



Record of Decision

DEC 21-H5

In the Matter of

Applicant BWXT Medical Ltd.

Subject Application for the Issuance of a Class IB
Nuclear Substance Processing Facility
Operating Licence

Public Hearing
Date June 9, 2021

Record of
Decision Date October 8, 2021

RECORD OF DECISION – DEC 21-H5

Applicant: BWXT Medical Ltd.

Address/Location: 447 March Road
Ottawa, Ontario
K2K 1X8

Purpose: Application for the Issuance of a Class IB Nuclear Substance Processing Facility Operating Licence

Application received: [December 17, 2018](#)

Notice of public hearing: [November 18, 2020](#); revised [February 12, 2021](#)

Date of public hearing: [June 9, 2021](#)

Location: [Virtual Hearing](#)

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Intervenors		
See appendix A		

Licence: Issued

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1.0 INTRODUCTION

1. BWXT Medical Ltd.¹ (BWXT Medical) has [applied](#) to the Canadian Nuclear Safety Commission² for the issuance of a Class IB Nuclear Substance Processing Facility Licence to operate the Nuclear Medicine Production Facility (NMPF) located in Ottawa, Ontario. BWXT Medical has requested that this licence be issued for a period of ten years. The NMPF is currently one of two production operations operated by Nordion (Canada) Inc. (Nordion) under its Class IB facility licence ([NSPFOL-11A.00/2025](#)).
2. The NMPF has been in operation at the 447 March Road, Ottawa site since 1982, and is co-located with Nordion’s Gamma Technologies facility, which was built in 1972. The NMPF processes a variety of radioisotopes used in nuclear medicine for both diagnosis and treatment.
3. BWXT Medical acquired Nordion’s medical isotopes business, including the equipment and personnel of the NMPF, in 2018. BWXT Medical workers have since continued to work at the facility as subcontractors to Nordion, under Nordion’s licence. If issued a licence, BWXT Medical will be the licensee responsible for the NMPF, while Nordion will continue to be the licensee responsible for its Gamma Technologies facility.

Issues

4. In considering BWXT Medical’s application for the issuance of a Class 1B licence to operate a medical isotope facility, the Commission is required first to decide which environmental assessment process is engaged, and whether there are any requirements that would be imposed. Satisfying any such requirements is generally a prerequisite to licensing.
5. Under the *Nuclear Safety and Control Act* (NSCA), the Commission must determine:
 - a) whether BWXT Medical is qualified to carry on the activities that the licence would authorize; and
 - b) whether in carrying on these activities, BWXT Medical 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.

¹ At the time of its application, BWXT Medical Ltd. was known as BWXT ITG Canada, Inc.

² The *Canadian Nuclear Safety Commission* is referred to as the “CNSC” when referring to the organization and its staff in general, and as the “Commission” when referring to the tribunal component.

6. As an agent of the Crown, the Commission recognizes its role in fulfilling the Crown's constitutional obligations, along with advancing reconciliation with Canada's Indigenous peoples. The Commission's responsibilities include the duty to consult and, where appropriate, accommodate Indigenous interests where the Crown contemplates conduct which may adversely impact potential or established Indigenous or treaty rights.³ As such, the Commission must determine whether the duty to consult is engaged and, if it is, what consultation steps and accommodation measures are called for.

Public Hearing

7. On November 18, 2020, the Commission published a [Notice of Public Hearing and Participant Funding](#) for this matter, which invited requests to intervene by April 26, 2021. The Commission subsequently published a [Revised Notice of Public Hearing](#) on February 12, 2021 to extend the deadline for interventions by one week.
8. Pursuant to section 22 of the NSCA, the President of the Commission established a Panel, including Dr. Sandor Demeter, Ms. Indra Maharaj and herself, to consider the application. The public hearing was conducted [June 9, 2021](#) in accordance with the [Canadian Nuclear Safety Commission Rules of Procedure](#). The Commission considered written submissions and heard oral presentations from BWXT Medical ([CMD 21-H5.1](#), [CMD 21-H5.1A](#), and [CMD 21-H5.1B](#)), CNSC staff ([CMD 21-H5](#) and [CMD 21-H5.A](#)), and 21 intervenors⁴. The hearing was [webcast](#) live, and an [archive](#) made available, via the CNSC's website.

2.0 DECISION

9. Based on its consideration of the matter, as described in more detail in the following sections of this *Record of Decision*, the Commission concludes the following:
 - The Commission is satisfied that an environmental assessment (EA) under the [Canadian Environmental Assessment Act, 2012 \(CEAA\)](#) or an impact assessment under the [Impact Assessment Act \(IAA\)](#) were not required in this matter.
 - BWXT Medical is qualified to carry on the activities that the licence will authorize; and
 - BWXT Medical, in carrying on these activities, 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.

³ *Haida Nation v. British Columbia (Minister of Forests)*, 2004 SCC 73; *Taku River Tlingit First Nation v. British Columbia (Project Assessment Director)*, 2004 SCC 74

⁴ See Appendix A for a list of interventions.

Therefore,

the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, issues the Class IB Nuclear Substance Processing Facility Licence to BWXT Medical Inc. for its Nuclear Medicine Production Facility located in Ottawa, Ontario. The licence, NSPFL-15.00/2031, is valid from November 1, 2021 until October 31, 2031.

10. The Commission delegates authority for the purposes of licence condition 3.2, *Reporting Requirements*, to the following CNSC staff:
 - Director, Nuclear Processing Facilities Division
 - Director General, Directorate of Nuclear Cycles and Facilities Regulation
 - Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch
11. The Commission directs that, following the first year of operations using its new Molybdenum-99 (Mo-99) process, BWXT Medical shall present to the Commission comprehensive updates on its licensed activities for its NMPF. This update will take place during a public Commission proceeding where Indigenous peoples, members of the public and stakeholders will be able to participate.
12. The Commission directs CNSC staff to report on the performance of BWXT Medical and the NMPF as part of the regular sector specific regulatory oversight report (ROR). CNSC staff shall present the ROR at a public proceeding of the Commission, where Indigenous peoples, members of the public and stakeholders will be able to participate.
13. The Commission notes that CNSC staff can bring any matter to the Commission as applicable. The Commission directs CNSC staff to inform the Commission on an annual basis of any changes made to the *Licence Conditions Handbook*.

3.0 APPLICATION OF THE CANADIAN ENVIRONMENTAL ASSESSMENT ACT, 2012 AND THE IMPACT ASSESSMENT ACT

14. The IAA came into force on August 28, 2019. Pursuant to the IAA and the [*Physical Activities Regulations*](#) made under it, impact assessments are to be conducted in respect of projects identified as having the greatest potential for adverse environmental effects in areas of federal jurisdiction. The Commission recognizes that BWXT Medical's licence application was submitted to the CNSC on December 17, 2018, prior to the coming into force of the IAA, and relates to the issuance of a licence for the operation of an existing facility. Operation of an existing facility is not a project designated in the *Physical Activities Regulations* under the IAA.

15. At the time of BWXT Medical's licence application, the CEAA and its regulations were the EA regime in place and specified the requirements for EAs for nuclear projects. The Commission recognizes that BWXT Medical's licence application is for the operation of an existing facility and notes that operation of an existing facility is not an activity identified in the [*Regulations Designating Physical Activities*](#).
16. Based on the information considered for this hearing, the Commission is satisfied that neither an EA under the CEAA nor an impact assessment under the IAA were required in regard to this licence application. The Commission notes that the NSCA provides a strong regulatory framework for environmental protection and the health and safety of persons.

4.0 ISSUES AND COMMISSION FINDINGS

17. In making its licensing decision, the Commission considered a number of issues and submissions relating to BWXT Medical's qualification to carry out the proposed licensed activities. The Commission also considered the adequacy of the proposed measures for protecting the environment, the health and safety of persons, national security and international obligations to which Canada has agreed. The Commission will focus its reasons on the issues that it deems the most relevant, specifically:
 - The Safety and Control Areas
 - Indigenous consultation and engagement
 - Other matters of regulatory interest
 - Licence length and conditions
18. The Commission notes that BWXT Medical has proposed that it will operate the NMPF using many of the same programs, procedures and staff, and within the same licensing basis, as Nordion. Therefore, the Commission considers the performance under the current Nordion licence informative with respect to BWXT Medical's qualification to carry out the proposed licensed activities.
19. In its consideration of this matter, the Commission also examined the completeness of BWXT Medical's [application](#) and the adequacy of the information submitted, as required by the NSCA, the [*General Nuclear Safety and Control Regulations*](#) (GNSCR), the [*Class I Nuclear Facilities Regulations*](#) (CINFR), and other applicable regulations made under the NSCA.
20. Many intervenors provided the Commission with information and views about the economic impacts of the NMPF, such as local job creation and the NMPF's role in the supply chain of other organizations. The NSCA provides the extent of the Commission's statutory authority, which does not include an economic mandate and its decisions are not based on economic impact.

4.1 Safety and Control Areas

21. The Commission examined CNSC staff's assessment of the conduct of licensed activities at the NMPF since 2018, when BWXT Medical began working as a subcontractor in the facility, in all 14 Safety and Control Areas (SCAs):
- 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
 - Packaging and Transport

4.1.1 Management System

22. The management system SCA covers the framework that establishes the processes and programs required to ensure that the NMPF achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture. Per the proposed licence, licence condition 1.1 requires BWXT Medical to implement and maintain a management system. Inspections carried out at the NMPF by CNSC staff since 2018 found that BWXT Medical workers are safely implementing the programs and procedures in place at the NMPF, and CNSC staff expressed that it expects this to continue under the proposed BWXT Medical licence.
23. BWXT Medical informed the Commission that it will adopt the existing Nordion *Management System for Safety*, and that its management system complies with Canadian Standards Association (CSA) standard N286-12, *Management System Requirements for Nuclear Facilities*⁵. CNSC staff assessed BWXT Medical's proposed management system against CSA N286-12 and confirmed that it meets regulatory requirements. CNSC staff noted that over 150 BWXT Medical employees, who will be performing the activities under this proposed licence, have been trained and are currently qualified to work in the NMPF under Nordion. BWXT Medical committed to monitor the effectiveness of its management system through relevant performance and safety indicators and to practice continuous improvement, throughout the proposed licence term.

⁵ The CSA makes its nuclear series standards freely viewable to members of the public on its [website](#) by means of a guest account.

24. BWXT Medical reported that, should the proposed licence be issued, it will update its management system to reflect BWXT Medical's specific corporate details and submit all relevant documents to the CNSC for consideration. CNSC staff stated that BWXT Medical has committed to revising and updating these documents within a 12-month period following the issuance of a licence. As these updates are administrative in nature, CNSC staff found that this approach will not affect the [licensing basis](#) of the NMPF. The Commission is satisfied that completing such administrative revisions following the issuance of a licence is acceptable and that CNSC staff will maintain regulatory oversight to ensure BWXT Medical's commitment is met.
25. CNSC staff informed the Commission that it found, following the assessment of the documentation submitted, that BWXT Medical's proposed management system meets the requirements of [REGDOC-2.1.2, Safety Culture](#) and includes measures to understand and promote safety within the organization. BWXT Medical committed to conducting safety culture surveys every three years, beginning shortly after issuance of the proposed licence. In their interventions, the Canadian Nuclear Association ([CMD 21-H5.18](#)) and Kinetrics ([CMD 21-H5.11](#)) each highlighted BWXT Medical's strong safety culture.
26. The Commission asked about the absence of direct reporting lines in the submitted organizational structure between the senior manager of radiation safety and the president. A BWXT Medical representative specified that committees discussing such matters have not historically involved the president. The representative explained that these committees include senior management, who better understand the details related to safe operation of the facility, and information is then communicated to the president. CNSC staff added that BWXT Medical's organizational structure meets CNSC requirements, which emphasize creating a safety culture that allows people to raise issues at any level in the organization.
27. In response to questions about its estimated corporate status at the end of the proposed licence term, a BWXT Medical representative explained that growth is anticipated. The representative estimated that staff levels may increase by roughly 100 persons by the end of the proposed licensing period. With respect to product expansion, the representative noted that BWXT Medical will continue to focus on similar products to what is currently produced.
28. The Commission concludes that BWXT Medical's management system and organizational structure for the NMPF meets the requirements of CSA N286-12 and REGDOC-2.1.2. On that basis, the Commission is satisfied that BWXT Medical will implement, maintain, and continuously improve its proposed management system during the proposed licence period. The Commission expects that BWXT Medical will complete any required administrative updates and revisions to the documents supporting its management system within the proposed 12-month period following the issuance of a licence.

4.1.2 Human Performance Management

29. The human performance management SCA covers programs that encompass activities that enable effective human performance through the development and implementation of processes that ensure that NMPF staff are sufficient in number in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties. Per the proposed licence, licence condition 2.1 requires BWXT Medical to implement and maintain a training program. In its submission, CNSC staff provided an assessment, based on ongoing compliance oversight, that an effective training program has been implemented at the NMPF under Nordion, which is expected to continue under BWXT Medical.
30. BWXT Medical submitted that its proposed training system was adopted from the existing Nordion training system. BWXT Medical explained that its training system employs a systematic approach to training (SAT)⁶. CNSC staff assessed BWXT Medical's proposed training system and found that it complied with the requirements of [REGDOC-2.2.2, Personnel Training, Version 2](#).
31. BWXT Medical stated that training is determined by job requirements, such as nuclear energy worker (NEW) classification, and reported that supervisors and managers are trained in accordance with the [Canada Labour Code](#) with respect to use of protective equipment, awareness of potential and actual hazards, and protection of workers. CNSC staff confirmed that BWXT Medical has proposed measures to ensure excellence in worker safety related performance.
32. The Commission asked whether there were any relevant differences between the proposed BWXT Medical training program and the existing Nordion program. A BWXT Medical representative provided an example of the training requirements for radiation surveyors. Radiation surveyors hired by either BWXT Medical or Nordion are trained to be able to fulfil emergency response roles in both the NMPF and Nordion's Gamma Technologies facility. The representative explained that BWXT Medical radiation surveyors will occasionally perform day-to-day activities for Nordion, and vice versa, in order to maintain this cross-training. The Commission is satisfied that BWXT Medical has considered necessary differences between Nordion's existing training program and the proposed training program.
33. Based on consideration of the information submitted by BWXT Medical and CNSC staff, the Commission concludes that BWXT Medical has proposed appropriate training programs for the NMPF that meet the objectives of REGDOC-2.2.2. The Commission is satisfied that the NMPF training programs proposed by BWXT Medical, and currently implemented by Nordion, will ensure that workers continue to have the knowledge and skills required to carry out their duties.

⁶ The SAT is a cyclical process providing analysis, design, development, implementation and evaluation functions intended to meet operational and organizational requirements and to react quickly to make changes to those requirements.

4.1.3 Operating Performance

34. The operating performance SCA covers the conduct of licensed activities and the activities that enable effective performance. Per the proposed licence, licence condition 3.1 requires BWXT Medical to implement and maintain an operating program and licence condition 3.2 requires BWXT Medical to implement and maintain a program for reporting to the Commission or a person authorized by the Commission. CNSC staff reported that the NMPF has been operated in a compliant manner, with no major inspection findings, and that this is expected to continue under BWXT Medical.

Conduct of Licensed Activity

35. BWXT Medical submitted that processing and manufacturing of a final product occur at the NMPF, with production of the radioisotopes and distribution activities occurring off-site. BWXT Medical explained that it will not duplicate the activities related to Nordion's Gamma Technologies facility, and that it will process the same types of radioactive products, in quantities below historical production levels, as the NMPF currently processes under Nordion's licence. BWXT Medical committed to continuous improvement in areas that affect the conduct of its proposed licenced activities.
36. CNSC staff expressed the opinion that BWXT Medical has appropriate programs and procedures in place to ensure that the operation of the NMPF will remain within the licensing basis for the facility. CNSC staff indicated that BWXT Medical's proposed programs and procedures were previously implemented at the NMPF by Nordion, and include a corrective and preventative actions system that CNSC staff found meets regulatory expectations.
37. Asked about differences in the licensing basis between the NMPF under Nordion's current licence and the proposed BWXT Medical licence, CNSC staff reported that the licences will remain very similar and that any changes were captured in the reference documents in the proposed *Licence Condition Handbook (LCH)*⁷. CNSC staff explained that the LCH for Nordion will have the NMPF removed and that Nordion will update their financial guarantee. The Commission is satisfied that CNSC staff will maintain adequate regulatory control over the NMPF and Nordion's Gamma Technologies facility as separate Class IB facilities during Nordion's current licence and the proposed BWXT Medical licence.
38. The Commission asked how any future new activities, should any be eventually proposed, would be introduced during the proposed licence. CNSC staff explained that BWXT Medical's application⁸ includes all of the specific isotopes that will be processed at the NMPF and that there is no change from those approved under

⁷ The draft LCH pertaining to BWXT Medical's proposed licence is included as part of CNSC staff CMD 21-H5

⁸ 3(1)(c) of Attachment 1 to BWXT Medical's application specifies $>1 \times 10^{15}$ Bq per calendar year of Mo-99 in solid form and $<1 \times 10^{15}$ Bq per calendar year of various isotopes with atomic number 1-89 in solid, liquid or gaseous form.

Nordion's current licence. CNSC staff explained that BWXT Medical would be required to provide detailed prior notification to the CNSC, demonstrating that any new activity is within the proposed licensing basis, for CNSC staff approval.⁹ CNSC staff stated that BWXT Medical has an ongoing obligation to keep the public informed of its activities under the proposed licence (See section 4.3.2, *Public Engagement*), and that any future changes would be publicly reported to the Commission as part of the ROR.

39. On the basis that the NMPF has been operated safely while BWXT Medical has worked as a subcontractor in the facility, the Commission is satisfied that BWXT Medical will operate the NMPF safely during the proposed licence period. The Commission is also satisfied that the applicable regulatory framework ensures that any changes to the facility or operations during the proposed licence will be adequately assessed by CNSC staff, disseminated to the public, communicated to the Commission, and that appropriate programs and procedures are in place to ensure the NMPF remains within the proposed licensing basis.

Molybdenum-99 Process

40. BWXT Medical submitted that it plans to produce Mo-99 at the NMPF, for the creation of Technetium-99m (Tc-99m) generators, using a new process that is currently under development. BWXT Medical explained that this new process will draw upon the established infrastructure, expertise, and systems currently in place. BWXT Medical is aiming for commercial launch of its new Mo-99 process in late 2022, depending on approval from the appropriate health authorities. In addition to the Mo-99 process, BWXT Medical noted that it will also seek a separate Class II licence for the operation of electron beam sterilization equipment, and that in the future it would request that its proposed Class 1B licence be amended to include these Class II activities.
41. CNSC staff informed the Commission that until 2016 the NMPF had historically been used to produce Mo-99 under its existing licensing basis. CNSC staff explained that BWXT Medical is proposing to restart this process with modified equipment to accommodate natural molybdenum. CNSC staff assessed BWXT Medical's submission and expect doses to workers, releases to the environment, and quantities and activities of waste to remain within those established for the NMPF and in line with the previous Mo-99 process. Based on the information provided to date, CNSC staff agrees with BWXT Medical's determination that the new Mo-99 process would be within the licensing basis of the proposed licence.
42. In response to concerns regarding the use of enriched uranium raised in Mr. Herrera's intervention ([CMD 21-H5.2](#)), BWXT Medical explained that its new process involves the neutron activation of natural molybdenum targets and not enriched uranium. BWXT Medical stated that Mo-99 would be produced off-site and then processed at the NMPF for the production of Tc-99m generators under the same licence conditions as the existing operating licence.

⁹ Any new activity outside of the licensing basis requires the licensee to come before the Commission for approval.

43. The Commission asked for information pertaining to the regulatory process for the off-site production of Mo-99. CNSC staff explained that a separate application for the production of Mo-99 will come before the Commission. CNSC staff confirmed that two proposed sources for Mo-99 are the Darlington Nuclear Generating Station and the MURR research reactor in the United States. A Bruce Power representative added that while it has signed a memorandum of understanding with BWXT Medical for Mo-99 production, it has no plans to produce Mo-99 at this time.
44. The Commission is satisfied that the new Mo-99 process, as it is within the bounds of the previous process, is within the licensing basis of the NMPF and that CNSC staff will assess any changes to any processes at the facility as part of ongoing compliance oversight. The Commission expects to be informed by CNSC staff and BWXT Medical through appropriate means, such as the ROR, of the performance of the Mo-99 process during the proposed licence period.

Reporting and Trending

45. BWXT Medical is required to implement and maintain a program for reporting to the Commission or a person authorized by the Commission, as per [REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills](#). In addition to reporting required under REGDOC-3.1.2, BWXT Medical committed to submit annual compliance and performance reports to the CNSC. Environmental, health and safety (EHS) related non-conformances as well as corrective and preventative actions will be reviewed and analyzed in an annual EHS performance report.
46. CNSC staff found that the reporting program proposed by BWXT Medical meets the requirements of REGDOC-3.1.2. CNSC staff added that specific reporting requirements associated with the sealed source tracking system (SSTS) are described in [REGDOC-3.1.3, Requirements for Waste Nuclear Substance Licensees, Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices](#). CNSC staff also found that BWXT Medical has proposed a program for SSTS reporting that meets CNSC expectations.
47. The Commission is of the view that BWXT Medical's application includes an adequate program for reporting to the CNSC. Further, the Commission is satisfied that this proposed reporting program meets the requirements described in REGDOC-3.1.2 and REGDOC-3.1.3.

Conclusion on Operating Performance

48. The Commission is satisfied that BWXT Medical, which currently works in the NMPF as a subcontractor, will operate the NMPF safely and meet its reporting requirements over the proposed licence term. The Commission concludes that CNSC staff have the proper regulatory tools to ensure that BWXT Medical implements the proposed new Mo-99 process within the proposed licensing basis of the NMPF.

4.1.4 Safety Analysis

49. The safety analysis SCA covers the systematic evaluation of the potential hazards associated with the conduct of the proposed licensed activity or the operation of the NMPF, and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards. Per the proposed licence, licence condition 4.1 requires BWXT Medical to implement and maintain a safety analysis program. CNSC staff reported that an effective program to manage and maintain safety analysis reports has been implemented at the NMPF and that it expects this to continue under BWXT Medical.
50. BWXT Medical included its final safety analysis report (SAR) with its application. BWXT Medical reported that it also prepared a fire hazard analysis compliant with CSA standard N393-13, *Fire Protection for Facilities that Process, Handle or Store Nuclear Substances*. BWXT Medical explained that proposed facility modifications are assessed for potential impact to the safety analysis. BWXT Medical stated that its EHS committee would review and approve the safety analysis for new medical isotope facilities as they arise and ensure the fire hazard analysis remains current.
51. CNSC staff found BWXT Medical's SAR and associated documents to be acceptable. CNSC staff explained that, should BWXT Medical be granted a license, it will ensure the upcoming [REGDOC-2.4.4, Safety Analysis for Class IB Nuclear Facilities](#) is implemented. The Commission expects that BWXT Medical will implement REGDOC-2.4.4 in a timely manner following its publication and in accordance with an implementation plan approved by CNSC staff.
52. Interventions by Mr. Drerup ([CMD 21-H5.3](#)) and the Kebaowek First Nation (KFN) ([CMD 21-H5.20](#)) raised concerns of possible impacts to the surrounding area and the proximity of the NMPF to the Ottawa River and the City of Ottawa. CNSC staff submitted that, under normal operations, the NMPF is expected to have negligible releases to the environment and doses to the public would remain well below regulatory limits. CNSC staff further indicated that under low-probability abnormal scenarios releases to the environment would be less than 1% of the Derived Release Limit (DRL).
53. The Commission concludes that the systematic evaluation of the potential hazards and the preparedness for reducing the effects of such hazards is adequate for the operation of the NMPF and the activities under the proposed licence. The Commission finds that BWXT Medical's safety analysis program for the NMPF meets regulatory requirements. On that basis, the Commission is of the view that BWXT Medical has adequate preventive measures and strategies in place at the NMPF to ensure the protection of workers, members of the public and the environment.

4.1.5 Physical Design

54. The physical design SCA includes the activities to design the systems, structures and components to meet and maintain the design basis of the NMPF. The design basis is the range of conditions, according to established criteria, that the NMPF must withstand without exceeding authorized limits for the planned operation of safety systems. Per the proposed licence, licence condition 5.1 requires BWXT Medical to implement and maintain a design program. CNSC staff reported that an effective design program has been implemented at the NMPF, and that it expects this to continue under BWXT Medical.
55. Nordion informed the Commission that the Cobalt sealed-source production occurs in a separate portion of the facility from the NMPF. BWXT Medical stated that it has leased the NMPF from Nordion and will retain ultimate responsibility for the buildings and equipment required for operation of the NMPF under its proposed licence. BWXT Medical added that Nordion, as landlord, will maintain base facilities such as fire protection, plumbing and climate control. BWXT Medical noted that any physical modifications require Nordion's approval under the lease and that its design control program includes conceptual, ergonomic, and final reviews.
56. CNSC staff submitted that the requirements under the physical design SCA are provided by national codes and standards, including CSA N393-13, the [*National Building Code of Canada*](#), and the [*National Fire Code of Canada*](#). CNSC staff reported that the proposed BWXT Medical design control program includes measures to ensure that designs meet all applicable requirements. BWXT Medical explained that all modifications that could impact fire protection are submitted for a third-party review, which is then provided to the CNSC for approval.
57. Asked about the arrangements in place between Nordion and BWXT Medical, a Nordion representative explained that the joint EHS committee is intended to facilitate communication. The representative noted that Nordion's role in the NMPF would be that of a subcontractor under BWXT Medical. A BWXT Medical representative added that part of the role of the joint EHS committee is to ensure both companies are able to maintain compliance with their own licences, and that neither company negatively impacts the licensing basis of the other's facility.
58. The Commission is satisfied that BWXT Medical will implement and maintain an effective design program at the NMPF, and concludes that the design of the NMPF is adequate for the operation period included in the proposed licence and meets all appropriate codes and standards. The Commission is also satisfied that the joint EHS will ensure continued cooperation between Nordion and BWXT Medical and that both will operate and maintain their respective facilities in accordance with applicable requirements.

4.1.6 *Fitness for Service*

59. The Fitness for Service SCA covers activities that are performed to ensure that the systems, structures and components at the NMPF continue to effectively fulfill their intended purpose. Per the proposed licence, licence condition 6.1 requires BWXT Medical to implement and maintain a fitness for service program. CNSC staff reported that an effective fitness for service program that meets regulatory requirements has been implemented at the NMPF and that there have been no major failures at the NMPF in recent years.
60. BWXT Medical submitted that it retains ultimate responsibility for maintenance of the buildings, systems and equipment required for operation of the NMPF. BWXT Medical noted that, as per the lease agreement, Nordion will be responsible for aging management of the base facilities as a subcontractor. BWXT Medical reported that it plans to replace its electronic system that manages the maintenance and calibration of equipment that supports the NMPF, and that it will implement this replacement under change control.
61. The Commission is satisfied with BWXT Medical's proposed programs for the inspection and life-cycle management of key safety systems at the NMPF. The Commission concludes that the equipment as installed at the NMPF is fit for service and that appropriate programs are in place to ensure its structures, systems and components remain effective over the proposed licence period.

4.1.7 *Radiation Protection*

62. The radiation protection SCA covers the implementation of a radiation protection (RP) program in accordance with the [*Radiation Protection Regulations*](#) (RPR). The program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained *as low as reasonably achievable* (ALARA). Per the proposed licence, licence condition 7.1 requires BWXT Medical to implement and maintain a radiation protection program, which includes a set of action levels. Inspections carried out since BWXT Medical began operating the NMPF have resulted in no major findings. CNSC staff reported that an effective radiation protection program has been implemented at the NMPF, and that it expects this to continue under BWXT Medical.

Application of ALARA

63. BWXT Medical submitted that its EHS committee will provide oversight of the radiation protection program. BWXT Medical stated that its workers receive radiological protection training in accordance with the management system and that the workers' commitment to radiation safety and keeping doses ALARA is assessed through internal audits. BWXT Medical explained that it ensures administrative action

levels are observed and issues are identified via timely review of dosimetry. BWXT Medical also expressed that its planning for unusual situations includes procedural and engineered controls.

64. CNSC staff found that BWXT Medical's RP program includes an ALARA program that complies with the RPR and CNSC licensing requirements. CNSC staff reported that BWXT Medical's ALARA program is based on the existing programs in place at the NMPF by Nordion, and that many BWXT Medical employees have been trained and qualified under them to keep radiation exposure and doses to persons ALARA. CNSC staff explained that BWXT Medical's ALARA program establishes annual performance objectives to maintain radiation doses to workers ALARA and has provisions to implement timely corrective actions.
65. The Commission is satisfied that the ALARA concept has been adequately applied by BWXT Medical workers to all NMPF activities and will continue to be appropriately applied during BWXT Medical's proposed licence period.

Radiological Hazard and Worker Dose Control

66. BWXT Medical submitted that there are currently several radiation hazard control measures in place at the NMPF. BWXT Medical detailed engineered controls include ventilation system interlocks, filtration, and shielding. BWXT Medical also detailed procedural controls including contamination zoning, signage, and activity limits. BWXT Medical explained that it performs routine radiation surveys, surface sampling, and continual air sampling.
67. CNSC staff submitted that BWXT Medical had proposed radiological survey and contamination controls to monitor and minimize radiological hazards in the facility. CNSC staff found that contamination control at the NMPF ensures that contamination is prevented from leaving radiological control areas. In its assessment, CNSC staff considered controls in place at the NMPF such as zoning, ventilation and filtration systems, access control, and routine monitoring of personnel and material.
68. With respect to controlling the dose to workers, BWXT Medical stated that the NMPF has successfully kept doses to workers low. BWXT Medical reported that, over the last five years¹⁰, the average effective dose to nuclear energy workers (NEWs) at the NMPF was 0.4 mSv and the maximum effective dose was less than 2.6 mSv¹¹. BWXT Medical explained that all workers who regularly work in the active area are classified as NEWs and assigned dosimeters.

¹⁰ The 2015 to 2019 reporting period includes two years where BWXT Medical was a subcontractor in the NMPF.

¹¹ The regulatory effective dose limit is 50 mSv per year, and 100 mSv over a 5 year period.

69. CNSC staff found that BWXT Medical's proposed action levels, which are based on the existing action levels under Nordion's licence, are acceptable. CNSC staff explained that BWXT Medical has proposed to conduct similar licenced activities to those currently carried out by Nordion, with the exception of operation of the cobalt facility which generally exposes workers to higher doses than the NMPF. CNSC staff reported that BWXT Medical proposed procedures for routine thyroid screening of NEWs working with radioiodine, and that urine analysis and whole body counting is available as necessary. CNSC staff expect that the implementation of such measures will effectively maintain worker doses well below regulatory limits and ALARA.
70. Ms. Tilman's intervention ([CMD 21-H5.5](#) and [CMD 21-H5.5A](#)) questioned radiation protection requirements for contractors. A BWXT Medical representative explained that contractor NEWs are trained to access the NMPF but are not permitted to handle or linger near radioactive materials. The representative expressed that greater control over contractor NEWs in the NMPF was desired, and that by subjecting them to the lower regulatory dose limits of non-NEWs¹² they are protected to a higher standard than employee NEWs.
71. The Commission asked why identical action levels to those currently in place under Nordion's licence have been proposed, since cobalt processing will not be part of the NMPF's activities. A BWXT Medical representative explained that the action levels are periodically adjusted as needed. The representative made reference to the proposed new Mo-99 process which will require revisiting the action levels and noted that BWXT Medical expects further insights with respect to possible revisions within the next 12 months. The Commission is satisfied that BWXT Medical will revisit its action levels in accordance with CNSC expectations and that processes are in place to adjust these action levels as required.
72. Asked about breathing air monitoring, a BWXT Medical representative explained that breathing air monitoring methodologies depend on the hazard assessment and could be either daily filter measurements or continuous monitoring of the air. The representative noted that radiation surveyors have the authority to stop any process should an air quality alarm sound.
73. The Commission is satisfied that that radiological hazards at the NMPF have been adequately identified and controlled under Nordion's current licence, and that this will continue under BWXT Medical's proposed licence owing to the fact that BWXT medical has proposed continuing the same programs. The Commission is also satisfied that doses to workers, including contractors, at the NMPF are adequately controlled.

¹² The dose limit for a non-NEW is 1 mSv per year and is equivalent to the dose limit to the public

Control of Dose to the Public

74. In its submission, BWXT Medical stated that all air in the facility is exhausted through three stages of filtration to remove both particulate and gaseous contamination. This air exhaust system is designed to reduce all contaminants, radiological or otherwise. BWXT Medical explained that it had established Derived Release Limits (DRLs) for emission to the environment from the facility to restrict the dose to a member of the public to less than 1 mSv per year. BWXT Medical noted that environmental dosimeters are also in place at the site boundary to measure direct gamma dose.
75. CNSC staff found that, owing to the very low quantities of nuclear substances released into the environment, public doses resulting from the operation of the NMPF have been negligible over Nordion's current licence period. CNSC staff reported that the levels of gamma radiation at perimeter environmental monitoring locations are in the range of natural background. BWXT Medical has proposed, in its application, the same procedures and operating limits for the NMPF as Nordion. Therefore, CNSC staff was of the opinion that BWXT Medical will control radiation doses to members of the public to levels well below regulatory limits.
76. The Commission asked about the increase of the cobalt-60 DRL between 2017 and 2018. CNSC staff stated that the revised DRLs are based on a more recent version of CSA standard N288.1, *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities*. CNSC staff explained that the more realistic and less conservative a model is, the higher the resulting DRLs generally will be, and that the accepted methodology is to be as realistic as possible while maintaining adequate conservatism. The Commission is satisfied with the rationale for revising the DRLs for the NMPF.
77. The Commission is satisfied that the RP program currently in place at the NMPF will continue to be implemented by BWXT Medical and that it reflects a prudent approach to radiation protection. On that basis, the Commission is of the view that radiological doses to the public have been adequately controlled at the NMPF under Nordion's current licence, and that this will continue under BWXT Medical's proposed licence.

Conclusion on Radiation Protection

78. The Commission concludes that BWXT Medical's proposed radiation protection program at the NMPF meets the requirements of the RPR based on its adherence to the ALARA principle, the control of doses to workers and the public, and control of radiation hazards. The Commission is satisfied that the appropriate processes and safety programs are currently in place at the NMPF to control radiation hazards and that BWXT Medical will continue these same processes and programs. Further, the Commission is satisfied that BWXT Medical's performance as a subcontractor provides a positive indication of its ability to provide for, and continue to provide for, the adequate protection of the health and safety of persons and the environment throughout the proposed licence period.

4.1.8 Conventional Health and Safety

79. The conventional health and safety SCA relates to the implementation of a program to manage workplace safety hazards (non-radiological) and to protect workers. Per the proposed licence, licence condition 8.1 requires BWXT Medical to implement and maintain a conventional health and safety program. CNSC staff reported that an effective conventional health and safety program that meets regulatory requirements has been implemented at the NMPF, and that it expects this to continue under BWXT Medical.
80. BWXT Medical submitted that its conventional health and safety program meets the requirements of the [*Canada Labour Code*](#) (CLC) and the [*Canada Occupational Health and Safety Regulations*](#) (COHSR). BWXT Medical reported that a workplace health and safety committee was established in 2019 to provide oversight of conventional safety and conduct regular safety inspections. BWXT Medical explained that potential accidents are captured through near-miss reporting and that conventional health and safety performance is reviewed regularly. CNSC staff found that BWXT Medical's conventional health and safety program meets the requirements of the CLC and the COHSR and assessed that BWXT Medical has proposed appropriate measures to meet CNSC requirements and expectations for the conventional health and safety SCA.
81. CNSC staff evaluated the lost-time injury rates for the 2015-2019 time period at the existing Nordion Class IB facility, which is inclusive of the NMPF. CNSC staff reported that the rates of injury are low and found that the measures to prevent injury are satisfactory. CNSC staff explained that the primary conventional health and safety hazards at the NMPF are related to ergonomics. BWXT Medical committed to continue assessing these ergonomic issues as part of the design review process.
82. The Commission asked if the upcoming Mo-99 process will require the handling of lead and how any resulting occupational health and safety risks would be considered. A BWXT Medical representative explained that existing products currently use lead shielding, but that the new Tc-99m generators will not involve handling lead and instead will use a combination of tungsten and stainless steel clad depleted uranium shielding. The representative noted that the CNSC requires 6-month verifications of the depleted uranium shields to ensure they are intact.
83. The Commission concludes that BWXT Medical's proposed conventional health and safety program meets the *Canada Labor Code*, the *Canada Occupational Health and Safety Regulations* and satisfies regulatory requirements. The Commission is satisfied that the health and safety of workers and the public has been adequately protected at the NMPF and that this will continue throughout BWXT Medical's proposed licence period. The Commission notes BWXT Medical's commitment to address ergonomic issues and encourages BWXT Medical to incorporate Gender Based Analysis Plus (GBA+) in its processes to help identify the unique needs of different segments of the population.

4.1.9 Environmental Protection

84. The environmental protection SCA covers programs which are intended to identify, control and monitor all releases of radioactive and hazardous substances, and aim to minimize the effects on the environment which may result from the proposed licensed activities. Per the proposed licence, licence condition 9.1 requires BWXT Medical to implement and maintain an environmental protection program, which includes a set of action levels. Inspections carried out since BWXT Medical began working in the NMPF as a subcontractor have resulted in no major findings. CNSC staff reported that effective environmental protection programs have been implemented at the NMPF, and that it expects this to continue under BWXT Medical.
85. CNSC staff were of the opinion that BWXT Medical will remain within the scope of the licensing basis established under Nordion's current licence as it will continue the same programs currently in place at the NMPF. CNSC staff submitted that BWXT Medical's proposed Environmental protection program documents comply with the requirements and principles of the following documents and standards:
- [REGDOC-2.9.1, Environmental Principles, Assessments, and Protection Measures, Version 1.1](#)
 - CSA standard N288.4-10, *Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*
 - CSA standard N288.5-11, *Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*
 - CSA standard N288.6-12, *Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills*
 - CSA standard N288.1-14, *Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities*
 - CSA standard N288.8-17, *Establishing and Implementing Action Levels for Releases to the Environment from Nuclear Facilities*

Effluent and Emissions Control (Releases)

86. BWXT Medical submitted that, from 2015 to 2019, airborne effluent releases at the current Nordion facility were less than 2% of the DRL¹³. Over the same period, the liquid effluent releases were less than 1% of the DRL. BWXT Medical explained that liquid effluent releases are conservatively reported using the limit of detection, rather than zero, when the measurement detects nothing. Airborne effluent is monitored using continuous qualitative methods and weekly quantitative analysis. Waste water that might potentially contain small amounts of radioactive contamination is collected in holding tanks and analysed against DRLs prior to release.

¹³ A DRL is a limit imposed by the CNSC to the rate of release of radionuclides based on limiting radiation exposures to members of the public.

87. CNSC staff found that the DRLs for airborne and liquid effluent meet the requirements set out in CSA N288.1-14. CNSC staff added that the established DRLs were set so that the joint releases of radionuclides from the NMPF and Nordion's Gamma Technologies facility are not likely to exceed the regulatory dose limit of 1 mSv/year for members of the public. CNSC staff confirmed that airborne and liquid releases at the current Nordion facility had remained well below regulatory limits.
88. CNSC staff found that BWXT Medical's proposal, that environmental action levels for the NMPF are not required at this time, meets the requirements of CSA N288.8-17. However, BWXT Medical will be required to reassess the need for environmental action levels at least every five years, or sooner if warranted by monitoring data or if there is a change at the NMPF that may result in an increase in releases to the environment.
89. The Commission asked how air quality is assessed in the NMPF stack release. A BWXT Medical representative explained that the monitoring sensors are located after the point where all of the various systems combine into the final airflow mass of each of three stacks. The representative noted that stack sampling is conducted by once-weekly filter measurement and continuous instrumentation.
90. The Commission is satisfied that adequate programs are in place for the control of effluent and emissions at the NMPF, as demonstrated by the performance measured against the DRLs, and that adequate measurements of stack air quality are conducted. The Commission is also satisfied that BWXT Medical will continue to control effluent and emissions at the NMPF to protect the environment and meet regulatory requirements under the proposed licence.

Environmental Management System

91. CNSC staff submitted that BWXT Medical's environmental management system (EMS) meets the requirements of REGDOC-2.9.1. CNSC staff stated that it will ensure that BWXT Medical implements the new version published in September 2020, [REGDOC-2.9.1, Environmental Principles, Assessments, and Protection Measures, Version 1.2](#), in accordance with an implementation plan. REGDOC-2.9.1 requires that BWXT Medical maintain and describe the integrated activities associated with the protection of the environment at the NMPF. CNSC staff noted that it reviews and assesses environmental objectives and targets as part of compliance verification activities. CNSC staff expect BWXT Medical to continue maintaining and implementing an effective EMS during its proposed licence period.
92. The Commission is satisfied that the current EMS in place at the NMPF, and that will continue under BWXT Medical's proposed licence, meets the requirements set out in REGDOC-2.9.1. The Commission is also satisfied that BWXT Medical will implement REGDOC-2.9.1 (Version 1.2) in a timely manner.

Environmental Monitoring

93. BWXT Medical submitted details on its environmental monitoring program, including dosimetry and sampling activities. Environmental dosimeters are installed at predetermined locations outside of the facility to monitor ambient radiation levels on an ongoing basis. Soil sampling is conducted at least every two years at various locations on the Nordion property to detect potential soil contamination. Collected soil samples are tested for both radiological and conventional contaminants.
94. CNSC staff reported that BWXT Medical's environmental monitoring program meets the requirements of CSA N288.4-10. CNSC staff found that the results of this program during Nordion's current licence demonstrate that the program protects the public and the environment. CNSC staff expect this performance to continue, as BWXT Medical's proposed activities are within the scope of the licensing basis for the Nordion facility.
95. The Commission is satisfied that an adequate environmental monitoring program, which includes environmental dosimetry and sampling, is in place for the NMPF. The Commission is also satisfied that BWXT Medical, through the continuation of the currently established programs at the NMPF under the proposed licence, will meet regulatory requirements and monitor the environment in the vicinity of the NMPF to ensure the public and environment are protected.

Independent Environmental Monitoring Program

96. CNSC staff submitted details of its [*Independent Environmental Monitoring Program*](#) (IEMP) with respect to the Nordion facility. CNSC staff reported that the results of the IEMP are below applicable guidelines and indicate that the public and the environment in the vicinity of the facility are protected and that there are no expected health impacts. The most recent IEMP samples for the Nordion facility were collected in 2018.
97. Numerous intervenors ([CMD 21-H5.7](#), [CMD 21-H5.9](#), [CMD 21-H5.9A](#), [CMD 21-H5.20](#), [CMD 21-H5.20A](#)) raised concerns regarding the participation of Indigenous peoples in the IEMP. The Kebaowek First Nation (KFN) described a lack of outreach to discuss its role in environmental monitoring and the need for involvement to verify results. The Algonquins of Pikwakanagan First Nation (AOPFN) expressed that participation should involve activities beyond reviewing reports. CNSC staff explained that no outreach specific to the NMPF has been conducted since the 2018 IEMP campaign in the area. CNSC staff stated that it is committed to earlier outreach to make participation easier and has reached out regarding upcoming IEMP campaigns for other facilities in the area.
98. Asked about the importance of local community participation in the IEMP, a representative of the AOPFN explained that monitoring is important to its members due to possible impacts to harvesting activities, such as hunting and fishing, within its traditional territory. The representative further explained that its members want to be

able to monitor projects such as the NMPF themselves, in order to verify and validate the safety of a project for the community. The Commission recognizes the importance of Indigenous community participation in monitoring programs such as the IEMP.

99. The Commission is satisfied that the CNSC's environmental monitoring, which showed no expected health impacts, demonstrates that the public and the environment around the NMPF site remain protected. The Commission is also satisfied that the CNSC will continue to involve relevant members of the public, including members of Indigenous communities, in the IEMP. The Commission strongly encourages CNSC staff to continue to engage with local indigenous communities, including the KFN and the AOPFN, for the purpose of participation in upcoming IEMP campaigns.

Environmental Risk Assessment

100. BWXT Medical's application included the environmental risk assessment (ERA) that was completed for the Nordion facility (inclusive of the NMPF) in May 2017. In April 2021, BWXT Medical also submitted a standalone ERA ([CMD 21-H5.1A](#)) for the NMPF. Both ERAs assessed the potential risks to human and non-human biota and concluded the risks to be negligible.
101. CNSC staff reported that it found both the Nordion and standalone ERA submitted by BWXT Medical acceptable. CNSC staff confirmed that the ERAs meet the requirements of CSA N288.6-12 and explained that, since the NMPF is expected to have no impact on groundwater, CSA standard N288.7-15, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills* does not apply to BWXT Medical's proposed license. CNSC staff noted that the applicability of CSA N288.7-15 would be re-evaluated if warranted by a change in operations or in the event environmental monitoring results indicate potential impacts to groundwater. CNSC staff accepted the conclusion of both ERAs, that the environmental risk from the NMPF is negligible, and added that CSA N288.6-12 requires the ERA to be reviewed at least every five years.
102. The Commission is satisfied that BWXT Medical has submitted an adequate ERA that shows risks to the environment to be negligible, and that it meets applicable standards and regulatory requirements. The Commission is also satisfied that BWXT Medical will review and update its ERA when required by CSA N288.6-12 or when warranted due to changes in facility operations or monitoring results.

Conclusion on Environmental Protection

103. On the basis of the information provided on the record for this hearing, the Commission is satisfied that the NMPF has, and will continue to have under BWXT Medical's proposed licence, adequate programs in place for the control of effluent and emissions to protect the environment and meet regulatory requirements. The

Commission concludes that environmental monitoring completed by BWXT Medical and CNSC staff demonstrate that the public and the environment around the NMPF remain protected, and that the NMPF environmental protection programs adequately meet the specifications of REGDOC-2.9.1.

104. The Commission further concludes that the ERAs for the NMPF were carried out in accordance with regulatory requirements. The Commission is of the view that the ERAs demonstrate that the environment in the vicinity of the NMPF site is adequately protected and that BWXT Medical has proposed adequate programs to mitigate the risk to members of the public from operations at the NMPF.

4.1.10 Emergency Management and Fire Protection

105. The emergency management and fire protection SCA covers the emergency preparedness programs and plans in place to respond to emergencies and non-routine conditions. Per the proposed licence, licence conditions 10.1 and 10.2 require BWXT Medical to implement and maintain an emergency preparedness program and a fire protection program respectively. Through routine inspections, document reviews and observation of emergency exercises, CNSC staff have identified no major findings. CNSC staff reported that effective emergency preparedness and fire protection programs have been implemented at the NMPF, and since these same programs have been adopted by BWXT Medical, that it expects this to continue under the proposed licence.

Emergency Management

106. BWXT Medical reported that its emergency response plan describes how it will prepare for, respond to and recover from emergencies. BWXT Medical noted that its program has been developed based on the requirements of [REGDOC-2.10.1, Nuclear Emergency Preparedness and Response, Version 2](#). BWXT Medical explained that under the proposed licence it retains the ultimate responsibility for emergency preparedness for the NMPF, and that there is a joint emergency response plan established between Nordion and BWXT Medical under the lease agreement.
107. BWXT Medical informed the Commission that an emergency response planning committee will be established with Nordion. This committee would meet on a regular basis and assess emergency planning needs, plan emergency drills and exercises, and review emergency response plans. BWXT Medical explained that it will work in partnership with Nordion and local first responders to ensure safe and appropriate response to potential emergency situations. BWXT Medical committed to providing orientation sessions to fire and police departments to familiarize them with the NMPF, and will ensure first responders are invited to participate in drills at the site.

108. CNSC staff assessed BWXT Medical's proposed emergency management program against the requirements set out in REGDOC-2.10.1 and CSA N393-13. CNSC staff found that the measures proposed by BWXT Medical, with respect to emergency management, meet regulatory requirements. CNSC staff noted that, being located on the same site, BWXT Medical and Nordion rely on Ottawa Fire Service (OFS) to provide fire response capability. To meet the requirements of CSA N393-13, both Nordion and BWXT Medical must conduct separate annual fire drills which will require additional coordination with OFS.
109. The Commission requested further details on how local first responders are involved in drills at the NMPF. Representatives from Nordion and BWXT Medical explained that local first responders are engaged in advance to provide opportunities for participation, but that other priorities could affect the availability of first responders on a given day. CNSC staff explained that efforts are made to accommodate the priorities of first responders, and that OFS is very engaged and willing to participate in the required annual fire response drills. CNSC staff noted that BWXT Medical has sought its own service agreement with OFS, and a BWXT Medical representative stated that it has not yet finalized this service agreement. The Commission is satisfied that BWXT Medical and CNSC staff will ensure suitable participation of local first responders in BWXT Medical's drills and expects that BWXT Medical will have finalized its service agreement with OFS in advance of the proposed licence coming into force.
110. Asked about the emergency response plan review frequency, CNSC staff explained that there is no set timeframe for review. Review of the emergency response plans would be triggered by events, changes to operations, or changes to the all hazard planning basis. CNSC staff noted that it would ensure reviews were conducted in response to such triggers through compliance verification activities. CNSC staff further explained that the compliance program looks at the level of risk for the facility to determine the baseline inspection frequency, and that there is the option to conduct additional inspection based on observations.
111. The Commission is satisfied that the proposed emergency management program meets the requirements described in REGDOC-2.10.1 and CSA N393-13. The Commission is also satisfied that suitable arrangements, such as the joint emergency response planning committee, exist between Nordion and BWXT Medical to ensure a coordinated emergency response.

Fire Protection

112. Fire protection is achieved through the implementation of a fire protection program, appropriate fire protection system design, fire safe operations and fire prevention. BWXT Medical submitted that its fire protection program outlines key fire protection requirements intended to reduce the risk of fire at the NMPF. BWXT Medical explained that it will retain ultimate responsibility for the fire protection program for the NMPF, but that Nordion will provide fire protection systems as per the lease

agreement. BWXT Medical noted that, in accordance with the *National Fire Code of Canada*, fire protection systems are inspected and tested following an established schedule.

113. CNSC staff assessed BWXT Medical's proposed fire protection program against the requirements of CSA N393-13, the *National Building Code of Canada, 2015*, and the *National Fire Code of Canada, 2015* and found that it meets regulatory requirements. CNSC staff expressed that the fire impact assessment for the NMPF, provided by BWXT Medical, demonstrated the risk of fire is low and effectively mitigated. CNSC staff noted that measures will be in place to minimize both the probability of occurrence and the consequences of a fire at the NMPF.
114. The Commission is satisfied that BWXT Medical has proposed an adequate fire protection program for the NMPF that meets regulatory requirements.

Conclusion on Emergency Management and Fire Protection

115. Based on the information considered for this hearing, the Commission concludes that the emergency management preparedness programs and the fire protection measures in place at the NMPF, and that will be in place under BWXT Medical's proposed licence, are adequate to protect the health and safety of persons and the environment. The Commission is satisfied that appropriate arrangements exist between Nordion and BWXT Medical to ensure that operation of the NMPF under the proposed licence continues to meet regulatory requirements with respect to emergency management and fire protection.

4.1.11 Waste Management

116. The waste management SCA covers internal waste-related programs that form part of the NMPF's operations up to the point where the waste is removed to a separate waste management facility. Planning for decommissioning is also covered in this area and discussed further in Section 4.3.3. Per the proposed licence, licence condition 11.1 requires BWXT Medical to implement and maintain a waste management program. CNSC staff found that an effective waste management program has been implemented at the NMPF, and expect this to continue under BWXT Medical.
117. BWXT Medical submitted that the production facilities within the NMPF are designed and operated to prevent radioactive waste from being released to municipal garbage or sewer systems, and that any such waste will be collected and sent to an approved radioactive waste management facility. BWXT Medical highlighted segregation and monitoring waste minimization programs which had successfully diverted waste from disposal at a licensed radioactive waste management facility to regular landfills.

118. CNSC staff found that BWXT Medical's proposed waste management program meets the requirements of CSA standard N292.3-14, *Management of Low- and Intermediate-Level Radioactive Waste*. CNSC staff reported that waste generated by BWXT Medical's operations will be considered low-level waste as per CSA standard N292.0-14, *General principles for the management of radioactive waste and irradiated fuel*, and that the proposed program meets the requirements of this standard. CNSC staff found that BWXT Medical's proposed measures address CNSC requirements concerning waste characterization, waste minimization and waste management.
119. Asked about the possible neutron activation of impurities in the new Mo-99 process, a BWXT Medical representative explained that the new process involves the irradiation of natural Molybdenum¹⁴, and not solely Mo-98. The representative stated that molybdenum exists in very pure commercial forms owing to its metallurgical use. The representative expressed that calculations using the supplier specification purity have been used to produce a worst case impurity level, but that test irradiations have shown the raw material is better than the specification. These calculations and test irradiations will inform the waste management planning, such as dose rates and decay times, which will be further validated over the next 12 months. The Commission is satisfied that BWXT Medical has adequately considered activation products in its new Mo-99 process waste stream.
120. With respect to concerns over possible increased waste from the new Mo-99 process raised by various interventions (CMD 21-H5.2, CMD 21-H5.5, CMD 21-H5.9, CMD 21-H5.20), the Commission requested more information on the waste streams of the new Mo-99 process and any associated risks. A BWXT Medical representative explained that the new production method greatly reduces the total waste generated and the associated risks, as it does not require the initial processing that was historically done at Chalk River. The representative further explained that, as the Mo-99 will arrive at the NMPF in a similar form as the former process, the waste streams at the NMPF site will be similar.
121. The Commission is satisfied that the waste-related program proposed by BWXT Medical and currently in place at the NMPF meet regulatory requirements, such as applicable CSA standards. On this basis, the Commission concludes that the proposed waste management program is adequate to protect the health and safety of persons and the environment. The Commission also concludes that BWXT Medical has adequately considered waste management related to the proposed new Mo-99 process.

4.1.12 Security

122. The security SCA covers the programs required to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the NMPF or proposed activities. Per the proposed licence, licence condition 12.1 requires

¹⁴ Natural molybdenum contains the stable isotopes Mo-92, Mo-94, Mo-95, Mo-96, Mo-97, Mo-98 and Mo-100.

BWXT Medical to implement and maintain a security program. CNSC staff reported that effective security measures have been implemented at the NMPF, and that it expects this to continue under BWXT Medical. Details on the measures implemented by BWXT Medical to meet the requirements of the security SCA are considered prescribed information as identified in Section 21 of the GNSCR.

123. BWXT Medical submitted that its security program outlines the systems, processes and responsibilities for performing security operations and maintaining the safety and security of the NMPF. BWXT Medical stated that its security program meets the requirements of the [Nuclear Security Regulations](#) (NSR) and [REGDOC-2.12.3, Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, Version 2.1](#). BWXT Medical explained that it will retain the ultimate responsibility for security of the NMPF, but that Nordion will provide physical security as per the lease agreement.
124. CNSC staff informed the Commission that REGDOC-2.12.3 provides regulatory expectations and guidance for the security SCA. In addition, BWXT Medical is subject to sections 39-48 of the NSR as per paragraph 40(1)(b) of the NSR¹⁵. CNSC staff noted that BWXT Medical has established a response protocol with the Ottawa Police Service, has satisfactory processes for testing and maintenance of security devices and systems, and has implemented a satisfactory facility access security clearance process. CNSC staff found that BWXT Medical's site security program meets regulatory requirements.
125. The Commission is satisfied that BWXT Medical's proposed security program for the NMPF meets regulatory requirements, and is of the view that, because BWXT Medical has proposed keeping the existing features of the security program in place, security will be maintained appropriately during the proposed licence period. On that basis, the Commission concludes that BWXT Medical has proposed adequate provision for the physical security of the NMPF.

4.1.13 Safeguards and Non-Proliferation

126. Pursuant to the [Treaty on the Non-Proliferation of Nuclear Weapons](#) (NPT), Canada has entered into a Comprehensive Safeguards Agreement and an Additional Protocol (safeguards agreements) with the International Atomic Energy Agency (IAEA). The safeguards and non-proliferation SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada/IAEA safeguards agreements, as well as other measures arising from the NPT. The objective of these agreements is for the IAEA to provide credible assurance on an annual basis to Canada and to the international community that all declared nuclear material is in peaceful, non-explosive uses and that there are no undeclared nuclear material or activities in this country. Per the proposed licence, licence condition 13.1 requires BWXT Medical to implement and maintain a safeguards program. CNSC staff reported

¹⁵ Nordion (Canada) Inc., formerly MDS Nordion, is identified as a named entity within Schedule 2 of the NSR.

that an effective safeguards program has been implemented at the NMPF, and that it expects BWXT Medical to continue this program under the proposed licence.

127. CNSC staff informed the Commission that the safeguards program proposed by BWXT Medical is the same as the program currently in place by Nordion. CNSC reported that the IAEA performed one Physical Inventory Verification and two Complementary Access inspections during 2017-2020, results of which were satisfactory. CNSC staff assessed the proposed safeguards program and found that it meets the requirements set out in [REGDOC-2.13.1, Safeguards and Nuclear Material Accountancy](#). CNSC staff noted that import and export of controlled nuclear substances identified in the [Nuclear Non-proliferation Import and Export Control Regulations](#) requires separate authorization from the CNSC, as per subsection 3(2) of the GNSCR and [REGDOC-2.13.2, Import and Export](#).
128. A new material balance area (MBA) for BWXT Medical, for the purpose of determining the inventory of nuclear materials on-site and changes in that inventory, will need to be established by the IAEA if the proposed licence is granted. BWXT Medical reported that it will apply to the CNSC to become an MBA separate from Nordion and that the timing will be determined by the CNSC.
129. Asked about the tracking and inventory control systems, a BWXT Medical representative explained that details relating to isotope quantity would be available in a timely manner if requested by an inspector. The representative noted that the inventory database is frequently updated, but that packages awaiting shipment would need to be visually verified. Another BWXT Medical representative added that irradiated material is received with an expected activity range and that upon arrival it is placed in a hot cell and measured for verification. The Commission is satisfied that BWXT Medical has adequate tracking and inventory control measures in place at the NMPF.
130. The Commission concludes that Nordion has provided for the implementation of adequate measures in the areas of safeguards and non-proliferation at the NMPF that are necessary for maintaining national security and for implementing international agreements to which Canada has agreed. The Commission is satisfied that BWXT Medical will continue the currently established programs to provide for the implementation of such adequate measures at the NMPF during its proposed licence. The Commission expects BWXT Medical to continue its collaboration with the CNSC to complete the process of establishing itself as an MBA separate from Nordion soon after the issuance of a licence to BWXT Medical.

4.1.14 Packaging and Transport

131. The packaging and transport SCA covers the safe packaging and transport of nuclear substances and radiation devices to and from the NMPF. The SCA includes meeting the requirements of the [Packaging and Transport of Nuclear Substances Regulations, 2015](#) (PTNSR) and [Transport Canada's Transportation of Dangerous Goods](#)

Regulations (TDG Regulations) for all shipments. Per the proposed licence, licence condition 14.1 requires BWXT Medical to implement and maintain a packaging and transport program. Inspections carried out at the NMPF by CNSC staff since 2018 have resulted in no major findings. CNSC staff reported that an effective packaging and transport program has been implemented at the NMPF, and that it expects this to continue under BWXT Medical.

132. BWXT Medical submitted that its packaging and transport program applies to various types of packages including Type A, Type B, and Excepted packages. BWXT Medical reported that it maintains a transport package quality plan which details how quality assurance requirements are achieved. BWXT Medical noted that it is a registered user of the transport packages required for shipments associated with the medical isotopes business and that it will routinely ship Type A and Type B packages by road and air.
133. CNSC staff found that BWXT Medical's packaging and transport program meets the requirements of the PTNSR and the TDG Regulations. The PTNSR apply to design, production, use, inspection, maintenance and repair of packages used for the transport of nuclear substances. The TDG Regulations require that workers involved in the handling, offering for transport, and transport of dangerous goods be appropriately trained and issued a training certificate.
134. The Commission requested further information on the requirements for the transportation of depleted uranium. CNSC staff explained that the transport regulations for Tc-99m generators would be the same for lead or depleted uranium shielding and that the packaging would have to meet all regulatory requirements. With respect to the safeguards considerations of depleted uranium, CNSC staff noted that Tc-99m generators hosted in Canada would be verified at the point of origin (i.e., the NMPF) rather than in transit at the hospitals.
135. The Commission is satisfied that BWXT Medical is meeting, and will continue to meet under the proposed licence, regulatory requirements regarding packaging and transport. The Commission concludes that BWXT Medical has proposed an adequate packaging and transport program for the NMPF that meets regulatory requirements.

4.2 Indigenous Consultation and Engagement

136. The Commission considered the various Indigenous engagement activities of BWXT Medical and CNSC staff in relation to this matter and whether the duty to consult is engaged by this application. Indigenous consultation refers to the common law duty to consult with Indigenous peoples pursuant to section 35 of the Constitution Act, 1982. This is distinct from engagement activities conducted by the applicant and CNSC staff, carried out as part of the application process or on an ongoing basis.

4.2.1 Indigenous Consultation

137. The common law duty to consult with Indigenous peoples applies when the Crown contemplates action that may adversely affect established or potential Indigenous and/or treaty rights. The CNSC, as an agent of the Crown and as Canada's nuclear regulator, recognizes and understands the importance of building relationships and engaging with Canada's Indigenous peoples. The CNSC ensures that its licensing decisions under the NSCA uphold the honour of the Crown and considers Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the [Constitution Act, 1982](#).
138. The duty to consult is engaged wherever the Crown has "knowledge, real or constructive, of the potential existence of an Aboriginal right or title and contemplates conduct that might adversely affect it".¹⁶ Licensing decisions of the Commission, where Indigenous interests may be adversely impacted by its decision, will therefore engage the duty to consult, and the Commission must be satisfied that the duty has been met prior to making the relevant licensing decision.
139. CNSC staff expressed the opinion that the duty to consult is not engaged by this decision because the proposed licence, as it does not pose a change to the footprint of the existing Nordion nuclear substance processing facility or significantly change the operations of the existing facility, would not cause any adverse impacts to any established or potential Indigenous and/or treaty rights. Therefore, BWXT Medical's licence application does not raise the formal requirements of [REGDOC-3.2.2, Indigenous Engagement, Version 1.1](#). The Commission is of the view that conducting the existing authorized activities under this new proposed licence does not give rise to novel adverse impacts that engage the consultation duty.

4.2.2 Indigenous Engagement

140. CNSC staff submitted that it had identified the First Nation and Métis groups who may have an interest in BWXT Medical's licence application to operate the NMPF in Nordion's existing nuclear substance processing facility. In July 2019, CNSC staff provided information regarding the proposed licence application, opportunities to participate in the Commission's public hearing process and the CNSC's PFP, to the following groups of Indigenous peoples:
 - Algonquin Anishinabeg Nation Tribal Council
 - Algonquins of Ontario (AOO)
 - Algonquins of Pikwakanagan First Nation (AOPFN)
 - Kebaowek First Nation (KFN)
 - Kitigan Zibi Anishinabeg
 - Métis Nation of Ontario
 - Mohawks of the Bay of Quinte

¹⁶ *Haida Nation v. British Columbia (Minister of Forests)*, 2004 SCC 73 at para 35

141. CNSC staff followed-up with each identified group in November 2020, providing information by mail, and in early December 2020 through email, phone, or virtual meeting to confirm receipt of the letters and to answer any questions about the regulatory process and participation in the Commission proceedings. CNSC staff stated that it was not aware of any specific concerns with regards to BWXT Medical's licence application at the time of its submission.
142. BWXT Medical informed the Commission that its parent company, BWXT Canada, has been a member of the Canadian Council for Aboriginal Business (CCAB) since 2017 and is participating in CCAB's Progressive Aboriginal Relations (PAR) program. BWXT Medical stated that the Canada-wide company policy for Indigenous relations was developed in 2017 and is publicly available on [BWXT Medical's website](#). BWXT Medical noted that it will use the PAR program framework to guide meaningful engagement with its identified communities of interest (COIs). The COIs are made up of the Algonquin Anishinabeg Nation Tribal Council, the AOO, and the Métis Nation of Ontario.
143. BWXT Medical expressed that it would use letter/electronic mail, meetings and tours, phone calls, and events to meaningfully engage with its COIs. BWXT Medical committed to keeping the COIs informed of the licence application process. BWXT Medical stated that it had face-to-face meetings with many of its COIs throughout 2019, and ensures that a suitable subject matter expert attends such meetings. BWXT Medical expressed that it plans to continue outreach to establish and maintain meaningful engagement and relationships with its COIs.
144. The AOO's intervention (CMD 21-H5.7) expresses support of BWXT Medical's licence application and provides recommendations to improve future engagement. The AOO recommended regular updates that summarize general NMPF operations, with the opportunity for meetings following review of each update. The AOO suggested that BWXT Medical include in its updates information on any new products being developed. The AOO further recommended that BWXT Medical provide details of their preliminary decommissioning plan for the NMPF such that the AOO may review and provide input where appropriate.
145. The AOPFN's intervention (CMD 21-H5.9, CMD 21-H5.9A) highlights recommendations to improve the engagement process. An AOPFN representative expressed the recommendation that Indigenous knowledge (IK) be more meaningfully included in all stages of the project life cycle. The representative expressed the AOPFN's hope to be involved in the project beyond document review and email correspondence, such as through active inclusion in monitoring programs like the IEMP discussed in section 4.1.9.
146. Asked about the AOPFN's concerns related to a lack of meaningful engagement, a BWXT Medical representative explained that engagement has been predominantly through email recently, due to COVID-19 and the AOPFN's busy schedule. The representative expressed that BWXT Medical is looking forward to in person meetings

when possible, and that it is committed to having a long term and meaningful dialog with the AOPFN. CNSC staff explained that it was focused on major projects in its engagement with the AOPFN, but that it intends to work directly with the AOPFN on broader activities noted in the recommendations. CNSC staff expressed that these recommendations were very helpful for understanding the AOPFN's vision.

147. The KFN's intervention (CMD 21-H5.20, CMD 21-H5.20A) expresses opposition to BWXT Medical's licence application. A KFN representative explained that it is of the opinion that insufficient meaningful consultation has taken place, with respect to BWXT Medical's current licence application and historically on KFN lands. The representative expressed that IK is not sufficiently incorporated into the regulatory process and recommended its further inclusion. The representative detailed BWXT Medical documents, referenced in CNSC staff's submission (CMD 21-H5), that were not provided to the KFN for review when requested.
148. The Commission asked why certain documents were not made available to the KFN's satisfaction. CNSC staff explained that intervenors are encouraged to request documents that belong to a licensee from the licensee directly. A BWXT Medical representative noted that it did receive the requests from the KFN and that document summaries were provided in lieu of redacting the program documentation. A KFN representative expressed that the summaries provided were not sufficiently detailed. The Commission pointed out the role of transparency and trust in building engagement and strongly encourages BWXT Medical to share complete documents when they are requested, with protected information redacted as necessary, wherever possible. The Commission also notes that the CNSC maintains internal processes to resolve differences of opinion pertaining to what is or is not protected information.
149. The Commission asked CNSC staff to identify where Indigenous engagement is considered if it is not a specific licence condition. CNSC staff responded that BWXT Medical had submitted a program for Indigenous consultation and engagement with its application. CNSC staff explained that Indigenous groups are listed as a key target audience under BWXT Medical's Public Information and Disclosure Program (PIDP) and that these activities are part of annual compliance reporting. CNSC staff noted that all licence applications are assessed for possible impacts on potential and established Indigenous and/or treaty rights and that all potentially interested or affected Indigenous groups are engaged with. The Commission is satisfied that BWXT Medical's application included documents, which will make up part of the licensing basis of the proposed licence, that appropriately consider Indigenous engagement.
150. Asked how IK is incorporated in its processes, CNSC staff stated that it is currently developing an IK framework. CNSC staff reported that Indigenous groups, including the AOPFN, reviewed a draft of this framework and provided valuable feedback that CNSC staff had incorporated into the framework. CNSC staff noted that IK is owned by the communities themselves and these communities have to authorize and help CNSC staff to incorporate such knowledge. The Commission notes the effort of CNSC staff with respect to IK and encourages further work to include this knowledge in its future activities, where appropriate.

151. The Commission finds that Indigenous engagement activities carried out for this licence application were adequate on the basis that the application is for existing authorised activities and no impacts to the health of persons or the environment are expected.

4.2.3 Conclusion on Indigenous Consultation and Engagement

152. The Commission acknowledges the current efforts and commitments made by BWXT Medical in relation to Indigenous engagement and CNSC staff's efforts in this regard on behalf of the Commission. The Commission concludes that this licence will not result in changes to NMPF operations that would cause adverse impacts to any potential or established Indigenous and/or treaty rights and that the duty to consult was not engaged in this matter. The Commission is also of the opinion that the engagement activities taken for the review of the NMPF licence application have been adequate.¹⁷
153. The Commission greatly values and appreciates the input and perspective of the Algonquins of Ontario, the Algonquins of Pikwakanagan First Nation, and the Kebaowek First Nation in relation to this matter. The Commission expects BWXT Medical and CNSC staff to continue to build meaningful long-term relationships with Indigenous communities.

4.3 Other Matters of Regulatory Interest

154. The Commission examined other matters of regulatory interest with respect to BWXT Medical's application, including participant funding, public engagement, decommissioning plans and financial guarantee, and cost recovery.

4.3.1 CNSC Participant Funding Program

155. The Commission assessed the information provided by CNSC staff regarding public engagement in the licensing process as enhanced by the CNSC's [Participant Funding Program](#) (PFP). CNSC staff submitted that, in [November 2020](#), up to \$75,000 in funding to participate in this licensing process was made available to Indigenous groups, members of the public and other stakeholders to review BWXT Medical's licence application and associated documents, and to provide the Commission with value-added information through topic-specific interventions. The PFP funding availability and deadlines was included with the Hearing notice.
156. A Funding Review Committee, independent of the CNSC, recommended that [five applicants](#) be provided with up to \$68,199.95 in participant funding. These applicants were required, by virtue of being awarded participant funding, to submit a written intervention and make an oral presentation at the public hearing commenting on

¹⁷ *Rio Tinto Alcan v. Carrier Sekani Tribal Council*, 2010 SCC 43[2010] 2 S.C.R. 650 at paras 45 and 49.

BWXT Medical's licence application. Participant funding was awarded to the following recipients:

- Algonquins of Ontario (AOO) – up to \$24,560¹⁸
- Algonquins of Pikwakanagan First Nation (AOPFN) – up to \$18,359.95
- Anna Tilman – up to \$1,500
- Kebaowek First Nation (KFN) – up to \$17,100
- Women in Nuclear (WIN) – up to \$6,500

157. The Commission is satisfied that Indigenous groups, members of the public and other stakeholders were properly notified of BWXT Medical's application and were provided with sufficient information on how to participate in the licensing process and the PFP through the posting of the [Notice of Public Hearing and Participant Funding](#) and CNSC staff's engagement described in section 4.2.2. The Commission notes that PFP funding was made available to Indigenous communities and the public to support their participation. On this basis, the Commission is satisfied that Indigenous groups, members of the public and other stakeholders were encouraged to participate in this licensing process.

4.3.2 Public Engagement

158. The Commission assessed the adequacy of the Public Information and Disclosure Program (PIDP) for the NMPF, included in BWXT Medical's licence application. Per the proposed licence, licence condition G.4 requires BWXT Medical to implement and maintain a PIDP for the NMPF. CNSC staff reported that BWXT Medical's PIDP meets the specifications of [REGDOC-3.2.1, Public Information and Disclosure](#).
159. BWXT Medical submitted that its PIDP provides the strategy and methodologies to be employed for public communications, information distribution and feedback. BWXT Medical detailed that the target audience for its PIDP is primarily based on proximity to the NMPF, but that it also selects target audiences based on their community role and includes any person who indicates interest in staying informed. This includes the local health unit, local schools, local first responders, community leaders, and community associations. BWXT Medical further indicated that its designated list of addresses is reviewed annually to ensure it remains current.
160. In its intervention ([CMD 21-H5.14](#)), Women In Nuclear (WIN) described a survey of its members conducted in April 2021. The survey was designed to assess the understanding of BWXT Medical's activities and identify concerns. WIN noted that the survey was responded to by 279 individuals and that 92 percent of respondents support BWXT Medical's application and believe the NMPF is beneficial to Canadians. With respect to the survey response rate, a WIN representative explained that it will increase communications efforts to members in the future.

¹⁸ The AOO were unable to provide an oral presentation.

161. The Commission asked BWXT Medical to describe its recent outreach events. A BWXT Medical representative noted that it held a webinar in March 2021, and that the public did not raise any significant concerns. The representative expressed that BWXT Medical is committed to conducting more events in the future and that understanding concerns, such as those raised by interventions in this licence hearing, makes the organization stronger.
162. The Commission is satisfied that BWXT Medical's NMPF PIDP has and will continue to communicate to the public information about the health, safety and security of persons and the environment, as well as other issues related to the NMPF. The Commission concludes that BWXT Medical's PIDP meets regulatory requirements and is, overall, effective in keeping Indigenous groups and the public informed of NMPF operations. The Commission acknowledges the many best practices already implemented by BWXT Medical and encourages its efforts in creating, maintaining and improving its dialogue with neighbouring communities.

4.3.3 Decommissioning Plans and Financial Guarantee

163. The CNSC requires that BWXT Medical has operational plans for the decommissioning and long-term management of waste produced during the lifespan of the NMPF. Per the proposed licence, licence condition 11.2 requires BWXT Medical to maintain a decommissioning plan. BWXT Medical is obliged to meet the specifications of [G-219, *Decommissioning Planning for Licensed Activities*](#) and CSA standard N294-09, *Decommissioning of facilities containing nuclear substances*. BWXT Medical provided its preliminary decommissioning plan (PDP) for the NMPF as part of its licence application.
164. CNSC staff assessed BWXT Medical's PDP and cost estimate for the NMPF and found that both meet regulatory requirements and that the cost estimate is credible and sufficient to fund the future decommissioning of the NMPF. The CNSC requires that PDPs be periodically updated to reflect any changes in the facility or operations at least every five years.
165. Asked about the end state following decommissioning, CNSC staff explained that it has accepted the end state proposed by BWXT Medical that was included in the PDP. The proposed end state foresees unrestricted use (i.e., clean). CNSC staff further explained that the decommissioning plan would have interactions with how Nordion intends to use the building upon completed decommissioning.
166. In order to ensure that adequate resources are available for safe and secure future decommissioning of the NMPF site, the CNSC requires that an adequate financial guarantee for realization of the planned activities is put in place and maintained in a form acceptable to the Commission throughout the licence period, pursuant to subsection 24(5) of the NSCA. The CNSC guidance document [G-206, *Financial*](#)

[Guarantees for the Decommissioning of Licensed Activities](#)¹⁹ provides regulatory guidance on financial guarantees and financial instruments and sets out the relevant considerations for adequacy.

167. CNSC staff submitted that BWXT Medical proposed a financial guarantee of \$10.54 million via a \$2.6 million letter of credit for putting the facility in a safe shutdown and a \$7.94 million surety bond for the remainder of the decommissioning costs. CNSC staff found the proposed financial guarantee amount and instruments meet the criteria of G-206. Asked about the long term viability of the letter of credit, a BWXT Medical representative explained that it is backed by its parent company, BWX Technologies Inc., which has market cap greater than \$6 billion. CNSC staff noted that it requires legally enforceable instruments and that the money is payable to the Commission on request, if certain conditions are met.
168. The Commission is satisfied with the cost estimate and the proposed financial guarantee amount. The Commission is also satisfied with the proposed financial instruments and the ratio between letter of credit and surety bond. On this basis, the Commission concludes that the preliminary decommissioning plan and related financial guarantee for the NMPF are acceptable for the purpose of the licence application.

4.3.4 Cost Recovery

169. The Commission examined BWXT Medical's standing under the [Cost Recovery Fees Regulations](#) (CRFR) requirements for the NMPF. Paragraph 24(2)(c) of the NSCA requires that a licence application is accompanied by the prescribed fee, as set out by the CRFR and based on the activities to be licensed.
170. CNSC submitted that BWXT Medical, as a new applicant, was required to submit an initial fee, and confirmed that BWXT Medical is in good standing with respect to the CRFR requirements and had paid its cost recovery fees in full.
171. Based on this information, the Commission is satisfied that BWXT Medical has fulfilled the requirements of the CRFR for the purpose of this licence application.

4.3.5 Nuclear Liability Insurance

172. In accordance with the [Nuclear Liability and Compensation Regulations](#) (NLCR) made under the [Nuclear Liability and Compensation Act](#) (NLCA), BWXT Medical's NMPF does not meet the criteria to be designated as a nuclear installation and is not under the purview of the NLCA. CNSC staff noted that BWXT Medical will maintain industrial insurance as a commercial necessity.

¹⁹ G-206 has since been superseded by [REGDOC 3.3.1, Financial guarantees for decommissioning of nuclear facilities and termination of licensed activities](#).

173. Based on this information, the Commission is satisfied that BWXT Medical is not designated as a nuclear installation in accordance with the NLCR and is not required to maintain nuclear liability insurance under the NLCA.

4.4 Licence Length and Conditions

174. The Commission was required to decide whether the proposed licence length and licence conditions were appropriate.

4.4.1 Licence Length

175. The Commission considered BWXT Medical's application for a licence to operate the existing NMPF for a period of 10 years. CNSC staff recommended that the licence be granted for a period of 10 years, from November 1, 2021 until October 31, 2031. CNSC staff submitted that BWXT Medical is qualified to carry on the licensed activities.
176. The majority of the interventions received for this proceeding were supportive of the BWXT Medical licence application. However, some interventions raised concerns related to the proposed new Mo-99 process and recommended a shorter licence term such that this new process can be considered. The Commission notes that it can amend, suspend in whole or in part or revoke a licence at any time, on its own motion, should it not be satisfied with a licensee's performance. Further, the Commission expects that, in addition to regular RORs, BWXT Medical present to the Commission comprehensive updates on its licensed activities for the NMPF following the first year of operations of its new Mo-99 process.
177. Asked about the concerns raised by some intervenors that BWXT Medical is a new entity that lacks a track record, CNSC staff explained that this was considered when assessing the proposed licence term. CNSC staff found that the activities under the proposed licence are within the licensing basis, processes and procedures currently in place at the NMPF, and that the risk profile of the NMPF is well understood. With respect to personnel, CNSC staff noted that much of BWXT Medical's workforce are former Nordion staff, and that BWXT Medical has been working in the NMPF as a subcontractor since 2018.
178. The Commission is satisfied that BWXT Medical, based in part on its work in the NMPF as a subcontractor since 2018, is qualified to carry out the activities indicated in the proposed licence. The Commission is of the view that a 10-year licence is justified on the basis of the past performance demonstrated at the NMPF and opportunities for public involvement during the 10-year licence period, such as through regular RORs.

4.4.2 Licence Conditions

179. CNSC staff submitted, as part of CMD 21-H5, a draft licence and LCH. Interventions by the AOO, the AOPFN, and the KFN suggested licence conditions pertaining to Indigenous engagement be included in the proposed licence. The Commission notes the Indigenous engagement activities discussed in section 4.2.2 and that the proposed licence includes licence condition G.4, which requires BWXT Medical to implement and maintain a public information and disclosure program. On this basis, the Commission concludes that a specific licence condition pertaining to Indigenous engagement is not required.
180. CNSC staff recommended that the Commission delegate authority for licence condition 3.2, which contains the phrase “a person authorized by the Commission,” to the following CNSC staff:
 - Director, Nuclear Processing Facilities Division
 - Director General, Directorate of Nuclear Cycles and Facilities Regulation
 - Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch

4.4.3 Conclusion on Licence Length and Conditions

181. Based on the information presented on the record for this hearing, the Commission concludes that a 10-year licence term is appropriate. The Commission includes in the licence the conditions as recommended by CNSC staff, and authorizes the delegation of authority as recommended by CNSC staff. The Commission notes that CNSC staff can bring any matter to the Commission as required.

5.0 CONCLUSION

182. The Commission has considered the licence application submitted by BWXT Medical. Based on its consideration of the information submitted, the Commission is satisfied that the application submitted by BWXT Medical meets the requirements of the NSCA, the GNSCR, the CINFR, and other applicable regulations made under the NSCA.
183. The Commission has also considered the information and submissions of BWXT Medical, CNSC staff and all participants as set out in the material available for reference on the record, as well as the oral and written interventions provided or made by the participants at the hearing.
184. The Commission is satisfied that BWXT Medical meets the test set out in subsection 24(4) of the *Nuclear Safety and Control Act*. That is, the Commission is of the opinion that BWXT Medical is qualified to carry on the activities that the proposed licence will authorize and that it will make adequate provision for the protection of the

environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

185. Therefore, the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, issues the Class IB Nuclear Substance Processing Facility Licence to BWXT Medical Inc. for the Nuclear Medicine Production Facility located in Ottawa, Ontario. The licence, NSPFL-15.00/2031, is valid from November 1, 2021 until November 1, 2031.
186. The Commission includes in the licence the conditions as recommended by CNSC staff in CMD 21-H5. The Commission also delegates authority for the purposes of licence conditions 3.2,²⁰ as recommended by CNSC staff.
187. The Commission is satisfied that neither an EA under CEAA 2012 nor an impact assessment under the IAA were required for the NMPF Class IB licence application and notes that the NSCA provides a strong regulatory framework for environmental protection. Further, the Commission is satisfied that BWXT Medical, which has worked in the NMPF as a subcontractor since 2018, will make adequate provision for the protection of the environment and the health of persons throughout the proposed licence period.
188. The Commission is satisfied that a 10-year licence is justified on the basis of the past performance at the NMPF and opportunities for public involvement through regular RORs during the proposed licence period. The Commission concludes that the performance exhibited over the course of Nordion's current licence – including since 2018 with BWXT Medical working in the NMPF as a subcontractor using the same programs, procedures, staff, and within the same licensing basis as those included in this licence application – is a positive indication of BWXT Medical's ability to carry out the proposed activities under the proposed licence.
189. The Commission agrees with CNSC staff's determination that the duty to consult was not engaged, and finds that the indigenous engagement activities carried out by CNSC staff for this licence renewal were adequate. The Commission encourages CNSC staff and BWXT Medical to continue their respective activities to engage with interested indigenous communities during the proposed licence term.
190. The Commission directs that BWXT Medical shall present to the Commission comprehensive updates on its licenced activities for its NMPF following the first year of operations using its new Mo-99 process. This update will take place during a public Commission proceeding where Indigenous peoples, members of the public and stakeholders will be able to participate.

²⁰ Licence condition 3.2 states that “*the licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission*”.

191. With this decision, the Commission directs CNSC staff to report on the performance of BWXT Medical and the NMPF as part of the regular *Regulatory Oversight Report for Uranium and Nuclear Substance Processing Facilities in Canada*. CNSC staff shall present this report at a public proceeding of the Commission, where Indigenous peoples, members of the public and stakeholders will be able to participate. The Commission notes that CNSC staff can bring any matter to the Commission that merits its attention at any time. The Commission directs CNSC staff to inform the Commission, on an annual basis, of any changes made to the *Licence Conditions Handbook*.

Velshi,
Rumina

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October 8, 2021

Rumina Velshi
President
Canadian Nuclear Safety Commission

Date

Appendix A – Intervenors

Intervenors – Oral Presentations	Document Number
Canadian Nuclear Isotope Council, represented by A. Thiele	CMD 21-H5.4
Anna Tilman	CMD 21-H5.5 CMD 21-H5.5A
Organization of Canadian Nuclear Industries, represented by R. Oberth	CMD 21-H5.6
Algonquins of Pikwakanagan First Nation, represented by A. Two-Axe Kohoko and A. McDonald	CMD 21-H5.9 CMD 21-H5.9A
Nordion, represented by K. Brooks and R. Wassenaar	CMD 21-H5.12
Women in Nuclear, represented by L. McBride and P. Larabie	CMD 21-H5.14
Canadian Nuclear Association, represented by J. Gorman and R. Found	CMD 21-H5.18
Boston Scientific, represented by W. Mullett	CMD 21-H5.19
Kebaowek First Nation, represented by V. McGregor, R. Van Schie and M. Jawbone	CMD 21-H5.20 CMD 21-H5.20A
Bruce Power, represented by J. Scongack	CMD 21-H5.22
Intervenors –Written Submission	Document Number
Juan Carlos Herrera	CMD 21-H5.2
Oliver Drerup	CMD 21-H5.3
Algonquins of Ontario	CMD 21-H5.7
Laurentis Energy Partners	CMD 21-H5.8
Ontario Power Generation	CMD 21-H5.10
Kinectrics	CMD 21-H5.11
United Pharmacy Partners	CMD 21-H5.13
Ontario’s Nuclear Advantage	CMD 21-H5.15
Nuclear Innovation Institute	CMD 21-H5.16
TRIUMF Innovations	CMD 21-H5.17
University of Alberta	CMD 21-H5.21