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Written submission from the Algonquins of Ontario

Mémoire des Algonquins de l'Ontario

In the Matter of the

BWXT Medical Ltd.

Application for a Class IB nuclear substance processing facility operating licence

Commission Public Hearing

June 9, 2021

À l'égard de

BWXT Medical Ltd.

Demande pour un permis d'exploitation d'une installation de traitement de substances nucléaires de catégorie IB

Audience publique de la Commission

9 juin 2021

Canada

Technical Review of BWXT Medical Ltd. Application for Class IB Nuclear Substance Processing Facility Operating Licence

Algonquins of Ontario

May 3, 2021

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Contents

1.0 Executive Summary

BWXT Medical Ltd. (the Proponent) have applied to the Canadian Nuclear Safety Commission (CNSC) for a Class IB nuclear substance processing facility licence. If granted, the licence would allow for BWXT Medical Ltd. to operate a medical isotopes facility located in the Kanata Research Park at 447 March Road in Ottawa, Ontario. The proposed facility is located within the existing nuclear substance processing facility, which has been operating for over 30 years and is currently operated by Nordion Canada Inc. BWXT Medical Ltd. acquired Nordion in 2018, and has been operating the facility under Nordion's licence since that time. The current licence being sought by BWXT Medical Ltd. is intended to cover a period of ten years, commencing on November 1, 2021 and ending on October 31, 2031.

BWXT Medical Ltd.'s operation will include the following product lines:

- Yttrium-90 (Y-99), which is an implantable device used to treat liver cancer
- Indium-111 (In-111), which is used to assess inflammation and infection within the body, for example assessing diabetic foot infection
- Molybdenum-99 (Mo-99) using a patent-pending innovative technology. Mo-99 is the parent isotope of Technetium-99m (Tc-99m), which is used around the globe in medical diagnosis procedures, including the diagnosis of heart disease and cancer[1]

BWXT Medical Ltd. has indicated in their application that they are committed to growing their portfolio in order to deliver other innovative medical isotope products in the future. The Proponent has indicated that the implementation of any new product lines will be produced under the Class IB license that they are currently seeking.

The Proponent has demonstrated in their licence application that, during normal facility operations, there are no detectable releases of radioactivity to the atmosphere or water resources. As there are no detectable releases of radioactivity from the facility, the maximum dose to a member of the public is considered to be negligible. There are no anticipated environmental effects from the facility operations, based on what was presented in the licence application regarding existing processes.

In their licence application, BWXT Medical Ltd. has outlined that they intend to continue engaging with Indigenous communities (including the Algonquins of Ontario [AOO]) on a regular basis by letter, email, phone calls, and meetings, even after the current licence hearing has concluded. They wish to establish and maintain meaningful engagement and relationships with Indigenous communities.

Based on SVS' evaluation of BWXT Medical Ltd.'s license application and the Proponent's stated commitment to Indigenous engagement and relationships, we recommend that the Proponent provide

[1] *According to the U.S. National Academy of Sciences, the "decay product of Mo-99, Tc-99m, is the workhorse isotope in nuclear medicine for diagnostic imaging. Tc-99m is used for the detection of disease and for the study of organ structure and function." (National Academy of Sciences, 2009, https://www.ncbi.nlm.nih.gov/books/NBK215133/)*

regular updates to the AOO in the form of bi-annual reports that summarize general site operations and any issues of concern, with an option for calling a meeting following review of each report.

Although no immediate environmental or human health concerns were identified during SVS' review of the licence application, we recommend that the Proponent provide updates to the AOO on research being conducted on any new products at the facility, via bi-annual reports. Additionally, we recommend that the Proponent provide the details of their preliminary decommissioning plan for the facility for AOO to review and provide input where appropriate.

A Note on Economic Reconciliation

The AOO may be in a position to assist BWXT Medical Ltd. to enhance its business revenues, and SVS recommends that the AOO enter into discussions with BWXT Medical Ltd. to advance economic reconciliation.

BWXT Medical Ltd.'s parent company, BWXT Nuclear Energy Canada Inc. has registered with the Canadian Council for Aboriginal Business (CCAB) as a Progressive Aboriginal Relations (PAR) "Committed Company." Through this designation, BWXT is signalling its intent to **move forward in the CCAB PAR process to** recognize the advantages of working with Indigenous businesses and communities, and advance strategic planning that leverages the beneficial impacts of collaboration with Indigenous-owned businesses, the benefits that Indigenous people bring to collaboration, and the potential of Indigenous communities.

BWXT is beginning a journey, moving toward developing the goals and action plans that position them to work with Indigenous communities, including the AOO. Moving further along the PAR continuum, BWXT would be seeking to put business partnerships in place with the AOO, and supporting investments in our communities and people, and moving to include Indigenous relations as a core part of the BWXT business strategy.

There are several key nuclear businesses that have achieved CCAB PAR Gold status or Silver status, including Bruce Power and Cameco at the Gold level, and OPG at the Silver level. Bruce Power, for example, has established a medical isotope partnership with Saugeen Ojibway Nation called "Gamzook'aamin aakoziwin" which translates to "We are teaming up on the sickness" – see www.fightingcancertogether.ca. Through this agreement, Bruce Power and Saugeen Ojibway Nation are exploring ways to collaboratively market new medical isotopes, and working together to create new economic opportunities within the Saugeen Ojibway Nation's territory.

The AOO could assist BWXT in moving forward with strategic planning that recognizes the beneficial impacts of working with AOO businesses, bringing AOO members to the workplace and enhancing the potential of AOO communities. The potential for the AOO to develop business partnerships and investments similar to "Gamzook'aamin aakoziwin" are strong, including jointly marketing medical isotopes that enhance health and well-being.

2.0 Introduction

2.1 Project Description and Regulatory Process

In December 2018, BWXT Medical Ltd. (the Proponent) applied to the Canadian Nuclear Safety Commission (CNSC) for the issuance of a Class IB nuclear substance processing facility licence. The licence would allow for BWXT Medical Ltd. to operate a medical isotopes facility located in the Kanata Research Park in Ottawa, Ontario. The proposed facility is located within the existing nuclear substance processing facility, currently operated by Nordion Canada Inc. The licence being sought by BWXT Medical Ltd. is intended to cover a period of ten years, commencing on November 1, 2021 and ending on October 31, 2031.

In mid-2018, BWXT Medical Ltd. commercially acquired Nordion's medical isotopes business, which includes one of the two production operations under Nordion Canada Inc.'s current CNSC licence. Since then, the Proponent has been working at the facility as a subcontractor to Nordion. If the requested licence is approved by CNSC through the current regulatory process, BWXT Medical Ltd. would become responsible for the safe operation of the medical isotope facility. The CNSC have previously reported on their oversight and compliance performance of the Nordion facility through the Regulatory Oversight Report for Uranium and Nuclear Substance Processing Facilities.

BWXT Medical Ltd. intends on using the medical isotope facility to produce molybdenum-99 (Mo-99) using a patent-pending innovative technology. The Mo-99 that is produced is the parent isotope of technetium-99m (Tc-99m), which is used in medical diagnostic procedures globally, including for the diagnosis of heart disease and cancer. The Proponent has indicated in their licence application that if they are granted the Class IB licence, they intend to use the same systems and procedures that were used prior to the acquisition and throughout the post-acquisition period when Nordion remained responsible for the site. However, BWXT Medical Ltd. has indicated that they are committed to growing their portfolio in order to deliver other innovative medical isotope products in the future. The Proponent has indicated that the implementation of any new product lines will be within the Class IB license that they are currently seeking.

CNSC will be holding a public hearing on June 9-10, 2021, to consider the application from BWXT Medical Ltd. for a Class IB nuclear substance processing facility operating licence. CNSC staff have reviewed the licence application based on the regulatory and technical requirements outlined in the Class I Nuclear Facilities Regulations, the General Nuclear Safety and Control Regulations, and the Nuclear Safety and Control Act. The results of the CNSC staff review and assessment will be considered at the Commission Public Hearing being held on June 9-10, 2021.

2.2 Review Scope and Objectives

The nuclear substance processing facility where BWXT Medical Ltd. is requesting to operate a medical isotope facility is located within the Algonquins of Ontario (AOO) Settlement Area, over which unextinguished Aboriginal Rights and title are asserted. As such, the CNSC has provided participant

funding to support the AOO's participation in the licence application review and Commission hearing process for BWXT Medical Ltd.'s licence application.

Shared Value Solutions Ltd. (SVS) has been retained by the AOO to review BWXT Medical Ltd.'s licence application and identify potential impacts to the AOO's Aboriginal [section 35] Rights. The scope of SVS' review focused on identifying any environmental, human health, or safety risks, in addition to any potential impacts to Aboriginal Rights and interests. SVS reviewed both the BWXT Medical Ltd. licence application and the CNSC review and assessment of the licence application, as presented in the Commission Member Document (CMD).

3.0 Algonquins of Ontario

3.1 Overview

The Algonquins of Ontario are on a journey of survival, rebuilding, and self-sufficiency – a journey of reconciliation. This journey began nearly 250 years ago when the first Algonquin petition was submitted to the Crown in 1772.

The Algonquins lived in present-day Ontario for thousands of years before Europeans arrived. Their territory originally extended from the St. Lawrence River to the French River in the west, south to the Adirondack mountains in New York State, and north above Lake Abitibi. Over the past several hundred years, the description of the unceded AOO Settlement Area has changed to be the lands and waters on both sides of the Kichi-Sìbì[2] watershed from modern Hawkesbury to Lake Nipissing and north past the headwaters of the Kichi-Sìbì. Today, the following ten Algonquin communities comprise the Algonquins of Ontario, all of whom share interest in the MLF:

- The Algonquins of Pikwakanagan First Nation
- Antoine
- Kijicho Manito Madaouskarini (Bancroft)
- Bonnechere
- Greater Golden Lake
- Mattawa/North Bay
- Ottawa
- Shabot Obaadjiwan (Sharbot Lake)
- Snimikobi (Ardoch)
- Whitney and Area

Based on a protocol signed in 2004, these communities are working together to provide a unified approach to negotiate a modern-day treaty. The AOO land claim includes an area of nine million acres

[2] The Ottawa River, otherwise known as the Big River, has also been referred to in the Algonquin language as "Kichi-Sìbì," "Kichissippi," "Kitchissippi" and "Kichisippi."

within the watersheds of the Kichi-Sìbì and the Mattawa River in Ontario. The majority of Algonquin Provincial Park lies within the Kichi-Sìbì watershed and thus within the unceded AOO Settlement Area.

The Algonquins of Pikwakanagan First Nation (known at the time as the Algonquins of Golden Lake) commenced the land claim by formally submitting the most recent petition with supporting research to the Government of Canada in 1983 and the Government of Ontario in 1985. The Province of Ontario accepted the claim for negotiations in 1991 and the Government of Canada in 1992. Since then, the negotiations, which are intended to culminate in an Algonquin Treaty, have grown to include ten communities that comprise the AOO.

The Algonquin Negotiation Team consists of the Chief and Council of the Algonquins of Pikwakanagan First Nation, who are elected under the Pikwakanagan Custom Election Code, and one representative from each of the nine other Algonquin communities, each of whom is elected by the enrolled Algonquin voters of each community for a three-year term.

The unceded AOO Settlement Area, shown in Figure 1 below, includes an area of more than nine million acres within the watersheds of the Kichi-Sìbì and the Mattawa River in Ontario, unceded territory that covers most of eastern Ontario, including Ottawa and most of Algonquin Provincial Park. More than 1.2 million people live and work within the unceded AOO Settlement Area. There are 84 municipal jurisdictions fully and partially located within the unceded AOO Settlement Area, including 75 lower- and single-tier municipalities and nine upper-tier counties.

Algonquins of Ontario Settlement Area Boundary

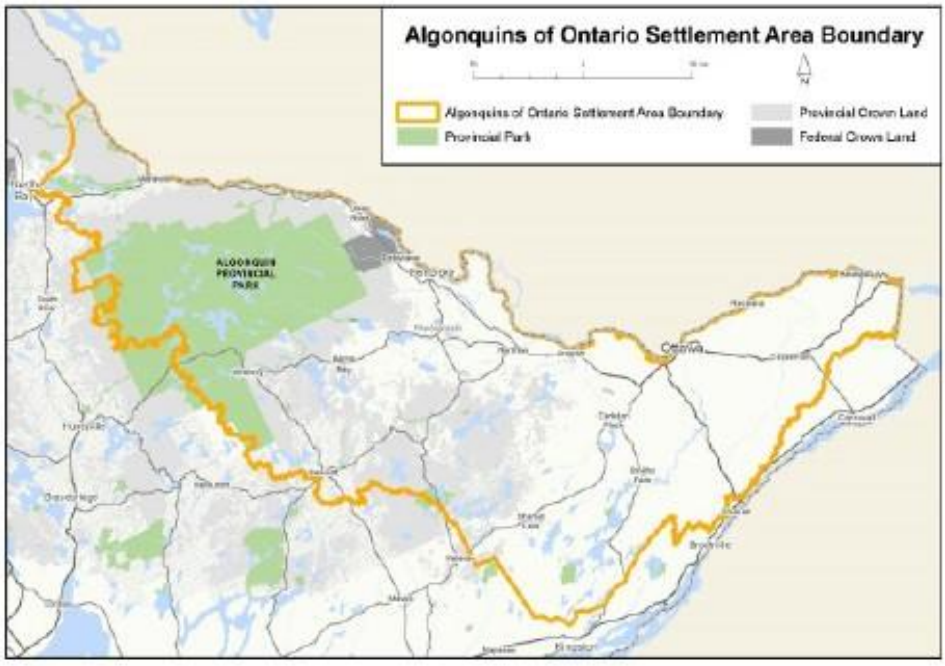

Figure 1: Algonquins of Ontario unceded Settlement Area Boundary (Source: Algonquins of Ontario)

3.2 Algonquin Values and Teachings

Today, Algonquins in Ontario share a history of common interests, traditions and needs arising from our common heritage. In the following section, we will outline several Algonquin practices and teachings that are fundamental to putting this consultation and accommodation protocol in context.

In developing these comments, we have been guided by the spirit and intent of the Teachings of the Seven Grandfathers. These teachings have been passed down from generation to generation and continue to be practiced today:

- Honesty (Kwayakoziwin): Honesty in facing a situation is to be brave;
- Humility (Tabasenindizowin): Humility is to know yourself as a sacred part of Creation;
- Respect (Manàdjìyàn): To honour all Creation is to have Respect;
- Bravery (Sòngideyewin): Bravery is to face the foe with integrity;
- Wisdom (Nibwàkàwin): To cherish knowledge is to know Wisdom;
- Love (Sàgìhidiwin): To know Love is to know peace; and
- Truth (Tebwewin): Truth is to know all of these things

Our survival on this land for thousands of years required us to apply our teachings to ensure the protection of the lands and waters upon which we rely. These teachings serve as the original instructions or "natural laws" that were built into our way of life. "Sustainability" is a modern term, but sustainability was long in practice by our people and our ancestors. There were consequences that occurred when we strayed from our natural teachings, instructions, and laws. We were constantly monitoring the environment and if changes occurred, we would adapt. It was (and is) a matter of survival. We had, and continue to have, deep connections to the land.

Some examples of teachings related to the protection of the environment of today and yesterday include the following:

- Harvest one area for one season then move on elsewhere so the area that has been recently harvest can replenish.
- Be conscious of where your feet touch the ground (even as an individual, we can have impacts on the land).
- We are stewards of the land and have a responsibility to protecting the lands and waters.
- Show love for all aspects of the environment, down to the smallest part.
- We are all a part of nature – we are all equal.

Protection and interaction with the lands and waters of our territory have been central to our existence for thousands of years. We maintained this connection to the land in spite of the arrival of Europeans to our territory. However, their arrival dramatically impacted our way of life.

Harvesting of flora and fauna for food and trade has been integral to the Algonquin way of life since time immemorial. These practices embody an inherent respect for the environment and a fundamental commitment to the sustainable management of resources which have been passed from generation to generation.

The rights of Aboriginal people in Canada to engage in traditional activities, including the harvesting of wildlife, fish, migratory birds, and plants, is recognized by the Constitution Act, 1982 and upheld by the Supreme Court of Canada. As stewards of our ancestral lands, the AOO recognize the importance of exercising this right in a responsible manner.

In 1991, the Algonquins of Golden Lake (Pikwakanagan) took a ground-breaking step with the establishment of its first Hunting Agreement which led into the development of today's AOO Harvest Management Plan (HMP) for Algonquin Park and the Wildlife Management Units (WMU) within the Algonquin Territory in Ontario. The Harvest Management Plan is a living document, which is reviewed annually and updated as new information becomes available. Its primary purpose is to clearly articulate the framework in which the Algonquin harvest is conducted by Algonquin harvesters. In particular, the Harvest Management Plan contains clear provisions which specify the season and the geographic locations in which harvesting can occur, what the Sustainable Harvest Target is to be and who is eligible to participate.

Each year, the AOO establishes its Sustainable Harvest Targets for moose and elk for both Algonquin Park and each WMU for the Algonquin Harvest. These Sustainable Harvest Targets are established with input from the Ontario Ministry of Natural Resources and Forestry (MNRF) and are based upon data that addresses wildlife conservation and the sustainability of wildlife populations. The AOO is the one of the first Aboriginal groups in Canada that has voluntarily enacted these types of harvest management practices.

In order to harvest moose and elk under the auspices of the AOO, eligible Algonquins have agreed to participate in a draw-based tag system that is coordinated by the ten individual AOO communities.

Our tradition of collectively sharing food and resources has been practiced by the Algonquins for millennia. In preservation of this long-held tradition, the sharing of food and resources continues to be commonly practiced today providing meat to Elders and other community members that are unable to participate in the harvest.

Despite such efforts as the Harvesting Agreement, we are now in great competition with many others on this land for the resources that are here.

3.3 AOO Rights and Interests

The BWXT Medical Ltd. facility falls directly within the AOO's unceded Settlement Area, as agreed to in the Agreement-in-Principle (AIP) signed by the AOO and the Governments of Ontario and Canada on October 18, 2016. The AOO assert unextinguished and constitutionally protected Aboriginal Rights and Interests, including title to the AOO Settlement Area. The signing of the AIP was a key step toward a Final Agreement, and a modern-day Treaty, of which negotiations remain ongoing and will eventually clarify the rights of all concerned. By signing the AIP, the AOO and the Crown expressed in a formal way their mutual intention and desire for a lasting partnership. This event signaled the beginning of a new relationship between the AOO and the Crown, one in which the mistakes of the past must be supplanted by a new type of mutual respect and cooperation.

Our land claim was accepted by the Governments of Canada and Ontario for negotiation in the early 1990s and is currently in the final stage of treaty negotiations. When ratified, the agreement will take the form of a modern treaty and will provide certainty about the ownership, use and management of land and natural resources for Algonquins across the unceded AOO Settlement Area.

4.0 Review Findings

4.1 Summary of Licence Application

BWXT Medical Ltd. announced in 2018 that they had developed a patent-pending innovative technology to produce Mo-99, which is the parent isotope of Tc-99m. The isotope Tc-99m is used in medical diagnostic procedures globally, including the diagnosis of heart disease and cancer. In 2018, the Proponent acquired the Nordion medical isotope business to support their technology and strive to provide a stable North American-based supply of Mo-99 and Tc-99m. At the time of acquisition, Nordion

obtained approval from the CNSC to allow the Proponent's employees to work at the facility as contractors under Nordion's Class IB licence, using the same systems and procedures that were in place prior to the acquisition.

BWXT's acquisition of Nordion's medical isotope business included all of the business assets: process facilities, equipment, contracts, and experienced staff. Nordion will remain as the licence holder for the facility until the Proponent is able to obtain its own Class IB licence, at which point the responsibility for the site and operations will shift from Nordion to BWXT Medical Ltd. The Proponent has indicated in their licence application that if they are granted the Class IB licence, they intend to use the same systems and procedures that were used prior to the acquisition and throughout the post-acquisition period when Nordion remained responsible for the site. However, BWXT Medical Ltd. has indicated that they are committed to growing their portfolio in order to deliver other innovative medical isotope products in the future. The Proponent has indicated that the implementation of any new product lines will be within the Class IB license that they are currently seeking.

The facility is located at 447 March Road in Ottawa and has been operating for over 30 years. The facility has two main production areas, a medical isotopes portion that involves the processing of radioisotopes used in nuclear medicine, and a gamma technologies portion that involves high activity sealed sources that are used in cancer therapy and irradiation technologies. Currently, both licensed activities occur under a single Class IB licence issued to Nordion. The Proponent's licence application pertains only to the medical isotopes production facility and will remain independent of Nordion's gamma technologies business. Under the agreement between Nordion and BWXT Medical Ltd., the medical isotopes portion of the facility is leased to the Proponent for a 20-year period, with the potential for renewal in five-year intervals up to four times. Under the proposed Class IB licence, the Proponent will have ultimate responsibility and accountability for security, fire protection, and facility maintenance, and they must seek Nordion's approval for building modifications or the introduction of new processes at the facility. Nordion and BWXT Medical Ltd. have developed and agreed to coordinate joint emergency response plans for the facility.

The Proponent's operation includes two main product lines, Y-90 and In-111. Y-90 is used within implantable devices used to treat liver cancer by delivering a high dose of radiation directly to a tumor while sparing normal tissue. In-111 is a diagnostic radiopharmaceutical that is used to assess inflammation and infection within the body, for example assessing diabetic foot infection. Prior to 2016, fission Mo-99 from the National Research Universal reactor at Chalk River had been produced at the facility since the mid-1980s. When the National Research Universal reactor at Chalk River was shutdown in 2016, production of fission Mo-99 at the Ottawa facility ceased. The patent-pending technology developed by the Proponent will allow for the production of Mo-99 at the facility again, but this time without the use of uranium or the generation of long-lived radioactive waste, unlike the fission Mo-99 that was previously produced.

The Proponent has mitigated the hazards identified for their new process through design and engineering, and increased automation and reduced operator intervention. Eventually, the Proponent will be seeking to install two electron beam accelerators that will be used to sterilize their Tc-99m product. BWXT Medical Ltd. has indicated that they will seek to obtain the necessary Class II licence from CNSC for the construction, commissioning, and operation of the electron beam accelerators at a later date.

In their licence application, the Proponent committed to ensure that risks to their employees, the environment, and members of the public are as low as reasonably achievable; to minimize waste and maximize reuse and recycling opportunities; and to seek opportunities to improve safety and minimize environmental impacts from their operations. The Proponent has also indicated that they will conduct annual internal audits to verify compliance with procedures and requirements, as a mechanism to ensure that their programs and systems are compliant both to regulatory requirements and internal policies and procedures.

As part of the Proponent's radiation protection program, radiation risks are minimized through the design of the facility itself, which has well-defined boundaries between areas that are completely clean of contamination, unlikely to be contaminated, areas that may contain contamination, and areas of known contamination. The facility ventilation system has a system of interlocks to ensure a balance of exhaust air flow to ensure no impact or loss of ventilation between processing units. The facility has back-up power supplied to all equipment to enable the facility operations to be shut down and contain and shield radioactive material during a primary power failure. Additionally, the facility has signs indicating the maximum radiation levels in the processing areas, and personal protective equipment for employees has been established. The facility also has multiple radiation detection devices placed at locations throughout the active area, with all locations simultaneously monitored through a computerized system. The Proponent will complete daily sampling and monitoring of floors, benches, fume hoods and glove boxes, change rooms, and support/service areas for contamination control at the facility. The Proponent will additionally conduct monthly radiation surveys on the perimeter of the active area, in the inactive office areas, and outside the facility to ensure no changed conditions that may impact the environment or exterior exposure.

In their licence application, BWXT Medical Ltd. confirmed that during normal facility operations, there are no detectable releases of radioactivity in airborne emissions or waterborne effluent. To ensure compliance with the public dose limit of 1 mSv/year as specified by CNSC regulations, the Proponent has established Derived Release Limits (DRLs) for emissions from the facility to the environment. There are currently no detectable releases of radioactivity from the facility, and therefore the maximum dose to a member of the public is considered to be negligible, and therefore well below the dose limit of 1 mSv/year. Over the past five years, the Proponent has demonstrated that worker doses for employees and contractors working in the facility have been consistently well below the regulatory limits. BWXT Medical Ltd. is planning to implement an automated packaging line for Tc-99m generators, and an automated storage retrieval system for Y-90 and In-111, all of which will reduce doses to workers even further.

BWXT Medical Ltd.'s environmental monitoring program will monitor and measure any potential releases to the environment, and contaminant concentrations in the environment. The Proponent will collect all radioactive liquid waste and transport it to a licensed radioactive waste management facility. Wastewater from emergency showers, personnel wash sinks, and water used for routine floor cleaning, which may potentially contain small amounts of radioactive contamination, will be collected in holding tanks then sampled and compared to DRLs to ensure safety and compliance with licence conditions before release to the municipal sewer system. Soil sampling will take place on the Nordion property at least every two years to test for the presence of radioisotopes, as well as for non-radiological contaminants.

BWXT Medical Ltd. indicate in their licence application that they have established a preliminary decommissioning plan for the facility and have submitted a proposed financial guarantee to the CNSC. The Proponent has indicated that the CNSC has accepted the preliminary decommissioning plan and the cost estimate for facility decommissioning, and that CNSC staff have confirmed that the proposed financial guarantee instruments are acceptable and meet their expectations.

BWXT Medical Ltd. has described in their licence application that they have been a member of the Canadian Council for Aboriginal Business (CCAB) since 2017 and are participating in the CCAB's Progressive Aboriginal Relations (PAR) program at the "Committed" level. BWXT Medical Ltd. participates in this CCAB program through its parent company, BWXT Nuclear Energy Canada Inc. The Proponent has also developed an Indigenous Relations Committee that is responsible for the development and execution of the four PAR drivers (leadership actions, employment, business development, and community relations). BWXT Medical Ltd. has outlined in their licence application that they intend to continue engaging with Indigenous communities (including the AOO) on a regular basis by letter, email, phone calls, and meetings, to ensure that materials and information is readily available and that there is a point-of-contact in case there are questions or concerns. The Proponent has further outlined that they intend to continue outreach to Indigenous communities after the current licence hearing has concluded, in order to establish and maintain meaningful engagement and relationships.

4.2 Summary of CNSC Review of BWXT Licence Application

CNSC staff reviewed the Proponent's licence application and have prepared a CMD based on their review and assessment. The CMD provides an overview of the CNSC staff review, assessment of the licence application and summary of past performance of the medical isotopes facility, and also includes a proposed licence and licence conditions handbook. The licence conditions handbook identifies compliance verification criteria, recommendations, and guidance to provide information to the Proponent on how to comply with the licence regulatory requirements.

As part of their review, CNSC staff assessed the Proponent's planned measures and programs and procedures for each Safety and Control Area to verify that the Proponent could meet all of the regulatory requirements and expectations associated with the issuance of the Class IB licence. The Safety and Control Areas evaluated as part of CNSC's review included: management system, human performance management, operating performance, safety analysis, physical design, fitness for service, radiation protection, conventional health and safety, environmental protection, emergency management and fire protection, waste management, security, safeguards and non-proliferation, and packaging and transport. Additionally, the CNSC evaluated BWXT Medical Inc.'s proposed financial guarantee of $2.6 million (as a letter of credit) for putting the facility in a safe shutdown state, and $7.94 million (as a surety bond) for the remainder of decommissioning costs. Based on their review, CNSC staff concluded that the cost estimate outlined by the Proponent is credible and that the outlined financial guarantee instruments are acceptable.

Based on their review, the CNSC staff concluded in the CMD that the Proponent is qualified to carry on the licenced activities and that they will appropriately protect the environment, human health and

safety, and maintain national security measures. The CNSC also verified that the Proponent's application is in compliance with the *Nuclear Safety and Control Act* and its regulations. CNSC staff provided the Commission with the recommendation to accept the assessment and conclusions outlined in the CMD, and issue a licence to BWXT Medical Inc. to operate the proposed nuclear substance processing facility for the requested ten-year period.

4.3 Evaluation and Recommendations

Based on our evaluation of BWXT Medical Inc.'s license application, we recommend the Proponent provide regular updates to the AOO in the form of bi-annual reports that summarize general site operations, and any issues of concern relating to issues of non-compliance and updates on contaminant releases exceeding regulatory limits, with an option for calling a meeting following review of each report.

The Proponent has reported that they will continue to develop new products that can be produced at the Nuclear Medical Production Facility (NMPF). Other radioactive products that the Proponent produces at the facility may also have potential impacts on Algonquin Rights and interests. We recommend that the Proponent provide updates in bi-annual reports to the AOO on research being conducted at the NMPF for new products, and products they are researching at their other facilities that may be produced at the NMPF.

In Section 2.0 (Business Plan; pp. 11-13) the Proponent reports that they will be using a proprietary new technology to produce Mo-99 isotopes. The Proponent has not indicated whether their new technology will produce different radioactive by-products in their airborne and liquid effluent that they will need to monitor. The Proponent has not specified if they will require any new non-radioactive hazardous chemicals that will require specific handling procedures to be protective of the environment. We recommend that the Proponent provide details on any new anticipated radioisotopes to be present in the airborne and liquid effluent, and any new non-radioactive hazardous chemicals that the Proponent will use in their proprietary process. We also request that the Proponent specify any management strategies they will employ specific to the waste generated from the new process.

Lastly, in Section 3.12.7 (Decommissioning Plan; p. 52) the Proponent indicates that they have established a preliminary decommissioning plan for the medical isotopes facility, and that the CNSC has accepted the plan. Aside from stating that the plan meets the criteria outlined in the CNSC regulatory guidelines, no other information on the decommissioning plan has been provided. We request that the Proponent provide the details of the preliminary decommissioning plan to the AOO for review and input where appropriate.

5.0 Summary and Conclusion

The work being conducted by BWXT Medical Ltd. at their nuclear substance processing facility in Ottawa is of great importance to the medical field in North America and globally. Their patent-pending technology for producing Mo-99 is an innovative way to ensure a reliable supply of Tc-99m for medical diagnosis procedures without the use of uranium or the generation of long-lived radioactive waste. If granted, the Class IB nuclear substance processing facility licence being sought by the Proponent will

allow them to continue processing medically important products. BWXT Medical Ltd. has indicated in their application that they are committed to growing their portfolio in order to deliver other innovative medical isotope products in the future.

The Proponent has demonstrated in their licence application that during normal facility operations, there are no detectable releases of radioactivity to the atmosphere or water resources, and the maximum dose to a member of the public is considered to be negligible. Although no immediate environmental or human health concerns were identified during SVS' review of the licence application, we recommend that the Proponent provide updates to the AOO on research being conducted on any new products at the facility, via bi-annual reports. Additionally, we recommend that the Proponent provide the details of their preliminary decommissioning plan for the facility for AOO to review and provide input where appropriate.

Additionally, BWXT Medical Ltd. has outlined in their licence application that they intend to continue engaging with Indigenous communities (including the AOO) on a regular basis even after the current licence hearing has concluded, and that they wish to establish and maintain meaningful engagement and relationships. We recommend that the Proponent provide regular updates to the AOO in the form of bi-annual reports that summarize general site operations and any issues of concern, with an option for calling a meeting following review of each report.

Appendix A: Issue Tracking Table

Table 1: List of Issues and Recommendations: Results of the technical review of the BWXT Medical Ltd. Application for Class IB Nuclear Substance Processing Facility Operating Licence

COMMENT #	SECTION REFERENCE	ISSUE	RECOMMENDATION	PROPONENT RESPONSE
1.	BWXT License Application, Section 2.0, pp. 11-13	The Proponent stated that they plan to continue to develop new products and are "increasing the portfolio of radiochemical and radiopharmaceutical products" to better leverage the facility. The AOO wish to maintain open lines of communication with the Proponent: to be informed of any changes to processes and products at the facility and to have the option to meet when further discussion is required.	a) The Proponent should commit to updating the AOO on research and development occurring at the NMPF, or research that is being done at other BWXT facilities that is likely to be commercially produced at the Ottawa facility, to ensure any new or heightened risks to the AOO's Rights and interests are understood and appropriately addressed. The AOO recommends the Proponent provide these updates through bi-annual reports to the AOO on general site operations and any issues of concern relating to issues of non-compliance and updates on contaminant releases exceeding regulatory limits.	
2.	BWXT Licence Application, Section 3.10.6, p. 43	The Proponent has not reported any additional hazardous non-radioactive chemicals that they will require for the technology they will be employing to produce Mo-99. As part of understanding the potential impacts of the operations at the facility on our rights and interests, the AOO are interested in knowing what additional chemicals the Proponent may plan on using at the facility, and any handling requirements that may need to be implemented.	a. The Proponent should provide a list of any new non-radioactive hazardous chemicals they will need to use as part of the new technology to produce Mo-99. b. The Proponent should report any handling procedures specific to the new chemicals, as well as any modifications to the facility design to accommodate handling new hazardous chemicals. c. The Proponent should commit to reporting all radioactive and non-radioactive releases from the facility. This could be a part of ongoing update meetings between the Proponent and the AOO on site operations more broadly.	
3.	BWXT Licence Application, Section 3.10.8 and	The Proponent has provided airborne and liquid effluent discharge information from the facility for 2015 to 2019 but have not identified whether the new technology to produce Mo-99 will result in any new radioisotopes being produced which require monitoring in the airborne and liquid effluent. The AOO require more	a. The Proponent should clarify whether they will need to modify the list of radioisotopes monitored in the airborne and liquid effluents as a consequence of the new processing technology.	

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	3.10.8.1, pp. 44-46	information on what contaminants will require monitoring as a consequence of operations at the facility, and their potential impact on AOO Rights and interests.	b. If the Proponent needs to monitor a different set of radioisotopes as a consequence of the new process, the Proponent should propose new derived release limits for those radioisotopes. The new derived release limits should be provided to the AOO for comment.	
4.	BWXT Licence Application, Section 3.12.5, p. 51	In the 2019 Regulatory Oversight Report for Uranium and Nuclear Substance Processing Facilities, CNSC reported that two reportable limit exceedances involving non-radiological releases occurred at the Nordion facility. The AOO submitted an information request for details on the contaminants that were released, and the respective concentration of contaminants and the total volume of the release. As of this time the AOO has not received the requested details. The AOO needs to have more frequent direct communication with the Proponent to understand potential impacts of the project on AOO Rights and interests.	a. The AOO reiterate information request #3 from the 2019 regulatory oversight report. b. The AOO request that the Proponent commit to providing bi-annual update reports on site operations with an option for scheduling an engagement meeting. Reports should cover general site activities, issues of non-compliance, and updates on contaminant releases exceeding regulatory limits. These meetings should include updates on contaminant releases above regulatory limits. c. The Proponent should develop a communication protocol in collaboration with the AOO to be implemented if accidents/malfunctions occur based on agreed upon criteria (e.g., thresholds) to ensure the AOO are notified in a timely manner and have the opportunity to engage with the Proponent to address concerns (as is necessary).	
5.	BWXT Licence Application, Section 3.12.7, p. 52	The Proponent has indicated that they have prepared, and the CNSC have accepted, a preliminary decommissioning plan for the facility, along with a cost estimate for decommissioning. Although the licence application states that the decommissioning plan meets the criteria of all necessary regulatory guidelines and standards, no details have been provided to the AOO on the details of the preliminary decommissioning plan.	The AOO request that the Proponent share the details of the preliminary decommissioning plan proposed for the medical isotope facility.	
6.	*General*	As a PAR Committed Company, BWXT is signalling its intent to **move forward in the CCAB PAR process to** recognize the advantages of working with Indigenous businesses and communities, and advance strategic planning that leverages the beneficial impacts of collaboration	The AOO would be pleased to assist BWXT in moving forward to advance strategic planning that recognizes leverages the mutually-beneficial impacts of business development collaboration with AOO-owned businesses, the value benefits that AOO members bring to	

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		with Indigenous-owned businesses, the benefits that Indigenous people bring to collaboration, and the potential of Indigenous communities. BWXT is beginning a journey, moving toward developing the goals and action plans that position them to work with Indigenous communities, including the AOO. Moving further along the PAR continuum, BWXT would be seeking to put business partnerships in place with the AOO, and supporting investments in our communities and people, and moving to include Indigenous relations as a core part of the BWXT business strategy. There are several key nuclear businesses that have achieved CCAB PAR Gold status or Silver status, including Bruce Power and Cameco at the Gold level, and OPG at the Silver level. Bruce Power, for example, has established a medical isotope partnership with Saugeen Ojibway Nation called "Gamzook'aamin aakoziwin" which translates to "We are teaming up on the sickness" – see www.fightingcancertogether.ca. Through this agreement, Bruce Power and Saugeen Ojibway Nation are exploring ways to collaboratively market new medical isotopes, and working together to create new economic opportunities within the Saugeen Ojibway Nation's territory.	collaboration the workplace, and the potential of AOO communities. The AOO is also very interested in exploring business partnerships and investments similar to "Gamzook'aamin aakoziwin," including jointly marketing medical isotopes that enhance health and well-being.	