Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

UNPROTECTED/NON PROTÉGÉ

ORIGINAL/ORIGINAL

CMD: 21-H5

Date signed/Signé le : 10 MARCH 2021

New Licence

BWXT Medical Ltd.

(formerly BWXT ITG Canada, Inc.)

Class IB Licence Application

Commission Public Hearing

Scheduled for:

9-10 June, 2021

Submitted by:

CNSC Staff

Un nouveau permis

BWXT Medical Ltd.

(anciennement BWXT ITG Canada, Inc.)

Demande de permis pour une installation nucléaire de catégorie IB

Audience publique de la Commission

Prévue pour :

9-10 juin 2021

Soumise par :

Le personnel de la CCSN

e-Doc 6428772 (WORD)
e-Doc 6496157 (PDF)

Summary

This CMD presents information about the following matters of regulatory interest with respect to BWXT Medical Ltd. (formerly BWXT ITG Canada, Inc.):

- Request the issuance of Class IB Nuclear Substance Processing Facility Licence NSPFL-15.00/2031 for a period of 10 years commencing on November 1, 2021 and ending on October 31, 2031.
- Request to accept the proposed financial guarantee of $10.54 million through two proposed instruments: a letter of credit in the amount of $2.6 million and a surety bond in the amount of $7.94 million.

CNSC staff recommend the Commission take the following actions:

- Issue a Class IB Nuclear Substance Processing Facility Licence to BWXT Medical Ltd. to operate its facility for a period of 10 years.
- Delegate authority as set out in section 4.8 of this CMD.
- Accept the proposed financial guarantee of $10.54 million through the two proposed instruments, and direct BWXT Medical Ltd. to provide the original instruments within 90 days of the issuance of a decision.

Résumé

Le présent CMD fournit de l'information sur un ensemble de questions d'ordre réglementaire concernant BWXT Medical Ltd. (anciennement BWXT ITG Canada, Inc.) :

- Demande de délivrance du permis d'exploitation d'une installation de traitement de substances nucléaires de catégorie IB NSPFL-15.00/2031 pour une période de dix ans commençant le 1 novembre 2021 et prenant fin le 31 octobre 2031.
- Demande d'approbation de la garantie financière proposée de 10,54 millions de dollars sous forme de deux instruments proposés, soit une lettre de crédit de 2,6 millions de dollars et un cautionnement de 7,94 millions de dollars.

Le personnel de la CCSN recommande à la Commission de prendre les mesures suivantes :

- Délivrer à BWXT Medical Ltd. un permis d'exploitation d'une installation de traitement de substances nucléaires de catégorie IB pour une période de dix ans.
- Accepter la délégation des pouvoirs telle qu'elle est établie à la section 4.8 du présent CMD.
- Accepter la garantie financière proposée de 10,54 millions de dollars sous forme des deux instruments proposés, et donner instruction à BWXT Medical Ltd. de fournir les instruments originaux dans les 90 jours suivant la décision.

The following items are attached:

- Proposed Class IB Nuclear Substance Processing Facility Licence NSPFL-15.00/2031
- Draft Licence Conditions Handbook

Les pièces suivantes sont jointes :

- Permis proposé d’exploitation d’une installation de traitement de substances nucléaires de catégorie IB NSPFL-15.00/2031
- Ébauche du Manuel des conditions de permis

Signed/signé le

10 March 2021

Murthy, Kavita

Digitally signed by Murthy, Kavita
DN: C=CA, O=GC, OU=CNSC-CCSN, CN="Murthy, Kavita"
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Kavita Murthy

Director General

Directorate of Nuclear Cycle and Facilities Regulation

Directrice générale de la

Direction de la réglementation du cycle et des installations nucléaires

TABLE OF CONTENTS

EXECUTIVE SUMMARY

In December 2018, BWXT Medical Ltd. (formerly BWXT ITG Canada, Inc.) (BWXT Medical) submitted an application to the Canadian Nuclear Safety Commission (CNSC) requesting a Class IB nuclear substance processing facility licence to operate a medical isotopes facility. The facility is located within the existing nuclear substance processing facility currently operated by Nordion (Canada) Inc. (Nordion) in Ottawa, Ontario under its CNSC licence. All of the proposed licensed activities are currently authorized to be carried out at the facility. The total radioactive material processed would remain below the historical production levels for the facility.

In mid-2018, BWXT Medical commercially acquired Nordion's medical isotopes business, including one of the two production operations at the Nordion Class IB nuclear substance processing facility. Since the acquisition, BWXT Medical workers have continued to work at the medical isotopes facility as subcontractors to Nordion. If issued a licence, BWXT Medical will be the licensee responsible for the safe operation of the medical isotope facility.

The purpose of this Commission Member Document (CMD) is to provide the results of CNSC staff's assessment of the BWXT Medical application, including conclusions and recommendations to inform the Commission decision on the licence application. This CMD has two parts. Part One presents CNSC staff's review and assessment of BWXT Medical's licence application and a summary of the past performance of the medical isotopes facility. Part Two presents a proposed licence and licence conditions handbook (LCH). The LCH provides information for each licence condition on how to comply with regulatory requirements by identifying compliance verification criteria, recommendations and guidance.

CNSC staff conclude, in accordance with subsection 24(4) of the ***NUCLEAR SAFETY AND CONTROL ACT*** (NSCA), that BWXT Medical is qualified to carry on the licensed activities, and will, in carrying on those activities, make adequate provision for the protection of the environment, the health and safety of persons, the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

CNSC staff recommend that the Commission accept CNSC staff's assessment and conclusions in this CMD and, pursuant to section 24 of the NSCA, issue a licence to operate the nuclear substance processing facility for a 10-year period.

The public, Indigenous groups and other stakeholders were invited to participate in the licensing process. To enable participation, up to $75,000 was made available through the CNSC Participant Funding Program.

Documents referenced in this CMD are available to the public upon request.

PART ONE

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

Part One includes:

1. An overview of the matter being presented;
2. Overall conclusions and overall recommendations;
3. General discussion pertaining to the safety and control areas (SCAs) that are relevant to this submission;
4. Discussion about other matters of regulatory interest; and
5. Addenda material that complements items 1 through 4.

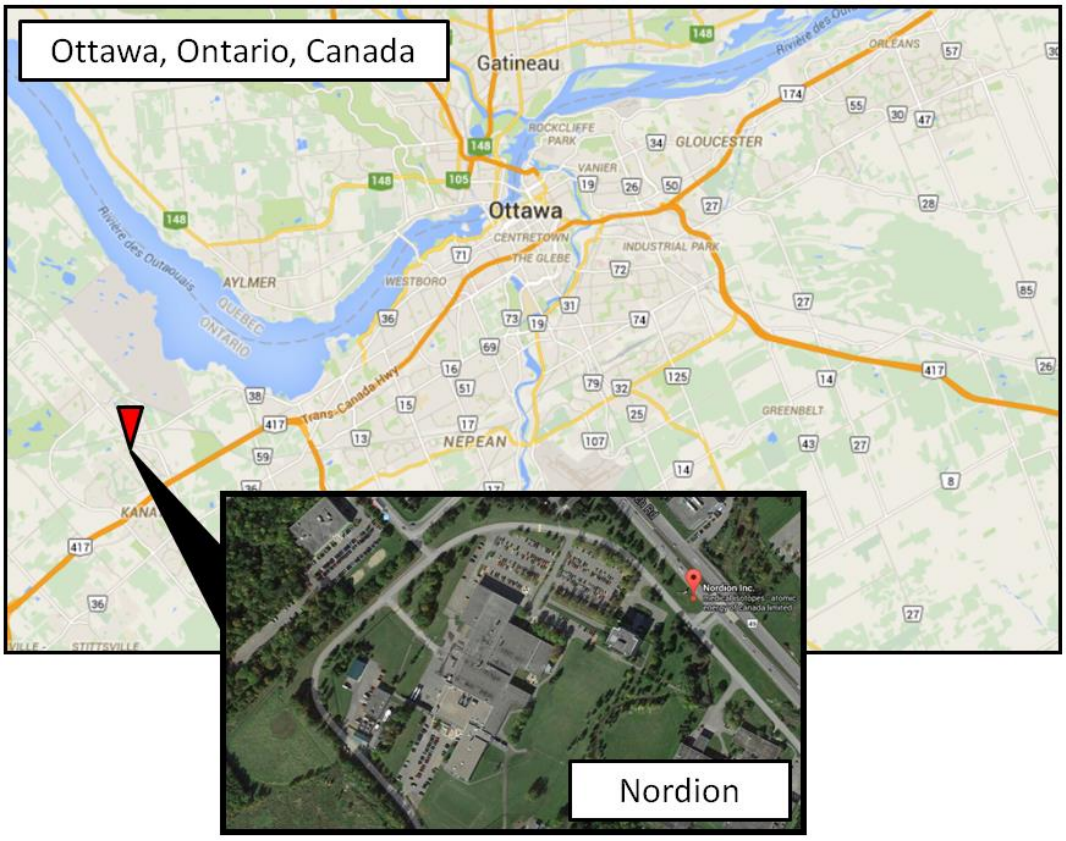
Part Two provides all available information pertaining directly to the proposed licence.

1. OVERVIEW

1.1 Background

Nordion (Canada) Inc. (Nordion) owns and operates a Class IB nuclear substance processing facility located at 447 March Rd, Ottawa, Ontario, in an industrial zone within the Kanata Research Park (Figure 1). The site has been used for industrial purposes since the 1960s. The surrounding area is a mixture of residential, commercial and industrial zoning. A perimeter road surrounds the Nordion buildings and the adjacent Best Theratronics Ltd. Class IB facility (Figure 2).

Figure 1: Location of Nordion (Canada) Inc. Class IB facility



(source: Google Maps)

Figure 2: Aerial view of the Nordion facility (highlighted in blue)

Pursuant to Section 24 of the *Nuclear Safety and Control Act* (NSCA), the Commission issued Nordion's current licence, NSPFOL-11A.01/2025, for a 10-year term following a public hearing in August 2015. The licence expires in October 2025. The licence authorizes Nordion to process unsealed radioisotopes for health and life sciences applications, and manufacture sealed radiation sources for industrial applications.

The Nordion Class IB facility is called the Kanata Operations Building (KOB), and is dedicated to acquiring, processing, storing and shipping radioactive isotopes. The KOB contains a Nuclear Medicine Production Facility (NMPF) and a Cobalt Operations Facility (COF). The NMPF has been in operation since 1982.

In April 2018, BWX Technologies Ltd. (BWXT) announced an agreement to acquire Nordion's medical isotope business (i.e., the NMPF portion). The acquisition was completed in August 2018, under a subsidiary of BWXT, BWXT Medical Ltd. (formerly BWXT ITG Canada, Inc.[1]) (BWXT Medical). Canadian Nuclear Safety Commission (CNSC) staff assessed the information provided by Nordion on the acquisition and determined that the proposed change would have no impact on safety. No licence amendment or Commission approval was required for the acquisition to proceed, as Nordion remained and would remain the licensee for the entire facility and all of the licensed activities until BWXT Medical obtained a licence.

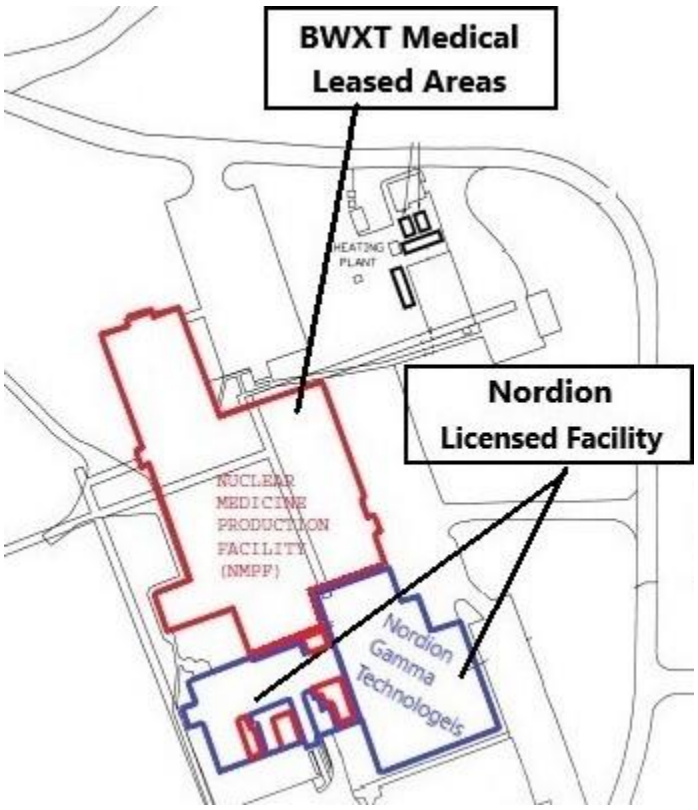
Approximately 100 former Nordion personnel were hired by BWXT Medical at the time of the acquisition. BWXT Medical workers have continued to work at the facility as subcontractors to Nordion.

[1] At the time of writing this CMD, BWXT ITG informed the CNSC that it had legally changed its corporation name to BWXT Medical Ltd. The name BWXT Medical is used throughout this CMD. The name change is further discussed in section 4.9.

In December 2018, BWXT Medical applied to the CNSC requesting the issuance of a Class IB nuclear substance processing facility licence to operate the NMPF located within the Nordion KOB [1]. The activities requested by the BWXT Medical licence application are currently authorized to be carried out at the facility by Nordion.

Nordion has leased the medical isotopes portion of the KOB and associated areas to BWXT Medical for a 20 year period (plus four five-year renewals), in a landlord-tenant agreement. As landlord, Nordion retains control and management of the KOB. Figure 3 shows an overview of the KOB, with the BWXT Medical leased areas shown in red, and the remaining areas that would continue to be operated by Nordion shown in blue.

Figure 3: BWXT Medical and remaining Nordion areas in the KOB



(source: BWXT Medical)

1.2 Highlights

BWXT Medical has applied for a licence to operate the NMPF to process medical isotopes. The proposed activities are currently authorized to be carried out at the facility under Nordion's licence. BWXT Medical's application largely consists of Nordion program documents, which are part of the licensing basis for the Nordion facility. If issued a licence, BWXT Medical will be responsible for the safe operation of the medical isotope facility. BWXT Medical will make administrative changes to the program documents to reflect the new organization.

BWXT Medical proposes to manufacture nuclear substances in excess of 1 x 10^{15} Bq / year. Isotopes with > 1 year half-life would not be manufactured, although some impurities (well below 1 x 10^{15} Bq / year) would be present that have longer half-lives. The total radioactive material processed would remain below the historical production levels for the facility. According to its application, BWXT Medical has developed a technology for producing molybdenum-99 (Mo-99) using a natural (stable) molybdenum-98 target that has been irradiated in a reactor. The NMPF has historically been used to process Mo-99 produced by the fission of highly enriched uranium targets in the National Research Universal (NRU) reactor at Chalk River Laboratories. The future Mo-99 process is further discussed in section 4.5 of this CMD.

As BWXT Medical is a new licence applicant, there are no trending data available with respect to performance history. This CMD includes information concerning Nordion's past performance at the facility, as it appropriately reflects CNSC staff's regulatory expectations for the operation of the facility. CNSC staff have reported to the Commission on the performance of the facility through the *Regulatory Oversight Report for Uranium and Nuclear Substance Processing Facilities* since 2014. The most recent regulatory oversight report was presented to the Commission in December 2020 [2].

CNSC Staff Assessment of BWXT Medical's Licence Application

CNSC staff assessed BWXT Medical's application with respect to the requested authorization to operate the NMPF under subsection 24(4) of the NSCA. The purpose of the assessment was to determine whether BWXT Medical is qualified and capable of performing the activities to be authorized by the Commission, and whether BWXT Medical, in carrying on these activities, will make adequate provision for the protection of the environment, the health and safety of persons, the maintenance of national security and the implementation of measures required to uphold international obligations to which Canada has agreed.

CNSC staff assessed BWXT Medical's proposed measures, including programs and procedures, for each Safety and Control Area (SCA), to verify that BWXT Medical would meet all regulatory requirements and expectations for the issuance of a licence. CNSC staff conclude that BWXT Medical is qualified and capable of carrying on the licensed activities it has requested per subsection 24(4) of the NSCA. A summary of CNSC staff's assessment of the licence application is provided in addendum A.2 to this CMD. A summary of results from CNSC staff's technical assessment is provided in Section 3 of this CMD.

Licence and Licence Conditions Handbook

The CNSC licence and licence conditions handbook (LCH) framework includes periodic reviews of the authorized safety case every five years, including revisions to the Environmental Risk Assessment (ERA) and safety analysis for the facility, as well as continuous improvement through the implementation of updated regulatory requirements.

The LCH associated with the proposed licence provides compliance verification criteria that would be used by CNSC staff to determine whether the conditions listed in the licence have been met. The LCH provides details associated with each licence condition, such as applicable standards or regulatory documents; regulatory interpretations; additional compliance verification criteria; version controlled documents; licensee's written notification documents; and guidance. If accepted by the Commission, BWXT Medical will be required by its licence to report to the CNSC annually through Annual Compliance and Operational Performance Reports. Section 4.8 of this CMD lists the delegation of authority associated with licence condition 3.2.

If a licence is issued, CNSC staff will verify compliance through inspections, document reviews, and event reviews. In addition, CNSC staff will report to the Commission on the CNSC's oversight and compliance performance of BWXT Medical in public meetings through the *Regulatory Oversight Report for Uranium and Nuclear Substance Processing Facilities*. CNSC staff will also update the Commission on changes to the LCH, as well as any facility-specific changes and licensee program documentation updates, through the Regulatory Oversight Reports.

CNSC staff recommend that the Commission accept BWXT Medical's request for a 10-year licence.

Financial Guarantee

As part of the licence application, BWXT Medical proposed a financial guarantee of $10.54 million: $2.6 million for putting the facility in a safe shutdown state and $7.94 million for the remainder of the decommissioning costs. CNSC staff conclude that the cost estimate is credible and the financial guarantee instruments are acceptable.

Impact to Nordion operations and licensing basis

The Nordion Class IB facility, the KOB, contains the NMPF and the COF. Should the Commission issue a licence to BWXT Medical, Nordion's activities would be reduced in a commensurate manner. The proposed BWXT Medical licence would authorize BWXT Medical to operate the NMPF, and the operation of this facility would be removed from Nordion's LCH. Nordion would continue to operate the COF only, in accordance with its licence, and no licence amendment would be required. CNSC staff confirm that Nordion understands and supports this approach [3].

If the Commission decides to issue BWXT Medical a licence, CNSC staff will revise the Nordion LCH prior to the BWXT Medical licence taking effect. This approach will ensure that the activities conducted at the Nordion facilities are accurately reflected in Nordion's LCH.

CNSC staff expect Nordion to submit a revised preliminary decommissioning plan, decommissioning cost estimate and financial guarantee for Commission approval once BWXT Medical has its financial guarantee in place.

1.3 Overall Conclusions

CNSC staff have concluded the following:

1. With respect to paragraphs 24(4)(*a*) and (*b*) of the *Nuclear Safety and Control Act* (NSCA), BWXT Medical:
   a. is qualified to carry on the activities authorized by the licence.
   b. will, in carrying on those activities, 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.
2. The proposed financial guarantee of $10.54 million is based on a credible cost estimate, with acceptable financial guarantee instruments.

1.4 Overall Recommendations

The licensing recommendations are based on CNSC staff's overall assessment of the applicant's compliance with the NSCA and its regulations, and the adequacy of the measures in place to ensure the health and safety of persons and the environment, and of the measures related to security, and Canada's international obligations during the period that the proposed licence covers. CNSC staff recommend the following:

1. The Commission accept CNSC staff's assessment and conclusions identified in section 1.3 of this CMD;
2. The Commission issue a Class IB Nuclear Substance Processing Facility Licence to BWXT Medical for a 10-year period, with the proposed licence conditions and the proposed delegation of authority as set out in subsection 4.8 of this CMD; and
3. The Commission accept the proposed financial guarantee of $10.54 million and direct BWXT Medical to provide the original instruments to the CNSC within 90 days of the issuance of a decision on this matter.

2. MATTERS FOR CONSIDERATION

2.1 Environmental Assessment

CNSC staff reviewed BWXT Medical's licence application in the context of the *Canadian Environmental Assessment Act, 2012* (CEAA 2012), as this was the Federal legislation that applied at the time the application was received, i.e., prior to the coming into force of the *Impact Assessment Act of Canada, 2019* (IAAC, 2019). CNSC staff determined that CEAA 2012 does not apply because the activities proposed in the application are not captured in its associated *Regulations Designating Physical Activities*. It should be noted that the proposed activities are also not contained in the *Physical Activities Regulations* of the IAAC, 2019.

CNSC staff conduct Environmental Protection Reviews for all licence applications with potential environmental interactions, in accordance with its mandate under the NSCA. CNSC staff's review can be found in section 3.9 of this CMD. CNSC staff conclude that BWXT Medical will make adequate provision for the protection of the environment.

2.2 Relevant Safety and Control Areas (SCAs)

The functional areas of any licensed facility or activity consist of a standard set of safety and control areas (SCAs). Each SCA is comprised of "specific areas" of regulatory interest; however, the specific areas associated with each SCA vary between facility types. See addendum B, "Safety and Control Framework", for further information about SCAs.

The relevance of each SCA to this CMD is indicated in the following table. Note that no ratings are available as BWXT Medical is a new licence applicant.

Functional Area	Safety and Control Area	Relevant to this CMD?
Management	Management System	Y
	Human Performance Management	Y
	Operating Performance	Y
Facility and Equipment	Safety Analysis	Y
	Physical Design	Y
	Fitness for Service	Y
Core Control Processes	Radiation Protection	Y
	Conventional Health and Safety	Y
	Environmental Protection	Y
	Emergency Management and Fire Protection	Y
	Waste Management	Y
	Security	Y
	Safeguards and Non-Proliferation	Y
	Packaging and Transport	Y

2.3 Other Matters of Regulatory Interest

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

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

These other matters of regulatory interest are discussed in section 4.

2.4 Regulatory and Technical Basis

The regulatory and technical bases for the matters discussed in this CMD are provided in addendum A to this document.

For this type of facility, the key requirements come directly from the *Class I Nuclear Facilities Regulations* (CINFR) and the *General Nuclear Safety and Control Regulations* (GNSCR) as well as other applicable requirements from the NSCA.

3. General Assessment of SCAs

The specific areas that comprise the SCAs for this facility or activity type are identified in addendum B, section B.2. If specific areas are listed for an SCA in section 3, then the related details about them are provided in addendum C to this document. If specific areas are not listed for a given SCA in section 3, then a decision has been made to encompass them in an overall approach to that SCA. Trending data are not presented in this CMD as BWXT Medical is a new licence applicant.

3.1 Management System

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

This CMD covers the following specific areas of Management System:

- Management system

- Organization
- Performance assessment, improvement and management review
- Operating experience (OPEX)
- Change management
- Configuration management
- Records management
- Management of contractors
- Business continuity
- Safety culture

3.1.1 Discussion

The regulatory requirements in the Management System SCA are obtained from paragraph 3(1)(k) and section 15 of the GNSCR, and paragraph 3(d) of the CINFR. The CINFR require that an application for a licence to operate a Class I nuclear facility contain the proposed management system for the activity to be licensed, including measures to promote and support safety culture. The CNSC requires that licensees of Class IB facilities comply with CSA N286-12, *Management System Requirements for Nuclear Facilities* [4], which establishes a management system standard that integrates requirements for quality, health, safety and the environment.

BWXT Medical's application includes a proposed management system that meets the requirements set out in CSA N286-12. CNSC staff assessed the proposed management system against that standard, and confirmed that it meets regulatory requirements. CNSC staff's assessment is summarized in the subsections below.

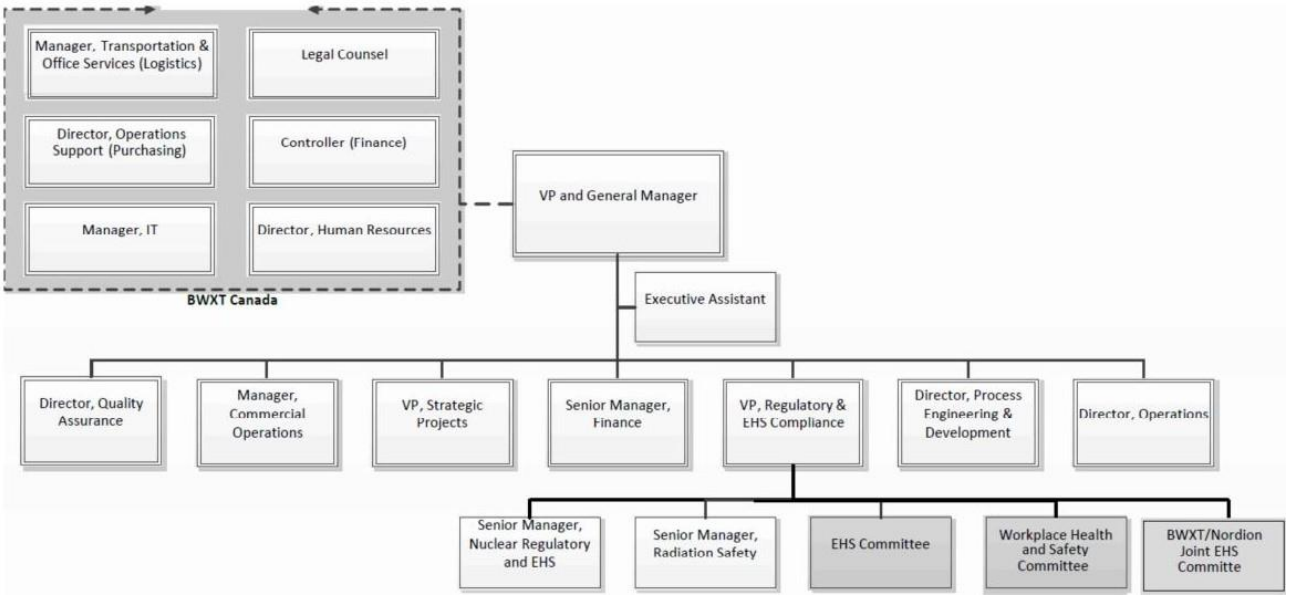
CNSC staff note that many documents supporting BWXT Medical's application and referenced in the BWXT Medical management system are adopted from Nordion, as these documents form part of the licensing basis for the facility. BWXT Medical has committed to revising and updating these documents within a 12-month period following the issuance of a licence, in order to update the organization's name and logo, and remove unnecessary references to Nordion. CNSC staff accepted this proposed approach as the updates to made are administrative in nature and will not affect the licensing basis of the facility. CNSC staff will confirm and verify that the documents are updated accordingly.

Organization

Figure 4 provides an overview of BWXT Medical's organizational structure. BWXT Medical is a subsidiary of BWXT Canada, and a business unit of BWXT's Nuclear Power Group. BWXT Medical's organizational and management structure is similar to Nordion's, and BWXT Medical proposes to continue to manage the licensed activities at the medical isotopes facility as they were prior to the change of ownership.

CNSC staff are satisfied that BWXT Medical's organizational structure, roles and responsibilities are appropriately documented in BWXT Medical's proposed management system. CNSC staff note that BWXT Medical has reported changes to its organization to the CNSC in accordance with section 15 of the GNSCR. BWXT Medical's proposed management system also describes measures and resources in place for business planning.

Figure 4: BWXT Medical Organizational Structure



(source: BWXT Medical)

Performance assessment, improvement and management review

CNSC staff confirm that BWXT Medical's proposed management system includes measures to assess performance and implement corrective action plans. BWXT Medical has proposed a program for management review in accordance with its Environmental, Health and Safety Policy [5].

Operating experience (OPEX)

CNSC staff confirm that BWXT Medical's proposed management system includes measures to collect and share information with other licensees, and follow operating experience and best industry practice. BWXT Medical and Nordion will have joint committees to ensure that relevant experience in the facility is shared across both organizations.

Change management

CNSC staff confirm that BWXT Medical's proposed management system includes an acceptable change and design control program to identify risks and ensure adequate mitigation measures are in place prior to any modifications to its systems, structures and components, including associated software. The program contains a list of potential hazards to be assessed prior to proceeding with proposed changes.

Records management

CNSC staff confirm that BWXT Medical's proposed management system includes measures to ensure that records are maintained in accordance with CNSC requirements.

Management of contractors

CNSC staff confirm that BWXT Medical's proposed management system includes acceptable measures to manage contractors. The scope of this program includes requirements that contractors possess the necessary qualifications and training. The program also ensures that contractors work in accordance with licensee requirements and deliver products and services while meeting regulatory requirements.

Safety culture

CNSC REGDOC-2.1.2, *Safety Culture* [6], requires that licensees document their commitment to fostering safety culture in their governing documentation. CNSC staff confirm that BWXT Medical's proposed management system includes measures to understand and promote safety within the organization. CNSC staff are satisfied that BWXT Medical is committed to the establishment and continuous improvement of a healthy safety culture. BWXT Medical will conduct safety culture surveys every three years, with its first survey to be done in late 2021 or in 2022, as a means to assess its safety culture.

3.1.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.1.2.1 Past Performance

Over 150 BWXT Medical employees have been trained and are qualified to work in the facility, and have continued to work at the facility as subcontractors to Nordion. CNSC inspections carried out since 2018 confirm that BWXT Medical workers are safely implementing the programs and procedures in place at the facility, and CNSC staff expect this to continue under BWXT Medical.

3.1.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this area through routine CNSC compliance activities, including inspections and reviews of documentation.

3.1.2.3 Proposed Improvements

CNSC staff expect that BWXT Medical will continually identify and implement improvements to its management system. As previously mentioned, BWXT Medical has committed to revising and updating documents supporting its management system within a 12-month period following the issuance of a licence in order to update the organization's name and logo, and remove unnecessary references to Nordion. CNSC staff will maintain regulatory oversight over BWXT Medical's revision of the documents to ensure that BWXT Medical's commitments are met, and that the licensing basis is maintained. CNSC staff will update the Commission on BWXT Medical's progress through Regulatory Oversight Reports.

3.1.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Management System SCA. CNSC staff are satisfied that the applicant's proposed management system meets the requirements set out in CSA N286-12, *Management System Requirements for Nuclear Facilities*, and REGDOC 2.1.2, *Safety Culture*.

3.1.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 1.1 requires BWXT Medical to implement and maintain a management system. Compliance verification criteria for this licence condition are included in the draft LCH.

3.2 Human Performance Management

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

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

- Human Performance Program;
- Work Organization and Job Design;
- Fitness for Duty; and
- Personnel Training

3.2.1 Discussion

The regulatory requirements in the Human Performance Management SCA are obtained from the GNSCR paragraphs 12(1)(a) and (b) and the CINFR section 6. Details of CNSC staff's assessment in this SCA are presented in the following sections.

Human Performance Program

CNSC staff assessed BWXT Medical's proposed measures for ensuring effective human performance at the facility. All BWXT Medical employees are responsible for working in a manner that conforms to BWXT Medical's Environmental, Health and Safety Policy and related company programs and procedures, including the BWXT Medical Management System for Safety. BWXT Medical has committed to continuous improvement of human performance.

CNSC staff confirm that BWXT Medical has proposed measures to ensure excellence in worker safety related performance. These measures are incorporated in BWXT Medical's standard operating procedures and work instructions.

Work Organization & Job Design

Minimum Shift Complement

The minimum shift complement is the minimum number of qualified workers who must be present at all times to ensure the safe operation of the nuclear facility and to ensure adequate emergency response capability. CNSC staff are satisfied that BWXT Medical has proposed measures to ensure the availability of the minimum number of personnel required to provide safety oversight during overnight operations and during emergency situations. BWXT Medical's proposed measures include requiring a minimum of one and normally two health physicists to be on-call at all times, and having security personnel on-site at all times.

CNSC staff note that BWXT Medical has agreements in place with Nordion to ensure that measures for security, fire protection and emergency response are in place at the NMPF. These measures are discussed in more detail in the assessment of the Emergency Management and Fire Protection SCA in section 3.10 of this CMD.

Fitness for Duty

Planned operations at BWXT Medical are 24 hours per day and seven days per week. CNSC staff confirm that BWXT Medical has a policy for worker fitness for duty, which requires all employees to report and remain fit for duty, free of the negative effects of alcohol and/or other drugs.

Personnel Training

The CNSC's regulatory requirements for the personnel training specific area are described in CNSC regulatory document REGDOC-2.2.2, *Personnel Training, Version 2 (2016)* [7], which sets out requirements and guidance for licensees for developing training programs based on a systematic approach to training (SAT).

A SAT-based training system ensures that workers through the process of performance-based assessment and program evaluation have attained required knowledge, skills and safety-related attributes. The SAT is a proven training methodology which enables training to be analyzed, defined, designed, developed, implemented, evaluated, documented and managed in order to meet and react quickly to changes in operational and organizational requirements.

CNSC staff assessed BWXT Medical's proposed training system and associated documents, which are adopted from the existing Nordion training system. CNSC staff are satisfied that these documents describe training system elements that address regulatory training and qualification requirements, including processes for implementing the various phases of a systematic approach to training in accordance with the requirements of REGDOC-2.2.2. CNSC staff conclude that BWXT Medical's proposed training system meets regulatory training and qualification requirements.

3.2.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.2.2.1 Past Performance

Nordion's past performance is presented as an indicator of the performance expected for BWXT Medical as BWXT Medical will adopt the existing Nordion training system and training programs. Through ongoing compliance oversight, CNSC staff have assessed that the facility has a well-established training system based on a SAT. CNSC staff are satisfied that an effective training program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.2.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this SCA through regulatory oversight activities including onsite inspections and desktop reviews of relevant program documentation.

3.2.2.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that BWXT Medical will continually identify and implement improvements to its human performance and training programs.

3.2.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Human Performance Management SCA. CNSC staff are satisfied that the applicant's proposed training program meets the expectations set out in CNSC REGDOC-2.2.2, *Personnel Training, Version 2 (2016)*.

3.2.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 2.1 requires BWXT Medical to implement and maintain a training program. Detailed compliance verification criteria, including REGDOC-2.2.2, *Personnel Training, Version 2 (2016),* are included under section 2 of the LCH.

3.3 Operating Performance

The Operating Performance SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance. For a new licence applicant, the focus is on the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility, as well as the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.

The specific areas that comprise this SCA for BWXT Medical include:

- Conduct of licensed activity
- Procedures
- Reporting and trending

3.3.1 Discussion

If issued a licence, BWXT Medical will be responsible for the safe operation of the medical isotope facility. A summary of BWXT Medical's proposed safety and control measures for the Operating Performance SCA are presented in the following subsections.

Conduct of Licensed Activity

The CNSC requires that a licensee's operations programs include an up-to-date set of operating limits for the facility and activities authorized under the licence, including:

- limits for the possession, use, management, transfer, storage of nuclear substances;
- an inventory of nuclear substances and prescribed equipment;
- a process to track high-risk sealed sources; and
- operational limits/specifications for the nuclear facility.

In its application, BWXT Medical has proposed measures to ensure that it will operate the medical isotopes facility in accordance with regulatory requirements. In addition to measures addressed through other safety and control areas described elsewhere in this CMD, BWXT Medical has proposed programs addressing inventories, activity limits, environmental health and safety targets, internal levels, and regulatory limits. CNSC staff are satisfied that BWXT Medical has proposed measures to ensure that procedures will be complied with, and that the operation of the facility will remain within the licensing basis for the facility.

CNSC staff are satisfied that BWXT Medical has appropriate programs and procedures in place to ensure that the operation of the facility would remain within the licensing basis if BWXT Medical were to make any modifications to the facility or its operations. BWXT Medical's application outlines the design specifications of the facility, as well as mitigation measures and operational procedures. BWXT Medical has proposed to establish an Environment, Health and Safety (EHS) Committee to review and approve, from a safety perspective, the design, construction, commissioning, operation, and decommissioning of BWXT Medical nuclear facilities and operations. A joint BWXT Medical - Nordion EHS Committee has been established to review changes that take place within the BWXT Medical leased space that could impact the Nordion facility.

Procedures

Paragraph 6(d) of the CINFR requires that a licence application contain the following information: the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility. CNSC staff have assessed BWXT Medical's application and are satisfied that it contains the requisite information.

BWXT Medical's application includes programs and procedures that were previously implemented at the facility by Nordion. These programs and procedures include a Corrective and Preventive Actions (CAPA) system to address incidents and non-conformances for regulatory actions, and events related to radiation, transport, contamination incidents, environmental incidents, fires, occupational injuries, hazardous occurrences, and near misses. CNSC staff have reviewed the CAPA system and conclude that it meets regulatory expectations.

BWXT Medical has proposed measures to continually identify and implement improvements to processes, equipment and programs. These measures include annual performance reports used to analyze non-conformances related to environment, health and safety. The data in such reports would be used for trending purposes to ensure that appropriate corrective actions have been taken and that they were effective.

Reporting and Trending

The CNSC's requirements for reporting are described in REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills* [8]. Licensees are required to report unplanned events and take necessary corrective actions to improve safety and to prevent the recurrence of such events, in accordance with regulations and its licence. Examples of other types of events include occupational injuries, environmental releases, radiation incidents including action level exceedances, and errors in reporting the movement of category 1 and 2 sealed sources. Licensees are also required to submit annual compliance and operational performance reports.

BWXT Medical's application includes a reporting program that addresses these requirements [9]. CNSC staff have assessed this program and are satisfied that it meets the requirements of REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills*.

Sealed Source Tracking

In January 2006, the CNSC implemented a comprehensive Sealed Source Tracking System (SSTS) integrated with the National Sealed Source Registry (NSSR). These systems were designed and built in accordance with Canada's commitment to the International Atomic Energy Agency (IAEA) *IAEA Code of Conduct on the Safety and Security of Radioactive Sources* [10]. There are specific reporting requirements associated with the SSTS, which were imposed onto licensees by the Commission as described in CMD 05-H32, *Licence Amendments to Strengthen Regulatory Controls on Sealed Sources* [11]. These reporting requirements 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* [12] and provide for an accurate and secure inventory of category 1 and 2 sealed sources in Canada.

The proposed reporting requirements for BWXT Medical, as related to the SSTS, are derived from those set out in CMD 05-H32. CNSC staff are satisfied that BWXT Medical has a program for SSTS reporting that meets CNSC expectations.

3.3.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.3.2.1 Past Performance

Through ongoing compliance oversight, CNSC staff have assessed that the facility has been operated in a compliant manner. CNSC inspections have resulted in no major findings. CNSC staff are satisfied that an effective operating program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.3.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this area through routine CNSC compliance activities, including inspections and reviews of documentation, as well as SSTS and event reporting.

3.3.2.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that BWXT Medical will continually identify and implement improvements to operation, equipment and programs.

3.3.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Operating Performance SCA. CNSC staff expect that the facility will continue to be operated safely, in accordance with the procedures and requirements of the proposed licence, and that BWXT Medical will implement improvements to processes, equipment and programs.

3.3.4 Recommendation

Two licence standardized licence conditions pertaining to this SCA are included in the proposed licence. Licence condition 3.1 requires BWXT Medical to implement and maintain an operating program, which includes a set of operating limits. 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. Compliance verification criteria for both licence conditions are included under section 3 of the LCH. CNSC staff recommend that the sealed source tracking reporting requirements, as described in the above section, be incorporated into the LCH as part of the licensing basis for BWXT Medical.

3.4 Safety Analysis

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

This CMD covers the following specific areas of Safety Analysis:

- Deterministic safety analysis
- Hazard analysis

3.4.1 Discussion

Section 6(c) of the CINFR, requires that an application for a licence to operate a Class I facility include a final safety analysis report (SAR). A safety analysis must include an analysis of the postulated sequences and consequences of conditions that could arise from initiating events and associated hazards.

BWXT Medical's application included a SAR for the NMPF [13], which describes the safety analysis that supports facility operations. The SAR includes a description of the facility and the measures in place to protect the safety of the workers, the public and the environment, under normal operations, abnormal operations and accident conditions. The SAR was developed and is maintained in accordance with a procedure that establishes the standard guidelines and criteria to be used, as well as the review and approval process.

BWXT Medical also submitted several related assessments that were conducted to ensure the safety of its operations. These assessments included earthquake risk analysis and an assessment for aircraft impacts, as well as an assessment of the impact of a fire.

According to the SAR, the primary hazards associated with the NMPF are worker radiation exposure, contamination release, and fire. Under normal operations, the NMPF is expected to have negligible releases to the environment, and doses to workers and the public would remain well below regulatory limits. The SAR further indicates that under abnormal, low-probability scenarios, releases to the environment would be less than 1% of the derived release limit (DRL), and doses to workers would be less than 50% of the CNSC's regulatory annual limit for gamma exposure.

To ensure that SARs remain valid and accurate, the CNSC requires that SARs be reviewed a minimum of once every five years, or whenever a facility undergoes significant changes. CNSC staff are satisfied that BWXT Medical has proposed programs and processes to meet these requirements.

CNSC staff assessed the SAR and associated documents and found them to be acceptable. Based on the review of the application and supporting documents, CNSC staff are satisfied that BWXT Medical has a process in place to identify and evaluate potential high risk safety hazards associated with the operation of the facility, and that BWXT Medical is in compliance with regulatory requirements for the Safety Analysis SCA.

3.4.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.4.2.1 Past Performance

CNSC staff are satisfied that an effective program to manage and maintain safety analysis reports has been implemented at the facility, and expect this to continue under BWXT Medical.

3.4.2.2 Regulatory Focus

CNSC staff will continue to monitor BWXT Medical's performance in this area through regulatory oversight activities including onsite inspections and desktop reviews of BWXT Medical compliance reporting and revisions to relevant program documentation pertaining to this SCA.

3.4.2.3 Proposed Improvements

At the time of writing this CMD, CNSC REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*, is in development. Should the Commission issue a licence to BWXT Medical, CNSC staff will ensure that BWXT Medical implements this REGDOC in accordance with an implementation plan to be developed following REGDOC-2.4.4's publication.

3.4.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Safety Analysis SCA. BWXT Medical has a proposed process to identify and evaluate potential high risk safety hazards associated with the operation of the facility.

3.4.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 4.1 requires BWXT Medical to implement and maintain a safety analysis program. Compliance verification criteria for this licence condition are included in the draft LCH.

3.5 Physical Design

The SCA Physical Design relates to activities that impact the ability of structures, systems and components to meet and maintain its design basis given new information arising over time and taking changes in the external environment into account.

The specific areas that comprise this SCA for BWXT Medical are:

- design governance
- facility design

3.5.1 Discussion

BWXT Medical is required to implement and maintain a physical design program such that the design of the facility and any changes made are managed and within the licensing basis. The licensing basis for the facility is described in applicable facility design documentation and safety analysis reports. The requirements under this SCA are provided by national codes and standards, including CSA N393-13: *Fire protection for facilities that process, handle, or store nuclear substances* [14], the *National Building Code of Canada* [15] and the *National Fire Code of Canada* [16] for structural design. CSA N286-12, *Management System Requirements for Nuclear Facilities* also includes factors to be considered in determining design inputs, including human factor considerations.

CNSC staff confirm that BWXT Medical's management system includes a documented process for design and change control that will ensure that all operational changes will be assessed, managed and documented. The BWXT Medical design control program includes measures to ensure that designs meet established codes and standards and all applicable requirements. The program also includes consideration for human factors and ergonomic impact assessments in the design and development process. CNSC staff are satisfied that these procedures will ensure that any modifications to the facility, such as upgrades to existing systems as part of facility maintenance and continuous improvement, will be done in accordance with regulatory requirements.

BWXT Medical is required to notify the CNSC of significant changes to its fire protection program and submit an accompanying third party assessment of the potential impact of these changes.

3.5.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.5.2.1 Past Performance

Nordion has managed upgrades to existing systems as part of facility maintenance and continuous improvement. Changes and alterations to facility equipment or processes have been managed under Nordion's design change control to ensure compliance with the licence, LCH, applicable national codes, and CSA Group standards. CNSC staff are satisfied that an effective design program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.5.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this SCA through regulatory oversight activities including onsite inspections and desktop reviews of relevant program documentation.

3.5.2.3 Proposed Improvements

According to its application, BWXT Medical has developed a technology for producing molybdenum-99 (Mo-99) using neutron activation of natural molybdenum-98 targets in a reactor. Mo-99 produced from highly enriched uranium targets irradiated at Chalk River Laboratories was previously processed at the NMPF. As described above, changes to the Mo-99 process must be made in accordance with regulatory and program requirements. The Mo-99 process is further discussed in section 4.5.

3.5.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Physical Design SCA. CNSC staff conclude that BWXT Medical's proposed measures for the physical design SCA, including documented processes for design and change control, meet regulatory requirements, as well as CNSC expectations in the topic of Human Factors in Design. CNSC staff are satisfied that the applicant has adequate resources in place to ensure that any changes can be made safely within the licensing basis.

3.5.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 5.1 requires BWXT Medical to implement and maintain a design program. Detailed compliance verification criteria are included under section 5 of the LCH.

3.6 Fitness for Service

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

The specific areas that comprise this SCA at Nordion include:

- equipment fitness for service/equipment performance
- maintenance

3.6.1 Discussion

The CINFR require that every licensee who operates a Class I nuclear facility keep a record of operating and maintenance procedures, and the results of the inspection and maintenance programs referred to in the licence.

BWXT Medical has proposed measures to maintain the facility to ensure that its systems, structures and components remain effective over time. These include programs for preventive and corrective maintenance, instrument maintenance and calibration, and equipment testing. The BWXT Medical management system includes measures to document and maintain all required records for maintenance and calibration.

CNSC staff are satisfied that the applicant's proposed programs and procedures address and meet CNSC regulatory requirements. CNSC staff are further satisfied that, under these programs, maintenance will be performed and documented as required.

3.6.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.6.2.1 Past Performance

There have been no major equipment failures at the facility in recent years. CNSC staff are satisfied that an effective fitness for service program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.6.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this area through routine CNSC compliance inspections.

3.6.2.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that BWXT Medical will continually identify and implement improvements to its maintenance programs.

3.6.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Fitness for Service SCA. CNSC staff conclude that BWXT Medical's proposed measures for this SCA, including documented processes for equipment maintenance and calibration, meet regulatory requirements. CNSC staff are satisfied that BWXT Medical will maintain the facility to ensure that its structures, systems and components remain effective over time.

3.6.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 6.1 requires BWXT Medical to implement and maintain a fitness for service program. Detailed compliance verification criteria are included under section 6 of the LCH.

3.7 Radiation Protection

The Radiation Protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. The program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained as low as reasonably achievable (ALARA).

This CMD covers the following specific areas of the Radiation Protection SCA:

- Application of ALARA
- Worker dose control
- Radiation protection program performance
- Radiological hazard control
- Estimated dose to public

3.7.1 Discussion

The *Radiation Protection Regulations* require licensees to establish a radiation protection (RP) program to keep exposures ALARA, through the implementation of a number of measures, including: management control over work practices; personnel qualification and training; control of occupational and public exposures to radiation; and, planning for unusual situations. The *Radiation Protection Regulations* also prescribe dose limits for workers and members of the public.

A summary of BWXT Medical's proposed safety and control measures for the Radiation Protection SCA are presented in the following subsections.

Application of ALARA

BWXT Medical's application includes an ALARA program based on the existing programs in place at Nordion. The ALARA program establishes annual performance objectives with the goal of maintaining radiation doses to workers ALARA. This program integrates ALARA into planning, scheduling and work control, and takes account of industry best practices and operating experience. Under the program, dose trends are analyzed and compared to internal levels and targets as well as the regulatory dose limits. Furthermore, provisions are in place to implement corrective actions, as necessary, in a timely manner. CNSC staff assessed BWXT Medical's ALARA program, and determined that it complies with the *Radiation Protection Regulations* and CNSC licensing requirements.

Many BWXT Medical employees have been trained and qualified to work in the facility, and have continued to work at the facility as subcontractors to Nordion. As such, BWXT Medical workers have experience implementing Nordion's RP program including measures to keep radiation exposures and doses to persons ALARA.

Worker Dose Control

BWXT Medical proposes to utilize a CNSC licensed dosimetry service to monitor, assess, record and report doses of ionizing radiation received by employees and contractors. Dose records are submitted to the National Dose Registry. The available types of dosimetry, the criteria and procedures for use were assessed by CNSC staff and found to meet regulatory requirements.

CNSC staff assessed BWXT Medical's proposed action levels to ensure that they are appropriately set and justified. CNSC staff found the proposed action levels to be acceptable.

For a comparison of risk and associated doses to Nuclear Energy Workers (NEWs), historical data from Nordion can be used as a conservative approximation as the licenced activity is similar with the exception of the work in Nordion's Cobalt Operations Facility; workers involved in Cobalt operations account for the highest doses received at the Nordion facility. Between 2015 and 2019, the maximum effective dose received by a worker was 5.49 millisieverts (mSv), approximately 11 percent of the regulatory dose limit of 50 mSv in a one-year dosimetry period. Annual average and maximum effective dose results from 2015 to 2019 are provided in Table 1 below. Table 2 provides an overview of dose statistics for NEWs working in the NMPF.

Table 1: Effective dose statistics for all NEWs, Nordion, 2015–19

Dose data	2015	2016	2017	2018	2019	Regulatory limit
Average effective dose (mSv)	0.43	0.51	0.49	0.60	0.57	**N/A**
Maximum individual effective dose (mSv)	5.24	4.90	5.49	4.23	4.79	**50 mSv/year**
Number of NEWs Monitored	264	267	263	248	278	

Table 2: Dose statistics for NMPF NEWs, Nordion, 2015–19

Dose data	2015	2016	2017	2018	2019	Regulatory limit
Average effective dose (mSv)	0.26	0.35	0.25	0.28	0.13	**N/A**
Maximum individual effective dose (mSv)	1.72	1.92	2.58	2.16	1.84	**50 mSv/year**
Average skin dose (mSv)	0.27	0.44	0.25	0.27	0.13	**N/A**
Maximum skin dose (mSv)	1.73	2.44	2.54	2.18	1.90	**500 mSv/year**
Average extremity dose (mSv)	0.40	0.67	0.48	0.88	0.64	**N/A**
Maximum extremity dose (mSv)	9.30	8.30	16.40	9.08	12.92	**500 mSv/year**

The maximum equivalent skin and extremity doses received by a worker from 2015 to 2019 were 2.54 mSv and 16.40 mSv, respectively. These values represent approximately 0.5 and 2.6 percent, respectively, of the regulatory dose limits of 500 mSv/one-year dosimetry period.

BWXT Medical's application includes proposed procedures to conduct routine thyroid screening of NEWs working with iodine-125 and iodine-131. Urine analysis and whole body counting is available to quantify doses to workers in the event of elevated screening results or if elevated air and/contamination monitoring indicates a potential intake.

BWXT Medical has proposed to conduct licensed activities similar to those previously carried out by Nordion, and within the scope previously established for the facility. BWXT Medical has adopted several of Nordion's procedures and retained employees currently performing work at the facility. As such, CNSC staff expect that BWXT Medical will effectively implement the measures needed to maintain worker doses well below regulatory dose limits and ALARA.

Radiological Hazard Control

CNSC staff are satisfied that BWXT Medical has proposed radiological survey and contamination controls to monitor and minimize radiological hazards in the facility. These methods include contamination control, radiation dose-rate control and airborne radiation monitoring and control.

Contamination control at BWXT Medical ensures that contamination is prevented from leaving radiological controlled areas, and that the spread of contamination within these areas is minimized. This is achieved by classifying areas based on the radiological hazards present, establishing radiological zones, ventilation and filtration systems, routine contamination monitoring, signage, access restrictions, and monitoring of personnel and material prior to leaving contaminated or potentially contaminated areas.

Radiation Protection Program Performance

BWXT Medical has set annual performance targets for RP. Both Nordion and BWXT Medical's Executive and Environmental Health and Safety management teams will routinely review progress against these targets. BWXT Medical will work with the landlord Nordion for future facility improvements.

BWXT Medical's application and supporting documentation identifies RP performance indicators for parameters such as worker doses and radiation incidents. BWXT Medical will perform internal assessments of the effective implementation of various components of the RP program on a regular basis in order to identify and correct any deficiencies in a timely manner.

Estimated Dose to the Public

Thermoluminescent dosimeters (TLD) have been deployed to monitor environmental gamma radiation at locations at and around the perimeter of the facility, as well as at the residences of some Nordion and BWXT Medical employees. The monitoring results over Nordion's licence period have shown that the levels of gamma radiation at those monitoring locations are in the range of natural background (Table 3 below). These results indicate that BWXT Medical's contribution to external doses to members of the public will be negligible.

Table 3: Dose to public, 2015-19

Year	Dose (mSv)	Regulatory Limit
2015	0.0057	1 mSv/year
2016	0.0021	
2017	0.000052	
2018	0.000067	
2019	0.00087	

Public doses resulting from operations at the facility have been negligible over Nordion's recent licensing period. This was due to the very small quantities of nuclear substances released into the environment. Doses to the public have decreased since 2016 as a result of the cessation of certain processes in the medical isotopes facility.

BWXT Medical has proposed to follow the same procedures and operate within the operating limits for the facility, in line with historical production levels. As such CNSC staff are satisfied that BWXT Medical will control radiation doses to members of the public to levels well below regulatory limits.

3.7.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.7.2.1 Past Performance

Through ongoing compliance oversight, CNSC staff have assessed that the facility has been operated in a compliant manner with respect to radiation protection performance. The performance data summarized in the above sections demonstrate that doses to workers in the facility have remained well below regulatory limits, and that the programs in place are effective in protecting the health and safety of workers and the public. CNSC inspections carried out since the acquisition in 2018 have resulted in no major findings. CNSC staff are satisfied that an effective radiation protection program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.7.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this area through routine CNSC compliance activities, including inspections and reviews of documentation.

3.7.2.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that BWXT Medical will continually identify and implement improvements to its radiation protection program and associated procedures.

3.7.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Radiation Protection SCA. CNSC staff confirm that BWXT Medical's proposed safety and control measures satisfy regulatory requirements for the requested licensed activity, and that the program for radiation protection provided by BWXT Medical meets regulatory requirements.

3.7.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 7.1 requires BWXT Medical to implement and maintain a radiation protection program, which includes a set of action levels. As part of this licence condition, BWXT is required to notify the Commission within seven days of becoming aware that an action level has been exceeded. Detailed compliance verification criteria for this licence condition are provided in the draft LCH.

3.8 Conventional Health and Safety

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

The specific areas that comprise this SCA for BWXT Medical include:

- Performance
- Practices; and
- Awareness

3.8.1 Discussion

BWXT Medical is obligated under the NSCA and its associated regulations to have policies, programs, methods and procedures in place for the safe operation and maintenance of its facilities. In addition to the NSCA and its associated regulations, BWXT Medical's activities must comply with the *Canada Labour Code*, and the associated *Canada Occupational Health and Safety Regulations*.

BWXT Medical's occupational health and safety program applies to all work performed by BWXT Medical employees and contractors. BWXT Medical will have a Workplace Health and Safety Committee in place to provide oversight of conventional safety and conduct regular safety inspections. This committee will be represented by union and management, and typically meet on a monthly basis.

In addition, BWXT Medical will have an EHS Committee and Senior Leadership Team that will set annual targets for Medical Treatment Incidents, Lost Time Incidents and Severity Rates; and annually review the overall performance of BWXT Medical's occupational health and safety program. BWXT Medical senior management and applicable health and safety committees will review conventional health and safety performance on a monthly basis. BWXT Medical has also proposed to have a program in place to prevent or mitigate potential accidents through near-miss reporting.

The primary conventional health and safety hazards at the facility are ergonomics issues related to manipulator use, including wrist injuries due to gripping action, elbow injuries due to rotation, and shoulder injuries due to lifting or over-reaching. BWXT Medical has committed that ergonomics issues related to processing and handling of radioactive materials will continue to be assessed as part of the design review process for new and existing facilities.

CNSC staff confirm that BWXT Medical has proposed appropriate measures to meet CNSC requirements and expectations for the Conventional Health and Safety SCA.

3.8.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.8.2.1 Past Performance

The number of lost-time injuries and corrective actions taken in response is a key performance indicator for the Conventional Health and Safety SCA. A Lost-time injury (LTI) is an injury that takes place at work and results in the worker being unable to return to work for a period of time. Accident severity rate measures the total number of days lost to injury for every 200,000 person hours worked at a facility, and the Accident frequency rate measures the number of LTIs for every 200,000 person hours worked at the facility. Table 4 below shows these metrics for the past five years at the Nordion facility.

Table 4: Injury Data for Nordion Class IB Facility (2015-2019)

Statistic	2015	2016	2017	2018	2019
LTI	0	3	1	0	2
Severity Rate	0	70.04	5.61	0	4.15
Frequency Rate	0	2.32	0.93	0	0.69

CNSC staff are satisfied that an effective conventional health and safety program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.8.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this area through routine CNSC inspections and documentation reviews.

3.8.2.3 Proposed Improvements

There are no changes anticipated in the near future for this SCA.

3.8.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Conventional Health and Safety SCA.CNSC staff conclude that BWXT Medical will implement an effective conventional health and safety program that will keep its workers safe from occupational injuries.

3.8.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 8.1 requires BWXT Medical to implement and maintain a conventional health and safety program. Detailed compliance verification criteria are included under section 8 of the LCH.

3.9 Environmental Protection

The Environmental Protection SCA covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.

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

- Effluent and emissions control (releases)
- Environmental management system (EMS)
- Assessment and monitoring
- Protection of the public
- Environmental risk assessment (ERA)

3.9.1 Discussion

CNSC regulations require that every licensee take all reasonable precautions to protect the environment and control the release of nuclear and hazardous substances into the environment. Licensees are required to implement and maintain environmental protection programs and procedures to ensure protection of the public and the environment from the operations of the facility.

BWXT Medical's application includes an Environmental Protection Program [17], Environmental Management System Manual [18], and the Radiation Protection Manual [19] as the framework for its Environmental Protection Program for the operation of NMPF. BWXT Medical has adopted these programs and procedures from Nordion. BWXT Medical's application confirms that BWXT Medical will remain within the scope of the licensing basis established for the Nordion facility.

BWXT Medical's proposed environmental protection program documents include a comprehensive environmental protection program and processes that cover:

- Radiation Protection
    - Derived release limits (DRL)
    - Radiation monitoring
    - Contamination monitoring program
    - Air sampling/monitoring programs
    - Delay tank sampling/monitoring (radiological)

    - Sanitary sampling (non-radiological)
- Hazardous chemical storage and handling
- Non-radiological environmental sampling
- Spill Containment

CNSC staff assessed BWXT Medical's proposed Environmental Protection Program documents and confirmed that they comply with the requirements and principles of:

- REGDOC-2.9.1: *Environmental Principles, Assessments, and Protection Measures, version 1.1* [20]
- CSA N288.4-10: *Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills* [21]
- CSA N288.5-11: *Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills* [22]
- CSA N288.6-12: *Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills* [23]
- CSA N288.1-14: *Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities* [24]
- CSA N288.8-17: *Establishing and Implementing Action Levels for Releases to the Environment from Nuclear Facilities* [25]

The established ERA and DRLs for the facility are applicable to cover the proposed licensed activities, as BWXT Medical will be contributing a portion of the environmental releases measured and reported.

To complement ongoing compliance activities, the CNSC has implemented its Independent Environmental Monitoring Program (IEMP). The IEMP results for Nordion indicate that the public and the environment in the vicinity of the Nordion facility are protected. The IEMP results for Nordion is published on the CNSC's website. *http://www.nuclearsafety.gc.ca/eng/resources/maps-of-nuclear-facilities/iemp/nordion.cfm*

A summary of BWXT Medical's proposed safety and control measures are presented in the following subsections. A description of the historical performance of the facility is also provided for context.

Effluent and emissions control (releases)

BWXT Medical's application includes programs to control and monitor airborne emissions and liquid effluent releases to the environment. CNSC staff confirmed that these programs comply with CSA N288.5-11, *Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*. CNSC staff are satisfied with BWXT Medical's proposed measures to control and monitor airborne emissions and liquid effluent releases to the environment, which are further described below.

To stay within the scope of the licensing basis established for the NMPF and ensure that the public and environment are protected, BWXT Medical proposed to use the DRLs established for the facility. CNSC staff have assessed the DRLs for airborne and liquid effluent, and confirm that they meet the requirements set out in CSA N288.1-14: *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities*. The DRLs ensure that the joint releases of radionuclides from the BWXT Medical and Nordion Class IB nuclear facilities will not result in an exceedance of the established regulatory dose limit of 1 mSv/year for a member of the public. The joint BWXT Medical-Nordion EHS Committee will monitor and ensure that the joint releases are being kept below the DRLs and regulatory public dose limit.

BWXT Medical also proposed that environmental action levels are not presently required for the NMPF because the ERA for the facility demonstrates that there is a very low risk to the environment from releases from the facility. CNSC staff assessed BWXT Medical's submissions and determined that they meet the requirements of CSA N288.8-17: *Establishing and implementing action levels for releases to the environment from nuclear facilities*. CNSC staff accept that action levels are not required at this time; 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 in operations that may result in an increase in releases to the environment.

Atmospheric Emissions

Process air in the facility is exhausted through up to three stages of filtration to remove both particulate and gaseous contaminants. The ventilation system comprises both primary and secondary filtration systems that include High Efficiency Particulate Air (HEPA) filters, and active charcoal absorption devices.

For reference of past performance and as an indicator of expected future performance with respect to atmospheric emissions, this CMD includes data from Nordion's activities during the current licensing period, as BWXT Medical will remain within the scope of the activities carried on by Nordion, according to the licensing basis for the facility. Airborne emissions from the Nordion facility have remained well below their respective regulatory limits (Table C.1, addendum C).

Liquid Effluent

Liquid effluent at the facility is collected in holding tanks, sampled and analyzed against DRLs to ensure compliance prior to release to the municipal sanitary sewer. For reference of past performance and as an indicator of expected future performance with respect to releases of liquid effluent, this CMD includes data from Nordion's activities during the current licensing period, as BWXT Medical will remain within the scope of the activities carried on by Nordion, according to the licensing basis for the facility. The liquid effluent releases have remained well below their respective regulatory limits (Table C.2, addendum C).

Environmental Management System (EMS)

CNSC REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures*, requires that licensees maintain an environmental management system (EMS) to describe the integrated activities associated with the protection of the environment at the facility. BWXT Medical's application includes an Environmental Management System Manual [18] based on Nordion's. BWXT Medical's EMS includes activities such as establishing annual environmental objectives and targets. CNSC staff review and assess these objectives and targets as part of compliance verification activities. CNSC staff expect BWXT Medical to continue maintaining and implementing an effective EMS.

Assessment and monitoring

BWXT Medical's application includes an environmental monitoring program to monitor the surrounding environmental media (soil, groundwater and environmental TLDs), and verify the effectiveness of emissions controls and the effluent monitoring program. CNSC staff have assessed BWXT Medical's proposed environmental monitoring program and confirm that it meets the requirements set out in CSA N288.4-10, *Environmental Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills*.

Nordion's environmental monitoring results (soil, groundwater, environmental TLDs) demonstrate that the environmental monitoring program currently in place 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. CNSC staff expect BWXT Medical to continue maintaining and implementing an effective environmental monitoring program.

Protection of the Public

This specific area within the Environmental Protection SCA is related to ensuring that members of the public are not exposed to "unreasonable" risk with respect to hazardous substances discharged from the nuclear facilities. Further information regarding the dose to the public is addressed in the Radiation Protection SCA section of this CMD.

During Nordion's licensing period, there have been no releases of hazardous substances to the environment from the facility that would pose a risk to the public or environment. CNSC staff expect BWXT Medical to continue protecting the public and the environment from hazardous substances discharged from the facility.

Environmental Risk Assessment

BWXT Medical's application included an ERA report that was completed for the Nordion facility in May 2017. BWXT Medical obtained permission from Nordion to use the report, which covers the licensed activities carried out in the KOB, including those in the NMPF. CNSC staff accepted that Nordion's ERA is applicable to BWXT Medical as BWXT Medical will be operating the NMPF, and BWXT Medical will be responsible for a portion of the environmental releases measured and reported.

CNSC staff assessed the site-wide ERA report submitted in support of BWXT Medical's application, and confirmed that it meets the requirements of CSA Standard N288.6-12, *Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills*. CNSC staff note that CSA N288.6-12 requires that ERAs be reviewed every five years or more often, if there is a change in operations or scientific knowledge. As the current ERA was completed in 2017, CNSC staff expect Nordion and BWXT Medical to provide separate, updated ERAs in 2022.

Due to the nature of the proposed licensed activities, BWXT Medical's operation of the facility is expected to have no impact on groundwater and therefore CSA N288.7-15, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills*, does not apply to the BWXT Medical facility and its proposed licensed activities. CNSC staff's assessment of the proposed activities and reviews of previous environmental monitoring results from Nordion supports the conclusion that nuclear and hazardous substances will not be released to groundwater during routine operations or during upset events. The applicability of this standard would be revaluated if warranted, such as from a proposed change in operation or in the event that environmental monitoring results, which are submitted to the CNSC, indicate potential impacts to groundwater.

3.9.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.9.2.1 Past Performance

Through ongoing compliance oversight, CNSC staff have assessed that the facility has been operated in a compliant manner with respect to environmental protection performance. The performance data summarized in the above sections demonstrate that airborne and waterborne releases of radioactive and hazardous substances have remained well below regulatory limits, and that the programs are effective in protecting the health and safety of the public and the environment. CNSC inspections carried out since 2018 have resulted in no major findings. CNSC staff are satisfied that effective environmental protection programs have been implemented at the facility, and expect this to continue under BWXT Medical.

3.9.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this SCA through regulatory oversight activities including onsite inspections and desktop reviews of relevant program documentation, including monitoring results and updated environmental protection program documents.

3.9.2.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that BWXT Medical will continually identify and implement improvements to its environmental protection program documents.

The CNSC published REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures, Version 1.2*, in September 2020. Should BWXT Medical be issued a licence, CNSC staff will ensure that BWXT Medical implements this REGDOC in accordance with an implementation plan.

3.9.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Environmental Protection SCA. CNSC staff conclude that BWXT Medical will make adequate provision for the protection of the public and the environment.

3.9.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 9.1 requires BWXT Medical to implement and maintain an environmental protection program, which includes a set of action levels. As part of this licence condition, BWXT is required to notify the Commission within seven days of becoming aware that an action level has been exceeded. Detailed compliance verification criteria for this licence condition are provided in the draft LCH.

3.10 Emergency Management and Fire Protection

The Emergency Management and Fire Protection SCA covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.

The specific areas that comprise this SCA for BWXT Medical include:

- Nuclear Emergency Preparedness and Response
- Fire Emergency Preparedness and Response

3.10.1 Discussion

The Emergency Management and Fire Protection SCA covers the provisions a licensee has in place, including an emergency preparedness plan and response capability, to mitigate the effects of accidental releases of radiological and hazardous substances to the environment during emergency and process upset conditions. This SCA also includes the implementation of a fire protection program to prevent or minimize the risk that fire poses to the environment and the health and safety of persons.

A summary of the applicant's proposed safety and control measures are presented in the following subsections. A description of the historical performance of the facility is also provided for context.

Section 6(k) of the CINFR, requires that an application for a licence to operate a Class I facility include the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security. These measures include assisting off-site authorities, and testing the implementation of measures to prevent or mitigate the effects of an accidental release.

Nuclear Emergency Preparedness and Response

With respect to emergency management, CNSC staff assessed BWXT Medical's application against the requirements set out in the following documents:

- CNSC REGDOC 2.10.1 version 2: Nuclear Emergency Preparedness and Response [26]
- CSA N393-13: Fire protection for facilities that process, handle, or store nuclear substances [14]

BWXT Medical has proposed that it continue to follow and be integrated in the emergency preparedness program established by Nordion. The emergency preparedness program includes details on the management and maintenance of the program, plans and procedures for responding to all hazards and scenario-specific events, as well as business continuity plans. CNSC staff are satisfied that the measures proposed by BWXT Medical with respect to this SCA are appropriate and meet regulatory requirements.

CSA N393-13 requires that a licensee conduct an annual fire response drill. Being located on the same site, BWXT Medical and Nordion will both rely on the Ottawa Fire Services (OFS) to provide fire response capability. As separate licensees, BWXT Medical and Nordion must conduct separate fire response drills in order to meet their regulatory requirements under CSA N393-13. This will require additional effort and coordination with OFS to facilitate. CNSC staff confirm that BWXT Medical has proactively worked with OFS on the development of a formal service agreement between BWXT Medical and OFS to ensure full and continued support to BWXT Medical.

Fire Protection

Fire Protection is achieved through the implementation of a fire protection program to minimize the risk to the health and safety of persons and to the environment from fire, through appropriate fire protection system design, fire safe operation and fire prevention.

With respect to fire protection, CNSC staff assessed BWXT Medical's application against the requirements set out in the following codes and standards:

- CSA N393-13, *Fire Protection for Facilities that Process, Handle, or Store Radioactive Substances*
- *National Building Code of Canada, 2015*
- *National Fire Code of Canada, 2015*

BWXT Medical's proposed safety and control measures for fire protection include a fire protection program and a fire safety plan. BWXT Medical also submitted an assessment of the impact of a fire in the NMPF demonstrating that the risks of fire are low and effectively mitigated.

CNSC staff determined that the applicant's proposed measures meet regulatory requirements and demonstrate that measures will be in place to minimize both the probability of occurrence and the consequences of fire at the facility.

3.10.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.10.2.1 Past Performance

CNSC staff are satisfied that effective emergency preparedness and fire protection programs have been implemented at the facility. These programs adequately protect workers, the public and the environment from emergency or upset conditions. Given that BWXT Medical has adopted Nordion's programs applicable to emergency management and fire protection, and has retained former Nordion personnel to implement the programs, CNSC staff expect this performance to continue under BWXT Medical.

3.10.2.2 Regulatory Focus

CNSC staff will monitor BWXT Medical's performance in this area through routine inspections; document reviews, including compliance reporting and revisions to relevant program documentation; and observation of emergency response exercises to verify that the integration between BWXT Medical and Nordion's emergency programs are effective.

3.10.2.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that BWXT Medical will continually identify and implement improvements to its programs.

3.10.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Emergency Management and Fire Protection SCA. CNSC staff conclude that the proposed emergency plans and fire protection program meet regulatory requirements, and that BWXT Medical's documentation and analyses related to fire protection meet regulatory requirements.

3.10.4 Recommendation

Two standardized licence conditions are included in the proposed licence for this SCA. Licence condition 10.1 requires BWXT Medical to implement and maintain an emergency preparedness program. Licence condition 10.2 requires BWXT Medical to implement and maintain a fire protection program. Detailed compliance verification criteria are included under section 10 of the LCH.

3.11 Waste Management

The Waste Management SCA covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.

This CMD covers the following specific areas of the Waste Management SCA:

- Waste characterization
- Waste minimization
- Waste management practices
- Decommissioning plans

3.11.1 Discussion

A summary of BWXT Medical's proposed safety and control measures for the waste management SCA are presented in the following subsections.

Waste characterization, waste minimization and waste management practices

BWXT Medical's application includes a waste management program that meets the requirements of CSA standard N292.3-14, *Management of Low- and Intermediate-Level Radioactive Waste* [27]. The objectives of this program are to minimize the generation of waste at the facility and manage wastes and by-products generated in accordance with CNSC regulatory requirements. As described in the waste program, in general, waste from BWXT Medical operations will be considered low-level radioactive waste as per CSA N292.0-14, *General principles for the management of radioactive waste and irradiated fuel*. BWXT Medical has also established a diversion program designed to divert waste with activity concentrations below the unconditional clearance levels in the *Nuclear Substances and Radiation Devices Regulations*. Less radioactive waste material is generated from the processing of radiopharmaceuticals, as the quantities of activity processed are relatively small and the materials are of high purity, resulting in fewer waste impurities.

CNSC staff assessed BWXT Medical's application, including waste management programs and procedures, and confirmed that it includes proposed measures to address CNSC requirements concerning waste characterization, waste minimization and waste management practices. CNSC staff are satisfied that the applicant's documentation meets CNSC regulatory requirements, including the requirements outlined in CSA N292.0-14, *General principles for the management of radioactive waste and irradiated fuel* [28], and CSA N292.3-14, *Management of low- and intermediate-level radioactive waste* [27].

Decommissioning plans

The decommissioning of a nuclear facility is required to be considered in all phases of the facility's life cycle. Paragraph 3(*k*) of the CINFR, requires that licence applications contain information concerning the proposed plan for the decommissioning of the nuclear facility or of the site. Decommissioning should be conducted in a manner that ensures that the health, safety, and security of workers, the public, and the environment are protected.

BWXT Medical's application includes a Preliminary Decommissioning Plan (PDP) and cost estimate for the Class IB facility. CNSC staff assessed BWXT Medical's PDP and cost estimate for decommissioning, and determined that they meet the criteria of CNSC Regulatory Guides G-219, *Decommissioning Planning for Licensed Activities* [29], and G-206, *Financial Guarantees for the Decommissioning of Licensed Activities* [30], as well as CSA N294-09, *Decommissioning of Facilities Containing Nuclear Substances* [31]. CNSC staff conclude that the cost estimate is credible and sufficient to fund the future decommissioning of the facility. Additional information on cost estimates and financial guarantee is presented in section 4.4 of this document.

The CNSC requires that PDPs be periodically updated to reflect any changes in the facility or operations at a minimum of every five years or when required by the Commission.

3.11.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.11.2.1 Past Performance

The facility has been operated by Nordion in a manner compliant with CNSC requirements for the waste management SCA. CNSC staff are satisfied that an effective waste management program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.11.2.2 Regulatory Focus

CNSC staff will continue to monitor BWXT Medical's performance for the Waste Management SCA through regulatory oversight activities, including on-site inspections and desktop reviews of relevant program documentation.

3.11.2.3 Proposed Improvements

There are no changes anticipated in the near future for this SCA. The PDP must be kept current to reflect any changes in the site or facility. CNSC staff expect BWXT Medical to review and update the decommissioning plan on a five-year cycle as documented in section 11 of the proposed LCH. During the review of the PDP, CNSC staff identified recommendations to be incorporated into the next revision of the PDP.

3.11.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Waste Management SCA. CNSC staff conclude that the submissions made by BWXT Medical in support of its waste management program, decommissioning plan and financial guarantee are satisfactory and meet regulatory requirements.

3.11.4 Recommendation

Two standardized licence conditions pertaining Waste Management are included in the proposed licence. Licence condition 11.1 requires BWXT Medical to implement and maintain a waste management program. Licence condition 11.2 requires BWXT Medical to maintain a decommissioning plan. Detailed compliance verification criteria are included under section 11 of the LCH.

3.12 Security

This SCA covers the programs required to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity. These programs also ensure that all workers are instructed on the facility security program at BWXT Medical.

The specific areas that comprise this SCA at BWXT Medical include:

- Facilities and equipment
- Response arrangements
- Security practices
- Drills and exercises

3.12.1 Discussion

The CNSC's regulatory requirements for the Security SCA are stipulated in the GNSCR. CNSC REGDOC 2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material* [32] provides regulatory expectations and guidance for licensees regarding the CNSC's expectations under the GNSCR.

CNSC staff note that in addition to the regulatory requirements stipulated in the GNSCR, BWXT Medical is subject to Sections 39-48 of the *Nuclear Security Regulations* (NSR). This is because Nordion (Canada) Inc., formerly MDS Nordion, is identified as a named entity within Schedule 2 of the NSR, as identified by subsection 40(*b*) of the NSR.

The CNSC expects licensees to have measures in place to:

- ensure that adequate provision is made for the security of nuclear substances;
- alert the licensee to the illegal use or removal of nuclear substances;
- alert the licensee to sabotage or attempted sabotage anywhere at the facility site; and
- instruct all workers on the licensee's security program.

BWXT Medical's application includes program documentation, including a Site Security Plan, which identifies how the applicant meets CNSC expectations for the Security SCA. CNSC staff have assessed BWXT Medical's documentation and determined that it meets the requirements of the NSR and GNSCR. CNSC staff are satisfied that BWXT Medical's Site Security Plan meets regulatory requirements.

Details on the measures implemented by the applicant to meet the requirements of this SCA are considered prescribed information as identified in Section 21 of the GNSCR. A summary of the applicant's proposed security control measures are presented in the following subsections.

Facilities and Equipment

CNSC staff are satisfied that BWXT Medical provided sufficient details on its security systems and devices for the facility and the areas that involve the processing, use, or storage of nuclear substances. BWXT Medical's application identified that all security systems and devices required by the CNSC have been implemented and maintained for the BWXT Medical facility. CNSC staff are further satisfied that the applicant has satisfactory processes in place for testing and maintaining all security devices and systems at the facility.

Response Arrangements

CNSC staff are satisfied that alarm detection and assessment systems will be in place and continuously monitored by an on-site security officer. BWXT Medical has established a response protocol with the Ottawa Police Service to ensure response of armed police officers in a timely manner, should a security related incident occur.

Security Practices

CNSC staff are satisfied that the facility's physical protection program includes administrative and technical measures that meet CNSC regulatory requirements for nuclear security. The program includes measures for controlling access to persons and vehicles, as well as measures for controlling access to and from areas where nuclear substances are processed, used or stored.

CNSC staff are satisfied that the applicant has implemented a satisfactory facility access security clearance process that includes a Criminal Record Name Check for individuals with facility site access clearances. In addition, BWXT Medical has a security awareness program for all staff and a supervisory awareness program for managers and supervisors to enhance capabilities in identifying and responding to changes in employee behaviour.

3.12.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.12.2.1 Past Performance

Through ongoing compliance oversight, CNSC staff have assessed that effective security measures have been implemented at the facility. The facility has been operated in a manner compliant with CNSC requirements for the security SCA. CNSC staff are satisfied that an effective security program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.12.2.2 Regulatory Focus

CNSC staff will continue to monitor BWXT Medical's performance for the security SCA through regulatory oversight activities, including on-site inspections and technical assessments of relevant program documentation.

3.12.2.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that BWXT Medical will continually identify and implement improvements to its programs.

3.12.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Security SCA.

3.12.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 12.1 requires BWXT Medical to implement and maintain a security program. Detailed compliance verification criteria are included under section 12 of the LCH.

3.13 Safeguards and Non-Proliferation

The Safeguards and Non-Proliferation SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons* [33].

This CMD covers the following specific areas of Safeguards and Non-Proliferation:

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

3.13.1 Discussion

Pursuant to the *Treaty on the Non-Proliferation of Nuclear Weapons*, Canada has entered into a Comprehensive Safeguards Agreement [34] and an Additional Protocol with the IAEA [35] (hereafter referred to as the safeguards agreements). The objective of the safeguards agreements is for the IAEA to provide annual assurance to Canada and to the international community that all declared nuclear material is in peaceful, non-explosive uses and that there is no indication of undeclared material.

The CNSC provides the mechanism, through the NSCA, regulations and licences, for the implementation of safeguards. Conditions for the application of safeguards are contained in CNSC facility operating licences and the criteria to meet those conditions are contained in the LCH and in regulatory document REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy* [36]. Compliance includes the timely provision of reports on the movement and location of nuclear material, provision of access and assistance to IAEA inspectors for safeguards activities, support for IAEA equipment, and the submission of annual operational information, additional protocol updates as well as accurate design information.

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

The import and export of controlled nuclear substances, equipment and information identified in the *Nuclear Non-proliferation Import and Export Control Regulations* require separate authorization from the CNSC, consistent with subsection 3(2) of the GNSCR. CNSC REGDOC-2.13.2, *Import and Export* [37] provides guidance on this type of authorization.

BWXT Medical's application included a proposed safeguards program, which is the same as the program used by Nordion. CNSC staff assessed BWXT Medical's proposed safeguards program and are satisfied that the program meets the requirements set out in REGDOC 2.13.1. The program conforms to measures required by the CNSC to meet Canada's international safeguards obligations as well as other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

3.13.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.13.2.1 Past Performance

CNSC staff are satisfied that an effective safeguards program has been implemented at the facility, and expect this to continue under BWXT Medical. Details pertaining to the specific areas within this SCA are presented in the following subsections.

Nuclear material accountancy and control

CNSC staff determined that the facility has complied with CNSC's regulatory requirements in accordance with REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy.*

Access and assistance to the IAEA

CNSC staff confirmed that the facility has granted adequate access and assistance to the IAEA for safeguards activities. During 2017-2020, the IAEA performed inspections and verifications that included one Physical Inventory Verification and two Complementary Accesses. In all cases, the facility provided the IAEA with the necessary access and assistance to perform the activities and complied with all regulatory requirements.

In all IAEA inspections, the facility had no major issues and the inspection results were satisfactory.

Operational and design information

CNSC staff are satisfied that annual operational programs, annual updates to the additional protocol, design information questionnaires, and other required information have been submitted to the IAEA and the CNSC in a timely manner.

Safeguards equipment, containment and surveillance

Not applicable. There is no IAEA safeguards equipment installed at the facility.

Import and export

The scope of the non-proliferation program under Nordion's licence is limited to the tracking and reporting of foreign obligations and origins of nuclear material. CNSC staff confirm that the CNSC's regulatory requirements in this respect have been met.

3.13.2.2 Regulatory Focus

CNSC staff will continue to monitor and evaluate the BWXT Medical's performance through participation in IAEA inspections, CNSC evaluations, and ongoing assessments of compliance with reporting requirements.

3.13.2.3 Proposed Improvements

CNSC staff note that a new material balance area (MBA) for BWXT Medical will need to be established by the IAEA if the Commission issues BWXT Medical a licence. All licensees that possess nuclear material subject to full-scope safeguards require the establishment of a MBA for the purposes of determining the inventory of nuclear material onsite and changes to that inventory. As part of this process, BWXT Medical is currently collaborating with the CNSC to draft a design information questionnaire and to update nuclear material accountancy records.

3.13.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Safeguards and Non-Proliferation SCA. CNSC staff conclude that BWXT Medical is qualified to carry on the activities covered in this SCA.

3.13.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 13.1 requires that BWXT Medical implement and maintain a safeguards program. Detailed compliance verification criteria are included under section 13 of the LCH.

3.14 Packaging and Transport

The packaging and transport SCA covers programs for the safe packaging and transport of nuclear substances to and from the licensed facility.

The specific areas that comprise this SCA are:

- Packaging and Transport
- Package Design and Maintenance
- Registration for Use

3.14.1 Discussion

The transport of nuclear substances must be in compliance with all requirements of the *Packaging and Transport of Nuclear Substances Regulations, 2015* and the *Transportation of Dangerous Goods Regulations.*

The *Packaging and Transport of Nuclear Substances Regulations, 2015* apply to the packaging and transport of nuclear substances, including the design, production, use, inspection, maintenance and repair of packages. These regulations also apply to the preparation, consigning, handling, loading, carriage and unloading of packages.

The *Transportation of Dangerous Goods Regulations* require that workers involved in the handling, offering for transport, and transport of dangerous goods be appropriately trained and issued a training certificate.

CNSC staff assessed BWXT Medical's application and supporting documents and are satisfied that BWXT Medical has proposed appropriate measures to ensure compliance with regulatory requirements for the Packaging and Transport SCA. BWXT Medical's application includes a packaging and transport program that meets the requirements of the *Packaging and Transport of Nuclear Substances Regulations, 2015* and the *Transportation of Dangerous Goods Regulations* for all shipments leaving and arriving at the facility.

CNSC staff are further satisfied that BWXT Medical's packaging and transport program also covers elements of package design and maintenance, as well as the registration for use of certified packages, as required by the regulations.

3.14.2 Summary

A summary of past performance, challenges and proposed improvements are presented in the following subsections.

3.14.2.1 Past Performance

Through ongoing compliance oversight, CNSC staff have assessed that the facility has been operated in a compliant manner with respect to the packaging and transport SCA. CNSC inspections carried out since 2018, including one focused on Type A packages shipped from the NMPF in 2019, have resulted in no major findings. CNSC staff are satisfied that an effective packaging and transport program has been implemented at the facility, and expect this to continue under BWXT Medical.

3.14.2.2 Regulatory Focus

CNSC staff will continue to monitor BWXT Medical's performance for the Packaging and Transport SCA through regulatory oversight activities, including on-site inspections and desktop reviews of relevant program documentation.

3.14.2.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that BWXT Medical will continually identify and implement improvements to operation, equipment and programs.

CNSC staff note that amendments to the *Transportation of Dangerous Goods Regulations* are expected to be published in the near future. These amended regulations may require new/additional training for workers.

3.14.3 Conclusion

Based on CNSC staff's assessment of BWXT Medical's licence application and supporting documents, CNSC staff conclude that BWXT Medical has proposed appropriate measures and programs to meet CNSC expectations for the Packaging and Transport SCA. CNSC staff conclude that BWXT Medical will implement and maintain an effective packaging and transport program that will ensure compliance with regulatory requirements.

3.14.4 Recommendation

One standardized licence condition is included in the proposed licence for this SCA. Licence condition 14.1 requires BWXT Medical to implement and maintain a packaging and transport program. Detailed compliance verification criteria are included under section 14 of the LCH.

4. OTHER MATTERS OF REGULATORY INTEREST

Other matters of regulatory interest are described in the sections below.

4.1 Indigenous Consultation and Engagement

The common-law duty to consult with Indigenous groups applies when the Crown contemplates actions that may adversely affect potential or established Indigenous and/or treaty rights. The CNSC ensures that all of its licence decisions under the NSCA uphold the honour of the Crown and consider Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the *Constitution Act, 1982*.

4.1.1 Discussion

CNSC staff identified the First Nation and Métis groups who may have an interest in BWXT Medical's licence application to operate the medical isotope facility in Nordion's existing nuclear substance processing facility. These groups include: Algonquins of Pikwakanagan First Nation, Algonquins of Ontario, Algonquin Anishinabeg Nation Tribal Council, Kitigan Zibi Anishinabeg, Kebaowek First Nation, Métis Nation of Ontario, and Mohawks of the Bay of Quinte. These groups were identified because they have previously expressed interest in being kept informed of CNSC licensed activities occurring in proximity to their traditional and/or treaty territories.

CNSC staff sent letters of notification in July 2019 to the Indigenous groups identified above, providing information regarding the proposed licence application, opportunities to participate in the Commission's public hearing process, and information about the CNSC's participant funding program to facilitate participation in the hearing process.

CNSC staff sent follow-up letters to each Indigenous group in November 2020, providing updated information on the specific hearing dates, further details on how to participate in the Commission's public hearing process, and updated information on the availability of participant funding. CNSC staff followed-up with each identified group in early December 2020 through email (Algonquins of Ontario, Mohawks of the Bay of Quinte), phone (Kitigan Zibi Anishinabeg, Kebaowek First Nation, Algonquin Anishinabeg Nation Tribal Council) and virtual meetings (Algonquins of Pikwakanagan First Nation, Métis Nation of Ontario) to confirm they had received the letters and to answer any questions about the regulatory process and participation in the Commission proceedings.

To date, CNSC staff have not been made aware of any specific concerns with regards to BWXT Medical's licence application. The CNSC is committed to continuing engagement activities with interested Indigenous groups in relation to BWXT Medical's activities and the CNSC's regulation of the facility and its activities.

CNSC REGDOC-3.2.2, *Indigenous Engagement* [38], sets out requirements and guidance for licensees whose proposed projects may raise the Crown's duty to consult. While the CNSC cannot delegate its obligation, it can delegate procedural aspects of the consultation process to licensees, where appropriate. The information collected and measures proposed by licensees to avoid, mitigate or offset adverse impacts from the proposed licence renewal, may be used by CNSC staff in meeting its consultation obligations. BWXT Medical's licence application does not raise the formal requirements of REGDOC-3.2.2. However, CNSC staff encourages BWXT Medical to continue engaging with interested Indigenous groups regarding their activities, including this licence application.

4.1.2 Conclusion

As BWXT Medical's licence application does not propose a change to the footprint of the existing Nordion nuclear substance processing facility or significantly change the operations of the existing facility, CNSC staff conclude that BWXT Medical's proposed licence will not cause any adverse impacts to any potential or established Indigenous and/or treaty rights. The CNSC conducted an engagement and outreach process in relation to this licence application with all interested Indigenous groups and is committed to meaningful, ongoing engagement with Indigenous groups that have an interest in CNSC regulated facilities and activities..

4.1.3 Recommendation

No specific licence condition is required for this matter.

4.2 Other Consultation

The CNSC made up to $75,000 available through its Participant Funding Program (PFP) to assist Indigenous peoples, members of the public, and stakeholders in participating in the regulatory process for BWXT Medical's proposed operating licence for a Class IB nuclear substance processing facility and to provide value-added information to the Commission through informed and topic-specific interventions. This funding was offered to review BWXT Medical's licence application and associated documents, and to prepare for and participate in the Commission's public hearing.

The deadline for applications was January 22, 2021. A Funding Review Committee (FRC), independent from CNSC staff, reviewed the funding applications received, and made recommendations on the allocation of funding to eligible recipients. Based on the recommendations from the FRC, the CNSC awarded a total of $68,199.95, in funding to the following recipients:

- Algonquins of Ontario
- Algonquins of Pikwakanagan First Nation
- Anna Tilman
- Kebaowek First Nation

- Women in Nuclear

4.3 Cost Recovery

Paragraph 24(2)(c) of the NSCA requires that licence applications be accompanied by a prescribed fee. The *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations* (CRFR) set out the specific requirements based on the activities to be licensed. Paragraph 7(1)(a) of the CRFR requires that an initial application for a facility for which an estimated annual fee has not been calculated, the applicant shall pay to the Commission, with the application, a deposit of $25,000, if the application is in respect of a facility.

4.3.1 Discussion

BWXT Medical's application was a new application and as such, BWXT Medical was required to submit the initial fee of $25,000. CNSC staff confirm that BWXT Medical is in good standing with respect to CRFR requirements and has paid its cost recovery fees in full. CNSC staff do not foresee any concerns regarding the payment of future cost recovery fees for this applicant.

4.3.2 Conclusion

CNSC staff conclude that BWXT Medical is in good standing with respect to the CRFR.

4.4 Financial Guarantees

Subsection 24(5) of the NSCA states "A licence may contain any term or condition that the Commission considers necessary for the purposes of this Act, including a condition that the applicant provide a financial guarantee in a form that is acceptable to the Commission".

CNSC regulatory guide G-206, *Financial Guarantees for the Decommissioning of Licensed Activities*, sets out guidance on the development of financial guarantees for licensed facilities and activities. Financial Guarantees must be updated every five years and submitted to the CNSC for review.

4.4.1 Discussion

As part of the licence application, BWXT Medical proposed a financial guarantee of $10.54 million through two proposed instruments: a letter of credit in the amount of $2.6 million for putting the facility in a safe shutdown state and a surety bond in the amount of $7.94 million for the remainder of the decommissioning costs. CNSC staff assessed the proposed financial guarantee amount and instruments, and determined that they meet the criteria of CNSC Regulatory Guides G-206.

4.4.2 Conclusion

CNSC staff conclude that BWXT Medical's proposed cost estimate is credible and the financial guarantee instruments are acceptable.

4.4.3 Recommendation

One standardized licence condition is included in the proposed licence for this matter of regulatory interest. Licence Condition G.3 requires BWXT Medical to implement and maintain a financial guarantee for decommissioning that is acceptable to the Commission.

CNSC staff recommend that the Commission accept the proposed financial guarantee amount and instruments. CNSC staff recommend that the Commission direct BWXT Medical to provide the original financial guarantee instruments to the CNSC within 90 days of the issuance of a decision.

4.5 Improvement Plan and Significant Future Activities

BWXT Medical intends to process Mo-99 at the NMPF. According to its application, BWXT Medical has developed a technology for producing Mo-99 using a natural molybdenum-98 target. BWXT Medical has assessed that this process is within the existing licensing basis for the NMPF, and that workers, the public, and the environment will continue to be protected.

4.5.1 Discussion

The NMPF has historically been used to process Mo-99 from highly enriched uranium targets. The enriched uranium Mo-99 process at the NMPF ceased in 2016, as a result of the shutdown of the National Research Universal (NRU) reactor at Chalk River Laboratories. BWXT Medical is proposing to restart the process with modified equipment to accommodate the natural molybdenum targets. The natural molybdenum target will be neutron activated in a reactor (^{98} Mo(n,γ)^{99} Mo). The neutron activation will take place at a reactor facility elsewhere, and not at the NMPF. The activated targets will be transported to the NMPF where they will be processed. The daughter isotope technitium-99m will be extracted from the Mo-99 using a technetium generator which will be loaded at the NMPF.

BWXT Medical estimates that releases to air and water from the proposed Mo-99 process will pose a negligible risk to persons or the environment. BWXT Medical further estimates that the waste volumes and activities of the proposed Mo-99 process will be within the amounts generated from the previous process, with the exception of an increased volume of low-level liquid waste. The total activity of the waste is estimated to remain below that of the previous process, and the waste would be managed in accordance with the established waste management program.

Based on the information assessed at the time of writing this CMD, CNSC staff are satisfied with BWXT Medical's determination that the new Mo-99 process is within the licensing basis. CNSC staff assessed BWXT Medical's submissions and are satisfied that doses to workers, releases to the environment, and quantities and activities of waste are expected to remain within those established for the facility, in line with the previous process.

In addition to the Mo-99 process changes, BWXT Medical has indicated its intent to install electron beam sterilization equipment within the NMPF. This equipment would be classified as Class II prescribed equipment in accordance with the *Class II Nuclear Facilities and Prescribed Equipment Regulations*. At the time of writing this CMD, CNSC staff expect BWXT Medical to file a separate application for this equipment. This application will be assessed by the CNSC in accordance with the *Class II Nuclear Facilities and Prescribed Equipment Regulations*.

4.5.2 Conclusion

As previously described in this CMD, CNSC staff are satisfied that BWXT Medical has adequate resources in place to ensure that any changes can be made safely within the licensing basis. CNSC staff will assess any changes to any processes at the facility as part of ongoing compliance oversight.

4.6 Applicant's Public Information Program

A Public Information and Disclosure Program (PIDP) is a regulatory requirement for licence applicants and licensees of Class I nuclear facilities, uranium mines and mills and certain Class II nuclear facilities. These requirements are found in REGDOC-3.2.1, *Public Information and Disclosure* [39].

The primary goal of the PIDP is to ensure that information related to the health, safety and security of persons and the environment, and other issues associated with the lifecycle of nuclear facilities, are effectively communicated to the public.

The program must include a commitment to, and protocol for ongoing, timely communication of information related to the licensed facility during the course of the licence period.

CNSC's expectations of a licensee's public information program and disclosure protocol are commensurate with the level of risk of the facility, as well as the level of public interest in the licensed activities. The program and protocol may be further influenced by the complexity of the nuclear facility's lifecycle and activities, and the risks to public health and safety and the environment perceived to be associated with the facility and activities.

4.6.1 Discussion

BWXT Medical's application includes a PIDP [40] for the facility. CNSC staff note that the BWXT Medical PIDP is separate and distinct from the public information programs for the BWXT Nuclear Energy Canada Peterborough and Toronto facilities.

CNSC staff have reviewed BWXT Medical's PIDP and determined that it:

- identifies clear goals and objectives in terms of dissemination of information to targeted audiences
- identifies that a public disclosure protocol will be available to the public and posted on the licensee's website

- identifies multiple target audiences such as residents and businesses in close proximity to the licensed facility, elected and government representatives, local schools, local health units and first responders, community leaders and associations, and local Indigenous groups
- provides contact information for members of the public who want to obtain additional information
- provides key topics intended for sharing with target audience and/or other interested parties
- outlines communications approaches that BWXT Medical will use to reach target audiences (newsletters, e-mail lists, web site, facility tours, social media, public meetings, public advertisements, volunteering, community investment and community relations activities).

BWXT Medical has committed to refine and update its PIDP on a regular basis to meet the changing information needs of its target audiences. CNSC staff will continue to monitor BWXT Medical's compliance with public information requirements and ongoing implementation of the PIDP.

4.6.2 Conclusion

CNSC staff conclude that BWXT Medical's PIDP meets the requirements of REGDOC-3.2.1, *Public Information and Disclosure*. CNSC staff will continue to oversee BWXT Medical's implementation of the PIDP to ensure that it meets obligations regarding disseminating and notifying the public and Indigenous communities on its licensed activities.

4.6.3 Recommendation

One standardized licence condition is included in the proposed licence for this matter of regulatory interest. Licence condition G.4 requires BWXT Medical to implement and maintain a public information and disclosure program.

4.7 Nuclear Liability Insurance

4.7.1 In accordance with the *Nuclear Liability and Compensation Regulations* made under the *Nuclear Liability and Compensation Act* the BWXT Medical facility is not designated as a nuclear installation. BWXT Medical's operations do not meet the criteria to be designated as a nuclear installation and are not under the purview of the *Nuclear Liability and Compensation Act*. CNSC staff note that BWXT Medical will maintain industrial insurance as a commercial necessity.

4.8 Delegation of Authority

The Commission may include in a licence any condition it considers necessary for the purposes of the NSCA. The Commission may delegate authority to CNSC staff with respect to the administration of licence conditions, or portions thereof.

There is one licence condition in the proposed licence for BWXT Medical that contains the phrase "the Commission or a person authorized by the Commission":

- LC 3.2: The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.

CNSC staff recommend the Commission delegate its authority for the purposes described in the above licence condition to the following staff:

- Director, Nuclear Processing Facilities Division;
- Director General, Directorate of Nuclear Cycles and Facilities Regulation; and
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch

4.9 Name Change to BWXT Medical Ltd.

At the time of writing this CMD, BWXT ITG Canada, Inc. informed the CNSC that it had legally changed its corporation name to BWXT Medical Ltd. CNSC staff are satisfied that this name change is administrative in nature and does not alter the conclusions of this CMD. The name change is reflected in the proposed licence and draft LCH.

5. OVERALL CONCLUSIONS AND RECOMMENDATIONS

CNSC staff have concluded the following:

1. With respect to paragraphs 24(4)(*a*) and (*b*) of the *Nuclear Safety and Control Act* (NSCA), BWXT Medical:
   a. is qualified to carry on the activities authorized by the licence.
   b. will, in carrying on those activities, 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.
2. The proposed financial guarantee of $10.54 million is based on a credible cost estimate, with acceptable financial guarantee instruments.

The licensing recommendations are based on the overall assessment of the applicant's compliance with the NSCA and its regulations, and the adequacy of the measures in place to ensure the health and safety of persons and the environment and of the measures related to security and Canada's international obligations during the period that the proposed licence covers. CNSC staff recommend the following:

1. The Commission accept CNSC staff's assessment and conclusions identified in section 1.3 of this CMD;
2. The Commission issue a Class IB Nuclear Substance Processing Facility Licence to BWXT Medical for a 10-year period, with the proposed licence conditions and the proposed delegation of authority, as set out in subsection 4.8 of this CMD; and
3. The Commission accept the proposed financial guarantee of $10.54 and direct BWXT to provide the original instruments to the CNSC within 90 days of the issuance of a decision on this matter.

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GLOSSARY

For definitions of terms used in this document, see REGDOC-3.6, *Glossary of CNSC Terminology* [41], which includes terms and definitions used in the *Nuclear Safety and Control Act* and the regulations made under it, and in CNSC regulatory documents and other publications. REGDOC-3.6 is provided for reference and information.

ALARA	as low as reasonably achievable
Bq	Becquerel
CAPA	Corrective and Preventive Actions
CEAA 2012	*Canadian Environmental Assessment Act, 2012*
CINFR	*Class I Nuclear Facilities Regulations*
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
COF	Cobalt Operations Facility
CRFR	*Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*
CSA	Canadian Standards Association
DRL	derived release limit
EHS	Environment, Health and Safety
EMS	Environmental management system
ERA	Environmental risk assessment
FRC	Funding Review Committee
GNSCR	*General Nuclear Safety and Control Regulations*
HEPA	High Efficiency Particulate Air
IAAC, 2019	*Impact Assessment Act of Canada, 2019*
IAEA	International Atomic Energy Agency
IEMP	Independent Environmental Monitoring Program
KOB	Kanata Operations Building
LCH	Licence Conditions Handbook
LTI	Lost-time injury
MBA	material balance area
Mo-99	Molybdenum-99
mSv	millisievert(s)
NEW	Nuclear Energy Worker

NMPF	Nuclear Medicine Production Facility
NRU	National Research Universal
NSCA	*Nuclear Safety and Control Act*
NSPFL	Nuclear Substance Processing Facility Licence
NSR	*Nuclear Security Regulations*
NSSR	National Sealed Source Registry
OFS	Ottawa Fire Services
OPEX	Operating experience
PDP	Preliminary decommissioning plan
PFP	Participant Funding Program
PIDP	Public Information and Disclosure Program
RP	Radiation Protection
SAT	systematic approach to training
SCA	Safety and control area
SSTS	Sealed Source Tracking System
TLD	Thermoluminescent dosimeters

A. BASIS FOR THE RECOMMENDATIONS

A.1 REGULATORY BASIS

The recommendations presented in this CMD are based on compliance objectives and expectations associated with the relevant SCAs and other matters. The regulatory basis for the matters that are relevant to this CMD are as follows.

Management System

The regulatory foundation for the recommendation(s) associated with Management System includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(d), the proposed management system for the activity to be licensed, including measures to promote and support safety culture.
- The *General Nuclear Safety and Control Regulations* require that an application for a licence shall contain, under paragraphs:
  - 3(1)(*k*), the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the NSCA and the regulations made under the NSCA, including the internal allocation of functions, responsibilities and authority.
  - 15(*a*), the persons who have the authority to act for them (the applicant/licensee) in their dealings with the Commission.
  - 15(*b*), the names and position titles of the persons who are responsible for the management and control of the licensed activity and the nuclear substance, nuclear facility, prescribed equipment or prescribed information encompassed by the licence.

Human Performance Management

The regulatory foundation for the recommendation(s) associated with Human Performance Management includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
  - 3(d.1), the proposed human performance program for the activity to be licensed, including measures to ensure workers' fitness for duty.
  - 6(*m*), the proposed responsibilities of and the qualification requirements and training program for workers, including the procedures for the requalification of workers
  - 6(*n*), the results that have been achieved in implementing the program for recruiting, training and qualifying workers in respect of the operation and maintenance of the nuclear facility.

- The *General Nuclear Safety and Control Regulations* require that licensees, under paragraphs:
  - 12(1)(*a*), ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the Act, the regulations made under the Act and the licence.
  - 12(1)(*b*), train the workers to carry on the licensed activity in accordance with the Act, the regulations made under the Act and the licence.
  - 12(1)(*e*), require that every person at the site of the licensed activity to use equipment, devices, clothing and procedures in accordance with the Act, the regulations made under the Act and the licence.

Operating Performance

The regulatory foundation for the recommendation(s) associated with operating performance includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence to operate a Class I nuclear facility shall contain, under paragraph:
  - 6(*d*), the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.
- The *Nuclear Substances and Radiation Devices Regulations*

Safety Analysis

The regulatory foundation for the recommendation(s) associated with safety analysis includes the following:

- The *General Nuclear Safety and Control Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(1)(*i*), a description and the results of any test, analysis or calculation performed to substantiate the information included in the application.
- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
  - 6(*c*), a final safety analysis report demonstrating the adequacy of the design of the nuclear facility.
  - 6(*h*), the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects.

Physical Design

The regulatory foundation for the recommendation(s) associated with physical design includes the following:

- Paragraph 3(1)(*d*) of the *General Nuclear Safety and Control Regulations* requires that an application for a licence shall contain a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
  - 3(*a*), a description of the site of the activity to be licensed, including the location of any exclusion zone and any structures within that zone;
  - 3(*b*), plans showing the location, perimeter, areas, structures and systems of the nuclear facility;
  - 6(*a*), a description of the structures at the nuclear facility, including their design and their design operating conditions;
  - 6(*b*), a description of the systems and equipment at the nuclear facility, including their design and their design operating conditions;
  - 6(*c*), a final safety analysis report demonstrating the adequacy of the design of the facility; and
  - 6(*d*), proposed measures, policies, methods and procedures for operating and maintaining the facility.

Fitness for Service

The regulatory foundation for the recommendation(s) associated with fitness for service includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraph:
  - 6(*d*), the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

Radiation Protection

The regulatory foundation for the recommendation(s) associated with radiation protection includes the following:

- The *General Nuclear Safety and Control Regulations* require, under subsection 3(1), that a licence application contain the following information under paragraphs:
  - 3(1)(*e*), the proposed measures to ensure compliance with the *Radiation Protection Regulations*.
  - 3(1)(*f*), any proposed action level for the purpose of section 6 of the *Radiation Protection Regulations*.
- The *Radiation Protection Regulations* require, under sections 4 to 6, that the licensee implement a radiation protection program, ascertain and record doses, and take the required actions in the case that an action level has been reached.
- The *Class I Nuclear Facilities Regulations* require that an application for a licence to operate a Class I nuclear facility shall contain, under paragraphs:
  - 6(*e*), the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.

- 6(*h*), the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measure that will be taken to prevent or mitigate those effects.

Conventional Health and Safety

The regulatory foundation for the recommendation(s) associated with Conventional Health and Safety includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(*f*), the proposed worker health and safety policies and procedures.
- BWXT Medical's activities and operations must comply with the *Canada Labour Code*, Part II: *Occupational Health and Safety*.

Environmental Protection

The regulatory foundation for the recommendation(s) associated with Environmental Protection includes the following:

- The *General Nuclear Safety and Control Regulations*, under paragraphs 12(1)(c) and (f), require that each licensee take all reasonable precautions to protect the environment and the health and safety of persons, and to control the release of radioactive nuclear substances and hazardous substances within the site of the licensed activity and into the environment.
- The *Radiation Protection Regulations* prescribe dose limits for the general public, which under Subsection 1(3) is 1 mSv per calendar year.
- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
  - 3(*e*), the name, form, characteristics and quantity of any hazardous substances that may be on the site while the activity to be licensed is carried on.
  - 3(*g*), the proposed environmental protection policies and procedures.
  - 3(*h*), the proposed effluent and environmental monitoring programs.
  - 6(*e*), the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.
  - 6(*h*), the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects.
  - 6*(i)*, the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics.
  - 6*(j)*, the proposed measures to control releases of nuclear substances and hazardous substances into the environment.

Emergency Management and Fire Protection

The regulatory foundation for the recommendation(s) associated with Emergency Management and Response includes the following:

- 12(1)(c) of the *General Nuclear Safety and Control Regulations* states that every licensee shall "take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security".
- 12(1)(f) of the *General Nuclear Safety and Control Regulations* states that every licensee shall "take all reasonable precautions to control the release of radioactive nuclear substances or hazardous substances within the site of the licensed activity and into the environment of the licensed activity".
- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraph:
  - 6(*k*) information on the licensee's proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security, including measures to:
    - Assist offsite authorities in planning and preparing to limit the effects of an accidental release;
    - Notify offsite authorities of an accidental release or the imminence of an accidental release;
    - Report information to offsite authorities during and after an accidental release;
    - Assist offsite authorities in dealing with the effects of an accidental release; and
    - Test the implementation of the measures to prevent or mitigate the effects of an accidental release.

Waste Management

The regulatory foundation for the recommendation(s) associated with Waste Management includes the following:

- The *General Nuclear Safety and Control Regulations* require that an application for a licence include, under paragraph:
  - 3(1)(*j*), the name, quantity, form and volume of any radioactive waste or hazardous waste that may result from the activity to be licensed, including waste that may be stored, managed, processed, or disposed of at the site of the activity to be licensed, and the proposed method for managing and disposing of that waste.

Security

The regulatory foundation for the recommendation(s) associated with Security includes the following:

- It is a requirement of all Class I licensees to comply with the *Nuclear Security Regulations*.

Safeguards and Non-Proliferation

The regulatory foundation for the recommendation(s) associated with Safeguards and Non-Proliferation includes the following:

- It is a requirement of the *General Nuclear Safety and Control Regulations* under paragraph 12(1)(i) that each licensee take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement, where the applicable agreements are:
  - The Agreement between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons.
  - The Protocol Additional to the Agreement between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons.

Packaging and Transport

The regulatory foundation for the recommendation(s) associated with Packaging and Transport includes the following:

- The *Packaging and Transport of Nuclear Substances Regulations, 2015*; and
- Transport Canada's *Transportation of Dangerous Goods Regulations*.

Decommissioning Strategy and Financial Guarantees

The regulatory foundation for the recommendation(s) associated with BWXT's Decommissioning Strategy and Financial Guarantees includes:

- The *General Nuclear Safety and Control Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(1)(*l*), a description of any proposed financial guarantee relating to the activity to be licensed.
- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(*k*), the proposed plan for the decommissioning of the nuclear facility or of the site.

Licensee's Public Information Program

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(*j*), information on the licensee's public information program.

Cost Recovery

- The *Nuclear Safety and Control Act* requires that, under paragraph:
  - 24(2)(*c*), a licence application be accompanied by the prescribed fee.

- The *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations* require that, under paragraph:
    - 7(1)(*a*), an initial application for a facility or activity for which an estimated annual fee has not been calculated, the applicant shall pay to the Commission, with the application, a deposit of $25,000, if the application is in respect of a facility.

A.2 DETAILED SUMMARY OF CNSC ASSESSMENT OF APPLICATION

CNSC staff's assessment of BWXT Medical's licence application included a completeness check, a sufficiency check, and a technical assessment against regulatory requirements. The completeness check verified whether the application included the prescribed information in accordance with the *Nuclear Safety and Control Act* and its regulations. The sufficiency check verified whether the application included sufficient and quality information in order for CNSC staff to conduct the technical assessment. The technical assessment verified whether the application included adequate safety and control measures to address CNSC requirements. Documents originally submitted as part of the application may have been revised, updated or replaced over the course of the assessment in order to address CNSC requirements.

Pursuant to Section 3 of the *General Nuclear Safety and Control Regulations* Licences – General Application Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(1) An application for a licence shall contain the following information:				
(a) the applicant's name and business address;	Attachment 1	Y	Y	Y
(b) the activity to be licensed and its purpose;	Attachment 1	Y	Y	Y
(c) the name, maximum quantity and form of any nuclear substance to be encompassed by the licence;	Attachment 1	Y	Y	Y
(d) a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence;	Attachment 1 Submission of Additional Information Related to BWXT ITG Canada, Inc. (BWXT ITG) Class 1B Licence Application	Y	Y	Y

Pursuant to Section 3 of the *General Nuclear Safety and Control Regulations* Licences – General Application Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(e) the proposed measures to ensure compliance with the *Radiation Protection Regulations*, the *Nuclear Security Regulations* and the *Packaging and Transport of Nuclear Substances Regulations, 2015;*	Attachment 1 BWXT ITG Response to CNSC Completeness Check, Appendix B (BWXT ITG Site Security Plan filed under separate cover)	Y	Y	Y
(f) any proposed action level for the purpose of section 6 of the *Radiation Protection Regulations*;	Attachment 1	Y	Y	Y
(g) the proposed measures to control access to the site of the activity to be licensed and the nuclear substance, prescribed equipment or prescribed information;	Attachment 1 BWXT ITG Response to CNSC Completeness Check, Appendix B (BWXT ITG Site Security Plan filed under separate cover)	Y	Y	Y
(h) the proposed measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information;	Attachment 1 BWXT ITG Response to CNSC Completeness Check, Appendix B (BWXT ITG Site Security Plan filed under separate cover)	Y	Y	Y
(i) a description and the results of any test, analysis or calculation performed to substantiate the information included in the application;	Attachment 1	Y	Y	Y

Pursuant to Section 3 of the *General Nuclear Safety and Control Regulations* Licences – General Application Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(j) the name, quantity, form, origin and volume of any radioactive waste or hazardous waste that may result from the activity to be licensed, including waste that may be stored, managed, processed or disposed of at the site of the activity to be licensed, and the proposed method for managing and disposing of that waste;	Attachment 1 BWXT ITG Response to CNSC Completeness Check, Appendix F	Y	Y	Y
(k) the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the *Act* and the regulations made under the *Act*, including the internal allocation of functions, responsibilities and authority;	Attachment 5 Organization charts for Regulatory, EHS and Compliance, and Senior Leadership Team	Y	Y	Y
(l) a description of any proposed financial guarantee relating to the activity to be licensed; and	Attachment 1 Submission of Additional Information Related to BWXT ITG Canada, Inc. (BWXT ITG) Class 1B Licence Application (SE-LIC-021[1], Preliminary Decommissioning Plan for BWXT ITG's Class 1B Facility)	Y	Y	Y

Pursuant to Section 3 of the *General Nuclear Safety and Control Regulations* Licences – General Application Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(m) any other information required by the *Act* or the regulations made under the *Act* for the activity to be licensed and the nuclear substance, nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.	As required	Y	Y	Y

Pursuant to Subsection 3(1.1) of the *General Nuclear Safety and Control Regulations* Other Information Requested by CNSC Staff	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(1.1) The Commission or a designated officer authorized under paragraph 37(2)(c) of the *Act* may require any other information that is necessary to enable the Commission or the designated officer to determine whether the applicant: (a) is qualified to carry on the activity to be licensed; or (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and	As required	Y	Y	Y

Pursuant to Subsection 3(1.1) of the *General Nuclear Safety and Control Regulations* Other Information Requested by CNSC Staff	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
measures required to implement international obligations to which Canada has agreed.				

Pursuant to Section 15 of the *General Nuclear Safety and Control Regulations* Obligations – Representatives of Applicants and Licensees	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
15 Every applicant for a licence and every licensee shall notify the Commission of:				
(a) the persons who have authority to act for them in their dealings with the Commission;	Attachment 1	Y	Y	Y
(b) the names and position titles of the persons who are responsible for the management and control of the licensed activity and the nuclear substance, nuclear facility, prescribed equipment or prescribed information encompassed by the licence; and	Attachment 1	Y	Y	Y
(c) any change in the information referred to in paragraphs (a) and (b), within 15 days after the change occurs.	As required	Y	Y	Y

Pursuant to Section 3 of the *Class I Nuclear Facilities Regulations* Licence Applications – General Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
3 An application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain the following information in addition to the information required by Section 3 of the *General Nuclear Safety and Control Regulations*:				
(a) a description of the site of the activity to be licensed, including the location of any exclusion zone and any structures within that zone;	Attachment 1	Y	Y	Y
(b) plans showing the location, perimeter, areas, structures and systems of the nuclear facility;	Attachment 1	Y	Y	Y
(c) evidence that the applicant is the owner of the site or has authority from the owner of the site to carry on the activity to be licensed;	Attachment 1 Attachment 6	Y	Y	Y
(d) the proposed management system for the activity to be licensed, including measures to promote and support safety culture;	Attachment 1 BWXT ITG Response to CNSC Completeness Check, Appendix B	Y	Y	Y
(d.1) the proposed human performance program for the activity to be licensed, including measures to ensure workers' fitness for duty;	Attachment 3	Y	Y	Y

Pursuant to Section 3 of the *Class I Nuclear Facilities Regulations* Licence Applications – General Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(e) the name, form, characteristics and quantity of any hazardous substances that may be on the site while the activity to be licensed is carried on;	Attachment 1 BWXT ITG Response to CNSC Completeness Check, Appendix E	Y	Y	Y
(f) the proposed worker health and safety policies and procedures;	Attachment 1	Y	Y	Y
(g) the proposed environmental protection policies and procedures;	Attachment 1	Y	Y	Y
(h) the proposed effluent and environmental monitoring programs;	Attachment 1	Y	Y	Y
(i) if the application is in respect of a nuclear facility referred to in paragraph 2(*b*) of the *Nuclear Security Regulations*, the information required by section 3 of those Regulations;	Not applicable	Y	Y	Y
(j) the proposed program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the activity to be licensed; and	Attachment 1	Y	Y	Y
(k) the proposed plan for the decommissioning of the nuclear facility or of the site.	Submission of Additional Information Related to BWXT ITG Canada, Inc. (BWXT ITG) Class 1B Licence	Y	Y	Y

Pursuant to Section 3 of the *Class I Nuclear Facilities Regulations* Licence Applications – General Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
	Application			

Pursuant to Section 6 of the *Class I Nuclear Facilities Regulations* Licence Applications – Licence to Operate	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
6 An application for a licence to operate a Class I nuclear facility shall contain the following information in addition to the information required by section 3:				
(a) a description of the structures at the nuclear facility, including their design and their design operating conditions;	Attachment 1	Y	Y	Y
(b) a description of the systems and equipment at the nuclear facility, including their design and their design operating conditions;	Attachment 1	Y	Y	Y
(c) a final safety analysis report demonstrating the adequacy of the design of the nuclear facility;	Attachment 1	Y	Y	Y
(d) the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility;	Attachment 1	Y	Y	Y
(e) the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances;	Attachment 1	Y	Y	Y

Pursuant to Section 6 of the *Class I Nuclear Facilities Regulations* Licence Applications – Licence to Operate	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(f) the proposed measures to facilitate Canada's compliance with any applicable safeguards agreement;	Attachment 1	Y	Y	Y
(g) the proposed commissioning program for the systems and equipment that will be used at the nuclear facility;	Attachment 1	Y	Y	Y
(h) the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;	Attachment 1	Y	Y	Y
(i) the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics;	Attachment 1	Y	Y	Y
(j) the proposed measures to control releases of nuclear substances and hazardous substances into the environment;	Attachment 1	Y	Y	Y

Pursuant to Section 6 of the *Class I Nuclear Facilities Regulations* Licence Applications – Licence to Operate	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(k) the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security, including measures to: (i) assist off-site authorities in planning and preparing to limit the effects of an accidental release; (ii) notify off-site authorities of an accidental release or the imminence of an accidental release; (iii) report information to off-site authorities during and after an accidental release; (iv) assist off-site authorities in dealing with the effects of an accidental release; and (v) test the implementation of the measures to prevent or mitigate the effects of an accidental release.	Attachment 1	Y	Y	Y

Pursuant to Section 6 of the *Class I Nuclear Facilities Regulations* Licence Applications – Licence to Operate	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(l) the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts;	Attachment 1 BWXT ITG Response to CNSC Completeness Check, Appendix B (BWXT ITG Site Security Plan filed under separate cover)	Y	Y	Y
(m) the proposed responsibilities of and qualification requirements and training program for workers, including the procedures for the requalification of workers; and	Attachment 1	Y	Y	Y
(n) the results that have been achieved in implementing the program for recruiting, training and qualifying workers in respect of the operation and maintenance of the nuclear facility.	Attachment 1	Y	Y	Y

Pursuant to Section 3 of the *Nuclear Substances and Radiation Devices Regulations*: Licence Applications – General Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**

Pursuant to Section 3 of the *Nuclear Substances and Radiation Devices Regulations*: Licence Applications – General Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
3(1) An application for a licence in respect of a nuclear substance or a radiation device, other than a licence to service a radiation device, shall contain the following information in addition to the information required by section 3 of the *General Nuclear Safety and Control Regulations*:				
(a) the methods, procedures and equipment that will be used to carry on the activity to be licensed;	Attachment 1 IS/SR 1070 Z000 [7], Final Safety Analysis Report for the Nuclear Medicine Production Facility	Y	Y	Y
(b) the methods, procedures and equipment that will be used while carrying on the activity to be licensed, or during and following an accident, to:				
(i) monitor the release of any radioactive nuclear substance from the site of the activity to be licensed;	Attachment 1	Y	Y	Y
(ii) detect the presence of and record the radiation dose rate and quantity in becquerels of radioactive nuclear substances at the site of the activity to be licensed;	Attachment 1	Y	Y	Y

Pursuant to Section 3 of the *Nuclear Substances and Radiation Devices Regulations*: Licence Applications – General Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(iii) limit the spread of radioactive contamination within and from the site of the activity to be licensed; and	Attachment 1	Y	Y	Y
(iv) decontaminate any person, site or equipment contaminated as a result of the activity to be licensed.	Attachment 1	Y	Y	Y
(c) a description of the circumstances in which the decontamination referred to in subparagraph (b)(iv) will be carried out;	Attachment 1	Y	Y	Y
(d) the proposed location of the activity to be licensed, including a description of the site;	Attachment 1	Y	Y	Y
(e) the roles, responsibilities, duties, qualifications and experience of workers;	Attachment 1	Y	Y	Y
(f) the proposed training program for workers;	Attachment 1	Y	Y	Y
(g) the proposed instructions for dealing with accidents, including fires and spills, in which the nuclear substance may be involved;	Attachment 1	Y	Y	Y
(h) the proposed inspection program for the equipment and systems that will be used to carry on the activity to be licensed;	Attachment 1	Y	Y	Y

Pursuant to Section 3 of the *Nuclear Substances and Radiation Devices Regulations*: Licence Applications – General Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(i) the methods, procedures and equipment that will be used to calibrate radiation survey meters in accordance with these Regulations;	Attachment 1	Y	Y	Y
(j) the methods, procedures and equipment that will be used to calibrate and verify the calibration of dosimeters referred to in paragraphs 30(3)(d) and (e);	Attachment 1	Y	Y	Y
(k) the methods, procedures and equipment that will be used to conduct the leak tests and surveys required by these Regulations;	Attachment 1	Y	Y	Y
(l) where the application is in respect of a nuclear substance that is an unsealed source and that is to be used in a room, the proposed design of the room;	Attachment 1	Y	Y	Y
(m) if the application is in respect of a nuclear substance that is contained in a radiation device, the brand name and model number of the radiation device, and the quantity of the devices;	Not applicable	-	-	-
(n) where the application is in respect of Category I, II or III nuclear material, as defined in section 1 of the *Nuclear Security Regulations*:	Not applicable	-	-	-

Pursuant to Section 3 of the *Nuclear Substances and Radiation Devices Regulations*: Licence Applications – General Requirements	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(i) the measures that will be taken to prevent nuclear criticality; and	Not applicable	-	-	-
(ii) the information required by section 3 or 4 of the *Nuclear Security Regulations*, as applicable.	Not applicable	-	-	-
(o) if the applicant will be manufacturing or distributing radiation devices referred to in paragraph 5(1)(c) or section 6 or 7, or check sources mentioned in section 8.1, the proposed procedure for the disposal of each radiation device or check source or for its return to the manufacturer.	Not applicable	-	-	-

Pursuant to Part 2 of the *Nuclear Security Regulations*: PART 2 SECURITY OF NUCLEAR FACILITIES LISTED IN SCHEDULE 2 – LICENCE APPLICATIONS	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
41 An application for a licence in respect of a nuclear facility shall contain, in addition to the information required by sections 3 to 8 of the *Class I Nuclear Facilities Regulations*, a description of the physical protection measures to be taken to ensure compliance with sections 42 to 48.	Attachment 1 BWXT ITG Response to CNSC Completeness Check, Appendix A (BWXT ITG Site Security Plan filed under separate cover)	Y	Y	Y

Pursuant to the *Radiation Protection Regulations*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
4 Every licensee shall implement a radiation protection program and shall, as part of that program: (a) keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as is reasonably achievable, social and economic factors being taken into account, through the implementation of:	Attachment 1.	Y	Y	Y
(i) management control over work practices;	Attachment 1	Y	Y	Y

Pursuant to the *Radiation Protection Regulations*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(ii) personnel qualification and training;	Attachment 1	Y	Y	Y
(iii) control of occupational and public exposure to radiation; and	Attachment 1	Y	Y	Y
(iv) planning for unusual situations.	Attachment 1	Y	Y	Y
(b) ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity: (i) by direct measurement as a result of monitoring; or (ii) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the quantity and concentration using that method, by estimating them.	Attachment 1	Y	Y	Y

Pursuant to the *Radiation Protection Regulations*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
5(1) For the purpose of keeping a record of doses of radiation in accordance with section 27 of the Act, every licensee shall ascertain and record the magnitude of exposure to radon progeny of each person referred to in that section, as well as the effective dose and equivalent dose received by and committed to that person.	SE-RP-004[10], External Personal Radiation Monitoring	Y	Y	Y
5(2) A licensee shall ascertain the magnitude of exposure to radon progeny and the effective dose and equivalent dose: (a) by direct measurement as a result of monitoring; or (b) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the amount of exposure and doses using that method, by estimating them.	SE-RP-004[10], External Personal Radiation Monitoring	Y	Y	Y

Pursuant to the *Radiation Protection Regulations*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
6(1) In this section, action level means a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program and triggers a requirement for specific action to be taken.	Attachment 1 SE-RP-001[9], Radiation Protection Manual - Ottawa Site SE-RP-002[7], Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)"	Y	Y	Y
6(2) When a licensee becomes aware that an action level referred to in the licence for the purpose of this subsection has been reached, the licensee shall: (a) conduct an investigation to establish the cause for reaching the action level; (b) identify and take action to restore the effectiveness of the radiation protection program implemented in accordance with section 4; and (c) notify the Commission within the period specified in the licence.	Attachment 3 SE-RP-001[9], Radiation Protection Manual - Ottawa Site SE-RP-002[7], Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)"	Y	Y	Y
7(1) Every licensee shall inform each nuclear energy worker, in writing: (a) that he or she is a nuclear energy worker;	Attachment 1	Y	Y	Y

Pursuant to the *Radiation Protection Regulations*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
(b) of the risks associated with radiation to which the worker may be exposed in the course of his or her work, including the risks associated with the exposure of embryos and foetuses to radiation;	Attachment 1	Y	Y	Y
(c) of the applicable effective dose limits and equivalent dose limits prescribed by sections 13, 14 and 15; and	Attachment 1	Y	Y	Y
(d) of the worker's radiation dose levels.	SE-RP-004[10], External Personal Radiation Monitoring	Y	Y	Y
8 Every licensee shall use a licensed dosimetry service to measure and monitor the doses of radiation received by and committed to nuclear energy workers who have a reasonable probability of receiving an effective dose greater than 5 mSv in a one-year dosimetry period.	SE-RP-001[9], Radiation Protection Manual - Ottawa Site	Y	Y	Y
13(1) Every licensee shall ensure that the effective dose received by and committed to a person described in column 1 of an item of the table to this subsection, during the period set out in column 2 of that item, does not exceed the effective dose set out in column 3 of that item.	Attachment 1	Y	Y	Y

Pursuant to the *Radiation Protection Regulations*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
14(1) Every licensee shall ensure that the equivalent dose received by and committed to an organ or tissue set out in column 1 of an item of the table to this subsection, of a person described in column 2 of that item, during the period set out in column 3 of that item, does not exceed the equivalent dose set out in column 4 of that item.	Attachment 1	Y	Y	Y
20(1) No person shall possess a container or device that contains a radioactive nuclear substance unless the container or device is labelled with: (a) the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT — DANGER — RADIATION"; and (b) the name, quantity, date of measurement and form of the nuclear substance in the container or device.	Attachment 1	Y	Y	Y

Pursuant to the *Radiation Protection Regulations*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
21 Every licensee shall post and keep posted, at the boundary of and at every point of access to an area, room or enclosure, a durable and legible sign that bears the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT-DANGER-RADIATION", if: (a) there is a radioactive nuclear substance in a quantity greater than 100 times its exemption quantity in the area, room or enclosure; or (b) there is a reasonable probability that a person in the area, room or enclosure will be exposed to an effective dose rate greater than 25 µSv/h.	Attachment 1	Y	Y	Y

Pursuant to the *Radiation Protection Regulations*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
22 Whenever the radiation warning symbol set out in Schedule 3 is used: (a) it shall be: (i) fully visible; (ii) of a size appropriate for the size of the container or device to which it is affixed or attached, or the area, room or enclosure in respect of which it is posted; (iii) in the proportions depicted in Schedule 3; and (iv) oriented with one blade pointed downward and centred on the vertical axis. (b) no wording shall be superimposed on it.	Attachment 1	Y	Y	Y

Pursuant to the *Packaging and Transport of Nuclear Substances Regulations, 2015*	**Location in Application or Supporting Document(s) as Noted by BWXT Medical**	**Complete?**	**Sufficient?**	**Adequate?**
Compliance of the licensee programs and procedures to these regulations	Attachment 1	Y	Y	Y

Pursuant to the *Nuclear Non-proliferation Import and Export Control Regulations*	Location in Application or Supporting Document(s) as Noted by BWXT Medical	Complete?	Sufficient?	Adequate?
Compliance of the licensee programs and procedures to these regulations.	Attachment 1	Y	Y	Y

A.3 TECHNICAL BASIS

The technical basis for the recommendations presented in this CMD are listed in the table below.

BWXT Medical - Applicable Standards and Codes per Safety and Control Area

SCA	Document Title	Sufficient?	Adequate?
Management System	CSA N286-12 (reaffirmed 2017): *Management System Requirements for Nuclear Facilities*	Y	Y
	CNSC REGDOC-2.1.2 (2018): *Safety Culture*	Y	Y
Human Performance Management	CNSC REGDOC-2.2.2 (2016): *Personnel Training, Version 2*	Y	Y
	CNSC REGDOC-2.2.5 (2019): Minimum Staff Complement [Formerly CNSC G-323 (2007): *Ensuring the Presence of Sufficient Qualified Staff at Class I Nuclear Facilities - Minimum Staff Complement*]	Y	Y
Operating Performance	CSA N286-12 (R2017): *Management System Requirements for Nuclear Facilities*	Y	Y
	CNSC REGDOC-3.1.2 (2018): *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills*	Y	Y
	CSA N393-13 (R2018): *Fire Protection for facilities that process, store and handle nuclear substances*	Y	Y
Safety Analysis	IAEA NS-R-5: *Safety of Nuclear Fuel Cycle Facilities* (guidance)	Y	Y
	CSA N286-12 (R2017): *Management System Requirements for Nuclear Facilities*	Y	Y
	CSA N393-13 (R2018): *Fire Protection for facilities that process, store and handle nuclear substances*	Y	Y
Physical	CSA B51-14 (2014): *Boiler Pressure Vessel and*	Y	Y

SCA	Document Title	Sufficient?	Adequate?
Design	*Pressure Piping Code*		
	CSA N286-12 (R2017): *Management System Requirements for Nuclear Facilities*	Y	Y
	CSA N393-13 (R2018): *Fire Protection for facilities that process, store and handle nuclear substances*	Y	Y
	NBC-2015 (2015): *National Building Code of Canada*	Y	Y
	NFC-2015 (2015): *National Fire Code of Canada*	Y	Y
Fitness for Service	CSA B51-14 (2014): *Boiler Pressure Vessel and Pressure Piping Code*	Y	Y
	CSA N286-12 (R2017): *Management System Requirements for Nuclear Facilities*	Y	Y
	NBC-2015 (2015): *National Building Code of Canada*	Y	Y
	NFC-2015 (2015): *National Fire Code of Canada*	Y	Y
Radiation Protection	CNSC G-129 Rev 1 (2004): *Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA)"*	Y	Y
	CNSC G-91 (2003): *Ascertaining and recording radiation doses to individuals*	Y	Y
	CNSC G-228 (2001): *Developing and Using Action Levels*	Y	Y
	CNSC S-260 (2004): *Making changes to dose related information filed with the national dose registry*	Y	Y
Conventional Health and Safety	*Canada Labour Code - Part II* and associated regulations	Y	Y
	CSA Z94.4 (2011), *Selection, Use and Care of Respirators*	Y	Y
Environmental Protection	CNSC REGDOC-2.9.1 (2017): *Environmental Protection: Environmental Principles, Assessments and Protection Measures*, version 1.1	Y	Y
	CSA N288.6-12 (2012): *Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills*	Y	Y
	CSA N288.4-10 (2010): *Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*	Y	Y
	CSA N288.5-11 (2011): *Effluent Monitoring*	Y	Y

SCA	Document Title	Sufficient?	Adequate?
	Programs at Class I Nuclear Facilities and Uranium Mines and Mills		
	CSA N288.1 (2014): *Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities*	Y	Y
	CSA N288.8-17 (2017): *Establishing and implementing action levels for releases to the environment from nuclear facilities*	Y	Y
	ISO 14001:2015 (2015), Environmental management systems — Requirements with guidance for use	Y	Y
Emergency Management and Fire Protection	CNSC REGDOC-2.10.1 (2016): *Nuclear Emergency Preparedness and Response*	Y	Y
	CSA N393-13 (R2018): *Fire Protection for facilities that process, handle or store nuclear substances*	Y	Y
	NBC-2015 (2015): *National Building Code of Canada*	Y	Y
	NFC-2015 (2015): *National Fire Code of Canada*	Y	Y
Waste Management	REGDOC-2.11.1 (2018): *Waste Management, Volume II: Assessing the Long Term Safety of Radioactive Waste Management*	Y	Y
	CSA N294-09 (2009): *Decommissioning of Facilities Containing Nuclear Substances*	Y	Y
	CNSC G-219 (2000): *Decommissioning Planning for Licensed Activities*	Y	Y
	CSA N292.0-14 (2014): *General Principles for the Management of Radioactive Waste and Irradiated Fuel*	Y	Y
	CSA N292.3-14 (2014): *Management of Low- and Intermediate –level Radioactive Waste*	Y	Y
Security	CNSC REGDOC-2.12.3 (2013): *Security of Nuclear Substances: Sealed Sources*	Y	Y
Safeguards	CNSC REGDOC-2.13.1 (2018): *Safeguards and Nuclear Material Accountancy*	Y	Y
	CNSC REGDOC-2.13.2 (2018): *Import and Export Version 2*	Y	Y
Packaging and Transport	REGDOC-2.14.1 (2016): *Information Incorporated by Reference in Canada's Packaging and Transport of Nuclear Substances Regulations, 2015*	Y	Y

SCA	Document Title	Sufficient?	Adequate?
	IAEA Regulation*: Regulations for the Safe Transport of Radioactive Material (2012)*	Y	Y
Public Information Program	CNSC REGDOC-3.2.1 (2018): *Public Information and Disclosure*	Y	Y
Aboriginal Consultation	REGDOC-3.2.2 (2016): *Aboriginal Engagement* (guidance)	Y	Y
Financial Guarantee	CNSC G-206 (2000): *Financial Guarantees Guide for the Decommissioning of Licensed Activities*	Y	Y

B. SAFETY AND CONTROL AREA FRAMEWORK

B.1 SAFETY AND CONTROL AREAS DEFINED

The safety and control areas identified in section 2.2, and discussed in summary in sections 3.1 through 3.14 are comprised of specific areas of regulatory interest which vary between facility types.

The following table provides a high-level definition of each SCA. The specific areas within each SCA are to be identified by the CMD preparation team in the respective areas within section 3 of this CMD

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

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

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

B.2 SPECIFIC AREAS FOR THIS FACILITY TYPE

The following table identifies the specific areas that comprise each SCA for BWXT Medical:

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
Management	Management System	▪ Management System ▪ Organization ▪ Performance Assessment, Improvement and Management Review ▪ Operating Experience (OPEX) ▪ Change Management ▪ Safety Culture ▪ Configuration Management ▪ Records Management ▪ Management of Contractors ▪ Business Continuity
	Human Performance Management	▪ Human Performance Program; ▪ Work Organization and Job Design; ▪ Fitness for Duty; and ▪ Personnel Training
	Operating Performance	▪ Conduct of Licensed Activity ▪ Procedures ▪ Reporting and Trending
Facility and Equipment	Safety Analysis	▪ Deterministic Safety Analysis ▪ Hazard Analysis
	Physical Design	▪ Design Governance ▪ Facility Design
	Fitness for Service	▪ Equipment Fitness for Service/Equipment Performance ▪ Maintenance
Core Control Processes	Radiation Protection	▪ Application of ALARA ▪ Worker Dose Control ▪ Radiation Protection Program Performance ▪ Radiological Hazard Control ▪ Estimated Dose to Public

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
	Conventional Health and Safety	▪ Performance ▪ Practices ▪ Awareness
	Environmental Protection	▪ Effluent and Emissions Control (releases) ▪ Environmental Management System (EMS) ▪ Assessment and Monitoring ▪ Protection to the Public ▪ Environmental Risk Assessment
	Emergency Management and Fire Protection	▪ Conventional Emergency Preparedness and Response ▪ Nuclear Emergency Preparedness and Response ▪ Fire Emergency Preparedness and Response
	Waste Management	▪ Waste Characterization ▪ Waste Minimization ▪ Waste Management Practices ▪ Decommissioning Plans
	Security	▪ Facilities and Equipment ▪ Response Arrangements ▪ Security Practices
	Safeguards and Non-Proliferation	▪ Nuclear Material Accountancy and Control ▪ Access and Assistance to the IAEA ▪ Operational and Design Information ▪ Import and Export
	Packaging and Transport	▪ Package Design and Maintenance ▪ Packaging and Transport ▪ Registration for Use

C. SUPPORTING DETAILS

C.1 ENVIRONMENTAL PROTECTION

The following tables shows the environmental releases over the current licence period for the Nordion Class IB facility, including the NMPF. These releases are well below release limits. As shown in the tables, new DRLs were implemented in 2018. The DRLs were established in accordance with CSA N288.1-14: *Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities.*

The releases associated with the NMPF include Beta emitters, radioiodines, radioxenons, Molybdenum-99, and Cobalt-60 (a waste impurity). The releases associated with the Cobalt Operations Facility (COF) include Cobalt-60, Niobium-95, Zirconium-95, and Cesium-137.

Table C.1: Air emissions monitoring results, 2015-19

Year	Co-60 (GBq/yr)	I-125 (GBq/yr)	I-131 (GBq/yr.)	Xe-133 (GBq/yr)	Xe-135* (GBq/yr)	Xe-135m* (GBq/yr)
DRL	**70.1**	**4,880**	**3,790**	**61,200,000**	**7,660,000**	**4,600,000**
2015	0.005	0.12	0.15	11,916	8,237	10,758
2016	0.006	0.21	0.35	7,277	4,299	5,421
2017	0.0034	0.0012	0.0008	0	0	0
DRL	**2.50E+02**	**9.52E+02**	**6.86E+02**	**6.77E+08**	**1.02E+08**	**6.90E+07**
2018	0.002	0	0.006	0	0	0
2019	0.00002	0	0	0	0	0

Table C.2: Liquid effluent monitoring results for release to sewer, 2015-19

	Parameter (GBq/yr)								
Year	Beta emitters <1MeV	Beta emitters >1MeV	Iodine-125	Iodine-131	Molybdenum-99	Cobalt-60	Niobium-95	Zirconium-95	Cesium-137
DRL	**66,000**	**210,000**	**73,600**	**23,300**	**1,120,000**	**155,000**	**558,000**	**749,000**	**137,000**
2015	0.191	0.044	0.111	0.006	0.060	0.019	0.0010	0.0010	0.0004
2016	0.222	0.051	0.144	0.006	0.052	0.026	0.0010	0.0015	0.0007
2017	0.212	0.048	0.145	0.006	0.049	0.022	0.0010	0.0020	0.0007
DRL	**763**	**35,000**	**1,190**	**389**	**10,200**	**35.4**	**3,250**	**2,060**	**24.8**
2018	0.243	0.055	0.146	0.007	0.055	0.027	0.0010	0.0017	0.0007
2019	0.162	0.038	0.063	0.004	0.036	0.020	0.002	0.0019	0.0007

Note: Production of Mo-99, I-125, I-131 and Xe-133 ceased in November of 2016.

PART TWO

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

1. Proposed licence; and
2. Proposed licence conditions handbook

PROPOSED LICENCE

Overview

BWXT Medical is a new applicant and would be issued its first licence. A proposed licence is provided on the following pages of the document. The proposed licence incorporates standardized licence conditions in a standard format.

Licence Conditions

The proposed licence incorporates the standardized licence conditions applicable to BWXT Medical as a nuclear substance processing facility, as developed by CNSC staff. The proposed licence for BWXT will contain conditions that authorize changes within the licensing basis as defined in CNSC's information document REGDOC-3.5.3, *Regulatory Fundamentals* [42], and reflects the current licensing framework.

Licence Format

The proposed licence uses the standard format applicable to BWXT Medical.

Licence Period

BWXT Medical has requested a licence period of 10 years. Based on CNSC staff review of BWXT Medical's application and supporting information, CNSC staff recommend that the Commission accept BWXT Medical's request for a licence period of 10 years. Over the proposed 10-year period, CNSC staff would provide reporting on regulatory oversight conducted at BWXT Medical in public Commission proceedings.

Proposed Licence:

e-Doc 6438142 (Word)

e-Doc 6505031 (PDF)

PDF Ref: e-Doc 6505031
Word Ref: e-Doc 6438142
File / dossier: 2.02

CLASS IB NUCLEAR SUBSTANCE PROCESSING FACILITY LICENCE

BWXT MEDICAL LTD.

I) LICENCE NUMBER: **NSPFL-15.00/2031**

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act*, this licence is issued to:

BWXT Medical Ltd.
002599290
447 March Road
Ottawa, Ontario
K2K 1X8

III) LICENCE PERIOD: This licence is valid from **November 1, 2021** to **October 31, 2031**, unless otherwise suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(i) operate the BWXT Medical Ltd. Nuclear Substance Processing Facility, at the location referred to in Section II of this licence (hereinafter "the processing facility"), for the purpose of processing and manufacturing nuclear substances used in health sciences;

(ii) possess, transfer, use, process, import, manage, store or dispose of nuclear substances and sealed sources that are required for, associated with, or arise from the activities described in (i);

(iii) possess, transfer, use, or import prescribed equipment that is required for, associated with, or arise from the activity described in (i);

(iv) possess and use prescribed information that is required for, associated with, or arise from the activity described in (i).

V) EXPLANATORY NOTES:

i) Nothing in this licence shall be construed to authorize non-compliance with any other applicable legal obligation or restriction.

ii) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* and associated Regulations.

iii) The BWXT Medical Ltd. Licence Conditions Handbook (LCH) provides compliance verification criteria used to verify compliance with the conditions set out in this licence, information regarding delegation of authority and applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria.

VI) CONDITIONS:

The licensee shall comply with the following conditions, established pursuant to subsection 24(5) of the *Nuclear Safety and Control Act*.

G. General

G.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

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

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

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

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

G.2 The licensee shall give written notification of changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.

G.3 The licensee shall implement and maintain a financial guarantee for decommissioning that is acceptable to the Commission.

G.4 The licensee shall implement and maintain a public information and disclosure program.

1. Management System

1.1 The licensee shall implement and maintain a management system.

2. Human Performance Management

2.1 The licensee shall implement and maintain a training program.

3. Operating Performance

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

3.2 The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.

4. Safety Analysis

4.1 The licensee shall implement and maintain a safety analysis program.

5. Physical Design

5.1 The licensee shall implement and maintain a design program.

6. Fitness For Service

6.1 The licensee shall implement and maintain a fitness for service program.

7. Radiation Protection

7.1 The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

8. Conventional Health And Safety

8.1 The licensee shall implement and maintain a conventional health and safety program.

9. Environmental Protection

9.1 The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

10. Emergency Management And Fire Protection

10.1 The licensee shall implement and maintain an emergency preparedness program.

10.2 The licensee shall implement and maintain a fire protection program.

11. Waste Management

11.1 The licensee shall implement and maintain a waste management program.

11.2 The licensee shall maintain a decommissioning plan.

12. Security

12.1 The licensee shall implement and maintain a security program.

13. Safeguards

13.1 The licensee shall implement and maintain a safeguards program.

14. Packaging And Transport

14.1 The licensee shall implement and maintain a packaging and transport program.

SIGNED at OTTAWA, this day of Month 2021

Rumina Velshi, President,
on behalf of the Canadian Nuclear Safety Commission

PROPOSED LICENCE CONDITIONS HANDBOOK

Overview

The licence conditions handbook (LCH) associated with the licence provides compliance verification criteria used by CNSC staff to determine whether the conditions of the licence have been met. Additionally, the LCH includes information such as applicable standards and/or regulatory documents, regulatory interpretation, references to relevant licensee documents and guidance. This structure allows more freedom for the licensee to improve and update its documentation within the licensing basis.

Proposed LCH:

e-Doc 6442566 (Word)

e-Doc 6505047 (PDF)

Canada's Nuclear Regulator

e-Doc 6442566 (Word)
e-Doc 6505047 (PDF)

LICENCE CONDITIONS HANDBOOK

LCH- NSPFL-15.00/2031

BWXT MEDICAL LTD.

Nuclear Substance Processing Facility Licence (NSPFL)

NSPFL-15.00/2031

Revision 0

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canada

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Licence Conditions Handbook **Effective:**

LCH-NSPF-15.00/2031

BWXT Medical Ltd.

Nuclear Substance Processing Facility Licence (NSPFL)

NSPFL-15.00/2031

SIGNED at OTTAWA this _____ day of _____ 2021

, Director
Nuclear Processing Facilities Division
Directorate of Nuclear Cycle and Facilities Regulation
Canadian Nuclear Safety Commission

Revision History:

Effective Date	Rev. #	LCH e-Doc #	Section(s) changed	Description of the Changes	Document Change Record
	0			Original document	N/A

Table of Contents

PART I: INTRODUCTION

The purpose of the licence conditions handbook (LCH) is to identify the regulatory requirements and other relevant parts of the licensing basis to help ensure that the licensee maintains facility operation in accordance with the licensing basis for the facility and the BWXT Medical Ltd. (BWXT Medical) Nuclear Substance Processing Facility Licence, NSPFL-15.00/2031. The LCH provides compliance verification criteria for conditions set out in the licence. The criteria are written in mandatory language.

1. BACKGROUND

1.1 Objective

This LCH identifies criteria that will be used by Canadian Nuclear Safety Commission (CNSC) staff to assess licensee compliance with the licence conditions (LCs) listed in licence NSPFL-15.00/2031. The LCH does not introduce new requirements but provides explanation on how to meet licence conditions and regulatory requirements. The LCH should be read in conjunction with the licence. The LCH contains applicable versions of documents referenced in the licence. It also provides dispute resolution.

The compliance framework for each licence condition consists of:

- a statement of the safety and control area, where applicable;
- a statement of the corresponding licence condition;
- a preamble; and
- compliance verification criteria for that licence condition.

In addition, a section for guidance is also provided for each licence condition.

Several appendices are attached to the LCH. They provide detailed criteria and clarifications where needed, and are integral and mandatory parts of the LCH. A short description of the appendices attached to the BWXT Medical LCH is provided below.

Appendix A: provides information on the control of the LCH and includes the LCH Change Request Form.

Appendix B: provides a glossary of terms used throughout the LCH.

Appendix C: provides a list of licensing documents relevant for BWXT Medical Ltd. The information regarding editions (revisions) of codes, standards, licensee, and CNSC documents is maintained in an Excel spreadsheet. For convenience of maintenance and updating of the BWXT Medical Ltd. LCH, and unless the context requires otherwise, these documents are referenced in the applicable criteria throughout the LCH without specifying their revisions.

Appendix D: provides a list of documents used as criteria or guidance.

2. DESCRIPTION OF THE SECTIONS IN THE NSPFL

2.1 Section I: Licence Number

The alpha numeric expression NSPFL-15.00/2031 stems from the CNSC standard convention for identifying licences. The following table provides a description of each identifier used in the expression:

Identifier	Description
NSPFL	Nuclear Substance Processing Facility Licence
15	Refers to facility name (15 = BWXT Medical Ltd.)
00	Licence version number (00 = Initial licence, 01 = Amendment No. 1, etc.)
2031	Expiration year

2.2 Section II: Licensee

This section of the licence provides the name and the address of the corporate entity that holds the licence, which is referred hereinafter as the “licensee”. The licensee is:

BWXT Medical Ltd.
002599290
447 March Road
Ottawa, Ontario
K2K 1X8

2.3 Section III: Licence Period

Identifies the duration for which the licence is valid, which in this case, for NSPFL-15.00/2031, is from November 1, 2021 to October 31, 2031 unless suspended, amended, revoked, replaced, or transferred during the licensing period.

2.4 Section IV: Licensed Activities

The licence identifies the activities that are being licensed. The box below contains a copy of the text in the licence. The authorized activities are from the list of activities described in section 26 of the *Nuclear Safety and Control Act* (NSCA).

Licensed Activities

This licence authorizes the licensee to:

a) **operate the BWXT Medical Ltd. Nuclear Substance Processing Facility, at the location referred to in Section II of this licence (hereinafter "the processing facility"), for the purpose of processing and manufacturing nuclear substances used in health sciences;**

b) **possess, transfer, use, process, import, manage, store, or dispose of nuclear substances and sealed sources that are required for, associated with, or arise from the activity described in a);**

c) **possess, transfer, use, or import prescribed equipment that are required for, associated with, or arise from the activity described in a);**

d) **possess and use prescribed information that is required for, associated with, or arise from the activity described in a).**

BWXT Medical Ltd. operates its facility to process and manufacture nuclear substances for medical purposes.

Facility Description: The location of the BWXT Medical Facility, at 447 March Rd, Ottawa, Ontario, is further defined in BWXT Medical document SE-LIC-018, "Facility Description".

2.5 Section V: Explanatory Notes

This section provides clarification of the licence and introduces the LCH as a compliance tool.

2.6 Section VI: Conditions

This section of the licence lists the LCs.

PART II: FRAMEWORK FOR EACH CONDITION

This section of the LCH provides additional information for each LC including information on the requirements and guidance for meeting each LC. The LCH also provides references to licensee documents submitted to meet the requirements and the compliance verification criteria (CVC) that will be used to verify that the condition is being met and to measure performance.

The information for each LC or group of conditions is organized in the following manner.

Preamble: Provides regulatory context related to the licence condition and provides where applicable, reference to related information including the related regulatory requirements contained in the NSCA and its associated Regulations.

Compliance Verification Criteria: This section identifies the compliance verification criteria or the sources from which the CNSC develops compliance verification criteria. Applicable standards such as Canadian Standards Association (CSA) standards, national codes and guidelines, and/or CNSC regulatory documents are identified. Implementation of programs will be assessed through the CNSC's compliance program and will be measured against performance objectives and regulatory expectations.

The documents that are used to assess compliance with LCs are identified in this section. Compliance verification will be conducted against documents referenced within this LCH. Current versions of documents are tracked and can be accessed through the document "BWXT Medical Ltd. Written Notice Tracking Sheet" e-Doc 6445457. This document is controlled by the CNSC's Nuclear Processing Facilities Division (NPFD).

Guidance: Guidance is non-mandatory. This section identifies CNSC documents and other documents that provide guidance associated with protection of the environment, health and safety, and other conditions of the NSCA and its associated Regulations. As guidance is non-mandatory, licensees may propose alternate ways to meet the licence condition.

1 GENERAL LICENCE CONDITIONS

G.1 Licensing Basis

Licence Condition G.1

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

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

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

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

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

Preamble

The licensing basis is discussed in CNSC REGDOC 3.5.3.

Compliance Verification Criteria

Part (i) of the licensing basis includes the NSCA and its associated Regulations, and the Canada/International Atomic Energy Agency (IAEA) Safeguards Agreement. The other applicable laws and regulations include but are not limited to:

- *Canadian Environmental Assessment Act, 2012*
- *Canadian Environment Protection Act, 1999*
- *Transportation of Dangerous Goods Act, 1992*
- *Radiation Emitting Devices Act*
- *Access to Information Act*
- *National Building Code of Canada*
- *National Fire Code of Canada*
- *Canada Labour Code Part II*

Part ii) of the licensing basis includes the conditions and safety and control measures described in the licence and the documents directly referenced in the licence.

Part iii) of the licensing basis consists of the safety and control measures described in the licence application and the documents needed to support that licence application. This does not mean that all details in those documents are part of the licensing basis; some of these documents may contain administrative elements, which are excluded from the licensing basis.

The safety and control measures include important aspects of analysis, design, operation, etc. They may be found in high-level, programmatic licensee documents but might also be found in lower-level, supporting licensee documentation. LC G.1 requires the licensee to conduct the activities described in Part IV of its licence, in accordance with the safety and control measures.

The licensing basis is established by the Commission at the time the licence is issued. Per LC G.1, operation during the licence period that is not in accordance with the licensing basis is only allowed based on the written approval of the Commission. Similarly, only the Commission can change the licensing basis during the licence period, and this would also be expected to be recorded in writing.

Where the licensing basis refers to specific configurations, methods, solutions, designs, etc., the licensee is free to propose alternate approaches that differ from those in the CVC, as long as they remain in accordance with the licensing basis for the facility.

LC G.1 is not intended to unduly inhibit the ongoing management and operation of the facility or the licensee's ability to adapt to changing circumstances and continuously improve. This LC does not explicitly prohibit changes (such as in management or operation) with a neutral or positive impact on safety. Changes shall be in accordance with the licensing basis and shall be made in accordance with the licensee's management system (see LC 1.1). Changes to licensee documents may require written notification to the CNSC; even if they are in accordance with the licensing basis (see LC G.2).

In the event of any conflict or inconsistency between two elements of the licensing basis, the licensee shall direct the conflict or inconsistency to CNSC staff for resolution. Any such conflict or inconsistency identified would be discussed between the licensee and CNSC staff; the outcome of such discussions will be documented to ensure a common understanding.

The licensee's safety and control measures are described in the following documentation provided at the time of the licence application, or in support of:

Date	Document Title	e-Doc #
December 17th 2018	BWXT ITG Licence Application	5759235
December 20th 2018	Supplementary Report to Support Class IB Licence Application	5743138

Guidance

When the licensee becomes aware that a proposed change or activity might be outside the licensing basis, it should first seek direction from CNSC staff regarding the potential acceptability of this change or activity. The licensee should take into account that certain types of proposed changes might require significant lead times before CNSC staff can make recommendations and/or the Commission can properly consider them.

G.2 Changes to the Documents in Support of the Licence Application

Licence Condition G.2

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

Preamble

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity, and thus establishes the basis for the CNSC's compliance program in respect of that regulated facility or activity. Licensees are required to operate nuclear facilities in accordance with the licensing basis; however, as changes to the programs and documents included or referenced in the licence application are to be expected during the licensing period, licensees are expected to assess changes for impact on the licensing basis. Any changes to the licensing basis require evaluation to determine impact, as related to the 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.

In general, it is expected that changes for which the licensee shall notify the CNSC will be captured as changes to specific licensee documents. This LCH identifies licensee documents that require written notification of changes to the CNSC. They are primarily selected from the set of documents supporting the application and which describe the licensee's safety and control measures (part (iii) of the licensing basis, as defined in LC G.1). In identifying the written notification documents for each LC, CNSC staff select licensee's documents that provide reasonable assurance that adequate safety and control measures are in place to satisfy the LC. See LC G.1 for additional discussion of the licensing basis.

Tables under each LC in the LCH identify the documents (if any) requiring written notification of change. Appendix A.2 describes some of the general criteria that CNSC staff will use to assess changes to documents subject to the written notification requirement. Written notification documents are subdivided into those that require prior written notification of changes and those that require written notification only.

CNSC staff will track the version history of all written notification documents cited in the LCH with the exception of security-related documents. A spreadsheet list controlled by the CNSC's Nuclear Processing Facilities Division entitled "BWXT Medical Ltd. Written Notification Tracking Sheet" (e-Doc 6445457) has been created for this purpose.

Compliance Verification Criteria

Licensee documents that require written notification of change are identified in this LCH under the most relevant LC. These documents represent the minimum subset of documents. For any change that is not captured as a change to a document listed in the LCH, if the change impacts designs, operating conditions, policies, programs, methods, or other elements that are integral to the licensing basis and the change is not clearly in the safe direction, the licensee shall provide written notification of the change.

Written notification is defined as a physical or electronic communication from a person authorized to act on behalf of the licensee to a CNSC staff member. For documents requiring prior written notification, the licensee shall submit the written notification to the CNSC prior to implementing the change. Typically, the requirement is to submit the proposed changes 30 days prior to planned implementation. However, the licensee shall allow sufficient time for the CNSC to review the change proportionate to its complexity and the importance of the safety and control measures being affected. For documents requiring notification only, the licensee needs only to submit the written notification at the time of implementing the change. All written notifications shall include a summary description of the change, the rationale for the change, and a summary explanation of how the licensee has concluded that the changed document remains in accordance with the licensing basis. A copy of the revised written notification document shall accompany the notification.

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

Guidance

None provided.

G.3 Financial Guarantee

Licence Condition G.3

The licensee shall maintain a financial guarantee for decommissioning that is acceptable to the Commission.

Preamble

The *General Nuclear Safety and Control Regulations* requires under paragraph 3(1)(l) that a licence application contain a description of any proposed financial guarantee relating to the activity to be licensed.

LC G.3 requires the licensee to maintain a financial guarantee (FG) for decommissioning that is acceptable to the Commission. The FG shall remain valid and in effect and adequate to fund the activities described in the preliminary decommissioning plan or decommissioning strategy. If the preliminary decommissioning plan is revised and significantly impacts the cost estimate for the FG, the expectation is that the FG is revised and submitted to the Commission for acceptance. In addition, the financial guarantee for decommissioning is to be reviewed and revised by BWXT Medical every five years, and when the Commission requires.

BWXT has provided a *Preliminary Decommissioning Plan* and an associated cost estimate. CNSC staff deemed these to be satisfactory and the Commission accepted the financial guarantee with the associated cost estimate. The current cost estimate for decommissioning is $10,540,000. BWXT Medical will use a letter of credit to cover the estimated cost ($2,600,000) for placing the facility in a safe state of storage (i.e., transfer of nuclear substances to a licensee authorized to possess them and removal of hazardous material). The remainder of the financial guarantee will be covered by a surety bond for $7,940,000.

Compliance Verification Criteria

1. The licensee shall maintain in effect a financial guarantee for decommissioning acceptable to the Commission which shall remain valid, in effect and adequate to fund the activities described in the preliminary decommissioning plan.

2. The financial guarantee for decommissioning is to be reviewed and revised by BWXT Medical every five years, when the Commission requires, or following a revision of the preliminary decommissioning plan.

3. The licensee shall report annually to the CNSC on the status of the financial guarantee to confirm that the financial guarantee remains valid, in effect and adequate to fund decommissioning of the facility.

4. The licensee shall develop its financial guarantee based on the guidance in the following regulatory guidance document.

Document Title	Document #	Effective Date
Financial Guarantees for the Decommissioning of Licensed Activities	G-206	June 2000

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Decommissioning Planning for Licensed Activities	G-219	June 2000
CSA	Decommissioning of Facilities Containing Nuclear Substances	N294	2020

G.4 Public Information and Disclosure

Licence Condition G.4

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

Preamble

The primary goal of the Public Information and Disclosure Program is to ensure that information related to the health and safety of persons and the environment and other issues associated with the lifecycle of the nuclear facility is effectively communicated to the public.

In addition, the program shall include a commitment to a disclosure protocol in regard to information and reports of interest to the public. The disclosure program shall include timely communication of items of interest to the public such as routine and non-routine situations, unplanned events and other incidents and activities related to the licensed facility that may be of interest to the public.

Compliance Verification Criteria

Licensee Document that Requires Notification of Change

Document Title	Document #	Prior Notification
Public Information and Disclosure Program for BWXT ITG	SE-LIC-020	No

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CNSC	Public Information and Disclosure	REGDOC-3.2.1	2018

Guidance

None provided.

1. SCA – MANAGEMENT SYSTEM

1.1 Management System Requirements

Licence Condition 1.1

The licensee shall implement and maintain a management system.

Preamble

Paragraph 3(k) of the *General Nuclear Safety and Control Regulations* requires that a licence application contain information on the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the *Nuclear Safety and Control Act* and the Regulations made under the Act, including the internal allocation of functions, responsibilities and authority.

Paragraph 3(d) the *Class I Nuclear Facilities Regulations* requires that a licence application contain information that includes the proposed quality assurance program for the activity to be licensed.

A management system for safety shall control activities at both the working level and at the corporate level from planning stages to completion, provide corporate direction and maintains overall accountability, and ensures effective quality and safety-related communications between individuals and organizations.

A licensee shall retain overall responsibility for assuring safety regardless of the delegation of any work or responsibilities to other organizations.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
BWXT ITG Management System for Safety	SE-LIC-022	Yes

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CSA	Management Systems Requirements for Nuclear Facilities	N286	2012
CNSC	Safety Culture	REGDOC 2.1.2	2018

1. BWXT Medical has committed to revising and updating Tier 1 and 2 documents identified in its Management System for Safety within a 12-month period following the issuance of a licence.

Group	Commitment
Group 1: Require updating only of the organization's name, and logo from Nordion to BWXT Medical and alignment of responsibilities to BWXT titles and roles.	Revision of Group 1 documents will be completed within 3 months of issuance of the Class IB licence.
Group 2:Require updating of the organization's name and logo, as well as removal of references to licensed activities that are relevant to Nordion.	Revision of Group 2 documents will be completed within 9 months of issuance of the Class IB licence.
Group 3: Require updating of the organization's name and logo, removal of references to licensed activities that are relevant to Nordion, and revision of responsibilities and process descriptions for activities that BWXT Medical remains responsible for but are conducted by Nordion employees on behalf of BWXT Medical. Revision of these documents will require more effort than Group 1 and 2 documents.	Revision of Group 3 documents will be completed within 12 months of issuance of the Class IB licence.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Commentary on N286-12, *Management system requirements for nuclear facilities*	N286.0.1	2020

2. SCA – HUMAN PERFORMANCE MANAGEMENT

2.1 Human Performance Management

Licence Condition 2.1

The licensee shall implement and maintain a training program.

Preamble

Paragraphs 12(1)(a) and 12(1)(b) of the *General Nuclear Safety and Control Regulations* require that a licensee shall ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the Act, the Regulations made under the Act and the licence, and train the workers to carry on the licensed activity in accordance with the Act, the Regulations made under the Act and the licence.

Paragraphs 6(m) and 6(n) of the *Class I Nuclear Facilities Regulations* require that licence applications include the proposed responsibilities, qualification requirements, training program, including the procedures for the requalification of workers, and the results that have been achieved in implementing the program for recruiting, training and qualifying workers.

Subsection 14(2) of the *Class I Nuclear Facilities Regulations* requires every licensee to keep a record of the status of each worker's qualifications, requalification and training, including the results of all tests and examinations completed in accordance with the licence.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Radiation Surveyors and Monitors On-the-Job Training Program	SE-TRN-001	No
Compliance Environment Health and Radiation Safety Training	SE-TRN-003	No
Systematic Approach to Training System	SE-TRN-006	No

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CNSC	Personnel Training	REGDOC-2.2.2	2016

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Minimum Staff Complement	REGDOC-2.2.5	2019

3. SCA – OPERATING PERFORMANCE

3.1 Operations Program

Licence Condition 3.1

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

Preamble

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain the following information: the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

An operating program defines the operating rules consistent with the safety analyses and other licensing support documentation within which the facilities will be operated, maintained and modified, all of which should ensure safety. An operations program establishes safe, uniform, and efficient operating practices within a nuclear facility.

An operations program includes an up-to-date set of operating limits for the facility and activities authorized under the licence, including: limits for the possession, use, management, transfer, storage of nuclear substances; an inventory of nuclear substances and prescribed equipment; and a process to track high-risk sealed sources and operational limits/specifications for the nuclear facility.

In addition, the operations program is to ensure that any building modifications are made in accordance with the *National Building Code*, the *National Fire Code*, and CSA N393 *Fire Protection for Facilities that Process, Handle or Store Nuclear Substances*. CSA N393 includes specific reporting requirements for reporting and follow-up of fire incidents and fire protection program audits.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
EHS Committee Approved Activity Limits for Facilities	SE-LIC-007	No
BWXT ITG Sealed Source Reporting	SE-OP-094	No
Radioactive Material Inventory	SE-LIC-015	No

Criteria for Facility Operation:

1. The licensee shall operate its facility using up-to-date procedures that have been through a formal development process which includes validation before the procedure is approved for use. In addition, such procedures shall be reviewed (and revised, as appropriate) on a regular basis.
2. As part of the operating program, the licensee shall implement and maintain a sealed source tracking program.
3. The licensee shall maintain a record of the nuclear substances and radiation devices in its possession, and provide details to show:
   a. the name, quantity, form and location of the nuclear substance;
   b. where the nuclear substance is a sealed source, the model and serial number of the sources;
   c. where the nuclear substance is contained in a radiation device, the model and serial number of the device, the quantity of the nuclear substance used, and the manner in which the nuclear substance is used; and
   d. any transfer, receipt including acquisition, and disposal of a nuclear substance including:
      - the date of transfer, receipt, disposal
      - the name and address of the supplier or the recipient
      - the number of the licence of the recipient
      - the name, quantity and form of the nuclear substance transferred, received, disposed of
      - where the nuclear substance is a sealed source, the model and serial number of the source
      - where the nuclear substance is contained in a radiation device, the model and serial number of the device.

Criteria for Fire Protection

1. The licensee shall design, build, modify and otherwise carry out work related to the facility with potential to impact protection from fire in accordance with the *National Building Code of Canada, the National Fire Code of Canada* and CSA N393.

2. The licensee shall operate, maintain, test, and inspect the facility in accordance with the *National Fire Code of Canada* and CSA N393.

3. The licensee shall implement the defence-in-depth principle to fire protection, providing measures to prevent fires from starting, to detect and extinguish quickly any fires that do start and to prevent the spread of fires and their effects in or to any area that may affect safety.

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
NRC	National Fire Code of Canada	IRC-10NFC	2015
NRC	National Building Code of Canada	IRC-10NBC	2015
CSA	Fire Protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2013

Guidance

None provided.

3.2 Reporting Requirements

Licence Condition 3.2

The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.

Preamble

This condition requires the licensee to implement and maintain a program for reporting information to the Commission. This includes compliance monitoring and operational performance, responses to unusual events, and sealed-source tracking reports, and notifications of various types.

The NSCA and applicable regulations describe reporting to the Commission or a person authorized by the Commission. Some reporting requirements are found in sections 29 - 32 of the *General Nuclear Safety and Control Regulations* and section 27 of the NSCA. Information regarding notification of action level exceedances is found in this LCH under LCs 7 and 9. A licensee is required to have a program that includes all reporting.

The CNSC has strengthened its regulatory controls on sealed sources, principally through establishment of a sealed source tracking system within an upgraded national sealed source registry and enhanced export and import controls for high-risk sealed sources. High-risk sealed sources are recorded in the CNSC database (the Sealed Source Tracking System) that tracks the location of each significantly hazardous radioactive source (IAEA Category 1 and 2 sources) in Canada.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
BWXT ITG Sealed Source Reporting	SE-OP-094	No
Investigations	SE-RP-003	No
EHS Regulatory Reporting and Notifications	SE-EHS-009	No

1. The licensee shall, in respect of a radioactive nuclear substance set out in column 1 of the table below, report in writing, according to the reporting schedule as set out in column 2 of the table, any transfer, receipt, export or import of a sealed source whose corresponding activity is equal to or greater than the value set out in column 3 of the table:

Activity Limits for Sealed Source Tracking

Column 1	Column 2	Column 3
Nuclear Substance	**Reporting Schedule**	**(TBq)**
Americium 241	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Americium 241/Beryllium	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Californium 252	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.2
Curium 244	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.5
Cobalt 60	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.3
Cesium 137	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	1
Gadolinium 153	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	10
Iridium 192	(a) prior to any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.8
Promethium 147	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	400
Plutonium 238	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Plutonium 239/ Beryllium	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Radium 226	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.4
Selenium 75	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	2
Strontium 90 (Yttrium 90)	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	10
Thulium 170	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	200
Ytterbium 169	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	3

The written report shall be in a form that includes:

(a) on transfer or export of a sealed source(s),

(i) the date of transfer, or for export, the date the sealed source(s) leaves the facility,
(ii) the export licence number (where applicable),
(iii) the name of the recipient and licence number,
(iv) the name of the importer,
(v) the address of the recipient's or importer's authorized location,
(vi) the nuclear substance (radionuclide),
(vii) activity (radioactivity) (Bq) per sealed source on the reference date,
(viii) the reference date,
(ix) the sealed source unique identifiers, and
(x) where the sealed source is incorporated in a prescribed equipment:

(1) the name and model number of the equipment, and
(2) the equipment serial number

(b) on receipt or import of a sealed source(s),

(i) the date of receipt of a transfer or import,
(ii) the name of the shipper and licence number,
(iii) the name of the exporter,
(iv) the address of the shipper's or exporter's authorized location,
(v) the nuclear substance (radionuclide),
(vi) activity (radioactivity) (Bq) per sealed source on the reference date,
(vii) the reference date,
(viii) sealed source unique identifiers, and
(ix) where the sealed source is incorporated in a prescribed equipment:

(1) the name and model number of the equipment; and
(2) the equipment serial number

2. As part of reporting, the licensee shall provide an annual compliance report by March 31 of each year, covering the operation for the 12-month period from January 1 to December 31 of the previous year. (See REGDOC-3.1.2 for information to include in the report).

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CNSC	Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills	REGDOC-3.1.2	January 2018

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Reporting Requirements for Waste Nuclear Substance Licensees, Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices	REGDOC-3.1.3	February 2020

The above guidance is applicable with respect to Sealed Source Tracking System (SSTS) reporting requirements.

4. SCA – SAFETY ANALYSIS

4.1 Safety Analysis Program

Licence Condition 4.1

The licensee shall implement and maintain a safety analysis program.

Preamble

Paragraph 3(1)(i) of the *General Nuclear Safety and Control Regulations* requires that a licence application contains information that includes a description and the results of any test, analysis or calculation performed to substantiate the information included in the application.

Paragraphs 6(c) and (d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contains information that includes a final safety analysis report demonstrating the adequacy of the design of the nuclear facility, and the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

LC 4.1 requires that the licensee implement and maintain a process to identify and assess hazards and risks on an ongoing basis. This would include identifying and evaluating new or unforeseen risks that were not considered at the planning and design stages and updating previous risk assessments by replacing important assumptions with performance data. The results of this process will be used to set objectives and targets and to develop preventative and protective measures.

CSA N286-12, *Management System Requirements for Nuclear Facilities*, includes specific requirements related to safety analysis that apply to isotope processing facilities. As such, the licensee's safety analysis process is to be performed and documented for the design and carried through the life of the nuclear facility. CSA N286-12 also requires that the safety analysis is periodically reviewed to ensure it is current.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Safety Analysis Reports	CPM-6-20	No
Final Safety Analysis report for the Nuclear Medicine Production Facility	IS/SR 1070 Z000	Yes

Licensing Basis Publications

None. Refer to section 1.1 Management System Requirements.

1. The licensee shall maintain the safety analysis reports described above to ensure they adequately consider the hazards associated with the facility. The safety analysis shall be a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and consider the effectiveness of preventative measures and strategies in reducing the effects of such hazards.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
IAEA	Safety of Nuclear Fuel Cycle Facilities	SSR-4	2017

5. SCA – PHYSICAL DESIGN

5.1 Design Program

Licence Condition 5.1

The licensee shall implement and maintain a design program.

Preamble

The *Class I Nuclear Facilities Regulations* require that a licence application contain a description of the structures, systems and components (SSC), and relevant documentation of the facility design.

A design program ensures that the plant design is managed using a well-defined systematic approach.

This licence condition requires that the licensee implement and maintain a design program to confirm that SSCs and any modifications to them continue to meet their design basis given new information arising over time and taking changes in the external environment into account. It also confirms that SSCs continue to be able to perform their safety functions.

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain the proposed measures, policies, methods and procedures to maintain the nuclear facility.

This licence condition requires that the licensee implement and maintain a design control process to ensure that design outputs (both interim and final) are reviewed, verified and validated against the design inputs and performance requirements, and to ensure that the design inputs are selected such that safety, performance and dependability of the design item are achieved.

The licensee is encouraged to make continuous improvements to the design of facilities and equipment, as long as the changes remain within the licensing basis authorized by the Commission.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System for Safety	See LC 1.1	
Facility Description	SE-LIC-018	Yes

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CSA	Management Systems Requirements for Nuclear Facilities	See LC 1.1	

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Boiler, pressure vessel, and pressure piping code	B-51	2019
CNSC	Physical Design General Design Considerations: Human Factors	REGDOC 2.5.1	2019

6. SCA – FITNESS FOR SERVICE

6.1 Fitness for Service Program

Licence Condition 6.1

The licensee shall implement and maintain a fitness for service program.

Preamble

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including the proposed measures, policies, methods, and procedures for operating and maintaining the nuclear facility.

It is expected that the licensee will conduct routine maintenance, inspection and testing to ensure that the availability, reliability and effectiveness of facilities and equipment that may impact the health, safety and protection of the environment.

This condition requires that the licensee implement and maintain a maintenance program to ensure that the operating condition of systems, equipment and devices is preserved so that they can perform their function reliably. Accuracy is maintained by planning and carrying out periodic adjustments, calibrations, repairs and replacement.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System for Safety	See LC 1.1	
Facilities Maintenance Master Plan	R-Master	No
Nordion Ottawa Site Instrument Maintenance and Calibration	CP-Master	No

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CSA	Fire Protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2013

1. The licensee shall carry out testing and maintenance sufficient to ensure the reliability and effectiveness of all structures, systems and components, and safety-related equipment.

2. The licensee shall determine the extent and frequency of preventive maintenance, testing, surveillance, and inspection of structures, systems and components through a systematic approach, following operating experience and best industry practices, taking into account :

   a) their importance to safety;

   b) their inherent reliability;

   c) their potential for degradation (based on operational and other relevant experience, research and vendor recommendations);

   d) the consequences of failure;

   e) results of condition monitoring; and

   f) the safety analysis.

3. The licensee shall establish, review and validate procedures for maintenance, testing, surveillance, and inspections.

4. Before any structure, system, equipment or component is removed from or returned to service, the licensee shall ensure full consideration and approval of the proposed reconfiguration, followed by a documented confirmation of its correct configuration and, where appropriate, functional testing.

5. Following any abnormal event due to which the safety functions and functional integrity of any structure, system or component may have been challenged, the licensee shall identify and revalidate the safety functions and carry out any necessary remedial actions, including inspection, testing, maintenance, and repair, as appropriate.

6. The licensee shall ensure that all items of equipment used for examinations and tests, together with their accessories, are qualified and calibrated before they are used.

7. The licensee shall properly identify all equipment in the calibration records, and shall establish a calibration program to ensure all equipment remains in calibrated state.

Guidance

None provided.

7. SCA – RADIATION PROTECTION

7.1 Radiation Protection Program

Licence Condition 7.1

The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

Preamble

The *Radiation Protection Regulations* require that the licensee implement a radiation protection program for any activity that is authorized by the *Nuclear Safety and Control Act* or is present at a place where that activity is carried on. This program must ensure that doses to workers do not exceed prescribed dose limits and are kept ALARA, social and economic factors being taken into account.

Note that the regulatory dose limits to workers and the general public are explicitly provided in sections 13, 14 and 15 of the *Radiation Protection Regulations*.

Action levels are designed to alert licensees before regulatory dose limits are reached. By definition, if an action level is reached, a loss of control of some part of the associated radiation protection program may have occurred, and specific action is required, as defined in the *Radiation Protection Regulations*.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
BWXT ITG Radiation Protection Manual	SE-RP-008	Yes
Keeping Radiation Exposures and Doses as Low as Reasonably Achievable	SE-RP-002	Yes

1. When the licensee becomes aware that an action level has been reached, it shall notify the CNSC within seven days.

2. If an action level has been reached, the licensee shall file a final report with the CNSC within 21 days of becoming aware of the matter.

The licensee action levels are as follows:

Application	Action Level
Effective Dose	2 mSv/Report 15 mSv/year
Pregnant NEW	1 mSv/balance of pregnancy
Skin	30 mSv/Report 200 mSv/year
Extremity	50 mSv/Report 200 mSv/year
Non-NEW: Effective Dose	0.75 mSv/year

3. The licensee shall review and if necessary, revise the action levels at a frequency of once per five years to validate their effectiveness.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable" (ALARA)	G-129	October 2004
CNSC	Developing and Using Action Levels	G-228	March 2001
CNSC	Ascertaining and Recording Radiation Doses to Individuals	G-91	June 2003
CNSC	Making Changes to Dose-Related Information Filed with the National Dose Registry	S-260	October 2004

8. SCA – CONVENTIONAL HEALTH AND SAFETY

8.1 Conventional Health and Safety Program

Licence Condition 8.1

The licensee shall implement and maintain a conventional health and safety program.

Preamble

Paragraph 3(f) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including the proposed worker health and safety policies and procedures.

The regulation of conventional health and safety is governed by the *Canada Labour Code Part II.*

The CNSC also has regulatory responsibilities for the oversight of the protection of the health and safety of workers.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System for Safety	See LC 1.1	

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CSA	Selection, Use and Care of Respirators	Z94.4	2018

Guidance

None provided.

9. SCA – ENVIRONMENTAL PROTECTION

9.1 Environmental Protection Program

Licence Condition 9.1

The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

Preamble

CNSC Regulatory Document 2.9.1: *Environmental Protection Policies, Programs and Procedures*, requires licensees to establish, implement and maintain an Environmental Management System that satisfies the requirements set by the Canadian Standards Association's (CSA) ISO 14001: 2004, *Environmental Management Systems – Requirements with Guidance for Use*.

Canadian Standards Association N288.1-14 *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities* provides guidelines and a methodology for calculating the upper limits (the Derived Release Limits) for the rate of release of radionuclides discharged into the atmosphere and surface waters, based on limiting radiation exposures to members of the public.

In accordance with the commitment described in e-Doc 6486514, the joint releases of nuclear substances to the environment from the BWXT Medical and Nordion (Canada) Inc. Class IB nuclear facilities located at 447 March Road, Ottawa, Ontario shall not exceed the Derived Release Limits (DRLs). The sum of all fractional DRL releases from these facilities must remain less than unity. Any exceedance indicates that the licensees are in non-compliance with the public dose limit of 1 mSv per year as per the *Radiation Protection Regulations*.

The Environmental Management System (EMS) captures the environmental protection policies, programs, and procedures of the licensed activity, and ensures that environmental protection is managed via an integrated set of documented activities that have the support and commitment of all levels of management within the licensee's organization. It shall be designed in a way that is appropriate to the nature, scale and environmental impacts of its activities with a commitment to pollution prevention and continuous improvement, such that environmental issues are identified, monitored, interpreted and acted upon in a manner that demonstrates "adequate precaution" to protect the environment and the health and safety of persons. Components of an EMS include Environmental Policy, Planning, Implementation and Operation, Checking, and Management Review.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Environmental Management System	SE-ENV-001	Yes
Environmental Protection Program	SE-ENV-015	Yes
Nordion Class 1B Facility Derived Release Limits	REP-EHS-009	Yes
BWXT ITG Environmental Action Levels	SE-ENV-031	Yes
BWXT ITG Radiation Protection Manual	See LC 7.1	

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CNSC	Environmental Protection Policies, Programs and Procedures	REGDOC-2.9.1	2017
CSA	Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	N288.1	2020
CSA	Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	N288.4	2019
CSA	Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills	N288.5	2016
CSA	Environmental Risk Assessments at Class 1 Nuclear Facilities and Uranium Mines and Mills	N288.6	2017
CSA	Establishing and implementing action levels for releases to the environment from nuclear facilities	N288.8	2017

1. The licensee's environmental protection program shall ensure the control, monitoring and recording of releases of radionuclides to the environment from the nuclear facility such that the joint releases of BWXT Medical and Nordion do not exceed the release limits specified in the table below:

Release Limits		
Radionuclide	DRL for Air Effluent at the BWXT Medical/Nordion Kanata Site (GBq/year)	DRL for Liquid Releases at the BWXT Medical/Nordion Kanata Site GBq/year
C-14	1.58E+06	1.10E+05
Co-60	2.50E+02	3.54E+01
Cs-137	3.02E+02	2.48E+01
I-123	4.59E+06	2.23E+08
I-125	9.52E+02	1.19E+03
I-131	6.86E+02	3.89E+02
In-111	8.38E+05	1.01E+04
Ir-192	1.66E+04	1.56E+03
Mo-99	5.17E+05	1.02E+04
Nb-95	3.88E+04	3.25E+03
Ni-63	2.37E+05	7.63E+02
Sr-82	9.35E+03	3.46E+02
Sr-85	3.34E+04	2.22E+03
Xe-131m	3.72E+09	n/a
Xe-133	6.77E+08	n/a
Xe-135	1.02E+08	n/a
Xe-135m	6.90E+07	n/a
Y-90	7.31E+05	3.50E+04
Zr-95	6.81E+03	2.06E+03
$\beta < 1$ MeV*		7.63E+02
$\beta > 1$ MeV*		3.50E+04

*The Ni-63 and Y-90 DRLs are used for $\beta < 1$ MeV and $\beta > 1$ MeV respectively since they are conservative among the pure beta-emitting radionuclides expected to be present in liquid releases.

2. The licensee's assessment demonstrating that action levels are not required because there is negligible risk to the environment shall be reviewed and updated as necessary once sufficient effluent monitoring data is available.

3. The licensee shall reassess the need for environmental action levels every five years, or if there is a modification to the facility or a change in operations that may result in an increase in releases to the environment. The results of such reviews shall be provided to CNSC staff.

4. The licensee's environmental protection program shall control and monitor the releases of hazardous substances.

Guidance

None provided.

10. SCA – EMERGENCY MANAGEMENT AND FIRE PROTECTION

10.1 Emergency Management Program

Licence Condition 10.1

The licensee shall implement and maintain an emergency management program.

Preamble

As part of the emergency management program, the licensee shall prepare an onsite emergency plan and establish the necessary organizational structure for clear allocation of responsibilities, authorities, and arrangements for coordinating onsite activities and cooperating with external response organizations throughout all phases of an emergency.

An effective Emergency Preparedness (EP) program is based on the following four components:

1. Planning basis: an analysis of the risks and hazards that the EP program will address.

2. Emergency response plan and procedures: a comprehensive description of how a response will be executed, with accompanying support material.

3. Preparedness: the processes to ensure that people, equipment and infrastructure will be ready to execute a response according to the emergency response plan and procedures.

4. Program management: the management system aspects that assure the effectiveness of the EP program.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Emergency Response Plan	SE-ERP-002	Yes

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CNSC	Nuclear Emergency Preparedness and Response	REGDOC-2.10.1	2017

1. The licensee will run a full-scale exercise at least once every three years that includes activation of the Emergency Response Plan.

Guidance

The licensee should test emergency measures listed in its emergency plan over a five-year period. The licensee's full-scale exercise, conducted at least once every three years, should involve any mutual aid partners identified in the emergency plan.

10.2 Fire Protection Program

Licence Condition 10.2

The licensee shall implement and maintain a fire protection program.

Preamble

Licensees shall prepare and implement a fire protection program (a set of planned, coordinated, controlled and documented activities) to ensure that the licensed activities do not result in an unreasonable risk to the health and safety of persons and to the environment due to fire and to ensure that the licensee is able to efficiently and effectively respond to emergency fire situations.

This SCA also includes the requirement for the licensee to have a fire protection program to minimize the risk to the health and safety of persons and to the environment from fire, through appropriate fire protection system design, fire safety analysis, fire safe operation and fire prevention.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Fire Safety Plan	SE-ERP-001	No
BWXT ITG Fire Protection Program	SE-EHS-031	No

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CSA	Fire protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2013

Guidance

None provided.

11. SCA – WASTE MANAGEMENT

11.1 Waste Management Program

Licence Condition 11.1

The licensee shall implement and maintain a waste management program.

Preamble

CNSC regulatory document REGDOC-2.11, *Framework for Radioactive Waste Management and Decommissioning in Canada* describes the philosophy underlying the CNSC's approach to regulating the management of radioactive waste and the decommissioning of facilities, and explains the principles taken into account in CNSC regulatory decisions.

CNSC regulatory document REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* defines radioactive waste in Canada as any material (liquid, gaseous, or solid) that contains a radioactive nuclear substance, as defined in section 2 of the NSCA, for which no further use is foreseen. In addition to containing nuclear substances, radioactive waste may also contain hazardous substances that are not radioactive, as defined in section 1 of the *General Nuclear Safety and Control Regulations*.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Waste Management Program	SE-ENV-022	Yes

Licensing Basis Publications

Document Title		Document #
CSA	General principles for the management of radioactive waste and irradiated fuel	N292.0-14
CSA	Management of low- and intermediate-level radioactive waste	N292.3-14

Transition

The licensee shall submit a gap analysis and implementation plan for the requirements of CNSC regulatory document REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* by June 30, 2022.

The licensee shall submit a gap analysis and implementation plan for the requirements of CSA Group standard N292.0-19, *General principles for the management of radioactive waste and irradiated fuel* by June 30, 2022.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Waste Management, Volume I: Management of Radioactive Waste	REGDOC-2.11.1	2021
CSA	General principles for the management of radioactive waste and irradiated fuel	N292.0	2019

11.2 Decommissioning Plan

Licence Condition 11.2

The licensee shall implement and maintain a decommissioning plan.

Preamble

Paragraph 3(k) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including the proposed plan for the decommissioning of the nuclear facility or of the site.

A decommissioning plan provides an overview of the proposed decommissioning approach that is sufficiently detailed to assure that the proposed approach is, in the light of existing knowledge, technically and financially feasible and appropriate in the interests of health, safety, security and the protection of the environment. The decommissioning plan defines areas to be decommissioned and the general structure and sequence of the principle work packages. The decommissioning plan forms the basis for establishing and maintaining a financial arrangement (see licence condition G.3) that will assure adequate funding of the decommissioning plan.

CNSC regulatory document REGDOC-2.11, *Framework for Radioactive Waste Management and Decommissioning in Canada* describes the philosophy underlying the CNSC's approach to regulating the management of radioactive waste and the decommissioning of facilities, and explains the principles taken into account in CNSC regulatory decisions.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Preliminary Decommissioning Plan for BWXT's Class 1B Facility	SE-LIC-021	Yes

Licensing Basis Publications

Document Title	Document #
Decommissioning of facilities containing nuclear substances	N294-09

1. The licensee shall maintain a decommissioning plan that reflects any changes in the site or nuclear facility. The decommissioning plan shall be revised at a minimum every five years or when required by the Commission.

2. The decommissioning plan was last revised and submitted to the CNSC in 2020. The licensee's next scheduled submission of the decommissioning plan is due to the CNSC in 2025.

Transition

The licensee shall submit a gap analysis and implementation plan for the requirements of CNSC regulatory document REGDOC-2.11.2, *Decommissioning* by June 30, 2022.

The licensee shall submit a gap analysis and implementation plan for the requirements of CSA Group standard N294-19, *Decommissioning of facilities containing nuclear substances* by June 30, 2022.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Financial Guarantees for the Decommissioning of Licensed Activities	G-206	June 2000
CSA	Decommissioning of Facilities Containing Nuclear Substances	N294	2019
CNSC	Decommissioning Planning for Licensed Activities	G-219	June 2000
CNSC	Decommissioning	REGDOC 2.11.2	2021

12. SCA – SECURITY

12.1 Security Program

Licence Condition 12.1

The licensee shall implement and maintain a security program.

Preamble

Paragraphs 3(1)(g) and (h) of the *General Nuclear Safety and Control Regulations* require that a licence application contain information including the proposed measures to control access to the site of the activity to be licensed and the nuclear substance, prescribed equipment or prescribed information.

Paragraph 6(l) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including he proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts.

The *Nuclear Security Regulations* describe the application of part 2 of these regulations which is relevant to this licensee.

Paragraphs 12(1)(c), (g), (h) and (j) of the *General Nuclear Safety and Control Regulations*, requires that the licensee take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security, implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, implement measures for alerting the licensee to acts of sabotage anywhere at the site of the licensed activity and instruct the workers on the physical security program at the site of the licensed activity and on their obligations under that program.

For a licensee that possesses or transfers sealed sources, a security program includes implementation and maintenance security measures for sealed sources.

CNSC Regulatory Document 2.12.3, *Security of Nuclear Substances: Sealed Sources* sets out the minimum security measures that licensees must implement to prevent the loss, sabotage, illegal use, illegal possession, or illegal removal of sealed sources during their entire lifecycle, including while the sources are in storage, transport or being stored during transportation.

This document also provides information and guidance on how to meet the minimum security measures, including measures related to transport vehicles, containers and security plans. This document applies only to the transport by road within Canada (there are other instruments and technical instructions that regulate the safe transport of dangerous goods by sea, air and rail).

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
BWXT ITG Security Plan (Prescribed Information)	n/a	No

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CNSC	Security of Nuclear Substances: Sealed Sources	REGDOC-2.12.3	2013

1. The licensee shall maintain the operation, design and analysis provisions specified in the security plan, including that they ensure adequate engineered safety barriers are in place for protection against malevolent acts.

2. Technical and administrative security measures shall be documented by the licensee in a site security plan.

3. The licensee shall implement and maintain a facility security plan, and ensure it is designated as prescribed information. The site security plan must be reviewed by the licensee when changes occur within the licensed facility and/or to address an increased threat level and updated if required.

4. The licensee shall implement satisfactory security measures to prevent the loss, sabotage, illegal use, illegal possession, or illegal removal of sealed sources while under licensee's control, including while the sources are in storage, transport or being stored during transportation.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
IAEA	Security in Transport of Radioactive Material	Nuclear Security Series # 9	2008
IAEA	Security of Radioactive Material and Associated Facilities	Nuclear Security Series # 11	2009
IAEA	Nuclear Security Recommendation on Radioactive Material and Associated Facilities	Nuclear Security Series # 14	2011
IAEA	Nuclear Security Recommendations on Nuclear and Other Radioactive Material out of Regulatory Control	Nuclear Security Series # 15	2011

13. SCA – SAFEGUARDS AND NON-PROLIFERATION

13.1 Safeguards and Non-Proliferation

Licence Condition 13.1

The licensee shall implement and maintain a safeguards program.

Preamble

The *General Nuclear Safety and Control Regulations* (GNSCR) require the licensee to take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement, and GNSCR subsections 30(1) and 30(2) defines reporting requirements for safeguards events.

Paragraph 6 (f) of the *Class I Nuclear Facilities Regulations* require that a licence application contain information on the licensee's proposed measures to facilitate Canada's compliance with any applicable safeguards agreement.

This LC requires that the licensee implement and maintain a safeguards program. Safeguards is a system of inspection and other verification activities undertaken by the International Atomic Energy Agency (IAEA) in order to evaluate a Member State's compliance with its obligations pursuant to its safeguards agreements with the IAEA.

Canada has entered into a Safeguards Agreement and an Additional Protocol (hereafter referred to as "safeguards agreements") with the IAEA pursuant to its obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons* (INFCIRC/140). The objective of the Canada-IAEA safeguards agreements is for the IAEA to provide assurance on an annual basis to Canada and to the international community that all declared nuclear materials are in peaceful, non-explosive uses and that there is no indication of undeclared nuclear materials or activities. This conclusion confirms that Canada is in compliance with its obligations under the following Canada-IAEA safeguards agreements:

- *Agreement between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons*; and

- *Protocol Additional to the Agreement between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons.*

These are reproduced in information circulars INFCIRC/164, and INFCIRC/164/Add. 1.

In addition, the import and export of controlled nuclear substances, equipment and information identified in the *Nuclear Non-proliferation Import and Export Control Regulations*, require separate authorization from the CNSC, consistent with subsection 3(2) of the GNSCR.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Safeguards Program	SE-LIC-016	No

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CNSC	Safeguards and Nuclear Material Accountancy	REGDOC-2.13.1	2018
CNSC	Import and Export	REGDOC-2.13.2	2018

The licensee shall implement and maintain a safeguards program in accordance with the requirements set out in REGDOC-2.13.1, *Safeguards and Nuclear Materials Accountancy*. According to the criteria set out in that document, BWXT Medical is currently classified as a Location Outside Facility and must comply with the appropriate requirements in REGDOC-2.13.1.

Guidance

None provided.

14. SCA – PACKAGING AND TRANSPORT

14.1 Packaging and Transport Program

Licence Condition 14.1

The licensee shall implement and maintain a packaging and transport program.

Preamble

Paragraph 6(e) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information on the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.

Every person who transports radioactive material, or requires it to be transported, shall act in accordance with the requirements of the *Transportation of Dangerous Goods Regulations* and the *Packaging and Transport of Nuclear Substances Regulations, 2015*.

The *Packaging and Transport of Nuclear Substances Regulations, 2015* and the *Transportation of Dangerous Goods Regulations* provide specific requirements for the design of transport packages, the packaging, marking and labeling of packages and the handling and transport of nuclear substances.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Transport of Radioactive Material	SE-OP-036	No
Receiving Radioactive Material	SE-OP-015	No
Shipping Radioactive Material	SE-OP-014	No

Guidance

None provided.

APPENDIX A – Control of the LCH

This appendix describes the administrative processes used to control the LCH, including LCH change control procedure, change review criteria, dispute resolution, records management and reporting to the Commission.

A.1 LCH Change Control Process

Only the following individual has the authority to make changes to the LCH.

- the Director, Nuclear Processing Facilities Division

A change control process is applied to the LCH to ensure that:

1. Preparation and use of the LCH are properly controlled.

2. All referenced documents are correctly identified and maintained.

3. Changes are conducted in accordance with CNSC REGDOC-3.5.3, *Regulatory Fundamentals.*

4. Procedures for modifying the LCH are followed.

The licensing basis is defined at licence issuance/renewal. A request to change this LCH can be initiated by either CNSC staff or the licensee. The licensee will be consulted on any changes to the LCH that are proposed by CNSC staff.

The Director, Nuclear Processing Facilities Division, may consent to the requested change only once they have determined that the proposed change will not change the objective of the licensing basis.

The following are examples of proposed changes that require a change to the LCH or a document referenced in the LCH:

1. Changes to the design and/or operation of facilities, processes and equipment.

2. Clarification of the compliance verification criteria (CVC) text to achieve a common understanding between the licensee and CNSC staff.

3. Changes to the codes, standards and regulatory documents which are identified as compliance verification criteria

4. Changes to guidance such as inclusion or amendment of CNSC regulatory guidance documents or recommendations

CNSC staff will take the following steps to update the LCH:

1. The CNSC receives or initiates a notification of proposed change.

2. Initiate a change request using the LCH Change Assessment Form (e-Doc 5009501).

3. Complete a technical review of the proposed change, if required.

4. Consult the licensee. In case of disagreement on the proposed change, the dispute resolution process outlined in section A.3 will apply.

5. Obtain consent for changes from both parties.

6. Update the LCH in accordance with the agreed amendment(s) and send the updated document to the parties identified on the distribution list (see section A.5).

If the change involves the revision of a Written Notification (WN) document, NPFD will also update the registry it uses to track the version history of the WN documents.

A.2 Document Control and Approval/Consent

Document Control and Oversight

Following CNSC staff's acceptance of version control documents, the CVC found in the LCH may require updates. The Director, Nuclear Processing Facilities Division, has the authority to make the changes to the CVC as long as the changes remain within the licensing basis.

The CNSC uses a risk-informed process to determine the type of regulatory oversight that is appropriate for each licensee document in the licensing basis.

CNSC Review Criteria Related to Document Changes and Approvals/Consent

For the acceptance of document changes described above, CNSC staff verify if the licensee submission includes the appropriate level of information with regards to the proposed changes or action, to the extent relevant:

- a summary description;
- an indication of the duration (temporary or permanent);
- a justification;
- any relevant supporting documentation;
- an evaluation of the impact on health, safety, security, the environment and Canada's international obligations; and
- an evaluation to determine if the resultant effects remain within the scope of the licensing basis.

The CNSC then assesses whether the following general criteria would be met for the proposed change/action:

- the proposed change or action will be made or done in accordance with the licensee's management system and change control processes, applicable design guides, design requirements, standards, operating documentation, regulatory documents, applicable safety principles and applicable safeguards agreement;
- following the proposed change or action, the licensee remains in compliance with the requirements set out in the applicable laws, regulations and LCs, including appendices of the licence;
- the proposed change or action will provide the equivalent level of safety or is in the safe direction.

- following the proposed change or action:
  - the licensee remains qualified to carry out the licensed activity;
  - the licensee has adequate provision for the protection of the health and safety of persons, protection of the environment, maintenance of national security and measures required to implement international obligations to which Canada has agreed; and
  - the licensed activity remains within the limits defined by the licensing basis.

(The above criteria can also apply when CNSC staff review a notification of a licensee change that was already made.)

A.3 Dispute Resolution

In case of a dispute between the licensee and CNSC staff regarding changes to the LCH, both parties will meet to discuss the dispute and reach a decision on the path forward. The decision, including its rationale will be documented. If any party is not satisfied with the decision, the resolution process will proceed up to the Director General or Executive Vice-President and Chief Regulatory Operations Officer level. If any party is still not satisfied with the decision, the issue will be brought to the attention of the Commission at a Commission meeting or hearing. The decision made by the Commission will be final.

A.4 Records Management

In order to track changes to the LCH, the document change request and accompanying documentation will be archived in records and referenced in the revision history of the LCH. Electronic communication related to the change, such as comments from reviewers will be stored in the CNSC Information Management System.

A.5 Distribution

NPFD staff will distribute a copy of the updated version of the LCH to the following parties:

- Project Officer, Nuclear Processing and Facilities Division
- BWXT ITG Canada Inc.

A.6 Reporting to the Commission

CNSC staff will report on the changes made to the LCH during the previous year in their annual report to the Commission.

APPENDIX B – Glossary of Terms

Acronyms

The following is the list of acronyms used in this document:

AL	Action Level
ALARA	As Low As Reasonably Achievable, social and economic factors taken into consideration
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
CSA	Canadian Standards Association
CVC	Compliance Verification Criteria
DNCFR	Directorate of Nuclear Cycle and Facilities Regulation
DRL	Derived Release Limits
EP	Environmental Protection
EMS	Environmental Management System
FG	Financial Guarantee
GNSCR	*General Nuclear Safety and Control Regulations*
IAEA	International Atomic Energy Agency
LC	Licence Condition
LCH	Licence Conditions Handbook
NPFD	Nuclear Processing and Facilities Division
NSCA	*Nuclear Safety and Control Act*
RP	Radiation Protection
SAT	Systematic Approach to Training
SCA	Safety and Control Area
SSC	Structures, systems and components
WN	Written Notification

APPENDIX C – Licensee Documents Requiring Notification of Change

Documents submitted by the licensee in support of the licence application and ongoing licensing requirements that are referenced within the LCH.

Notes:

No = Notification Required, as described in LC G.2.

Yes = Prior Notification, as described in LC G.2.

e-Doc 4768292 maintains document version control of the documents referenced below.

Document Title	Document #	Notification Requirement	Licence Conditions
Facility Description	SE-LIC-018	Yes	G.2, 5.1
Public Information and Disclosure Program for BWXT ITG	SE-LIC-020	No	G.4
BWXT ITG Management System for Safety	SE-LIC-022	Yes	1.1, 3.1, 5.1, 6.1, 8.1
Radiation Surveyors and Monitors On-the-Job Training Program	SE-TRN-001	No	2.1
Compliance Environment Health and Radiation Safety Training	SE-TRN-003	No	2.1
Systematic Approach to Training System	SE-TRN-006	No	2.1
EHS Committee Approved Activity Limits for Facilities	SE-LIC-007	No	3.1
BWXT ITG Sealed Source Reporting	SE-OP-094	No	3.1, 3.2
Radioactive Material Inventory	SE-LIC-015	No	3.1
Investigations	SE-RP-003	No	3.2
EHS Regulatory Reporting and Notifications	SE-EHS-009	No	3.2
Safety Analysis Reports	CPM-6-20	No	4.1
Final Safety Analysis report for the Nuclear Medicine Production Facility	IS/SR 1070 Z000	Yes	4.1

Document Title	Document #	Notification Requirement	Licence Conditions
Facilities Maintenance Master Plan	R-Master	No	6.1
Nordion Ottawa Site Instrument Maintenance and Calibration	CP-Master	No	6.1
BWXT ITG Radiation Protection Manual	SE-RP-008	Yes	7.1, 9.1, 11.1
Keeping Radiation Exposures and Doses as Low as reasonably Achievable	SE-RP-002	Yes	7.1
Environmental Management System	SE-ENV-001	Yes	9.1
Environmental Protection Program	SE-ENV-015	Yes	9.1
Emergency Response Plan	SE-ERP-002	Yes	10.1
Fire Safety Plan	SE-ERP-001	No	10.2
BWXT ITG Fire Protection Program	SE-EHS-031	No	10.2
Preliminary Decommissioning Plan for BWXT ITG's Class IB Facility (KOB)	SE-LIC-021	Yes	11.2
BWXT ITG Security Plan (PROTECTED)	N/A	Yes	12.1
Nordion General Canadian Transportation Security Plan (PROTECTED)	N/A	Yes	12.1
Safeguards Program	SE-LIC-016	No	13.1
Transport of Radioactive Material	SE-OP-036	No	14.1
Receiving Radioactive Material	SE-OP-015	No	14.1
Shipping Radioactive Material	SE-OP-014	No	14.1

APPENDIX D – List of Documents used as Guidance or Criteria

Document #	Document Title	L.C.
G-206	Financial Guarantees for the Decommissioning of Licensed Activities	G.3, 11.2
G-219	Decommissioning Planning for Licensed Activities	G.3, 11.2
CSA N294	Decommissioning of Facilities Containing Nuclear Substances	G.3, 11.2
RD/GD-99.3	Public Information and Disclosure	G.4
REGDOC 3.2.1	Public Information and Disclosure	G.4
CSA N286	Management systems requirements for nuclear facilities	1.1, 4.1, 5.1
REGDOC 2.2.2	Personnel Training	2.1
CSA N393	Fire protection for Facilities that Process, Handle or Store Nuclear Substances	3.1, 6.1, 10.2, 15.1
IRC-10NFC	National Fire Code of Canada	3.1, 15.1
IRC-10NBC	National Building Code of Canada	3.1, 15.1
REGDOC-3.1.2	Reporting Requirements for Non-Power Reactor: Class I Facilities and Uranium Mines and Mills	3.2
IAEA SSR-4	Safety of Nuclear Fuel Cycle Facilities	4.1
CSA B-51	Boiler, pressure vessel, and pressure piping code	5.1
G-129	Keeping Radiation Exposures and Doses “As Low As Reasonably Achievable (ALARA	7.1
G-228	Regulatory Guide, “Developing and Using Action Levels”	7.1
G-91	Ascertaining and Recording Radiation Doses to Individuals	7.1
S-260	Making Changes to Dose-Related Information Filed with the National Dose Registry	7.1
CSA Z94.4	Selection and Use of Respirators	8.1
REGDOC 2.9.1	Environmental Protection Policies, Programs and Procedures	9.1

Document #	Document Title	L.C.
CSA N288.4	Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	9.1
CSA N288.5	Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	9.1
CSA N288.6	Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills	9.1
CSA N288.7	Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	9.1
CSA N288.8	Establishing and implementing action levels for releases to the environment from nuclear facilities	9.1
REGDOC-2.10.1	Nuclear Emergency Preparedness and Response	10.1
REGDOC-2.11.1	Waste Management, Volume II: Assessing the Long-Term Safety of Radioactive Waste Management	11.1
CSA N292.0	General principles for the management of radioactive waste and irradiated fuel	11.1
CSA N292.3	Management of Low and Intermediate-Level Radioactive Waste	11.1
REGDOC 2.12.3	Security of Nuclear Substances Sealed Sources	12.1
IAEA Nuclear Security Series # 9	Security in Transport of Radioactive Material	12.1
IAEA Nuclear Security Series # 11	Security of Radioactive Material and Associated Facilities	12.1
IAEA Nuclear Security Series # 14	Nuclear Security Recommendation on Radioactive Material and Associated Facilities	12.1
IAEA Nuclear Security Series # 15	Nuclear Security Recommendations on Nuclear and Other Radioactive Material out of Regulatory Control	12.1
REGDOC-2.13.1	Safeguards and Nuclear Material Accountancy	13.1
REGDOC-3.5.3	Regulatory Fundamentals	Appendix A