined safety goals. As a part of the PSA review, a qualitative impact analysis was performed on the operation of the IPS on the Bruce Power reactors internal and external hazards assessment. The results of the internal and external hazards assessment were provided to the CNSC. The assessment found that none of the identified hazards were impacted by the operation of the IPS. Therefore, the existing Bruce B internal and external hazards assessment remains valid.

4.2.2 Past Performance

In 2018, the fire hazard assessment was completed in accordance with CSA N293 and accepted by the CNSC.

The Bruce Power PSA was updated in 2019 to comply with REGDOC-2.4.2. The PSA includes fire, seismic, and internal/external hazard analysis.

4.2.3 Future Plans

Updates to the fire hazard assessment will be made, if required as determined by the Engineering Change Control process.

The PSA is updated every five (5) years in accordance with REGDOC-2.4.2 and REGDOC-3.1.1. The next update for Bruce Power is in 2024. Consideration of the impact of the IPS will be included in this update.

4.3 Probabilistic Safety Analysis

4.3.1 Relevance and Management

Bruce Power integrates DSA and PSA to ensure nuclear safety requirements are met for issues that may impact the station's design basis or safety analysis basis.

Safety analysis is performed in accordance with REGDOC-2.4.1, Deterministic Safety Analysis, and REGDOC-2.4.2, PSA for Nuclear Power Plants, to verify that regulatory requirements (such as dose limits) are met, to assist in defining the SOE, and to verify that special safety systems and safety-related systems can perform their mitigating role for design basis accidents.

Bruce Power has a set of PSA-based quantitative safety goals and administrative targets which assure acceptable risk from the operation of Bruce A and B. The Bruce A and Bruce B PSAs meet the safety goals.

A qualitative review of the impact of the IPS on the Bruce B PSA was performed. Each of the PSA elements was reviewed to determine the impact from the IPS, through qualitative analysis on the impact of the installation and operation of the IPS equipment on the Internal and External Hazards Screening assessments and on each of the Bruce B PSA studies (i.e., Level 1 and Level 2 Internal Events, Internal Fire, Internal Flood, Seismic, and High Wind).

The results of the PSA were provided to the CNSC. The assessment demonstrated that the overall impacts from the IPS on the quantification of Severe Core Damage Frequency and Large Release Frequency in the various PSA elements are negligible.

4.3.2 Past Performance

The Bruce Power PSA was updated in accordance with REGDOC-2.4.2 in 2019 and submitted to the CNSC. The CNSC review of the assessment is ongoing.

4.3.3 Future Plans

The PSA is updated every five (5) years in accordance with REGDOC-2.4.2 and REGDOC-3.1.1. The next update for Bruce Power is in 2024. Consideration of the impact of the IPS will be included in this update.

4.4 Criticality Safety

4.4.1 Relevance and Management

Bruce Power has a process to manage nuclear criticality safety practices, which are consistent with international standards and with REGDOC-2.4.3, Nuclear Criticality Safety. Bruce Power always prevents the possibility for enriched reactor fuel to form a critical configuration outside the reactor core.

Nuclear criticality safety requirements are also integrated into the Bruce Power processes for controlling changes, for implementing new design and operating requirements, and for ensuring workers are qualified.

Any active nuclear criticality safety project would be subject to the requirements of the process for management of nuclear criticality safety practices as per BP-PROC-00324, Nuclear Criticality Safety Management.

Lutetium-177 does not emit neutrons and therefore cannot have any impact on criticality safety.

4.4.2 Past Performance

Not applicable

4.4.3 Future Plans

Not applicable

4.5 Severe Accident Analysis

4.5.1 Relevance and Management

Bruce Power has a robust process for PSA in order to evaluate the safe operation of the stations against defined safety goals. PSAs include assessments of severe accidents as part of the Level 2 PSA, in accordance with REGDOC-2.4.2, Probabilistic Safety Analysis for Nuclear Power Plants.

A qualitative impact analysis of the installation and operation of the IPS was performed on the severe accident fission product source terms. The results of the severe accident assessment were provided to the CNSC. The assessment documents that there is no impact on the severe accidents source terms due to the installation of the IPS equipment and/or operation of the IPS. It was also concluded that no changes are required to the Bruce Power MAAP-CANDU parameter file due to the IPS, and the IPS has no impact on the release categories assigned to different Plant Damage States.

4.5.2 Past Performance

The Bruce Power PSA was updated in 2019 to comply with REGDOC-2.4.2.

4.5.3 Future Plans

The PSA is updated every five (5) years per REGDOC-2.4.2 and REGDOC-3.1.1. The next update for Bruce Power is in 2024. Consideration of the impact of the IPS will be included in this update.

4.6 Management of Safety Issues (including R&D programs)

4.6.1 Relevance and Management

As committed in the Canadian Nuclear Utility Executive Forum/CNSC Executive Forum held in 2007, the CNSC initiated a project intended to identify a list of safety issues associated with the design and analysis of Canadian CANDU reactors, and to develop the path forward to address, in a risk-informed manner, any outstanding concerns on nuclear safety. These safety issues were classified into three broad categories. Bruce Power has worked to obtain reclassification of all Category 3 issues to Category 2 or Category 1.

These categories are defined by:

- Category 1 – not an issue in Canada;
- Category 2 – the issue is a potential concern in Canada, however, appropriate measures are in place to maintain safety margins;
- Category 3 – the issue is a concern in Canada, however, measures are in place to maintain safety margins but the adequacy of these measures needs to be confirmed given the impact of aging on operating plants.

A survey was performed of the Category 2 issues in regards to impact of installation and operation of the IPS. Most were deemed not applicable.

The remaining CANDU Safety Issues (CSIs) were reviewed and found not to be impacted by installation of the IPS, as noted below:

- GL2, Environmental qualification (EQ) of equipment and structures: Bruce Power processes were followed in design of the IPS meeting EQ requirements;
- SS3, Severe core damage accident management measures: No impact. See Section 3.6;
- SS8, Availability of the moderator as a heat sink: In-core failure analysis was performed and provided to the CNSC. A review of in-core failure showed there would be minimal impact, and that operation of the IPS is bounded by the existing safety case;
- IC9, Establishment and surveillance of set points in instrumentation: No impact, as demonstrated in the Slow Loss of Regulation analysis provided to the CNSC;
- IH1, Need for systematic fire hazards assessment: No impact. See Section 4.2&4.3;
- EH1, Need for systematic assessment of seismic effects: No impact. See Section 4.2&4.3;
- EH3, External hazard assessment: No impact. See Section 4.2&4.3;
- AA1, Adequacy of scope and methodology of design basis accident analysis: A safety analysis case was prepared to comply with REGDOC-2.4.1 and was submitted to the CNSC for acceptance;
- AA7, Analysis for pressure tube failure with consequential loss of moderator: No impact. In-core Loss of Coolant Accident (LOCA) and Loss of Moderator Inventory analysis has been provided to the CNSC;

- AA8, Analysis for moderator temperature predictions: No impact. Analysis demonstrated that no local moderator boiling will occur due to installation of the IPS. In-core LOCA analysis has been provided to the CNSC;

- AA9, Analysis for void reactivity coefficient: Analysis demonstrates the IPS has minimal impact on the reactor physics characteristics of the Bruce B reactors, including flux and coolant void reactivity and reactivity worth;

- PF12 (GAI 00G01), Channel voiding during a Large LOCA: See AA 9;

- PF9 Fuel behaviour in high temperature transients: No impact. Following the installation of the IPS, the change in the bundle power is no more than 0.2 per cent;

- PF18 Fuel Bundle/Element Behaviour under Post-dryout conditions: The IPS has negligible effect on dryout power for all channels.

Analysis has demonstrated that the IPS has minimal impacts on the reactor physics characteristics of the Bruce B reactors, including flux and coolant void reactivity, and reactivity worth. It has also demonstrated that the IPS has negligible effect on the global thermal hydraulic response of the Heat Transport System.

4.6.2 Past Performance

In November 2019, CNSC accepted Bruce Power's request for reclassification of the following large LOCA CSIs from Category 3 to Category 2:

- AA9: Analysis for void reactivity coefficient;

- PF9: Fuel behaviour in high temperature transients, and;

- PF10: Fuel behaviour in power pulse transients.

With this, Bruce Power has addressed all CSIs originally classified as Category 3.

4.6.3 Future Plans

With reclassification of all Category 3 CSI items to lower Categories, there are no future plans with respect to the IPS.

5.0 PHYSICAL DESIGN

Relates to activities that impact the ability of structures, systems and components to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.

5.1 Design Governance

5.1.1 Relevance and Management

The physical design of the Bruce site facilities is managed through the Plant Design Basis Management, BP-PROG-10.01, Engineering Change Control, BP-PROG-10.02, and Configuration Management, BP-PROG-10.03. These business programs provide a disciplined approach to the control of the physical configuration, design requirements, and facility configuration information such that structures, systems, and components are fully functional and support safe, reliable plant operations.

The overall objective of the program suite is to ensure that Structures, Systems, Components, and Tools (SSCTs) meet design basis requirements and enable the plant to operate safely, reliably, and efficiently for the duration of its operating life. This program suite includes processes that ensure:

- Design requirements are defined and documented;
- Changes are correct, documented, controlled, and approved, and;
- Operations, maintenance, and training documents are up to date and are consistent with the plant design.

Organizational responsibilities and change approval authority are assigned to promote proficiency through standard processes and activities while maintaining Bruce Power's commitment to the four pillars of safety of nuclear safety (reactor, radiological, environmental, and industrial safety).

With respect to the IPS, the Isogen vendors (Kinectrics and Framatome) are on the Approved Vendor List and are performing the design activities within their own organizational quality assurance programs, as accepted by Bruce Power. Bruce Power is performing design oversight, and is responsible for final review and approval of all design deliverables.

5.1.2 Past Performance

The Engineering Change Control (ECC) process used to perform the physical design of the IPS was updated due to the implementation of the new enterprise asset management system (Maximo) in 2020.

The ECC processes have been implemented to:

- Establish the required design process for each engineering change type;
- Incorporate risk management and a graded approach to change commensurate with nuclear safety;
- Document a process which ensures that requirements are systematically demonstrated as satisfied prior to being returned to Operations;
- Update site facility configuration information in a timely manner following completion of the engineering change;
- Sufficient deliverables provided to ensure operational sustainability and maintainability of the SSCT(s) for the intended life cycle.

5.1.3 Future Plans

Using Bruce Power's processes, effective use of stakeholder involvement and the corrective action program continue to drive further improvements in design engineering governance. Bruce Power also plans to benchmark the broader nuclear industry to optimize safety and performance during design and implementation of modifications.

5.2 Site Characterization

5.2.1 Relevance and Management

The Bruce Power site is located on the eastern shore of Lake Huron in the Municipality of Kincardine, Bruce County, Ontario. The site hosts two nuclear generating stations, Bruce A and Bruce B, comprising of four (4) reactors and four (4) turbines at each station. The addition of the IPS will not have any impact on overall site characterization as the system is completely contained within the reactor side of the unit.

Figure 8: Aerial Image of Bruce B Station at Bruce Power

5.2.2 Past Performance

Not applicable

5.2.3 Future Plans

Not applicable

5.3 Facility Design

5.3.1 Relevance and Management

There are no impacts to the Bruce B facility design as a result of the IPS as the system is being designed within the existing facility design.

5.3.2 Past Performance

Not applicable

5.3.3 Future Plans

Not applicable

5.4 Structure Design

5.4.1 Relevance and Management

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.

5.4.2 Past Performance

Not applicable

5.4.3 Future Plans

Not applicable

5.5 System Design

5.5.1 Relevance and Management

This section provides a brief, high-level overview of the proposed IPS (confidential technical details are not provided).

The IPS is being designed using the ECC procedures (design governance is discussed in Section 5.1). In essence, the IPS is a pneumatic transfer system that has been designed for compatibility with CANDU technology.

The production process begins with the targets. Target material is to be contained completely within sealed, leak-tested ampules that are compatible with the temperature and radiation fields inside the reactor core. For Lutetium-177, the target material consists of Yttberbium-176 in powder form.

Target ampules are inserted into a target carrier, which is designed to maintain the integrity of the ampules during insertion and retrieval.

An operator will load one or more target carriers into the IPS. A delivery device is used to control and monitor the system operations. The delivery device is located outside of containment and provides the main operator interface.

The delivery device interfaces with an inert carrier gas supply and pneumatic tubing. The carrier gas passes through a distributor head and is contained within a spare vertical guide tube. The guide tube serves as the pressure boundary and ensures no contact between the IPS and the D_2O moderator.

The delivery device will pneumatically insert one or more targets into the reactor core. The number of targets to be irradiated simultaneously will depend on business requirements.

After the required irradiation period, the delivery device retrieves the targets, which after a delay period in a shielded area will be deposited directly into a shielded, transport container (see Section 14.1). The transport container will protect the targets from damage, while allowing workers to safely transport the targets for off-site processing.

During use, the carrier gas is directed to the contaminated exhaust system (see Section 9.1).

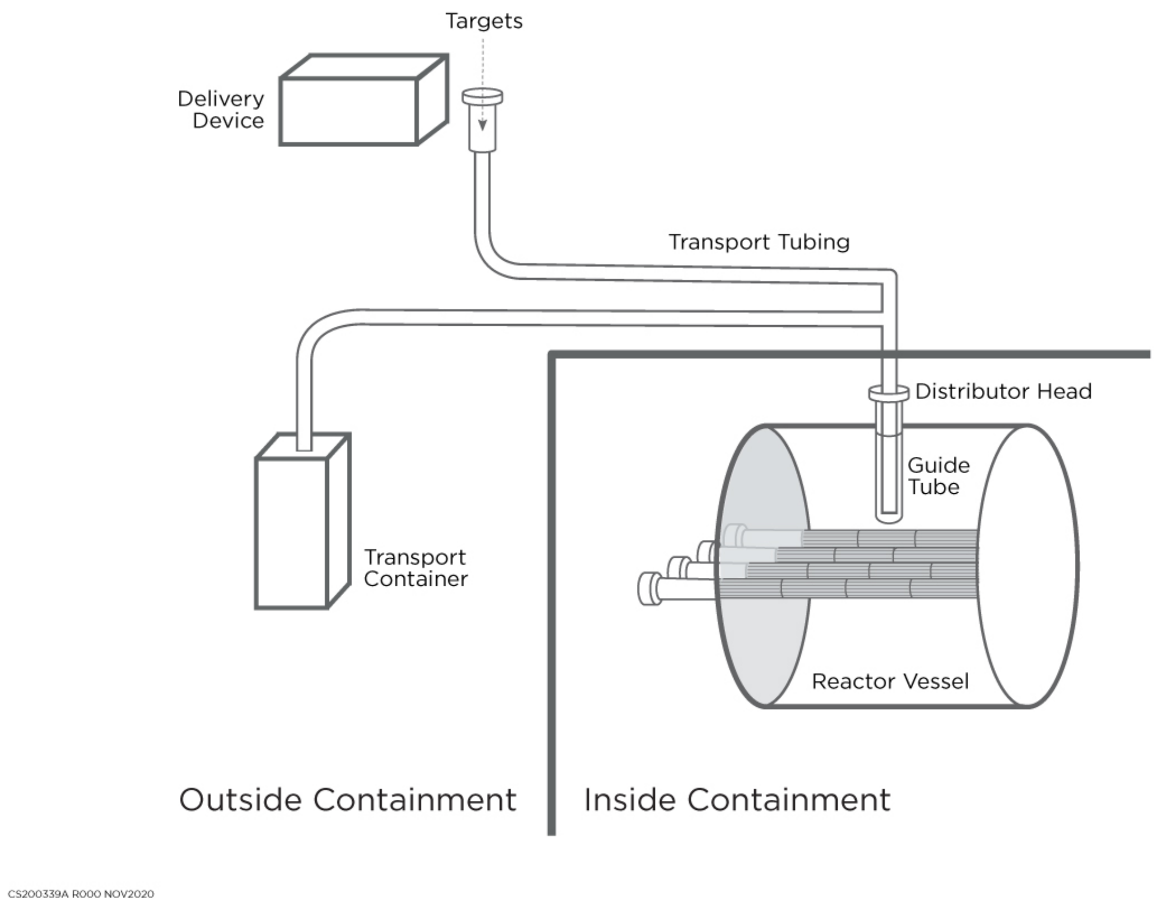

Figure 9: Conceptual Design of the Proposed IPS

5.5.2 Past Performance

Not applicable

5.5.3 Future Plans

Modifications and elaborations may occur as a result of the design process. Additionally, the IPS may be modified slightly as a result of operating experience prior to installation in other units. In both cases, no material change to the general design is anticipated.

5.6 Component Design

5.6.1 Relevance and Management

Components in the system will be designed using the ECC implementing procedures.

5.6.2 Past Performance

Not applicable

5.6.3 Future Plans

Not applicable

6.0 FITNESS FOR SERVICE

Covers activities that impact the physical condition of structures, systems and components to ensure that they remain effective over time. This area includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.

6.1 Equipment Fitness for Service, Equipment Performance

6.1.1 Relevance and Management

The Equipment Reliability program, BP-PROG-11.01, is intended to ensure that Structures, Systems and Components (SSCs) perform in a safe, reliable, and cost-effective manner. Bruce Power's integrated and coordinated equipment reliability business program is based on the Institute of Nuclear Power Operations (INPO) AP-913, Equipment Reliability Process Description, with appropriate enhancements to address the regulatory and business requirements applicable to Bruce Power.

Bruce Power's equipment reliability objectives and processes apply to operation of the IPS. BP-PROG-11.01 requires that equipment and system performance criteria are established, and that system data is collected to enable performance monitoring, identification of adverse trends and implementation of corrective actions as required.

Bruce Power plans to incorporate pre-requisite functional and performance checks and tests into standard operating procedures in order to ensure equipment reliability prior to use.

Preventative maintenance is a key part of the BP-PROG-11.01. Accordingly, Bruce Power plans to add the new IPS components to Bruce Power's master equipment list so that data such as the critical category, duty cycle and service condition are identified and the preventative maintenance strategy and frequency are determined.

The IPS will interface with service systems that supply (for example) power. The requirements of the IPS are within the design of the service systems. Accordingly, no changes are expected for interfacing systems and associated equipment reliability requirements. However, this will be formally assessed as part of the Engineering Change Control (ECC) process.

6.1.2 Past Performance

Not applicable

6.1.3 Future Plans

Equipment reliability and overall system health of the IPS will be tracked as per business program requirements.

6.2 Maintenance

6.2.1 Relevance and Management

BP-PROG-11.04, Plant Maintenance, establishes processes to effectively maintain plant structures, systems, and components, such that the availability and reliability of safety-related and production sensitive equipment is maximized, and that operators are not challenged by equipment failure.

The new components being introduced to the station due to the IPS will be added to Bruce Power's Master Equipment List so that data such as the critical category, duty cycle and service condition can be identified to determine the required preventative maintenance strategy and frequency.

Additional maintenance activities may be prescribed based on technical input from the designers and manufacturers of components, as well as from the system failure modes and effects analysis. The conduct of maintenance (i.e., use and adherence to maintenance procedures, fundamentals and technical skills, training, qualified staff working on pressure boundary systems, etc.) will be in accordance with the maintenance program.

6.2.2 Past Performance

Not applicable

6.2.3 Future Plans

Not applicable

6.3 Structural Integrity

6.3.1 Relevance and Management

Structural integrity is maintained by lifecycle management practices which includes inspection, testing and maintenance activities under BP-PROG-11.01. The IPS will be constructed, operated and maintained within structural integrity requirements of Bruce B to ensure the safety of personnel, equipment and the environment.

6.3.2 Past Performance

Structural assessments have been performed to ensure the addition of the new loads from the system's shielding and equipment have no impact to the structural integrity of Bruce B.

6.3.3 Future Plans

Not applicable

6.4 Aging Management

6.4.1 Relevance and Management

Aging Management is performed as part of the lifecycle management process of SSCs under BP-PROG-11.01. The business program is based on REGDOC 2.6.3, Fitness for Service - Aging Management and the INPO AP-913 and uses technical basis assessments, plant inspections, performance monitoring, health reports and other sources of data to develop and implement long-term SSC monitoring and maintenance strategies. The life-cycle management processes and procedures apply to the new IPS under USI 31790B and will ensure safe operation and maintenance of the system.

6.4.2 Past Performance

Not applicable

6.4.3 Future Plans

After detailed design is completed which includes the failure modes and effects analysis, the need for future Performance Monitoring, BP-PROC-00781, Preventative Maintenance Implementation, BP-PROC-00780, Plant Inspection, BP-PROC-00387 and other implementing procedures supporting age management will be determined.

6.5 Chemistry Control

6.5.1 Relevance and Management

The Chemistry Management business program, BP-PROG-12.02, is used to preserve the integrity of structures, systems, and components important to safety by limiting and controlling corrosion that can cause degradation.

This program supports ECC in any design change or modification. As part of ECC, chemistry considerations are included to ensure that the changes will not impact the safety, reliability and life-cycle requirements of the systems.

A chemistry review was completed during the IPS design phase, and the IPS is meeting the chemistry program requirements.

6.5.2 Past Performance

Not applicable

6.5.3 Future Plans

Not applicable

6.6 Periodic Inspection and Testing

6.6.1 Relevance and Management

The periodic inspection and testing process ensures the requirements for periodic inspection of safety-related plant SSCs are established and documented through creating, updating, and revising Periodic Inspection Plans (PIPs) and schedules. Procedures are used to document the methods for review, evaluation, and dispositions of periodic inspection findings, and are used to identify the roles and responsibilities for relevant workers.

6.6.2 Past Performance

Not applicable

6.6.3 Future Plans

New portions of the IPS will be incorporated into the system PIP.

7.0 RADIATION PROTECTION

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 are monitored, controlled and As Low As Reasonably Achievable (ALARA) principles maintained.

7.1 Application of ALARA

7.1.1 Relevance and Management

The Radiation Protection Program, BP-PROG-12.05, governs the processes used to control contamination and monitor radiation doses received by workers. Radiological hazards are identified, measured and controlled to ensure worker doses remain below regulatory limits and collective dose is reduced to be As Low As Reasonably Achievable (ALARA).

Bruce Power has a suite of procedures that govern the planning, execution and supervision of radioactive work. Anchored by BP-RPP-00044, ALARA Program, and supported by BP-RPP-00041, Execution of Radiological work, and BP-RPP-00040, Oversight of Radiological work, these documents lay the foundation for safe execution of radiological work at Bruce Power.

With respect to the IPS, applications of ALARA are being utilized during the design phase. For example, determining areas of reduced background radiation dose for equipment installation and shielding is being incorporated into the design to minimize dose received by the workers.

7.1.2 Past Performance

Not applicable

7.1.3 Future Plans

Execution of installation and operation supporting activities will follow all aspects of BP-PROG-12.05. The work will fall under requirements for ALARA planning and oversight as determined by BP-RPP-00044.

Oversight of radiological performance will be provided through established processes that include periodic self-assessments and continuous improvement initiatives.

7.2 Worker Dose Control

7.2.1 Relevance and Management

See Section 7.4.1.

7.2.2 Past Performance

Not applicable

7.2.3 Future Plans

Not applicable

7.3 Radiation Protection Program Performance

7.3.1 Relevance and Management

The radiation protection program supports Bruce Power's commitment to ensure that safety is the paramount consideration guiding decisions and actions by documenting procedures and standards for:

- Personnel roles, responsibilities, and expectations;
- Planning radiological work and oversight;
- Facilities and equipment;
- Executing radiological work to control contamination and dose;
- Verification, assessment and oversight; and,
- Incident response and change management.

The program is implemented by a suite of implementing procedures. Employees and temporary contract workers are selected, trained and qualified in accordance with BP-PROG-02.02, Worker Learning and Qualification. Additional oversight of worker dose and radiation protection fundamentals is provided by Radiation Protection business program, as well as both Site and Station ALARA committees.

As described in Section 1.1.3, Bruce Power plans to implement a new irradiation services business program. As part of the integrated Bruce Power Management System (BPMS), this business program interfaces with, and complies with, BP-PROG-12.05.

7.3.2 Past Performance

Not applicable

7.3.3 Future Plans

Not applicable

7.4 Radiological Hazard Control

7.4.1 Relevance and Management

For the radiological work of the IPS, radiological hazards are identified, measured and controlled in accordance with BP-RPP-00040. Work is then planned and executed in a manner that minimizes worker doses and prevents dose to the public.

Personal protective equipment, alarming dosimeters and area radiation monitors are used extensively - in addition to work surveys - to prevent unplanned exposures and to ensure worker doses do not exceed regulatory limits for the installation or the operation of the IPS.

Monitoring, tracking and limiting the movement of radioactive material are required for safe handling. This process will be followed for the installation of the IPS and movement of target carriers during routine operation.

Figure 10: Employee Equipped with Personal Protective Equipment Entering the Vault

7.4.2 <u>Past Performance</u>

Bruce Power's radiation protection technicians and operators have a long history of safe isotope production. Bruce Power has extensive experience in performing routine performance of Cobalt-60 harvests. Accordingly, that experience and robust radiation protection practices will also apply to isotope production within the IPS.

7.4.3 <u>Future Plans</u>

Radiation protection information plans to be submitted to the CNSC.

7.5 Estimated Dose to the Public

7.5.1 <u>Relevance and Management</u>

Assessment of doses to the public is an element of the Environmental Management Program, BP-PROG-00.02, which ensures that radiation doses to the public are below regulatory limits. The radiological environmental monitoring process is used to estimate the actual or potential doses to representative persons from the presence of radiation fields or radioactive materials in the environment as a result of the operations on the Bruce Power site.

The operation of the IPS to produce Lutetium-177 is expected to result in no measureable changes to the dose to the public.

7.5.2 Past Performance

For 28 consecutive years, the maximum dose to a member of the public has been less than the 10 µSv per year, a value that is regarded as the lower threshold of significance. In 2019, the maximum dose to a member of the public was 0.15% of the annual legal limit of 1000 µSv.

7.5.3 Future Plans

Not applicable

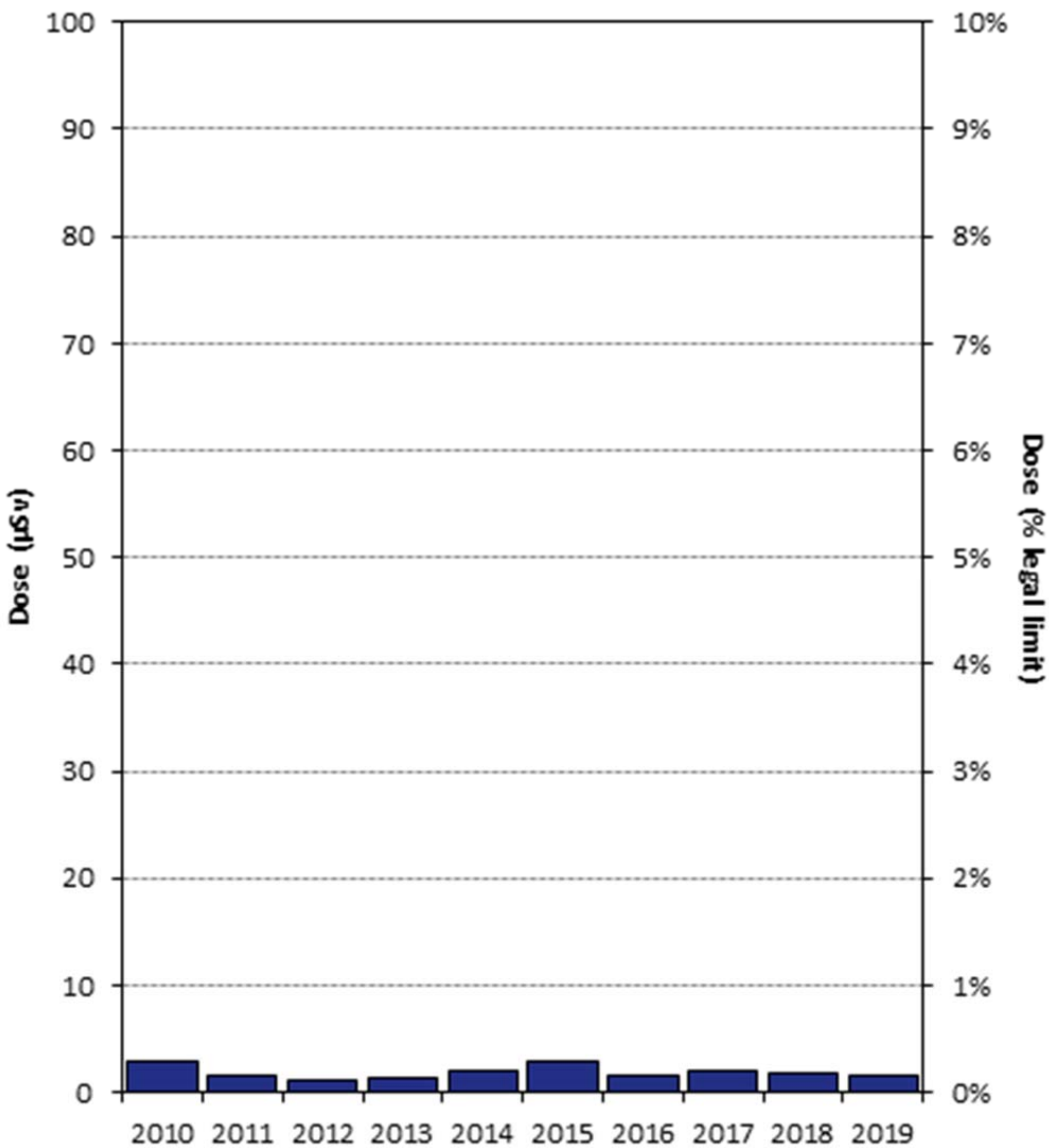

Figure 11: Maximum Dose to Public (2010-2019)

8.0 CONVENTIONAL HEALTH AND SAFETY

Covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment.

8.1 Performance, Practices, Awareness

8.1.1 Relevance and Management

Bruce Power has a well-established Occupational Health and Safety management system which is designed to identify, assess and control conventional health & safety hazards. The Health and Safety Management Program, BP-PROG-00.06, is structured to ensure legal, as well as other requirements to which Bruce Power subscribes, are met.

Design activities for the IPS are being managed through Bruce Power's Engineering Change Control (ECC) process. Conventional health and safety issues are being identified and mitigated as part of this process.

The following elements of BP-SM-00064, Hazard Identification, are also applicable and will be employed for insertion and retrieval activities:

- Job Safety Analysis;
- Pre-Job Brief;
- Take Two For Your Safety; and,
- Use of 2x2 matrix.

The following Performance Improvement Tools will also apply:

- Human Performance Tools as per BP-PROC-00617; and,
- Observation and Coaching.

8.1.2 Past Performance

Bruce Power has experience harvesting Cobalt-60 of which some processes are applicable, and will be applied to, Lutetium-177 harvests.

8.1.3 Future Plans

Performance monitoring of issues will be facilitated through:

- Observation and Coaching;
- Condtion Reports; and,
- Station Condition Reports as required by BP-PROC-00060.

9.0 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.

9.1 Effluent and Emissions Control (releases)

9.1.1 Relevance and Management

BP-PROG-00.02, Environmental Management, defines governance for processes used to identify, control, and monitor releases of radioactive and hazardous substances. The effluent monitoring sub-program is in accordance with CSA N288.5-11, Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills.

Radiological emissions are identified, controlled, and monitored. The following radioactive effluent controls and limits are in place to ensure the protection of the environment and members of the public:

- Legal limit for release: The derived release limit is the upper bound of emissions for a specific radionuclide (or radionuclide group) and specific emissions pathway. The derived release limit is based on the legal limit for dose to a member of the public. These limits are determined in accordance with 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.

- Level for external (regulatory) notification: Action levels are set well below the derived release limits to provide early warnings of any actual or potential losses of control to the Environmental Protection Program. Exceedance of an action level requires regulatory notification and corrective actions to return to normal operating conditions. Currently, the action levels are approximately 10% of the derived release limits. However, Bruce Power is transitioning to more conservative values with the implementation of CSA N288.8-17, Establishing and Implementing Action Levels for Releases to the Environment from Nuclear Facilities.

- Level for internal investigation: Internal investigation levels are set well below the action levels and are the upper range of normal. Exceedance of an internal investigation level requires identification of cause and corrective actions to return to normal operating conditions.

The IPS is not expected to generate radioactive effluents or emissions. The target ampules are sealed and leak-tested before being inserted in a target carrier. The target carrier is designed to maintain the integrity of the ampules during insertion and retrieval from the core. The carrier gas generates very few activation products.

The system is also designed to handle accident situations. In case of breakage of the ampules, potential contamination will be managed and monitored. The IPS is connected to the contaminated stack through a high-efficiency particulate air (HEPA) filter, which captures and contains radioactive substances to prevent release. The low levels of emissions that are not contained by the HEPA filters are released through the stack, which is continuously monitored with particulate, iodine and noble gas monitors. The environmental impact of breakage would be included in the Weekly Effluent Report (WER), and would be reported as part of the station compliance monitoring.

9.1.2 Past Performance

Not applicable

9.1.3 Future Plans

Not applicable

9.2 Environmental Management System (EMS)

9.2.1 Relevance and Management

Bruce Power has an environmental policy that establishes guiding principles for environmental management and environmental performance. The environmental policy commits Bruce Power to go beyond compliance and to promote stewardship and sustainability as a fundamental aspect of Bruce Power's business.

Environmental management is governed by BP-PROG-00.02, which integrates requirements with respect to safety, environmental management, and quality.

Internal assessments are made to evaluate the performance of BP-PROG-00.02. These assessments include annual performance reviews and focus area self-assessments, as well as internal audits conducted by the Quality Division.

Following these assessments, Bruce Power takes action to correct deficiencies, in accordance with the corrective action program. External audits are conducted annually, with respect to compliance with ISO 14001. A surveillance audit is conducted for two years, with a re-registration audit in the third year. These audits are conducted by the external registrar for ISO 14001 registration.

9.2.2 Past Performance

Bruce Power maintains ISO 14001, Environmental Management System, certification as required by REGDOC-2.9.1, Environmental Protection: Environmental Principles, Assessments and Protection Measures.

Bruce Power had a successful re-registration audit in 2017 to acquire certification to an enhanced version of the ISO 14001 standard. Bruce Power's ISO 14001:2015 surveillance audits were conducted by an external registrar in 2019. The auditor determined that the management system is effectively implemented and meets the requirements of the standard.

Bruce Power recently completed its ISO 14001 re-registration audit in September 2020, with no non-conformances identified. The final report and certification are pending.

9.2.3 Future Plans

The environmental aspect of the IPS will be managed within the existing BP-PROG-00.02

9.3 Assessment and Monitoring

9.3.1 Relevance and Management

BP-PROG-00.02 includes assessment of environmental risks in terms of likelihood and magnitude. This assessment is integrated into environmental and overall business practices. An Environmental Risk Assessment (ERA) is completed every 5 years (or earlier if significant operational or facility changes occur that would necessitate an update) in accordance with CSA N288.6-12, Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills.

The effluent monitoring program is in accordance with CSA N288.5-11, and is designed using a graded approach based on risk. The monitoring requirements are evaluated with consideration of the probability and severity of a radiological emission from each effluent stream and pathway. Compliance monitoring is in place for effluent streams with higher risk based on normal operating levels, maximum probable emissions rates and derived release limits. The effluent monitoring program is reviewed on an annual basis and updated following any changes to operations or following an update to the ERA.

The planned IPS has been reviewed and is not expected to have an impact on the environment. In the unlikely event of a failure and the generation of activation products, emissions would be directed to the exhaust stack and be contained by the HEPA filters. As discussed in Section 9.1, releases through the stack are detected via continuous monitoring, and are reported to the CNSC.

9.3.2 Past Performance

There is compliance monitoring in place for the exhaust stack for particulate gross beta/gamma emissions. Historically, the airborne particulate gross beta/gamma emissions are very low and typically near or below the minimum detectable activity of the instrumentation. These are measured on a weekly basis (cumulative emissions) and reported to the CNSC on a quarterly basis.

9.3.3 Future Plans

Not applicable

9.4 Protection of the Public

9.4.1 Relevance and Management

Protection of the public is ensured in part through the monitoring and control of radiological emissions. Releases are controlled through the application of derived release limits, action levels, and internal investigation levels and impacts on human and ecological health are assessed through the ERA.

As part of the radiological environmental monitoring sub-program, a variety of environmental media are collected in the local area each year and analyzed for radiological contaminants. This includes air, precipitation, drinking water, surface and well water, milk, fish, fruit and vegetables, deer (when available) and eggs. Media is collected near and far field of the site and the results are compared to provincial values where possible. The information is used in verifying both the environmental monitoring program design and ERA conclusions. The information is also used in calculating the dose to public each year to ensure that radiation doses are below regulatory limits.

Doses to the public are calculated using a computer program called IMPACT (used to assess the transport of contaminants through specified environmental pathways), annual meteorological data, annual effluent and environmental monitoring data for the Bruce site (including data for all on-site facilities licensed by the CNSC), and site-specific survey results (last completed in 2016).

For the 28th consecutive year, Bruce Power's calculated dose to a member of the public is less than the 10 μSv/year value that is regarded as the lower threshold for significance.

9.4.2 Past Performance

Not applicable

9.4.3 Future Plans

The IPS is not expected to release radiological contaminants to the environment. It is expected that there will be no measureable change to the annual dose to the public each year.

9.5 Environmental Risk Assessment

9.5.1 Relevance and Management

Effects on the environment are assessed through an ERA, prepared in accordance with N288.6-12, Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills. In an ERA, the Tier 1 screening level risk assessment is conducted to identify receptors and stressors that require further quantitative assessment. For those receptors and stressors, a subsequent quantitative assessment is completed at a preliminary level (Tier 2) or, if of potential concern, at a detailed level (Tier 3).

An ERA was completed in 2017 with updates in 2018. The ERA is to be updated at least every five years, with the next update planned for June 2022. The ERA, which incorporated Major Component Replacement activities, included a human health risk assessment as well as an ecological risk assessment.

Key conclusions include:

- The operation of the Bruce A and Bruce B facilities has not resulted in adverse effects on human health of nearby residents or visitors, including radiological exposure and non-radiological substances.
- Risks to ecological receptors are limited to exposure in soil in a small number of former industrial areas.

9.5.2 Past Performance

CNSC staff confirmed that the Bruce Power ERA met the requirements of CSA N288.6-12. Bruce Power is continuing to review and consider CNSC recommendations and other comments for addressing in ongoing work and for disposition in future ERAs.

9.5.3 Future Plans

The 2022 ERA will include assessment of impacts as a result of any relevant changes to operations, including isotope production. The results of the ERA will be incorporated into the existing effluent and environmental monitoring processes.

The ERA Gap Analysis for Isotope Production Activities is submitted as Enclosure 1 of this document.

10.0 EMERGENCY MANAGEMENT AND FIRE PROTECTION

Covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.

10.1 Conventional Emergency Preparedness and Response

10.1.1 Relevance and Management

The Emergency Management Program, BP-PROG-08.01, ensures that Bruce Power is ready to manage the consequences of any events (“all-hazards” approach) that have the potential to impact workers, the public, the environment, and infrastructure. Bruce Power is ready to respond to on-site emergencies without external assistance for a minimum of 72 hours even with loss of external power.

BP-PROG-08.01 addresses prevention, mitigation, preparedness, response, and recovery.

Emergency response is implemented through emergency response plans and associated procedures, using the Incident Management System approach. Specific emergency response plans include plans for nuclear emergencies, winter storm transportation, electricity emergencies, radioactive material transportation emergencies, conventional emergencies, fire safety management, and business continuity. Bruce Power recovery process is managed by business continuity plans; see section 1.10.1 for more information.

Prevention and mitigation measures are identified in advance, workers are trained and drilled to ensure high-level performance, and capabilities are established and maintained for effective, rapid response.

The response to emergencies is led by the Emergency Response Organization (ERO), which includes shift, on-call, and call-in workers. Shift ERO workers are located primarily in the stations and on-site labs to ensure a minimum number of qualified workers available at all times to respond to an emergency. Additionally, all Bruce Power workers are expected to know their responsibilities and to remain prepared in the event of an emergency.

An on-site, 24/7 Emergency Services organization supports emergency preparedness and response (fire, medical and environmental response). Emergency Services workers are highly trained and are continuously tested through drills and exercises.

Mutual aid and support agreements are maintained with external organizations to assist Bruce Power’s emergency response.

BP-PROG-08.01 is assessed through a continuous series of quarterly drills and annual corporate-level exercises to test whether the integrated emergency response processes, command structure, equipment, systems, and workers are capable of responding to and mitigating the effects of emergencies.

Bruce Power has invested in world-class equipment and implemented a training regime consistent with industry top performers. Bruce Power trains and exercises extensively and rigorously to evaluate performance against the best in the industry. Bruce Power's workers are well-equipped, well-trained and well-prepared, but are not complacent, as emergencies will present new and unique challenges that have not been drilled or exercised.

Note that the scope of conventional emergencies includes fire, rescue, first aid, and chemical/biological spills. Nuclear emergency preparedness is discussed in Section 10.2, while fire emergency preparedness is discussed in Section 10.3

Installation and operation of the IPS does not add additional requirements to the existing BP-PROG-08.01.

10.1.2 Past Performance

The latest corporate exercise, Huron Resilience, simulated an on-site scenario caused by an earthquake (which is extremely unlikely). The exercise was held over a three-day period in October 2019, and included approximately 1,200 employees as participants. Additional participants included the CNSC, Health Canada, the Provincial Emergency Operations Centre, and the Municipality of Kincardine. The exercise demonstrated that Bruce Power's ERO is prepared to implement the Provincial Nuclear Emergency Response Plan.

In the past three years, the ERO has been activated twice.

The ERO was activated in December 2018 as discussed in Section 10.3.2.

Additionally, the ERO was activated in March 2020 due to the COVID-19 pandemic. This led to the standing up of some members of the ERO for a prolonged period of time while arrangements and communications were set up and established in order to keep the essential elements of the Bruce Power site running safely.

These demonstrate the effectiveness of the ERO in an "all-hazards" situation and that the structure and protocols set up for the ERO allow the team to respond to any situation or event successfully in order to protect personnel, public and the plant.

10.1.3 Future Plans

Not applicable

10.2 Nuclear Emergency Preparedness and Response

10.2.1 Relevance and Management

The overall Emergency Management plan is described in Section 10.1.

Bruce Power maintains a nuclear emergency plan, along with a set of abnormal incident manuals and emergency operating procedures. The nuclear emergency plan addresses nuclear emergencies and transportation-related emergencies, as well as treatment of individuals with radioactive contamination.

Additionally, Bruce Power maintains equipment, procedures and staff to support off-site response activities in the unlikely event of any release of radioactivity.

The existing document suite is adequate to deal with any potential event due to operation of the IPS.

10.2.2 Past Performance

Not applicable.

10.2.3 Future Plans

It is necessary for ERO team members to have an appropriate understanding of the IPS in the event of an emergency. Bruce Power plans to provide this information to the ERO teams through presentations at quarterly scheduled table top exercises.

10.3 Fire Emergency Preparedness and Response

10.3.1 Relevance and Management

The overall emergency management plan is described in Section 10.1.

Bruce Power has implemented a robust fire safety management plan to address the planning, implementation, and control of activities in order to minimize the risk of fire-related consequences to the nuclear safety systems, workers, power generation, structures, systems, equipment and the environment.

Bruce Power is compliant with the requirements of CSA N293-12, Fire Protection for Nuclear Power Plants, with an on-site fire department that is ready to respond around the clock.

Installation and operation of the IPS does not add additional requirements to the existing fire emergency preparedness and response plans, except as noted in Section 10.3.3.

10.3.2 Past Performance

In December 2018, a fire in the Unit 8 System Service Transformer required activation of the Emergency Management Centre and the ERO team to assist station and site staff in managing the fire.

10.3.3 Future Plans

With respect to the IPS, upon completion of the detailed design engineering phase, an update may be required to the pre-fire plan element of the fire response documentation. Additionally, updates to the fire hazard assessment and fire safe shutdown analysis (Section 4.2) will be completed, if needed, as per the Engineering Change Control process.

11.0 WASTE MANAGEMENT

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. This area also covers the planning for decommissioning.

11.1 Waste Characterization

11.1.1 Relevance and Management

Waste Management, Characterization and Minimization practices are applicable to all Bruce Power facilities and all qualified workers performing radioactive waste activities at Bruce Power, whether they are full time or part time staff, or contractors.

For more information, see section 11.3.1.

11.1.2 Past Performance

Not applicable

11.1.3 Future Plans

Not applicable

11.2 Waste Minimization

11.2.1 Relevance and Management

Operations, maintenance, and project planning and practices include a strong focus on limiting the production of waste and facilitating the handling, storage and disposal of waste.

General practices include:

- Prevention of unnecessary contamination;
- Control of materials that can become contaminated;
- Separation of radioactive materials from non-radioactive materials;
- Reuse or decontamination of materials; and,
- Segregation of radioactive waste.

Further requirements for how staff should minimize, segregate and dispose of routine solid waste are detailed in BP-RPP-00010, Minimization, Segregation, and Handling of Radioactive Waste.

11.2.2 Past Performance

Not applicable

11.2.3 Future Plans

In general, operation of the IPS is not expected to generate additional nuclear waste beyond normal plant operations. With the prospect of producing other isotopes, the amount of waste could vary depending on contractual agreements or the specific isotope, but producing Lutetium-177 should not increase the waste generated at the Bruce Power site.

For waste generated during installation of the IPS, see section 11.3.1.

11.3 Waste Management Practices

11.3.1 Relevance and Management

Bruce Power manages many different forms of waste, including radioactive, hazardous (oils and chemicals), recyclables (glass, cardboard, plastic, paper, metal) and organic (compost). Waste which is not radioactive, not hazardous, non-recyclable, and non-compostable is landfill waste.

Bruce Power's waste management policy is to ensure that safe, reliable disposal pathways are available for all waste produced on site, while striving to reduce the volume of waste generated.

Conventional and hazardous waste is managed in BP-PROG-00.02, Environmental Management and implemented by procedures.

For waste management of radioactive waste, Radiation Protection Program, BP-PROG-12.05, implements and maintains a program 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.

BP-PROC-000878, Radioactive Waste Management, provides guidance for processing radioactive waste in accordance with Bruce Power's Radioactive Waste Management Policy for all Bruce Power employees in the following areas:

- Minimization;
- Handling and segregation;
- Collection and processing;
- Packaging, transport, storage and disposal; and,
- Receipt and processing.

11.3.2 Past Performance

Not applicable

11.3.3 Future Plans

A Waste Management and Demobilization Plan (WMDP) will be created for the IPS. This plan will outline all the waste to be generated by the project and all materials, tools and equipment to be demobilized. The following activities will be required:

- Completion of FORM-11803, Waste Minimization Plan;
- Execution contractor is required to and responsible for outlining the waste management plan including: packaging, labelling, demobilization and disposal.

There is work required on the reactor core prior to the installation of the IPS. Any internal reactor components will be considered intermediate-level waste.

11.4 Decommissioning Plans

11.4.1 Relevance and Management

Ontario Power Generation (OPG) is responsible for decommissioning Bruce A, Bruce B and the Central Maintenance and Laundry Facility. OPG is also responsible for life-cycle management of all used fuel, as well as low-and-intermediate-level waste produced by these facilities.

OPG provides the CNSC with a decommissioning cost estimate and technical update every five years.

11.4.2 Past Performance

Not applicable

11.4.3 Future Plans

OPG is informed of any changes Bruce Power makes to the site which could result in changes to the decommissioning cost estimate and plan. OPG will add the Central Storage Facility to the decommissioning plan.

OPG will be advised of any modifications to the plant as a result of the IPS once installed, and the decommissioning plan and decommissioning cost estimates will be updated to reflect the changes, as required.

12.0 SECURITY

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.

12.1 Facilities and Equipment

12.1.1 Relevance and Management

The Bruce Power site is protected by a series of defense-in-depth security measures, starting at the outer boundary of the Bruce site. The Nuclear Security program, BP-PROG-08.02, satisfies all requirements of high-security sites pursuant to the *Nuclear Security Regulations* and associated regulatory documents.

The existing security-related facilities and equipment will not be impacted by the operation of the IPS.

12.1.2 Past Performance

BP-PROG-08.02 has continued to perform to high standards and to meet all expectations of the CNSC.

Bruce Power submits a quarterly report on operational security to the CNSC, pursuant to REGDOC-3.1.1, to communicate key security-related performance data. (This quarterly report contains prescribed information and cannot be released to the public).

12.1.3 Future Plans

Bruce Power site is implementing the requirements of CSA N290.7-14, Cyber Security for Nuclear Power Plants and Small Reactor Facilities.

Bruce Power is implementing standards including physical and information security to its Cyber Essential Assets (CEA), which will protect from both internal and external threats. If detailed design demonstrates cyber security is required for specific pieces of equipment associated with the IPS, these standards will be applied.

12.2 Response Arrangements

12.2.1 Relevance and Management

The Ontario Provincial Police and Bruce Power have established arrangements for off-site response force through a memorandum of understanding. The operation of the IPS has no impact on these arrangements.

12.2.2 Past Performance

Not applicable

12.2.3 Future Plans

Not applicable

12.3 Security Practices

12.3.1 Relevance and Management

Bruce Power's Nuclear Security program defines the requirements, elements and key responsibilities associated with providing best-in-business nuclear security services and practices in accordance with the *Nuclear Safety and Control Act*, applicable regulations and other CNSC requirements and expectations.

All workers accessing Bruce Power site, including IPS project workers, are required to follow the existing security practices under BP-PROG-08.02. This includes, but is not limited to:

- Site access security clearance;
- Site visitor sponsorship and registration with security;
- Protected area access controls; and,
- Escort requirements for visitors accessing the station.

12.3.2 Past Performance

Not applicable

12.3.3 Future Plans

The transportation vehicle required to access the Bruce site when transporting isotopes and transport containers will adhere to any existing security practices.

12.4 Drills and Exercises

12.4.1 Relevance and Management

The existing BP-PROG-08.02 establishes processes to meet requirements of the Nuclear Security Regulations. This includes security drills performed by each shift crew on a monthly basis to test the operation of one or more of the physical protection measures and the readiness of the nuclear response team members.

A bi-annual force-on-force exercise is conducted in cooperation with off-site response (Ontario Provincial Police) under the CNSC performance testing program. The program sets objectives to meet with each test and evaluates the response based on the response applied. Each test has lessons learned that are applied to ensure improving standards.

The operation of the IPS will have no substantive impact on BP-PROG-08.02.

12.4.2 Past Performance

Not applicable

12.4.3 Future Plans

Not applicable

13.0 SAFEGUARDS AND NON-PROLIFERATION

Covers the program and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the Treaty on the Non-Proliferation of Nuclear Weapons.

13.1 Nuclear Material Accountancy and Control

13.1.1 Relevance and Management

Pursuant to the Power Reactor Operating Licence, Bruce Power supports the CNSC and the International Atomic Energy Agency (IAEA) in implementing Canada's obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons*.

Bruce Power accounts for the nuclear material on site and reports to the CNSC in accordance with REGDOC-2.13.1, Safeguards and Nuclear Material Accountancy. This includes tracking of inventory, conducting regular physical inventories, and providing monthly and annual nuclear material accountancy reports through the CNSC electronic system.

Installation and operation of the IPS has no impact on the processes used for nuclear material accountancy and control.

13.1.2 Past Performance

Not applicable

13.1.3 Future Plans

Not applicable

13.2 Access and Assistance to the IAEA

13.2.1 Relevance and Management

Pursuant to the Power Reactor Operating Licence, Bruce Power supports the CNSC and IAEA in implementing Canada's obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons*.

Bruce Power provides prompt access for IAEA inspectors to perform announced and unannounced inspections of site facilities.

In addition, Bruce Power provides services and assistance for the IAEA to install, operate, and maintain safeguards equipment, including detectors and surveillance cameras.

Installation and operation of the IPS has no impact on Bruce Power's commitment to provide access and assistance to the IAEA. No change to any IAEA safeguards equipment is anticipated.

13.2.2 Past Performance

Not applicable

13.2.3 Future Plans

Not applicable

13.3 Operational and Design Information

13.3.1 Relevance and Management

Pursuant to the Power Reactor Operating Licence (PROL), Bruce Power supports the CNSC and IAEA in implementing Canada's obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons*.

In accordance with REGDOC-2.13.1, Bruce Power is required to provide up-to-date design information to the CNSC, as it relates to nuclear material accountancy and control. This information is subsequently provided to the IAEA. The IAEA has the right to request - and Bruce Power provides - prompt access to facilities for the purpose of verifying the design information.

Additionally, Bruce Power provides operational information to the CNSC, on an annual basis, in accordance with REGDOC-2.13.1. Operational information includes planned date of; physical inventory taking, anticipated outage dates, expected transfers of nuclear material, expected harvest and shipment of Cobalt-60, and other information relevant to nuclear safeguards. The CNSC provides this information to the IAEA to facilitate the IAEA's verification activities.

13.3.2 Past Performance

Not applicable

13.3.3 Future Plans

The IAEA has requested routine operational information regarding isotope production. Bruce Power plans to provide this information to the CNSC and IAEA, in alignment with established processes for provision of operational information.

13.4 Safeguards Equipment, Containment and Surveillance

13.4.1 Relevance and Management

Pursuant to the PROL, Bruce Power supports the CNSC and IAEA in implementing Canada's obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons*.

In order to verify the accountancy reports and ensure Canada has met its obligations under the *Treaty*, the IAEA uses surveillance (mainly cameras) and containment (mainly seals) techniques, as well as radiation detectors. This allows for continuous, remote monitoring by the IAEA (in-person inspections are also conducted, as discussed in Section 13.2). Seals are used by the IAEA to ensure that equipment is free from tampering.

As noted in Section 13.2, Bruce Power provides services and assistance for the IAEA to install, operate, and maintain safeguards equipment, including detectors and surveillance cameras. Additionally, workers are trained to not interfere with or move safeguards equipment and seals, nor to position equipment so as to advertently block the view of safeguards cameras. Unplanned interruptions to IAEA equipment (for example, loss of power) are reported and are addressed expeditiously.

Installation and operation of the IPS will have no impact on existing safeguards equipment and seals. Based on discussion with the CNSC and IAEA, the IAEA is not expected to request installation of any additional safeguards equipment.

13.4.2 Past Performance

Not applicable

13.4.3 Future Plans

Not applicable

13.5 Import and Export

13.5.1 Relevance and Management

The PROL does not authorize the import or export of nuclear substances associated with the IPS.

Our partners will apply for any applicable CNSC licences in order to authorize export for processing and subsequent import for use.

13.5.2 Past Performance

Not applicable

13.5.3 Future Plans

Not applicable

14.0 PACKAGING AND TRANSPORT

Programs that cover the safe packaging and transport of nuclear substances to and from the licenced facility.

14.1 Package Design and Maintenance

14.1.1 Relevance and Management

Pursuant to the *Packaging and Transport of Nuclear Substances Regulations, 2015*, radioactive material is required to be transported within a package for which the design was certified by the CNSC. Additionally, package designs must be certified and users of that package design must apply to the CNSC to register their intended use of the package.

Bruce Power fully complies with these requirements.

14.1.2 Past Performance

Not applicable

14.1.3 Future Plans

Operation of the IPS is intended to produce radioactive material for shipment. A shielded transport container is currently undergoing certification with the CNSC. Pursuant to the regulatory requirements, Bruce Power will prepare and ship radioactive material only if that package design has been certified by the CNSC and if Bruce Power has been registered as a user of that package.

14.2 Packaging and Transport

14.2.1 Relevance and Management

Bruce Power has extensive experience in safely packaging radioactive materials for transport. The process for managing radioactive shipments is one element of Bruce Power's robust Radiation Protection Program, BP-PROG-12.05, which is described at a high level in Section 7.0.

The process for managing radioactive shipments complies with the *Transportation of Dangerous Goods Regulations*, *Packaging and Transport of Nuclear Substances Regulations, 2015*, and IAEA SSR-6, *Regulations for the Safe Transport of Radioactive Material*.

Only trained and qualified workers may prepare radioactive materials for shipment. Oversight and associated reporting is provided by a qualified Transport Coordinator. In brief, materials are prepared for shipment, surveyed for radioactivity, classified, packaged securely in a container consistent with the requirements of the classification, and then surveyed for radioactivity on the exterior of the package. The package is then inspected, labelled, and provided to a qualified carrier in association with appropriate documentation.

Figure 12: Bruce Power Employee preparing Cobalt-60 for Shipment

14.2.2 Past Performance

On a daily basis, nuclear substances are safely handled and transported throughout Ontario and Canada, following strict regulatory requirements (cited above) with oversight by the CNSC and Transport Canada.

Note that Bruce Power does not act as a carrier (transporter) for radioactive materials off site. Transport services are provided by qualified carriers. Procedures and processes supporting these shipments ensure strong compliance with transport regulations. The packaging and transport processes are mature and periodically reviewed for the purpose of continuous improvement.

Over the licensing period (since September 2018), two transportation events occurred related to material shipped from the Bruce site. In April 2019, a package containing Cobalt-60 was found to have external damage upon arrival. A boss used for the jack bolt was cracked, due to a gap in the loading procedure. There was no impact to public safety, and the package was capable of functioning as intended under normal and accident conditions. In October 2019, a truck carrying low-level radiological waste was involved in a vehicular accident. The packages remained intact with no release of radioactivity, and the carrier completed the shipment on the same day.

14.2.3 Future Plans

With the production of Lutetium-177, the frequency of nuclear substance shipments will increase. To ensure interruption of the transportation schedule is minimized, Bruce Power has chosen to start training a group of Class 7 shippers.

14.3 Registration for Use

14.3.1 Relevance and Management

Bruce Power is a registered user of various packages of certified designs, pursuant to the *Packaging and Transport of Nuclear Substances Regulations, 2015*.

14.3.2 Past Performance

Not applicable

14.3.3 Future Plans

Pursuant to the regulations, Bruce Power will apply to be a registered user of an appropriate certified package, prior to any shipment.

15.0 OTHER MATTERS

15.1 CNSC Consultation – Indigenous Relations

15.1.1 Relevance and Management

Community sessions were held in Saugeen and Nawash First Nations in July 2019 and included Saugeen Ojibway Nation (SON) leadership, the SON environment office, Bruce Power leadership and staff, the Canadian Nuclear Safety Commission (CNSC) as well as participants from Kinectrics – Nuclear Engineering. The format of the community sessions followed a passport style which involved each community being provided with a passport book that facilitated engagement with the SON Environment Office, Bruce Power, CNSC, Kinectrics and supported by project information. This information included; what is an isotope, how we treat cancer, how isotopes are used to treat and diagnose cancer, what is Lutetium-177, SON and Bruce Power collaboration opportunity, Production process, and benefits to SON. The event included providing community members a survey as well as allowing them to provide additional information with a feedback wall.

Building on feedback from information sessions held in SON communities (Saugeen and Neyaashiinigmiing), the partners engaged SON knowledge keepers and an artist to develop a project logo and name in Anishinaabemowin. Community Knowledge Holder Polly Keeshig-Tobias met with other Knowledge Holders and Elders, and developed a short list of potential names. 'Gamzook'aamin aakoziwin' was chosen. This name translates to "We are teaming up on the sickness", and captures the spirit of the partnership – fighting cancer together. More information on the partnership can be found on the www.fightingcancertogether.ca website.

In addition, presentations were made to MNO and HSM on September 3, 2020 and September 8, 2020, respectively. These meetings were attended by the MNO staff, HSM staff, (at their respective meetings), Bruce Power Environment team, Bruce Power Isotope project team and Indigenous Relations.These presentations explained the importance, purpose and benefits of medical isotopes. They also included a description of the current isotope project, including information on Lutetium-177 and the operation of the IPS.

Comments and questions were encouraged throughout the presentation and any concerns were addressed. During the presentations questions were asked regarding:

- Releases into the environment;
- Increase of nuclear waste; and,
- Increased dose to the public.

These comments were addressed by:

- Explaining the IPS has been reviewed and not expected to have any releases into the environment;
- This project is not excepted to increase nuclear waste beyond that produced during normal plant operation; and,

- The operation of the IPS is expected to result in no measureable changes to the dose to the public.

As a follow up to these presentations, Bruce Power has provided a “frequently asked questions” information sheet as supporting material to the local Indigenous communities. Ensuring our relationship with them is collaborative and inclusive is an important part of this project.

15.1.2 Past Performance

The Saugeen Ojibway Nation (SON) and Bruce Power have established a partnership to produce new medical isotopes. Through our partnership, our medical isotope project will deliver benefits beyond the local community, include reducing barriers to economic self-sufficiency, improve the socioeconomic circumstances of SON members, as well as have a positive impact on cancer treatments around the world.

One of the opportunities that have emerged from working together was the partnership in the production of radioisotopes for medical and research purposes. Discussions on this subject have developed as part of efforts to ensure that the Bruce Power facility is operated in a manner that recognizes and respects SON rights, interests and territorial jurisdiction and includes participation from SON in the ongoing operations of the facility - particularly as Bruce Power now looks to extending its operations on SON Territory to 2064 with the life-extension project.

Discussions began with SON in January 2019 to find common ground on creating an economic partnership. There were reviews of a number of projects, including sharing our plans around increasing isotope production with Lutetium-177. Bruce Power and SON met several times over the next six months and laid out the framework of what is now our marketing and collaboration partnership agreement. This agreement followed extensive dialogue and community engagement sessions at both Saugeen First Nation and the Nawash Unceded First Nation.

This progress has created confidence in the ability to work together, a stronger commitment of continuing to build a positive and sustainable relationship. The foundation of this progress is recognition of the importance of meaningful and reciprocal dialogue towards creating opportunities to work together.

15.1.3 Future Plans

Follow-up protocols were established with each of the three community groups respectively, and updates are planned to be provided at future meetings, which typically occur on a quarterly basis.

Enclosure 1

B-REP-03443-19NOV2020

Environmental Risk Assessment
Gap Analysis for Isotope Production Activities

Environmental Risk Assessment Gap Analysis for Isotope Production Activities

Calian Report BP-00025-01
Version 5.0
19 November 2020

Bruce Power

[x] Acceptable [ ] Acceptable as noted
[ ] Unacceptable

Print Name Cherie-Lee Fietsch

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QUALITY ASSURANCE AND VERSION TRACKING

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1. INTRODUCTION

1.1 Background

Bruce Power has requested a license amendment to allow the neutron irradiation of targets and adding medical radioisotope production to its operations. Following approval from the Canadian Nuclear Safety Commission (CNSC), production is expected to start in 2022.

Bruce Power intends to produce Lutetium-177 (Lu-177) for targeted cancer therapy by irradiation of Ytterbium-176 (Yb-176) targets in the Bruce Power reactors without causing adverse impacts on operations and reactor safety. The use of Lu-177 for treatment of prostate cancer is currently in phase 3 clinical trials and approval is expected in 2022.

Analysis of potential environmental effects is required to determine whether Lu-177 production activities will impact the environment and trigger an Environmental Risk Assessment (ERA) update. Clause 11.1 in CSA N288.6-12 (R2017) identifies the circumstances in which an ERA update is required [1]:

Facility ERA updates should be performed on a five-year cycle, or more frequently if major facility changes are proposed that would trigger a predictive assessment. Prior to each update, the most recent ERA should be reviewed to identify…

> *(b) changes to the physical facility or facility processes that have the potential to change the nature of facility effluent(s) and the resulting risks to receptors…*

Bruce Power's most recent ERA was completed in 2017 [2]. The ERA is scheduled to be updated in 2022.

1.2 Purpose

The *ERA Gap Analysis for Isotope Production Activities* Memo describes the new isotope production activities that are planned at Bruce B Unit 7. It analyzes potential environmental impacts of the new activities and determines whether an ERA update is triggered as per CSA N288.6-12 (R2017) requirements.

This memo is a predictive assessment to examine if the production of Lu-177 has the potential to change the nature of facility effluents and risk to receptors. As such, it will assist Bruce Power in deciding if the isotope production activities will trigger an ERA update as per CSA N288.6-12 (R2017) requirements, or if the ERA will instead be updated within the expected five-year cycle. Refer to Annex A for a discussion on specific ERA sections which require revision due to Lu-177 production activities.

1.3 Report Contents

This memo presents:

- Bruce Power Lu-177 isotope production activities (Section 2);
- Bruce Power's Environmental Protection program, as it relates to Lu-177 production (Section 3);
- Potential environmental effects of Lu-177 production activities (Section 4);
- Effects of Lu-177 production activities on the Bruce Power ERA, specifically the Radiological Human Health Risk Assessment (HHRA) and Radiological Ecological Risk Assessment (EcoRA) (Section 5);
- A conclusive statement on whether these changes trigger an ERA update (Section 6); and
- Discussion on specific ERA sections which require revision due to Lu-177 production activities (Annex A).

2. BRUCE POWER LUTETIUM-177 PRODUCTION

2.1 Properties of Lu-177

The radio-isotope Lu-177 is a beta emitter that decays to stable Hafnium-177 (Hf-177) with a half-life of 6.647 days. Lu-177 emits beta radiation with three branching ratios having a maximum energy of 498 keV (79.4%), 385 keV (9.0%) and 177 keV (11.6%) and low-energy gamma radiation at 113 keV (6.17%) and 208 keV (10.36%) [3].

2.2 Production of Lu-177

Lu-177 can be produced by neutron activation of Yb-176. This creates Ytterbium-177 (Yb-177) which decays into Lu-177 with a half-life of 1.9 hours

2.3 Production Activities at Bruce Power

The production of Lu-177 in Bruce B Unit 7 will be managed and operated by Bruce Power personnel. Bruce Power operators will load fresh targets in the Isotope Production System (IPS) and retrieve them after irradiation.

The IPS delivers Yb-176 targets to the reactor core, retrieves the irradiated product after the activation period, and deposits it into canisters for transportation to processing facilities:

- The targets will be pushed pneumatically through a line connected to the Target Finger Tubes (TFTs), into the reactor core.
- After one week of irradiation, the targets will be extracted pneumatically and dropped into a Transport Container (TC).
- The TC will be sealed, checked for contamination, and shipped to an external processing facility.
- There will be no radioactive waste generated at the Bruce Power site; the processing facility will be responsible for its own waste.

The initial production will be achieved with one TFT in a Guide Tube Assembly accessible from the Reactivity Mechanism Deck. The targets will be irradiated for one week, and all targets will be harvested each week. The irradiation process uses greater than 99.6% enriched Yb-176 in the form of oxide ceramic powder (Yb_2O_3).

2.4 Design Requirements

The technical specifications used for the design of the system ensure that the operation of the IPS will contain activated material within the Target Assembly.

1. The Target Ampules, displayed in Figure 1, are sealed and leak-tested before being inserted in a Target Carrier.
2. Target Carrier provides protection for the Target Ampule placed within it. The Target Carrier is designed to maintain its ability to act as an additional barrier (in addition to the Ampule and foil) against leakage/release of the target material during insertion and withdrawal from the reactor.
3. The IPS uses helium gas to pneumatically move the targets through the system. Helium gas is chemically and radiologically inert. During each operation, carrier gas flow will only be required for short periods of time for target insertion, target retrieval and system purge.
4. Since the carrier gas is routed through the reactor, the spent carrier gas from the IPS may contain potentially activated particulates. The carrier gas vent lines will be connected to contaminated exhaust stack.
5. The vent lines are each equipped with a 3-micron particulate filter to prevent the entry of activated material into the Unit Ventilation System contaminated exhaust.
6. In addition, the gaseous effluent stream will be routed to one of the contaminated exhaust system’s four filter banks. Each bank contains a prefilter and an absolute filter. The absolute filter removes 99.97% of all particles 0.3 microns or larger.
7. The effectiveness of the filters is validated with radioactive stack monitors located prior to discharge to atmosphere through the stack.
8. There will be no radioactive waste generated at the Bruce Power site; the processing facility will be responsible for its own waste.

In summary, the IPS is not expected to generate radioactive effluents or emissions that materially change the current emissions from the station.

Figure 1: Target Ampule – Cylindrical fused quartz body containing target material

3. BRUCE POWER ENVIRONMENTAL PROTECTION

3.1 Effluent Monitoring Program

The Bruce Power effluent monitoring program has been developed in accordance with CSA N288.5-11 (R2016), *Effluent Monitoring Programs at Nuclear Facilities and Uranium Mines and Mills* [4], and applies a graded approach based on risk. Radiological Effluent monitoring is described in BP-PROC-00171 [5].

Any release is monitored, detected and reported. Monitoring requirements are evaluated with consideration of the probability and severity of a radiological emission and are based on Normal Operating Levels, Maximum Probable Emission Rates and Derived Release Limits. Control monitoring is in place for effluent streams with higher risk and compliance monitoring is in place for effluent streams with lower risk. The effluent monitoring program is reviewed on an annual basis and updated following any changes to operations or an update to the ERA [2].

See Section 4.3 for details on effluent monitoring specific to Lu-177 production.

3.2 Radiological Environmental Monitoring Program

The Bruce Power environmental monitoring program was developed in accordance with CSA N288.4-10 *Environmental Monitoring Programs at Nuclear Facilities and Uranium Mines and Mills* [6]. Radiological environmental monitoring is described in BP-PROC-00076 [7]. As part of the Radiological Environmental Monitoring Program, a variety of environmental media are collected in the local area each year and analyzed for radiological contaminants. This includes air, precipitation, drinking water, surface and well water, milk, fish, fruit and vegetables, deer (when available) and eggs. Media is collected near and far field of the site and the results are compared to Provincial values where possible. The information is used in verifying both the environmental monitoring program design and ERA conclusions. The information is also used in calculating the dose to public each year to ensure that radiation doses are below regulatory limits.

Assessment of doses to the public is an element of the Environmental Management program which ensures that radiation doses to the public are below regulatory limits. Protection of the public is ensured in part through the monitoring and control of radiological emissions. Releases are controlled through the application of derived release limits, action levels, and internal investigation levels and impacts on human and ecological health are assessed through the ERA.

Doses to the public are calculated using IMPACT (used to assess the transport of contaminants through specified environmental pathways), based on annual meteorological data, annual effluent and environmental monitoring data for the Bruce site (including data for on-site facilities operated by Ontario Power Generation, Canadian Nuclear Laboratories and KI North), and site-specific survey results (last completed in 2016).

See Section 5 for details on the potential effects of Lu-177 production activities on the Bruce Power ERA, specifically dose to humans and non-human biota.

4. POTENTIAL ENVIRONMENTAL EFFECTS

The environmental effects under normal operation were examined, as per CSA N288.6-12 (R2017) clause 1.2 [1]:

> *The ERA described in this Standard is applicable where human and/or non-human biota might be routinely be exposed to*
> *(a) low-level emissions of nuclear and hazardous substances released to the environment as a result of the normal operation … of a nuclear facility; or*
> *(b) physical stressors imposed on the environment as a result of the normal operation of a nuclear facility.*
>
> *This Standard does not address acute or high-level exposures that can result from accidents (including spills).*

In addition, the possibility of potential effects due to a target failure are also considered.

4.1 Normal Operation

The target ampules are sealed and leak-tested before being inserted in a Target Carrier, so no activity from the target material is expected in the carrier gas.

As mentioned in Section 2.5, the IPS periodically uses helium gas to pneumatically move the targets through the system which, when routed through the reactor, may contain potentially activated particulates. Particulates potentially created by the movement of the Target Assembly could potentially include:

- Zirconium-95 (Zr-95), an activation product of zircalloy which is a material widely used in the reactor. Zr-95 has a half-life of about 64 d and is already monitored in the effluent streams of the station; and
- Aluminum-28 (Al-28), an activation product of aluminum which is the material used in the Target Carrier. Al-28 has a short half-life of 2.25 m, which means its activity becomes negligible very quickly after the target leaves the reactor core.

It should also be noted that very small volumes of carrier gas are expected, since the gas flow will only be required for short periods of time for target insertion, target retrieval and system purge. The gaseous effluents stream will be discharged to the Unit Ventilation System contaminated exhaust where particulates are filtered twice, as described in Section 2.4. This means that any small quantities of particulates that may be present would be attenuated considerably by the filters.

As described in Section 2.4, the IPS is not expected to generate radioactive effluents or emissions that materially change the current emissions from the station.

4.2 Target failure

Under normal operation, the activated target material is sealed within the Target Ampule. In the unlikely event of a failure of the ampule, most of the activated material would be contained within the Target Carrier. A small fraction of the target powder could escape the Target Carrier and enter the carrier gas stream. The particulates in the exhaust of the carrier gas would be attenuated by the multiple filtration barriers described in Section 2.4.

Emissions entering the gas stream would be bound by the activity inside an irradiated Target Assembly. The most radiologically significant radionuclides present in an irradiated target are Lu-177, Yb-175 and Yb-177 because of their activity and half-life. These radionuclides are the most likely to be detectable on the particulate filters from the stack monitor. Other radionuclides have lower activity, shorter half-life or both and would be less likely to be detectable.

4.3 Gaseous Effluent Monitoring of Lu-177 Production

All gaseous effluents exhausted into the Unit Ventilation System contaminated exhaust are monitored with particulate, iodine, and noble gas (PING) monitors located prior to discharge to atmosphere through the stack. Releases are continuously monitored and any releases of particulate gross beta/gamma emitting radionuclides to the environment would be detected and analyzed.

Any increase in the activity released through the contaminated stack due to the operation of the IPS would be detected by the PING monitor. The environmental impact of increased activity would be included in the weekly effluent report and would be reported as part of the station compliance monitoring.

Although no impact on the environment is expected, Bruce Power will collect data to verify and confirm that there are no changes atmospheric emissions. 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. The results will be used to confirm that there is no impact on gaseous effluents.

4.4 Liquid Effluent Monitoring of Lu-177 Production

The IPS is completely dry and doesn't contain any liquid. There is no potential leak or spill of radiological or conventional liquid that could affect the environment. No changes to the liquid effluents are expected as a result of Lu-177 production.

4.5 Transportation of Radioactive Material

After being placed in a Type B(U) Transport Container, the irradiated targets will be transported off-site to a licensed processing facility. The Transport Containers are robust and designed to protect the radioactive material.

If there was a transport accident, the Transport Container would contain the radioactive material and an emergency response team would be deployed to recover the container. There are no environmental effects expected from the transportation of the irradiated targets.

4.6 Radioactive and Conventional Waste

The irradiated targets will be sent to the processing facility in the same form as they arrived at the Bruce Power site. No residual material or waste will be generated by the isotope production activities. The processing facility is responsible for managing its own waste.

5. EFFECT ON BRUCE POWER ENVIRONMENTAL RISK ASSESSMENT

5.1 Radiological Human Health Risk Assessment

The Human Health Risk Assessment (HHRA) assesses the dose to members of the public based on emissions and measurements of radionuclides in the environment.

Since there are no emissions from the Lu-177 production, no measurable changes to the dose to the public are expected.

5.2 Radiological Ecological Risk Assessment

The EcoRA estimates radionuclide concentrations in environmental media, as well as activity concentrations in and dose rates to non-human biota. Radiation dose to non-human biota is estimated via exposure assessment, therefor relying on the existence of exposure pathways, i.e., external exposure (air immersion, ground shine, water immersion, sediment external) and internal consumption of contaminated foods (food chain or water uptake).

Since there are no emissions from the Lu-177 production, no new exposure pathways exist. As such, no measurable changes to the dose to non-human biota are expected.

6. CONCLUSIONS

During normal operation, the IPS periodically uses helium gas to pneumatically move the targets through the system which may contain potentially activated particulates. Volumes are expected to be small and, due to the nature of the particulates, the nuclides will either decay to negligible activity or will be captured on HEPA filters.

Since there are no expected emissions from Lu-177 production, there is no change of facility effluent(s) or resulting risks to receptors. Based on the CSA N288.6-12 (R2017) requirements (described in Section 1.1 of the current document), the isotope production activities will not trigger an ERA update, and the ERA will instead be updated within the expected five-year cycle.

In the event of a Target Ampule failure, the IPS vent lines are each equipped with a particulate filter to prevent the entry of released material into the Unit Ventilation System contaminated exhaust. The gaseous effluent stream will be routed to one of the contaminated exhaust system's four filter banks, which removes 99.97% of all particles 0.3 microns or larger. Therefore, any activated target material release in the carrier gas would be greatly attenuated once it is released to the atmosphere. The main radionuclides that are likely to be detectable are Lu-177, Yb-175 and Yb-177.

The effectiveness of the contaminated exhaust system filters is validated with PING monitors located prior to discharge to atmosphere through the stack. Releases are continuously monitored and any releases of particulate gross beta/gamma emitting radionuclides to the environment would be detected and reported in the weekly effluent report.

Although no impact on the environment is expected, Bruce Power will collect data to verify and confirm that there are no changes atmospheric emissions. 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 Yb-175, Yb-177 and Lu-177 in the gaseous effluents. Bruce Power will review the additional monitoring data to validate the assumptions contained in this memo.

7. REFERENCES

[1] Canadian Standards Association (CSA), "Environmental risk assessments at Class I nuclear facilities and uranium mines and mills," CSA N288.6-12, 2017.

[2] Bruce Power, "Bruce Power Environmental Quantitative Risk Assessment," B-REP-03443-29JUN2017-01, October 2017.

[3] IAEA, "Live Chart of Nuclides," IAEA - Nuclear Data Section.

[4] Canadian Standards Association (CSA), "Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills," N288.5-11 (R2016), Jan 2016.

[5] Bruce Power, "Radiological Emissions," BP-PROC-00171, R20, 2020.

[6] CSA, "CSA N288.4-2010 Environmental Monitoring Programs At Class 1 Nuclear Facilities And Uranium Mines And Mills," 2010.

[7] Bruce Power, "Radiological Environmental Monitoring," BP-PROC-00076, R11, 2019.

[8] A. D. e. a. al., "Production of 177Lu for Targeted Radionuclide Therapy: Available Options," Nuclear Medicine and Molecular Imaging 49:85-107, 2015.

ANNEX A. DESCRIPTION OF INSERTIONS AND CHANGES IN THE NEXT VERSION OF ERA

A.1 CHANGES TO THE MAIN BODY OF THE REPORT

A.1.1 Future Site Activities

1) Add additional sub-section after "*Major Component Replacement Activities*":

Bruce Power Lutetium-177 Production Activities

Bruce Power has requested a license amendment to allow the neutron irradiation of targets and adding medical radioisotope production to its operations. Following approval from the CNSC, production is expected to start in 2022.

Bruce Power intends to produce Lu-177 for targeted cancer therapy by irradiation of Yb-176 targets in the Bruce Power reactors without causing adverse impacts on operations and reactor safety. The use of Lu-177 for treatment of prostate cancer is currently in phase 3 clinical trials and approval is expected in 2022.

Lutetium-177 can be produced by neutron activation of Ytterbium-176 (Yb-176). This creates Ytterbium-177 which decays into Lu-177 with a half-life of 1.9 hour.

The targets will be pushed pneumatically through a line connected to the target finger tubes (TFT), into the reactor core. After one week of irradiation, the targets will be extracted pneumatically and dropped into a transport container (TC). The TC will be sealed, checked for contamination, and shipped to the processing facility. There will be no radioactive waste generated at the Bruce Power site; the processing facility will be responsible for its own waste.

Full details on the Lu-177 production activities can be found in References [A].

2) Add references:

[A] A. D. e. a. al., "Production of 177Lu for Targeted Radionuclide Therapy: Available Options," Nuclear Medicine and Molecular Imaging 49:85-107, 2015.

A.1.2 Interactions and Predictive Evaluation of Future Site Activities with the Environment

1) Revise first paragraph wording to:

This section presents an identification and assessment of potential interactions between future site activities, including MCR **and Lu-177** production activities, and the existing environment (i.e., the Tier 1 screening assessment). Where a potentially increasing interaction is identified, text is provided to describe and evaluate the interaction and the change during future site activities. Proposed activities and the associated hazards are compared to periods of similar activity that have taken place.

2) After the last paragraph of sub-section "*Major Component Replacement Activities*", add in additional sub-section:

Bruce Power Lutetium-177 Production Activities

During normal operation of the IPS, the target ampules are sealed and leak-tested before being inserted in a Target Carrier, so no activity from the target material is expected in the carrier gas.

The IPS periodically uses helium gas to pneumatically move the targets through the system which, when routed through the reactor, may contain potentially activated particulates. Particulates potentially created by the movement of the Target Assembly could potentially include:

- Zirconium-95 (Zr-95), an activation product of zircalloy which is a material widely used in the reactor. Zr-95 has a half-life of about 64 d and is already monitored in the effluent streams of the station; and
- Aluminum-28 (Al-28), an activation product of aluminum which is the material used in the Target Carrier. Al-28 has a short half-life of 2.25 m, which means its activity becomes negligible very quickly after the target leaves the reactor core.

It should also be noted that very small volumes of carrier gas are expected, since the gas flow will only be required for short periods of time for target insertion, target retrieval and system purge. The gaseous effluents stream will be discharged to the Unit Ventilation System contaminated exhaust where particulates are filtered twice. This means that the small quantity of particulates would be attenuated considerably by the filters. As a result, the IPS is not expected to generate radioactive effluents or emissions that materially change the current emissions from the station.

Under normal operation, the activated target material is sealed within the Target Ampule. In the unlikely event of a failure of the ampule, most of the activated material would be contained within the Target Carrier. A small fraction of the target powder could escape the Target Carrier and enter the carrier gas stream. The particulates in the exhaust of the carrier gas would be attenuated by the multiple filtration barriers described.

Emissions entering the gas stream would be bound by the activity inside an irradiated Target Assembly. The most radiologically significant radionuclides are Lu-177, Yb-175 and Yb-177 because of their activity and half-life. These radionuclides are the most likely to be detectable on the particulate filters from the stack monitor. Other radionuclides have lower activity, shorter half-life or both and would be less likely to be detectable.

Although no impact on the environment are expected, Bruce Power will collect data to verify and confirm that there are no changes to atmospheric emissions. 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 Yb-175, Yb-177 and Lu-177 in the gaseous effluents.

The IPS is completely dry and doesn't contain any liquid. There is no potential leak or spill of radiological or conventional liquid that could affect the environment. No changes to the liquid effluents are expected as a result of Lu-177 production.

After being placed in a Type B(U) Transport Container, the irradiated targets will be transported off-site to a licensed processing facility. The Transport Containers are robust and designed to protect the radioactive material. If there was a transport accident, the Transport Container would contain the radioactive material and an emergency response team would be deployed to recover the container.

The irradiated targets will be sent to the processing facility in the same form as they arrived at the Bruce Power site. No residual material or waste will be generated by the isotope production activities. The processing facility is responsible for managing its own waste.

In summary, there are no expected emissions from Lu-177 production, both in normal operations and if target failure were to occur. As such, there is no change of facility effluent(s) or resulting risks to receptors.

3) Add references:

[A] Calian Group Ltd. "Environmental Risk Assessment Gap Analysis for Isotope Production Activities", BP-0025-01, November 2020