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Written submission from BWXT Medical Ltd. (formerly BWXT ITG Canada, Inc.)

Mémoire de BWXT Medical Ltd. (anciennement BWXT ITG Canada, Inc.)

In the Matter of the

BWXT Medical Ltd.

Application for a Class IB nuclear substance processing facility operating licence

Commission Public Hearing

June 9-10, 2021

À l'égard de

BWXT Medical Ltd.

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

Audience publique de la Commission

9 et 10 juin 2021

Canada

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Table of Contents

Executive Summary

In 2018, BWX Technologies, Inc. (BWXT) announced its patent-pending technology to produce molybdenum-99 (Mo-99), the parent isotope of technetium-99m (Tc-99m), which is used globally in more than 40 million diagnostic medical procedures each year. These medical procedures have an impact on patient quality of life by providing information critical to their future treatment plans. To support this technology and to provide a stable North American-based supply of Mo-99 and Tc-99m, BWXT acquired Sotera Health's Nordion medical isotope business in July 2018.

On December 17, 2018, BWXT ITG Canada Inc. submitted an application to the Canadian Nuclear Safety Commission (CNSC) to request issuance of its own Class 1B nuclear substance processing facility operating licence (instead of operations being managed under the Nordion licence).

On January 22, 2021, BWXT ITG Canada Inc. changed its legal name to BWXT Medical Ltd. (BWXT Medical). The name change was by way of Articles of Amendment and neither the Canada Revenue Agency (CRA) business number or corporation number changed.

The need for medical isotopes used in modern diagnostic imaging is ever increasing; concerns about an adequate supply to diagnose heart disease and cancer, and to perform other important medical applications are compelling. BWXT Medical is committed to meeting this demand by continuing to manufacture existing critical medical isotopes. Medical isotopes have been produced at the Nordion 447 March Road, Ottawa site for over 30 years.

BWXT Medical systems to protect employees, the environment and members of the public against environment, health and safety hazards are well established and BWXT Medical is committed to continuously improving them. BWXT Medical will work to implement programs and objectives to conserve natural resources, prevent pollution and minimize waste. Maintaining a safe and healthy work environment for employees is a top business priority.

Upon issuance of its own Class IB licence, BWXT Medical will adopt the existing Nordion Management System for Safety. This Management System ensures applicable buildings and facilities, process equipment, and processes used in support of licensed activities are conducted in accordance with the Nuclear Safety and Control Act [1] and supporting Regulations, applicable CNSC requirements, and best practices.

The licence application, supplemental information provided subsequent to the application, and this written submission demonstrate that BWXT Medical is qualified to undertake the licensed activities and that adequate provisions will be made for the protection of the environment, employees and the public.

1.0 INTRODUCTION

1.1 Background

In 2018, BWXT Technologies, Inc. (BWXT) announced its patent-pending innovative technology to produce molybdenum-99 (Mo-99), the parent isotope of technetium-99m (Tc-99m), which is used globally in more than 40 million diagnostic medical procedures each year. These medical procedures have an impact on patient quality of life by providing information critical to their future treatment plans. To support this technology and to provide a stable North American-based supply of Mo-99 and Tc-99m, BWXT acquired Sotera Health's Nordion medical isotope business in July 2018, through its subsidiary, BWXT ITG Canada Inc..

On January 22, 2021, BWXT ITG Canada Inc. changed the legal name to BWXT Medical Ltd. The name change was by way of Articles of Amendment and neither the CRA business number or Corporation Number changed. Throughout the remainder of this document BWXT Medical will be referenced and is synonymous with BWXT ITG Canada Inc.

The acquisition terms provided BWXT Medical a long term lease of the portions of the Ottawa facility dedicated to the Medical Isotope business. BWXT Medical found the acquisition to be an attractive alternative to a greenfield approach, as it allowed for acquisition of a facility with an operating history, staff that are trained and skilled in working with radioisotopes intended for human use, and developed systems that support a licence that allowed for flexibility in the type of business BWXT Medical intends to carry out at the site.

Due to the short half-life of the existing medical isotope products, it was critical at the time of the acquisition to maintain the uninterrupted ability to operate. Nordion obtained approval from the CNSC to allow BWXT Medical employees to work as contractors within the Medical Isotopes facility under Nordion's Class IB licence and to utilize the systems and procedures in place prior to the acquisition. BWXT Medical was contracted to provide operational and support personnel. This arrangement will continue until BWXT Medical obtains its own Class IB licence, and at that point, although responsibility will shift from Nordion to BWXT Medical, the BWXT Medical staff will continue to use the same systems and procedures that were used prior to the acquisition and through the period post acquisition where Nordion remained responsible.

The acquisition included the Medical Isotope business assets (staff, process facilities and equipment and contracts). Approximately 118 employees (roughly half of the Nordion personnel present at the Ottawa site at the time of the acquisition) were hired by BWXT Medical. At the time of the acquisition, the average length of service for the transferred employees was 19 years and the average length of service for the transferred management team was 29 years.

Since the acquisition, BWXT Medical has significantly increased its workforce. As of February, 2021, BWXT Medical has 187 employees in Ottawa. Of the current number of employees, 55% are former Nordion employees (some employees retired since the acquisition). The current number of employees includes those hired to work in the facility as a Nuclear Energy Worker (NEW). This number also includes those required to support licensed activities (i.e. in Environment, Health and Safety, Quality Assurance, Engineering, and Development). BWXT Medical plans to continue to add more local skilled jobs as new and innovative products are developed for the medical industry. Continued growth is backed by BWXT Medical's parent company and both anticipate a long future in the Ottawa community.

Under the agreement with Nordion, Nordion has leased the medical isotopes portion of the building, and associated areas, to BWXT Medical for a 20-year period, with agreement that the lease can be renewed by five year intervals up to four times. BWXT Medical will have ultimate responsibility and accountability for security, fire protection and facility maintenance requirements under its Class IB licence. Nordion will be subcontracted to provide those services for BWXT Medical. BWXT Medical must seek Nordion's approval for building modifications and introduction of processes that were not carried out previously at Nordion. Coordinated joint emergency response plans have been developed between Nordion and BWXT Medical.

1.2 Facility and Processes

The Nuclear Medicine Production Facility (NMPF) has operated at the 447 March Road, Ottawa site for over 30 years. In 1972, the Cobalt-60 Source Production Facilities were built. In 1982, the Nuclear Medicine Production Facility was constructed and in 2000, the Kanata Radiopharmaceutical Manufacturing Facility (KRMF) was completed. The site location is shown in Figures 1 - 3, and the facility layout of BWXT Medical leased areas in Figure 4.

The site is a parcel of 56.8 acres located to the southwest of the Carling Avenue and Solandt Road intersection. The site is located in Kanata North, which is the area of Kanata north of Highway 417 and includes the following communities: South March, Morgan's Grant, Kanata Lakes and Beaverbrook. The area surrounding the site is a mixture of industrial park and subdivisions. The nearest urban population is the Beaverbrook community, which is located 0.5 km from the site boundary. According to the 2016 Census, the Kanata North ward has an approximate population of 37,000 [https://ottawa.ca/en/living-ottawa/statistics-and-demographics/2016-census].

The facility is comprised of two major production areas. The Medical Isotopes portion involves processing a variety of radioisotopes used in nuclear medicine. The Gamma Technologies portion involves high activity sealed sources used in cancer therapy and irradiation technologies. Licensed activities are currently conducted under a single Class IB licence issued to Nordion as the site is owned and the facility is operated by Nordion.

The medical isotopes facility is inclusive of the radiochemical and radiopharmaceutical facilities in the Nuclear Medicine Production Facility (NMPF) and the radiopharmaceutical facilities in the Kanata Radiopharmaceutical Manufacturing Facility (KRMF). Unless otherwise indicated, reference to NMPF throughout this document is inclusive of the KRMF. The activities to be conducted by BWXT Medical are independent of and will not duplicate those activities related to Nordion's Gamma Technologies business.

The Medical Isotopes area comprises an administrative area known as the "Non-Active Area" and a controlled access production area known as the "Active Area." The Active Area encompasses the KRMF and the radiochemical and radiopharmaceutical facilities in the NMPF. Products produced are used for diagnosis and treatment of disease, benefiting the lives of millions of people around the world.

The handling of radioisotopes takes place in processing containment units such as hot cells, glove boxes and fume hoods (See Figures 5 and 6). The hot cell wall shielding (lead wall, lead bricks, steel, concrete) is selected to minimize dose rates to the operator. The hot cells are typically grouped in banks which have a step down pressure differential to facilitate clean processing. While high radioactivity materials are handled in hot cells, lower activity amounts are handled in glove boxes where the level of radiation and the amount of required shielding is reduced. Glove boxes are typically constructed of Lucite and stainless steel. They are typically equipped with general and localized lead shielding of sufficient thickness to minimize occupational radiation exposure. Neoprene gloves are sealed in place over the flanges at the glove ports. Lucite will eventually be phased-out for construction of future glove boxes due to amendments to regulations on glove box materials.

Fume hoods are generally designed to handle low levels of radioactivity (i.e., Quality Control samples, decontamination of equipment, etc.) and allow easier unrestricted manipulation of parts and chemicals used by the operator. Fume hoods are constructed of stainless steel, inside and out, with service controls located on the exterior face. Localized shielding is used where required to minimize occupational radiation exposure.

Figure 1: 447 March Road Site Location

Figure 2: 447 March Road Site - Aerial View

Figure 3: 447 March Road Site

Figure 4: BWXT Medical and Nordion Facilities

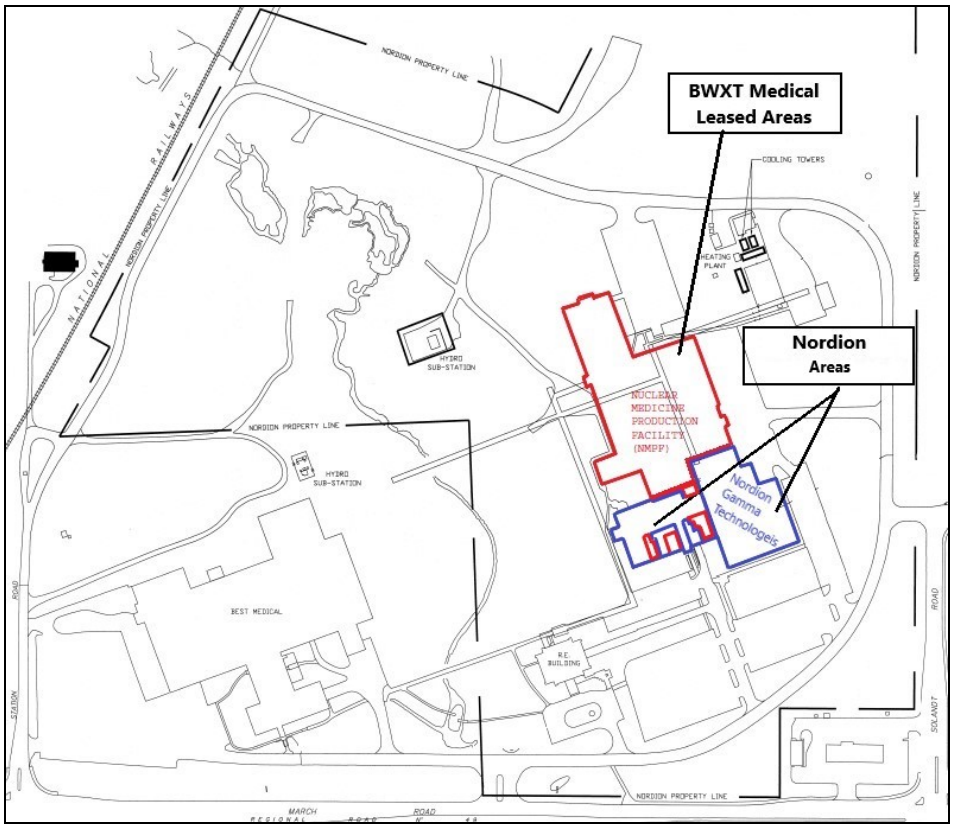
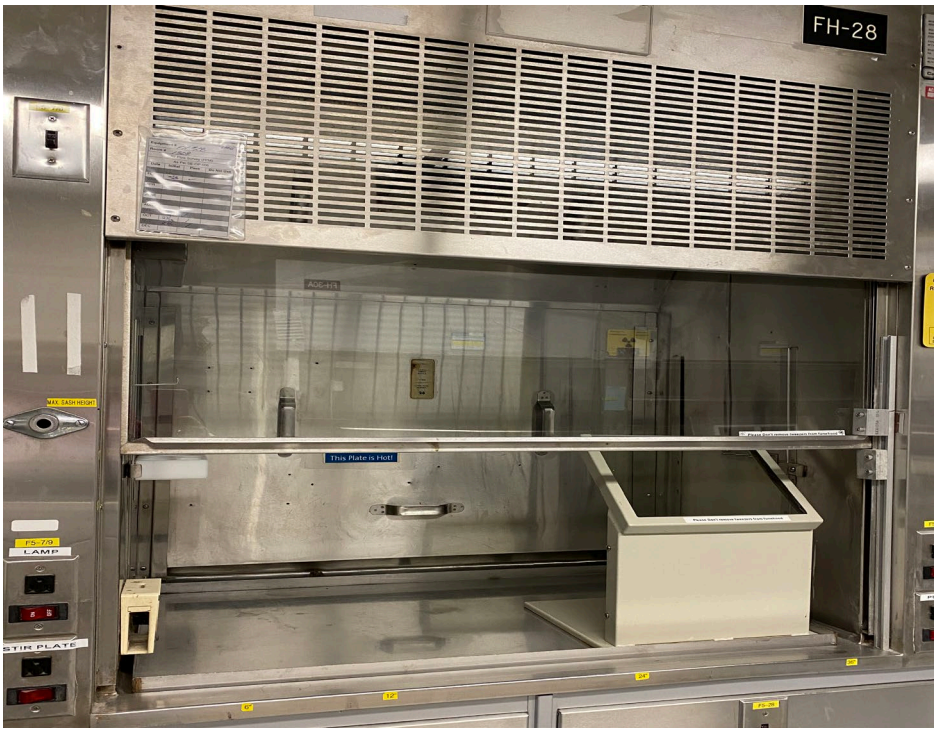


Figure 5 – Hot Cell

Figure 6 – Fume Hood



1.3 Licence Application

BWXT Medical's application for a Class IB nuclear substance processing facility operating licence was submitted to the CNSC on December 17, 2018. The purpose of the application was to request issuance of a Class IB licence to BWXT Medical to operate the existing medical isotope facility currently being operated by Nordion. The activities to be conducted by BWXT Medical are independent of and will not duplicate those activities related to Nordion's Gamma Technologies business.

This licence is required so that BWXT Medical can continue to produce and supply critical radioisotopes for diagnosing and treating disease. The existing products include medical isotopes for diagnosing and treating serious illnesses such as cancer and heart disease. BWXT Medical is committed to growing its portfolio and delivering innovative medical isotope products.

This document provides the CNSC with supporting information regarding BWXT Medical's proposed operations and summarizes programs that have been adopted from Nordion in each of the 14 Safety and Control Areas. This document also outlines any challenges and future plans for BWXT Medical.

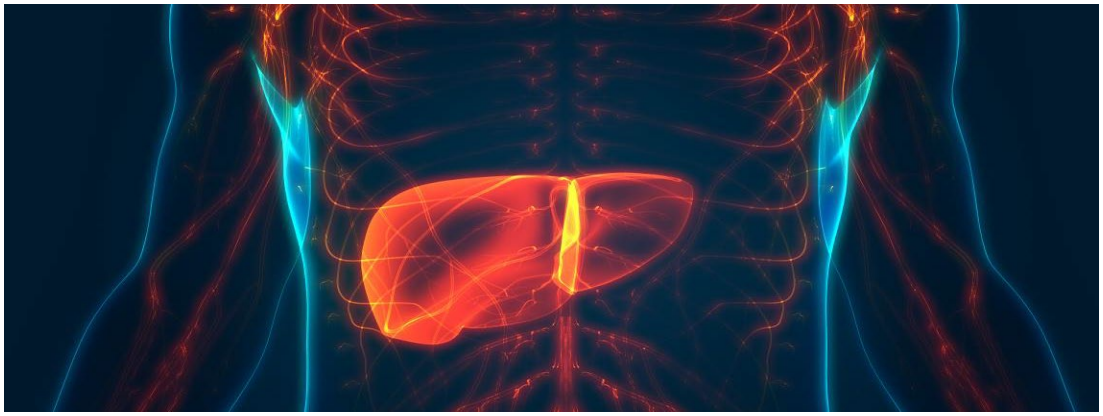
The application included information required to be contained in a licence in respect of a Class IB nuclear facility as required by the Nuclear Safety and Control Act and Regulations [1], and included additional information as requested by the CNSC. BWXT Medical has requested that the licence be issued for a period of ten years.

This application is specific to the Ottawa-based facility and is not inclusive of BWXT Medical's Vancouver-based facility which operates independently under a separate licence issued by the CNSC.

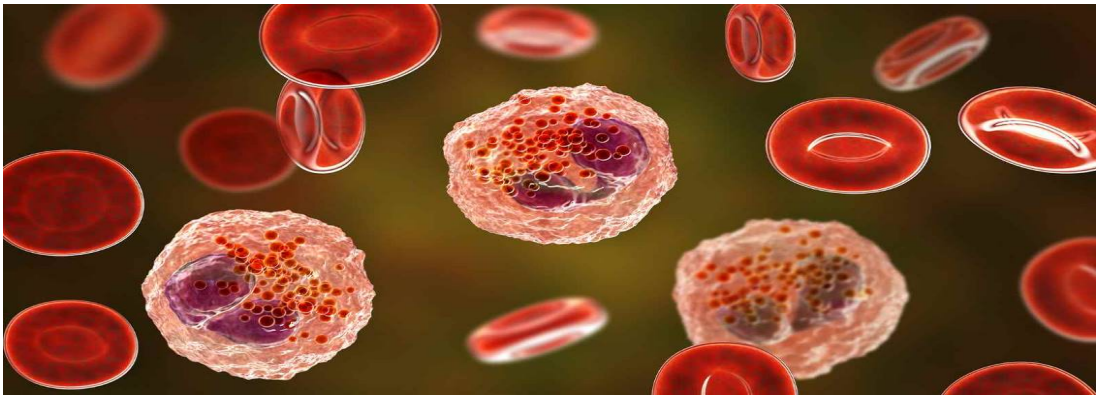
2.0 Business Plan

Today, BWXT Medical's Ottawa operation is comprised of two product lines: Yttrium-90 (Y-90) and Indium-111 Oxine (In-111).

Y-90 is a sterile, active implantable Class III medical device used to treat liver cancer and is manufactured under the Nordion operating licence for BWXT Medical. BWXT Medical is under contract by a third party to supply this product.



In-111 is a diagnostic radiopharmaceutical used for the assessment of inflammation and infection within the body. An example of this is the assessment of diabetic foot infection. The Indium-111 product line was approved in 2018 by the US Food and Drug Administration and was commercially launched in late 2019. The product is produced in the NMPF using In-111 obtained from BWXT Medical's Vancouver operation.



The production of Molybdenum-99 (Mo-99) has a long history at the Ottawa facility. Fission Mo-99 from the National Research Universal (NRU) reactor at Chalk River had been produced at the Nordion facility since the mid-1980's and previously at Atomic Energy of Canada Limited (AECL) Tunney's Pasture. This process was associated with long–lived radioactive waste, highly enriched uranium, noble gases and radioiodines. Production of fission Mo-99 ceased in late 2016 with the shutdown of the NRU reactor.

In 2018, BWXT Technologies, Inc. announced its patent-pending innovative technology to produce molybdenum-99 (Mo-99), the parent isotope of technetium-99m (Tc-99m) which is used in over 40 million diagnostic imaging procedures every year worldwide. This process differs from the fission Mo-99 process and does not require the use of uranium or generate the associated long-lived waste.

Through development of this innovative technology, BWXT seeks to furnish a stable North American-based supply of Tc-99m generators. Tc-99m is the most widely sought after medical isotope used in the diagnosis of serious illnesses, such as heart disease and cancer. Together, intellectual property, licensed infrastructure and highly trained and experienced personnel are paramount in creating this lifesaving product.

The Tc-99m generator program will be the next new product for BWXT Medical, with the aim for a commercial launch in late 2022, pending approval by Health Canada and the US Food and Drug Administration. This program will utilize new, patent pending technology to produce Mo-99 for the Tc-99m generator product. This process differs from the fission Mo-99 process and does not require the use of uranium or generate the associated long-lived waste.

The Tc-99m generator program will draw upon much of the established infrastructure, expertise and quality systems that are in place. Establishing the manufacturing and testing capability has involved the modification to some existing processing hot cell facilities and the construction of new ones; all of which are planned to be within the existing NMPF and KRMF building perimeter. The facility design and modifications have proceeded within the licensing basis established by Nordion's existing Class IB licence and under Nordion's oversight and approval. This licensing basis will be adopted by BWXT Medical. The facility modifications may be completed under Nordion's Class IB licence depending on the timing of issuance of a Class IB licence to BWXT Medical.

The safety assessments for the Tc-99m generator process are being completed following the Nordion Management System for Safety. The preliminary safety assessments have not identified any hazards related to the Tc-99m generator process that are different in nature from those historically identified. Any identified hazards have been mitigated through design and engineering with increased automation and reduced operator intervention. BWXT Medical's preliminary safety assessments conclude that safety requirements for worker safety, public safety and the environment will be met during normal operations and accident scenarios. BWXT Medical further concludes that the process remains within the licensing basis. With regard to the facility design and modifications for the Tc-99m development project, BWXT Medical has followed and will continue to follow well-established procedures that have been internally and externally verified through audits and inspections.

The Tc-99m product line will be sterilized by electron beam accelerators. BWXT Medical is planning to install two electron beam accelerators each with a 7.5 MeV (Mega electron-volt) energy, accelerating electrons which are lower than 4 AMU (atomic mass unit).

Accelerator installation and commissioning is expected to be completed in the third quarter of 2021 (July-September, 2021). The accelerators would then be put in use for product validation activities. BWXT Medical will obtain the necessary Class II licences for construction, commissioning and operation of the electron beam accelerators. At a later date, BWXT Medical will request that the Class 1B licence be amended to incorporate the Class II activities and that the Class II operating licence be revoked.

BWXT Medical plans to continue developing innovative products for the medical industry. The implementation of any new products will be within the licensing basis of BWXT Medical's Class IB licence. The overall intent is to better leverage the medical isotope assets in Ottawa by increasing the portfolio of radiochemical and radiopharmaceutical products.

BWXT Medical will manufacture nuclear substances in excess of 1×10^{15} Bq (Becquerel)/year. Isotopes with > 1-year half-life will not be manufactured, although some impurities will be present that have longer half-lives, all well below 1×10^{15} Bq/year. Production will remain below historical capacity (total radioactive material processed) for the foreseeable future.

3.0 Safety and Control Areas

3.1 General

The CNSC evaluates how well licensees meet regulatory requirements and CNSC expectations for the performance of programs in 14 safety and control areas (SCAs). The SCA's are grouped in functional areas:

- Management: address the organizational and human elements of safety in Canadian nuclear facilities. Specifically, they cover management systems, human performance management, and operating performance.

- Facility and equipment: include safety analysis, physical design, and fitness for service. These areas assess the potential hazards and risks of operating (as well as the preventative measures taken to minimize risk), the integrity of facility infrastructure design, and the overall long-term performance of equipment and systems.

- Core control processes: include radiation protection, conventional health and safety, environmental protection, emergency management and fire protection, waste management, security, safeguards and non-proliferation, and packaging and transport. What these SCAs have in common is that they all cover how a facility operates; they measure actions and plans that are in place, all against the unique and specific nature of each facility.

3.2 Management System

The Management System Safety and Control Area (SCA) is a management framework that establishes the processes and programs required to ensure the organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

3.2.1 Relevance and Management

BWXT Medical will adopt the existing Nordion Management System for Safety. which complies with CSA N286-12, "Management System Requirements for Nuclear Facilities" [2]. BWXT's new Management System for Safety is inclusive of the 14 SCA's described in this CMD. The BWXT Management System controls work carried out to perform, or in support of, licensed activities from the planning stages to completion and covers the control of activities both at the working level, and at the corporate level. The latter ensures the oversight needed to provide corporate direction and maintain overall accountability, and to ensure that communication between individuals and organizations is effective and in the interest of safety. The BWXT Management System includes mechanisms, such as audits, self-assessments and management reviews to ensure continuous improvement and effectiveness. The BWXT Management System consists of the following key elements:

- Organization and Responsibilities;
- Personnel Capability;
- Use of Experience;
- Work Planning Control;

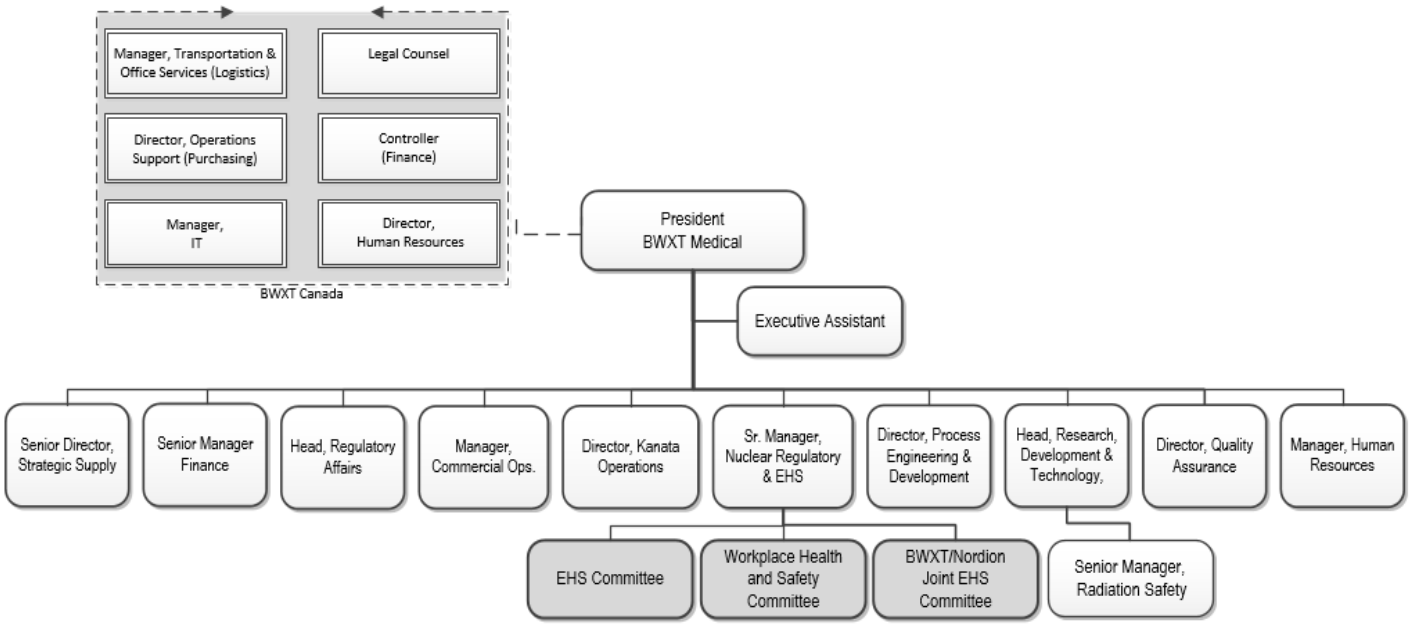
- Work Processes Control Practice;
- Verification;
- Non-conformances;
- Corrective Action;
- Change Control;
- Document Control and Records;
- Audits;
- Management Self-Assessment; and,
- Management Program Review.

3.2.2 Organizational Structure

The President of BWXT Medical is responsible for all activities within BWXT Medical. Operations and the various functional groups, such as Human Resources, Environment Health and Safety, and Quality Assurance, report directly or indirectly to the President. Senior management is accountable for the effectiveness of the Management System.

Figure 7 outlines the leadership organization. The President of BWXT Medical is responsible for total operations of BWXT Medical and reports to the President of BWXT Canada Ltd.). The Senior Manager, Nuclear Regulatory and EHS has been delegated the authority to act on behalf of the President of BWXT Medical on regulatory matters with the CNSC.

Figure 7 – Leadership Organization Structure



3.2.3 EHS Committees

Currently, key BWXT Medical personnel participate on Nordion's Environment, Health and Safety (EHS) Committee. BWXT Medical will establish a similar, independent EHS Committee which will be responsible for reviewing and approving, from a safety perspective, the design, construction, commissioning, operation, and decommissioning of BWXT Medical manufacturing facilities and processes. The BWXT Medical EHS Committee will be comprised of senior management and technical professionals. Reviews by the new BWXT Medical EHS Committee will consider the potential impact of the facility and process hazards on the health and safety of employees, members of the public and the environment, and will ensure measures are taken to minimize risk. The BWXT Medical EHS Committee will regularly review occupational health and safety, radiation safety, and environmental management performance metrics. Sub-committees will be appointed as necessary, to conduct detailed technical reviews and report back to the BWXT Medical EHS Committee.

In addition to the BWXT Medical EHS Committee, a Joint Nordion-BWXT Medical EHS Committee will be established. This committee will be responsible for reviewing, monitoring and recommending changes to the implementation of environmental health and safety protocols and procedures that could impact environmental health and safety on the site, public safety, security, regulatory compliance and the ability to operate the licensed nuclear facilities. The joint committee will review and approve proposed changes that could impact the licensing basis of either company. The joint committee will review environmental performance data, nuclear, environmental and occupational health and safety incidents, occurrences, and accidents, and safety critical issues/matters and will share operating experience (OPEX).

3.2.4 Environmental, Health and Safety Policy

BWXT Medical has an established policy for environmental, health and safety which describes the company's commitment to conduct its business in a safe and environmentally responsible manner. This includes a commitment to maintain risks to employees, members of the public and the environment to be as low as reasonably achievable (ALARA), to minimize waste and maximize reuse and recycling opportunities throughout our business and to routinely seek opportunities to improve our safety and minimize our environmental impacts.

3.2.5 Safety Culture

BWXT Canada's corporate policy describes the company's commitment to the establishment and continuous improvement of a safety culture. The safety culture refers to the core values and behaviors resulting from a collective commitment by BWXT Medical leaders and individuals to emphasize safety, quality, ethics and security over competing goals to ensure protection of people and the environment. BWXT Medical is committed to maintaining a strong safety culture and clearly states the expected safety culture behavior. BWXT Medical employees are encouraged to correct or coach co-workers who are working unsafely.

BWXT Medical's commitment to a strong safety culture is measured by means such as audits and self-assessments, use of experience and corrective action program metrics which measure the effects of safety culture improvements. BWXT Medical is committed to performing routine safety culture surveys and to use a variety of means to promote safety culture. External agencies such as the CNSC will audit BWXT Medical's operations against Canadian Standards Association (CSA) standards which include Safety Culture requirements (e.g., CSA N286-12 [2]).

3.2.6 EHS Program Objectives and Target

BWXT Medical will set annual Environment, Health and Safety (EHS) Program objectives and targets. The performance of the BWXT Management System will be evaluated on whether EHS objectives and targets are met and the effectiveness of the program as determined by the overall review. The results of the performance review will drive continuous improvements to the Management System.

3.2.7 Internal Performance and Safety Indicators

BWXT Medical will establish internal performance and safety indicators as a means to monitor the effectiveness of its Management System. Indicators will be established for each SCA and may include indicators such as:

- Overall performance against the EHS program objectives and targets;
- Number and nature of non-conformances, EHS incidents and reportable events;
- External and internal radiation exposures against EHS targets, internal levels, and regulatory limits;
- The number of lost-time and medical treatment injuries;
- The number and nature of near-miss and concern reports;
- The results of internal Workplace Health and Safety Committee inspections;
- Results of internal and external audits;
- Effluent and emission releases against EHS targets, internal levels, and regulatory limits;
- The results of environmental dosimetry, monitoring and assessments; and,
- Safety culture survey results.

3.2.8 Improvements to the Management System

BWXT Medical commits to continuous improvement of the BWXT Management System for Safety, including safety culture.

3.2.9 Future Plans

Once the licence has been issued, revisions to a number of documents will be required to reflect BWXT Medical's organizational structure. BWXT Medical will revise these documents according to a schedule provided to the CNSC as part of the application. Relevant documents will be submitted to the CNSC for approval as required by the anticipated BWXT Medical Licence Conditions Handbook.

Updates to the BWXT Management System will be implemented in line with any future version releases of CSA N286.

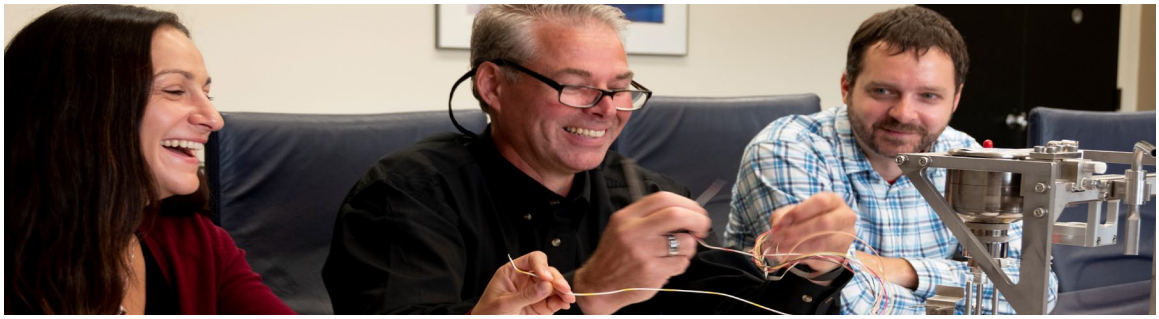
3.2.10 Challenges

No challenges are foreseen at this time.

3.2.11 Requests

BWXT Medical has no requests concerning this SCA at this time.

3.3 Human Performance Management



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

3.3.1 Relevance and Management

BWXT Medical's Training Program is designed to educate applicable employees to meet regulatory and certification requirements and minimize potential impacts to environment, health and safety. Qualifications and training requirements are identified and personnel are assigned the appropriate training to ensure they are competent in the work they perform. Such training includes on-the-job training, radiation protection, and other safety training. Workers only perform functions for which they are qualified.

Management identifies qualifications and training requirements. Employees are given appropriate training and instruction, and tasks are assigned to employees who have been properly trained. Training programs are monitored and assessed regularly, and the competency of personnel is reviewed to maintain their effectiveness and skill levels. Records of training, qualifications, and experience are maintained.

Initial selection of qualified personnel is first performed through the Human Resources hiring process. Employees who are assigned responsibilities are competent on the basis of applicable education, training, skills, and experience. Established training programs ensure personnel have the required training to perform their job functions. BWXT Medical's employee training programs support the Management System for Safety and ensure that it is understood, implemented and maintained.

Departmental directors and managers are responsible for ensuring that their employees are competent and qualified to perform their required job functions and for determining and documenting the training needs of each employee in their department. Departmental directors and managers are responsible for ensuring the effectiveness of the training provided to the employee, managing the completion of employee training, and maintaining paper records as required.

3.3.2 Systematic Approach to Training

BWXT Medical's training system employs a systematic approach to training (SAT). SAT is a cyclical process which allows for training to be systematically analyzed, designed, developed, implemented, evaluated, documented and managed to meet operational and organizational requirements and to react quickly to make changes to those requirements. The application of SAT is done in a manner commensurate with the risks and characteristics of the business activity. The SAT program meets the requirements of REGDOC-2.2.2 (2016), Personnel Training, Version 2 [3].

3.3.3 EHS Training

Employees who are not classified as a Nuclear Energy Worker (NEW) receive a basic course on Health, Safety and Environment, which provides information on the facilities, emergency response procedures and alarms, and basic procedures to follow for safety in the workplace. Employees who are classified as a NEW receive training as described in section 3.2.4.

Supplementary EHS training is provided to all personnel depending on the nature of the job and the requirements specified by their manager. This training includes such topics such as:

- Emergency Response Awareness;
- Care and Use of Respirators;
- Material Handling;
- Working Safely with Fume-hoods;
- Working at Heights; and,
- Confined Space.

3.3.4 Radiation Protection Training

A variety of radiation safety training courses have been designed and maintained at BWXT Medical. Nuclear Energy Workers receive a NEW indoctrination course. To be authorized to enter the Active Area unescorted, the employee must complete and pass a written test as evidence of understanding the principles of radiation protection and safe work practices. NEW retraining and retesting is conducted on a three-year frequency. In addition, NEWs are provided with a half day radiation instrumentation workshop. This workshop focuses on the selection and use of radiation survey and contamination meters for the Active Area.

3.3.5 Supervisor and Management Training

As required by the Canada Labour Code-II [4], managers and supervisors are trained to ensure that workers use prescribed protective equipment; workers are advised of potential and actual hazards; and that every reasonable precaution is taken for the protection of workers. In addition, to protect workers and to ensure nuclear security, managers and supervisors are trained to anticipate and respond to changes in employee behavior in accordance with both the violence prevention requirements under the Canada Labour Code-II and the Nuclear Security Regulations [5].

3.3.6 Number of Qualified Staff

BWXT Medical will ensure the availability of the minimum number of personnel required to provide safety oversight during overnight operations and during emergency situations is achieved. Site security personnel are on site at all times. Radiation Surveyors are always on site when production involving radioactive materials is occurring.

Currently, BWXT Medical's employees have been trained on Nordion's emergency response program and a joint Nordion-BWXT Medical emergency response plan has been established. A number of BWXT Medical employees fill roles on the emergency response team. Key emergency response personnel, facilities and production managers are on-call at all times. The Incident Manager, or the person in charge of the response, can initiate a call-in of both on-call and regular emergency response personnel. Currently, there are approximately 70 Fire Wardens and Marshalls and over 80 other emergency response personnel.

The availability of qualified staff to respond to emergency situations is routinely assessed as part of the Emergency Response Program and through drills and exercises. The emergency call list is tested annually and the results have demonstrated year over year that within one hour of the onset of an emergency, adequate emergency response personnel and at least one representative from each of the key emergency response groups is available on-site. A formal on-call roster is maintained.

There is a minimum of one and normally two Health Physicists on call who are qualified to establish and direct radiation safety activities to protect personnel, the public, and the environment from radiation hazards and to develop and maintain safe work methods and procedures.

3.3.7 Future Plans

BWXT Medical will continue to improve Human Performance Management across its operations to ensure that employees have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

3.3.8 Challenges

BWXT Medical does not anticipate any specific challenges with respect to Human Performance Management. The BWXT Medical employee base is comprised of highly qualified, experienced employees hired during the acquisition of Nordion's medical isotope division. Employees hired since the acquisition have been trained according to the well established Nordion training programs.

3.3.9 Requests

BWXT Medical has no requests concerning this SCA at this time.

3.4 Operating Performance

The Operating Performance SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

3.4.1 Relevance and Management

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

3.4.1.1 Conduct of Licensed Activities

Licensed activities will be conducted in accordance with established programs and procedures. These programs require work to be planned and controlled. Work activities will be identified, sequenced, and defined in approved plans, procedures, instructions and drawings. Work activities include design control, procurement, operations, shipping, receiving, handling and maintenance.

Requirements will be identified for avoiding damage, contamination, foreign material ingress, for maintaining clean and protective conditions, and for proper handling, storing, shipping and preservation. Independent verifications are identified and scheduled to verify that specific requirements are met. Procedures, instructions, drawings, programs and tools will be identified, prepared and approved for use.

3.4.2 Operational Review

Operating performance is monitored with key performance indicators and program goals. In accordance with EHS program requirements, internal audits are conducted annually to assess conformance to internal and external requirements. Reporting of EHS-related concerns are encouraged and tracked to completion, which is also used as a measure of employee engagement.

Performance reviews of the BWXT Management System will be conducted on a routine basis by BWXT Medical's EHS Committee. At each committee meeting, the committee will review EHS performance, including the status of environmental, health and safety corrective actions and preventive actions (CAPAs), results of EHS incidents or investigations, status of EHS objectives and targets, internal EHS audit findings, and the status of actions from previous meetings. The EHS Committee will review this information and document any actions resulting from the review in the meeting minutes.

In addition, the committee will conduct an annual management review of the BWXT Management System to ensure this program remains suitable and effective. Results from the annual EHS Performance Report will be reviewed. The annual management review will involve the evaluation of:

- Status of actions from previous management reviews;
- Adequacy of resources;
- Trends in non-conformances for closure metrics;
- Extent to which EHS objectives and targets have been met;
- Radiation dose trends;
- Changing circumstances, including compliance obligations;
- Opportunities for continuous improvement; and,
- Evaluation of the effectiveness and continuing suitability of the EHS; policy and the EHS program.

Actions and decisions resulting from the annual review of the BWXT Management System will be documented in meeting minutes.

3.4.3 Operating Experience

BWXT Medical's EHS Committee will be responsible for conducting reviews of OPEX. The OPEX process involves gathering and reviewing information to identify, obtain and evaluate in-house and external experience related to the operations conducted under BWXT Medical's future facility operating licence. The analysis of this information will be used and action will be taken to improve safety and management processes. OPEX will be shared with and gathered from Nordion via the Joint Nordion-BWXT Medical EHS Committee.

3.4.4 Reporting and Trending

When EHS-related non-conformances (i.e. deficiencies in equipment, systems or management processes which are used to carry out, or in support of, licensed activities) are found, they will be identified, recorded and reported as required. Events including occupational injuries, hazardous occurrences, near-miss situations, and radiation, environmental and contamination incidents will be investigated.

Incidents and non-conformances will be identified through non-conformance procedures, investigations, and internal audits. As part of the BWXT Management System, internal audits will be conducted annually to verify compliance with applicable procedures and requirements. These audits will ensure that BWXT Medical's programs and systems are compliant to applicable standards and regulatory requirements, conform to internal policies and procedures, and are properly implemented and maintained.

Corrective Action and Preventive Actions (CAPAs) will be issued as required to address incidents and non-conformances. There is will be a CAPA process to investigate and identify the root cause of environmental and safety issues and to implement and track corrective actions needed to prevent recurrence. CAPA will also be used to initiate preventive actions to deal with potential problems.

Annually, EHS related non-conformances and corrective and preventive actions from the previous year will be reviewed and analyzed in an EHS Performance Report. The data will be analyzed to determine the presence of any undesirable trends, the effectiveness of corrective action taken and whether additional corrective action is required. The EHS Performance Report will be distributed to and reviewed by the BWXT Medical EHS Committee in the annual management review of the BWXT Management System.

Annual compliance and performance reports will be submitted to the CNSC to demonstrate BWXT Medical's compliance with the Nuclear Safety and Control Act [1], applicable Regulations, licence conditions and Licence Conditions Handbook. Other regulatory reporting will take place as required and meet the requirements of REGDOC-3.1.2 (2018), Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills [6]

3.4.5 Future Plans

BWXT Medical is committed to continuous improvement in areas that affect operating performance and the conduct of licensed activities. Actions will be taken as required to improve safety performance and the management process.

3.4.6 Challenges

BWXT Medical does not anticipate any specific challenges with maintaining a high level of operating performance. Operational performance will be maintained and improved with ongoing monitoring and consideration of issues and problems as they arise.

3.4.7 Requests

BWXT Medical has no requests concerning this SCA at this time.

3.5 Safety Analysis

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

3.5.1 Relevance and Management

At BWXT Medical, safety is based on the defence-in-depth principle. First, hazards are prevented or eliminated if possible. There are robust procedural controls to ensure that all hazardous material is reviewed and approved by EHS prior to being introduced into the facility. Activity limits are established based on the results of safety analysis to ensure that the amount of radioactivity is limited appropriately in each work location. Finally, the hazards associated with facility additions or modifications are assessed and eliminated if possible at the design stage prior to operation.

If the hazard cannot be prevented or eliminated, passive engineered features are then considered. These primarily relate to hot cells, glove boxes, fume hoods and transfer containers – all of which are specifically designed to provide an adequate level of containment and shielding for radioactivity and other types of hazardous material.

In addition to passive engineered features, there are multiple active engineered features (e.g., safety interlocks, heat-activated fire suppression systems) and administrative controls throughout the facility.

3.5.2 Facility Safety Analysis

Under the safety analysis process, Final Safety Analysis Reports (FSARs) are prepared to encompass risk analysis, safety and environment reviews. Safety assessments are performed for new medical isotope processing facilities or supporting processes such as packaging lines and waste storage areas, or when significant changes are made to existing medical isotope processing facilities or supporting processes.

It is a fundamental premise of the safety analysis for normal operations and accident scenarios that:

- Nuclear substances are processed inside a hot cell, glove box or fume hood, which is exhausted to the Nuclear Ventilation System (NVS);
- Nuclear substances are transferred and stored in containers with the appropriate amount of shielding; and,
- Activity limits are established and maintained as a primary administrative control. An activity limit is the maximum activity of a given radionuclide that is permitted in each hot cell, glove box and fume hood. Activity limits are determined based on the analyses contained in FSARs, and are reviewed and approved by the EHS Committee.

FSARs must be approved by the BWXT Medical EHS Committee before a new medical isotope processing facility or supporting process goes into routine use or prior to unrestricted start-up following modifications. FSARs are reviewed routinely as per an established review schedule.

The safety case for the overall facility is maintained in the primary Nuclear Medicine Production Facility FSAR. This FSAR requires CNSC approval in addition to the approval provided by the BWXT Medical EHS Committee.

Secondary FSARs for each individual processing facility and support area provide analysis of the safety hazards unique to those areas. When modifications are made to secondary FSARs, an assessment will be performed and details will be captured in the overall primary FSAR, as required.

Modifications to the facilities are made in accordance with the change control program, which requires review of EHS parameters for new or modified facilities, processes, and new or relocated machinery, apparatus and equipment. Under this process, a proposed modification is assessed for potential impact on the facility safety analysis. Where assessment identifies a potential impact, a more detailed review of the proposed modification is conducted to identify if the change impacts a safety system, or the basis of the safety assessment (e.g. materials, quantities, locations, etc.). Third-party reviews or regulatory approvals are conducted as required. Impacts on the safety analysis are identified and the safety analysis is validated and updated where necessary.

3.5.3 Fire Hazard Analysis

A Fire Hazard Analysis compliant with CSA Standard CSA-N393-13 “Fire Protection for Facilities that Process, Handle or Store Nuclear Substances” [7] has been accepted by the CNSC. The Fire Hazard Analysis was conducted by a qualified third party and assessed potential risks from a fire to personnel safety, property and operations, and the environment to ensure these risks are managed in a manner that minimizes potential impacts.

Any changes to the facility that potentially impact fire protection systems will be reviewed by a qualified third party to ensure that these changes do not pose a risk to life, safety or the environment. These reviews will be submitted to the CNSC. Annually a third party will conduct a compliance review regarding inspection, testing and maintenance of the Fire Protection System. These reviews will be submitted to the CNSC.

3.5.4 Future Plans

BWXT Medical’s EHS Committee will review and approve the safety analysis for new medical isotope processing facilities, equipment, or operations and significant changes, as they arise and ensure the fire hazard analysis for the facility remains current. Depending on when the CNSC issues BWXT Medical its own Class IB licence, review and approval of the final safety analysis for the Mo-99/Tc-99m generator process will be performed by the BWXT Medical EHS Committee or the Nordion EHS Committee.

3.5.5 Challenges

No challenges are anticipated at this time.

3.5.6 Requests

BWXT Medical does not have any requests concerning this SCA.

3.6 Physical Design

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

3.6.1 Relevance and Management

BWXT Medical will retain ultimate responsibility for buildings, systems and equipment required for operation of the NMPF. Under the lease with Nordion, Nordion will maintain the base facilities infrastructure such as fire protection, mechanical, plumbing, electrical and heating, ventilating, air conditioning and all other climate control systems. BWXT Medical will be responsible for maintenance and inspection of equipment within the leased premises, specifically related to the processing of radioisotopes, including hot cells, fume hoods and glove boxes. BWXT Medical will ensure that outside firms used to carry out work on equipment specifically related to medical isotopes processing are qualified.

The design control program entails conceptual, ergonomic, and final design reviews. This program ensures that designs meet established codes and standards and all applicable requirements. Design control is applicable to all process equipment and buildings, systems and equipment in support of licensed activities.

Design control is the responsibility of the Design Authority. The Design Authority is responsible for ensuring all design activities related to the licensed activities are controlled and meet all applicable licences, regulations, codes and standards. In practice, the Design Authority may delegate responsibility to Technical Design Authorities who have been assigned based on specific product lines and facility requirements.

Changes made to the physical facilities, equipment, processes, procedures or practices that could adversely affect employee and public health and safety or the environment due to the operation of BWXT Medical's facilities are assessed through the change control program. Any changes to the design basis are identified and assessed through this program, including third-party reviews as required. Adequate mitigations are applied including modification of the proposed change, up to rejection of the proposed change.

A comprehensive EHS requirements checklist which is part of the change control process will ensure that changes within BWXT Medical that may have environment, health, and safety impacts are appropriately evaluated by qualified EHS personnel. This will apply to acquisitions of capital equipment, new products, materials, or chemicals that are being brought on site for the first time, and for projects that could have a significant impact on the environment, health and safety (e.g. the installation of new facilities, the design of new production processes, modifications to existing facilities or processes, and changes to the Nuclear Ventilation System (NVS)). The design, installation, operation and maintenance of boilers and pressure vessels will be done in accordance with CSA B51 2014: *Boiler, pressure vessel, and pressure piping code* [8].

The change control fundamentals as described include:

- Recognition of the need for change control and detailed description of the change;
- Thorough assessment of the change impact on the original system design intent and development of any mitigation requirements (i.e., to manage any effects of unsuccessful changes and unforeseen events);
- Authorization to proceed with the change plan;
- Controlled installation, commissioning, qualification and communication of the change; and,
- Update of associated documentation and training for the change(s).

The BWXT Medical EHS Committee will approve significant changes to facilities which could alter any conclusions reached regarding the safety of the facility as established in the approved safety analysis. Any physical facility modifications require Nordion's approval under the lease. The BWXT Medical's EHS Committee will approve any safety systems that are intended to protect the operator, other employees and the public from a radiation hazard.

3.6.2 Fire Protection System Design Changes

Prior to the implementation of any proposed modification to BWXT Medical's facility with the potential to impact protection from fire, the following will be completed:

- The proposed modification is submitted for third-party review;
- The review is carried out by one or more independent external reviewer(s) having specific expertise with such reviews; and,
- Results of the review are submitted to the CNSC or a person authorized by the CNSC.

Plant modifications at BWXT Medical's facility will also be made in accordance with National Building Code 2015 [9], National Fire Code 2015 [10] and CSA N393-13, Fire Protection for Facilities that Process, Handle or Store Nuclear Substances [7].

3.6.3 Future Plans

BWXT Medical is committed to continuously improve the physical design process that is in place to assess the impact to the ability of structures, systems and components to continue to meet and maintain their design basis given new information arising over time and taking into account changes in the external environment.

3.6.4 Challenges

BWXT Medical does not anticipate any challenges with ensuring the physical design is maintained for structures, systems and components specific to medical isotope processing, including hot cells, fume hoods and glove boxes.

3.6.5 Requests

BWXT Medical does not have any requests concerning this SCA at this time.

3.7 Fitness for service

The Fitness for Service SCA 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.

3.7.1 Relevance and Management

BWXT Medical will retain ultimate responsibility for the facilities buildings, systems and equipment required for operation of the NMPF. Under the lease, Nordion will maintain and is responsible for aging management of the base facilities infrastructure. BWXT Medical will be responsible for maintenance and inspection of equipment within the leased premises specifically related to the processing of medical isotopes, including hot cells, fume hoods and glove boxes, and radiation detection equipment.

BWXT Medical has an electronic system in place to manage the maintenance and calibration of equipment that supports the facility. All equipment requiring calibration or maintenance is identified with a unique number and all equipment information including maintenance and calibration frequency and issued work orders is documented.

3.7.2 Future Plans

BWXT Medical is committed to continuous improvement to fitness for service to ensure the physical condition of structures, systems and components remain effective over time and all equipment is available to perform its intended design function when called upon to do so.

BWXT Medical is planning to implement a different electronic system for management of maintenance and calibration in the future. Implementation of this system will be done under change control ensuring that any potential impacts to safety, the environment or licensing commitments are assessed. This change may be implemented under Nordion's oversight depending on scheduling and timing of issuance of the BWXT Medical's licence.

3.7.3 Challenges

BWXT Medical does not anticipate any challenges with ensuring continued fitness for service.

3.7.4 Requests

BWXT Medical does not have any requests concerning this SCA at this time.

3.8 Radiation Protection

The Radiation Protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations SOR/2000-203* [11]. This program must ensure that contamination and radiation exposure are monitored and controlled, and maintained as low as reasonably achievable (ALARA).

3.8.1 Relevance and Management

The BWXT Radiation Protection Program identifies the measures and systems in place to ensure that contamination levels and radiation exposure to employees and the public are kept as low as reasonably achievable (ALARA), social and economic factors are taken into consideration, and to monitor and measure environmental releases. This reflects the BWXT Canada's corporate commitment to provide employees with a safe and healthy work setting and to protect the natural environment.

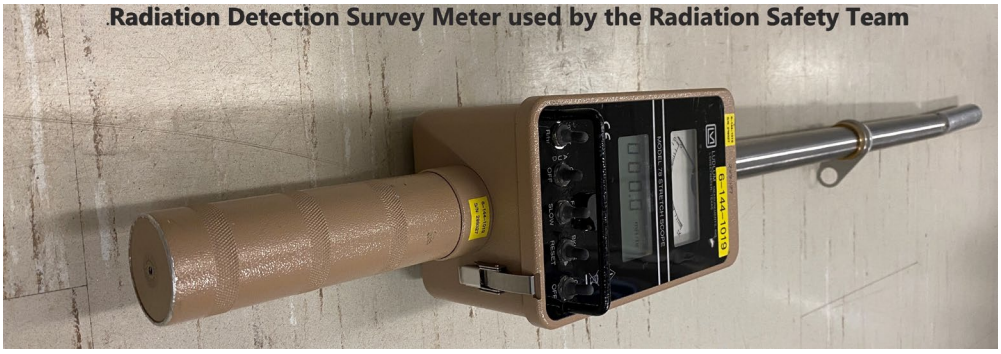
This program has been implemented in accordance with the CNSC *Radiation Protection Regulations* [11], and CNSC Guidance Document G-129, "*Keeping Radiation Exposures and Doses As Low As Reasonably Achievable*" [12]. The radiation protection program identifies corresponding procedures to ensure that radiation exposures and doses are kept ALARA. Key components of BWXT Medical's radiation protection program include:

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

The program includes all worker radiation safety elements, demonstrating compliance to relevant regulations, codes and standards including:

- EHS policy commitment to ALARA;
- Area classifications and requirements;
- Material handling;
- Non-routine or high-risk work controls;
- Internal and external radiation hazard assessments; and,
- Internal and external radiation monitoring and recording.

3.8.2 Radiation Protection Control Measures



3.8.2.1 Prevention

3.8.2.1.1 Zones

Radiation risks are minimized through the design of the facility, with well-defined boundaries between areas that are completely clean of contamination (Zone 4, non-active area), unlikely to be contaminated (Zone 3), areas that may contain contamination (Zone 2), and areas of known contamination (Zone 1). Zones 1, 2 and 3 comprise the active area.

3.8.2.1.2 Ventilation System Interlocks

The ventilation system has a system of interlocks to ensure a balance of exhaust air flow when opening the door of one processing unit which is tied into the same ducting as a second processing unit. This will ensure no impact or loss of ventilation to the second unit.

3.8.2.1.3 Pressure Differentials

For typical processing cells, to contain any radioactive contamination to the interior of the cell, the ambient pressure in the cell is typically maintained below the room ambient pressure.

For the special case of production clean rooms, there are two conflicting requirements. Particles and organisms must be prevented from entering the clean room so airflows must be from the clean areas to the dirty areas (i.e. from the laboratory to the corridor). However, to control the spread of any radioactive contamination, the opposite is required; airflows must be from the inactive areas to the active areas. To meet these conflicting requirements, an anteroom is required between a clean room and a corridor.

3.8.2.1.4 Back-up Power

Back-up power is supplied to all equipment required to enable the facility operations to be shut down and to safely contain and shield radioactive material during a primary power failure.

3.8.2.1.5 Safety Signs

Signs indicating the maximum radiation levels in the working area are located in processing areas. In addition, radiation field intensity signs are located as required on walls and doors throughout the active area. Lastly, there is signage for hot cells requiring the use of proper cell door opening procedures.

3.8.2.1.6 Personal Protective Equipment

The requirements for personal protective equipment (PPE) have been defined and include protective eyewear, footwear, protective clothing, gloves and dosimeters.

3.8.2.1.7 Activity Limits

The maximum activity for each radioisotope permitted in the hot cells, glove boxes, and fume hoods has been defined to control employee exposure during normal operations and postulated abnormal events. Use of activity in excess of these limits is only allowed under an approved work permit.

3.8.3 Detection

3.8.3.1.1 Radiation and Contamination Monitoring System

The radiation monitoring system for the Medical Isotopes area consists of multiple radiation detection devices that are strategically placed at locations within the active area. All locations are simultaneously monitored via a computerized system. This includes an exhaust stack monitoring system that is also monitored via the computer system. This displays radioactivity build-up on the filtration systems and allows process releases to be immediately addressed.

Primary personnel protection devices include permanently mounted air samplers to monitor airborne contamination and radiation alarms to register elevated exposure rates. Portable, hand held instruments for checking local fields are also available. Full body monitors or contamination meters are provided at personnel barriers and are to be used when leaving the active area.

3.8.3.1.2 Air Monitors and Samplers

Air monitoring is conducted at all hot cell, glove box and fume hood locations in the facility on a continuous basis. Sampling points are located throughout the service areas and work rooms, and where practical, close to the employee work area. As well, sampling points are located between the source and the point of inhalation where practical. When this is impractical, the sampling point is located in the work area where it is best able to sample the room air so that it is representative of contamination levels in the general room air.

3.8.3.1.3 Material Transfer

Radioactive material transfers may take place only under certain conditions. Cells having low contamination levels may be loaded through the normally locked rear access door only under the supervision and control of a Radiation and Contamination Monitor. Transfers of high activity materials that take place through the floor openings are subject to contamination control and radiation monitoring requirements.

3.8.3.1.4 Contamination Control

For the active area, contamination control includes routine sampling and monitoring on a daily basis of the floors, benches, fume hoods and glove boxes, change rooms and support/service areas. Regular sampling by wipe testing of the corridors and office areas is conducted several times daily to ensure areas are maintained contamination free and, should contamination be found, to decontaminate immediately to “clean on swipe.” In addition, equipment leaving the active area is monitored by wipe test and/or direct measurement to provide assurance that equipment leaving the active area meets administrative and regulatory requirements.

3.8.3.1.5 Routine Radiation Surveys

As part of the radiation survey program, radiation measurements are taken within the active area and on the perimeter and exterior of the facility. Within the active area, radiation surveys are typically conducted on a daily basis, throughout all labs and rooms, operational requirements permitting. Areas where radiation fields are above 0.025 mSv (millisievert)/hour (2.5 mrem (millirem)/hour) are posted with radiation warning signs in accordance with CNSC Radiation Protection Regulations [11]. In addition, surveys are conducted at employee work areas, cells, glove boxes and fume hoods during production and test operations to ensure radiation fields during processing are within acceptable levels.

On a monthly basis, radiation surveys are conducted on the perimeter of the active area and within the inactive office areas. The monthly survey also includes measurement of radiation fields outside the facility to ensure conditions have not changed in the operations that may impact the environment/exterior exposure.

3.8.3.1.6 Special Surveys

Special surveys are conducted on new processes and equipment to provide information on their safety performance.

3.8.4 Control

3.8.4.1 Shielding

The handling of radioisotopes takes place in processing containment units such as hot cells, glove boxes and fume hoods. The wall shielding (lead wall, lead bricks, steel, concrete) is selected to minimize radiation dose.

3.8.4.2 Supply Air Filtration

A filtered air supply system is used to reduce the spread of airborne contamination in the event of cell pressurization and reversal of airflow.

3.8.4.3 Radiation Evacuation Alarms

Several high level radiation alarm units are positioned in the active area. The monitors of these units respond to high radiation fields from the Nordion Gamma Technologies facility with a steady Klaxon (loud horn) alarm and a flashing light. Alarms are monitored at the Security Control Centre.

3.8.4.4 Exhaust Ventilation System

The air exhaust system is designed to reduce all contaminants, radioactive or otherwise, that were added while the air was resident within the building or within various processes to insignificant levels. All air in the facility is exhausted through one to three stages of filtration to remove both particulate and gaseous contaminates. The ventilation system is comprised of primary and secondary filtration systems that include high efficiency particulate air (HEPA) filters and, for volatile substances, activated charcoal adsorption devices (CADs).

3.8.4.5 Control Air

Compressed air is used to operate the nuclear ventilation system controls. All low air pressure alarms are monitored.

3.8.4.6 Decontamination of Equipment and Containers

Decontamination rooms have been designated in the NMPF. In these rooms, air ventilation is provided through fume hoods and directed exhaust ports to minimize the potential for airborne contamination. Shipping containers, process equipment, and any material coming in contact with radioactive materials are decontaminated, monitored and then released for use.

3.8.5 Potential Radiological Hazards

The radiation protection program addresses the potential radiological hazards associated with medical isotope processing. The primary potential worker hazard is external radiation exposure. A lesser potential hazard is inhalation of airborne particulate which could result if a spill of radioactive material were to occur. Controls and mitigation measures are in place to address both potential external and internal radiation hazards.

Currently, there are no detectable releases of radioactivity in airborne emissions or waterborne effluent from the NMPF during normal operations. Additionally, there is no detectable gamma radiation field outside the facility that is directly attributable to operations inside the facility.

BWXT Medical's radiation protection program ensures that surface and airborne contamination and radiation doses to employees and the public are monitored and controlled.

3.8.6 Radiation Monitoring Program

At BWXT Medical, a monitoring program to control radiation exposure is in place. An intensive program of routine radiation surveys is carried out in all active areas to ensure that the external exposure of NEWs to ionizing radiation from all routine work is kept to a minimum and within safe limits. Workplace air sampling and monitoring programs help to identify any release of contamination into the air or onto surfaces. Process controls are present throughout the facility to help prevent employee exposures to radioactive materials.

All employees who regularly work in the active area are classified as NEWs and are assigned dosimeters from a dosimetry service company licensed by the CNSC. Optically Stimulated Luminescent Dosimeters (OSLD's, but referred to as TLDs) are used as body and ring dosimeters. BWXT Medical refers to personnel dosimeters as TLDs regardless of the technology used. Production technicians are trained to work in various production processes and move from one production area to another during the year. In the NMPF, personnel may receive exposure from working with more than one radionuclide. Personnel who routinely work in the Active Area are assigned monthly TLDs. Other employees who normally work outside the Active Area and visit the Active Area on a regular basis are also classified as NEWs, but are assigned quarterly TLDs.

Contractors who are given access to the Active Area are called "Contractor NEWs." They are trained as NEWs, tested and have security clearance, but are subject to the regulatory dose limit and internal administrative levels of non-NEWs. Contractor NEWs are not permitted to handle radioactive material.

TLD's are sent to a CNSC licensed dosimetry service provider. The dosimetry service provider processes the TLDs and provides the results to BWXT Medical and the National Dose Registry.

Radiation doses to employees are reviewed and assessed in accordance with the ALARA principle.

Although personal dosimetry by use of TLDs provides a satisfactory estimate of exposure to external sources of ionizing radiation, bioassay techniques are necessary to detect and quantify the potential internal deposition of radioactive materials for Active Area personnel. BWXT Medical does not plan to process radioiodines; however, in the event that internal dose of radioiodines or other radionuclides is determined to be possible, BWXT Medical will institute routine thyroid measurements and special bioassay as assurance that the air sampling and monitoring program is effective in determining low-level exposure.

3.8.7 Application of ALARA Principle

Measures to keep radiation doses received by workers and members of the public ALARA include:

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

The ALARA concept takes into consideration relevant social and economic factors.

BWXT Medical is committed to a policy of safety and good radiation protection to keep all doses ALARA. BWXT Medical's EHS Committee will provide oversight of the radiation protection program.

The commitment of workers to radiation safety is an important element of the ALARA program. Demonstration of this commitment through adherence to radiation protection practices and procedures derived from the written policy statements will be assessed through internal audits.

BWXT Medical is committed to ensuring personnel qualification and training is in accordance with the BWXT Management System. Workers are provided with specific working procedures that take into account existing and potential radiological hazards.

Routine and timely review of dosimetry collected from TLD badges and thyroid bioassay data will ensure that the Administrative Levels are observed. These levels are designed to trigger an investigation, and where warranted, initiate changes to work practices to lower the risk of exposure.

Planning for unusual situations, such as a spill of radioactive material, loss of containment, or loss of shielding for processes, is a requirement of the safety analysis process. This planning is completed before routine production of new processes can begin. Engineering and procedural controls are put in place as required.

Major projects will be reviewed and approved by the EHS Committee. Work Permits or Change Forms (CFs) will be required for lower level unusual situations (e.g. maintenance or repair activities). Work Permits and Change Forms will receive appropriate review by EHS Compliance to ensure the potential exposures resulting from the work are ALARA.

3.8.8 Public Dose Assessment and Limits

The public dose limit (1 mSv/year) is specified in the CNSC's Radiation Protection Regulations [11] and this requirement has been embedded as part of BWXT Medical's radiation protection program. To ensure compliance with the public dose requirements, BWXT Medical has established Derived Release Limits (DRLs) for emissions to the environment from the facility. The facility DRLs account for realistic exposure pathways to restrict the dose to a member of the public to less than 1 mSv per year. Through direct correlation with the facility DRLs, the estimated effective dose as a result of air and water releases is calculated annually.

Additionally, environmental TLDs at the site boundary are in place and are used to estimate the direct gamma dose to a member of the public.

As stated in section 3.7.5, there are currently no detectable releases of radioactivity in airborne emissions or waterborne effluent from the NMPF during normal operations. Additionally, there is no detectable gamma radiation field outside the facility that is directly attributable to operations inside the facility. Therefore, the maximum dose to a member of the public is considered to be negligible - well below the dose limit of 1 mSv/year.

Table 1: Estimated Dose to the Public

(CNSC Public Dose Limit = 1 mSv/year)

Year	Public Dose (mSv)
2015	0.0057
2016	0.0021
2017	0.000052
2018	0.000067
2019	0.00087

3.8.9 Action Levels

BWXT Medical has established facility-specific CNSC approved Action Levels for radiation exposure. An Action Level is defined in the CNSC Radiation Protection Regulations [11] as "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." Investigations of action level exceedance are documented in a Radiation Incident Report (RIR).

Action Levels are established in accordance with the CNSC's regulatory document G-228, "Developing and Using Action Levels" [13], which are approved by the CNSC and will be specified in BWXT Medical's Licence Conditions Handbook (LCH). Although Action Levels are set below regulatory limits, exceeding an Action Level is a CNSC reportable event in which BWXT Medical must notify the CNSC within 24 hours of becoming aware that an Action Level has been exceeded.

3.8.10 Internal Control Levels

BWXT Medical has established internal control levels (Administrative Levels) for radiation exposure that are well below the regulatory dose limits. Administrative Levels are set below Action Levels to give an indication of conditions prior to a potential loss of control. An internal control level exceedance results in an internal investigation and corrective actions as appropriate.

Routine and timely review of dosimetry collected from TLD badges and thyroid bioassay data ensures that Administrative Levels are observed. The Administrative Levels trigger investigation and, where warranted, initiate changes to work practices to lower the risk of exposure. These events are documented as ALARA incidents.

3.8.11 Dosimetry Data

Following review by BWXT Medical's EHS compliance staff, dosimetry data will be reviewed by management. In addition, an electronic database will be maintained to permit generation of radiation exposure reports for communication of dose to employees as well as the preparation of performance metrics. This data will be presented at each BWXT Medical EHS Committee meeting to ensure the radiation safety programs performance is evaluated continuously throughout the year. Radiation safety performance metrics will also be presented to senior management on a monthly basis. The metrics will be presented alongside targets that constitute BWXT Medical's commitment to ALARA.

3.8.12 Contamination Control

In addition to routine contamination detection sampling and testing in section 3.7.3.1.4, Air sampling and monitoring is also conducted to:

- Monitor the adequacy of radioactive dust or gas containment systems;
- Assess employee exposure and likelihood of intake, which assists in selection and frequency of bioassay techniques;
- Promptly identify abnormal situations that require immediate attention to limit exposure;
- Assist in determining any sources of exposure; and,
- Demonstrate compliance with the CNSC regulations and licence conditions.

Contamination incidents, defined as the uncontrolled movement of radionuclides indicating a potential loss of process and/or engineering controls will be investigated.

3.8.13 Worker Doses

The average and maximum annual worker dose data for NEW employees and contractors working in the NMPF are shown in Table 2.

Over the past five years (2015 to 2019 inclusive), the annual average effective dose was less than 0.4 mSv and the maximum effective dose was less than 2.6 mSv. These doses are well below the regulatory limit of a total of 50 mSv per year (100 mSv averaged over 5 years (i.e., less than 20 mSv/year)).

The annual average skin dose was less than 0.5 mSv and the maximum skin dose was less than 2.6 mSv. The annual average extremity dose (i.e., dose to the skin of the hands) was less than 0.9 mSv and the maximum extremity dose was less than 16.4 mSv. These doses are well below the regulatory limit of 500 mSv/year.

The groups with the highest doses are:

- Surveyors;
- Shippers; and,
- Radiation and Contamination Monitors.

The predominant dose contributors are packaging and shipping activities. These involve Surveyors and Shippers working in close proximity to final product packages to measure the Transport Index (TI) and apply shipment documentation. Efforts are currently underway to consider technological advancements to packaging and shipping (i.e., automated equipment and robots). If operationally and financially viable, these advancements would reduce the worker doses in accordance with the ALARA principle.

Radiation and Contamination Monitors receive their doses from a variety of tasks including removal of shielded product from hot cells and decontamination of hot cells and fume hoods. These workers are well trained and experienced to ensure that their exposure to radiation is kept ALARA.

The radiation doses to workers resulting from future additional manufacturing processes will be assessed individually in the corresponding secondary FSARs.

Table 2: 5-year dose statistics for NMPF personnel

	2015	2016	2017	2018	2019	Max
Effective dose (mSv) *Regulatory Limit 50 mSv/year (100 mSv per 5 year dosimetry period)*						
Average	0.26	0.35	0.25	0.28	0.13	0.35
Maximum	1.72	1.92	2.58	2.16	1.84	2.58
Skin dose (mSv) *Regulatory dose limit of 500 mSv per year*						
Average	0.27	0.44	0.25	0.27	0.13	0.44
Maximum	1.73	2.44	2.54	2.18	1.90	2.54
Extremity dose (mSv) *Regulatory dose limit of 500 mSv per year*						
Average	0.40	0.67	0.48	0.88	0.64	0.88
Maximum	9.30	8.30	16.40	9.08	12.92	16.40

3.8.14 Future Plans

BWXT Medical will continue to ensure that radiation exposures to employees and the public are kept ALARA. Radiation protection action levels will be reviewed periodically to ensure they remain a constructive threshold based on current operations and associated radiological risk. Efforts are underway to further address the highest dose contributors in accordance with the ALARA principle. Measures such as the planned implementation of an automated packaging line for the Tc-99m generators and an automated storage retrieval system for Y-90 and In-111 pots will reduce dose to workers. The design and safety of new processes is ensured by the design guidelines and other conservative elements of the safety analysis process.

3.8.15 Challenges

BWXT Medical does not anticipate any challenges to the radiation protection program. Continued monitoring and assessment will ensure that contamination and radiation doses received are monitored and controlled, and maintained as low as reasonably achievable (ALARA).

3.8.16 Requests

BWXT Medical does not have any requests concerning this SCA at this time.

3.9 Conventional health and safety

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

3.9.1 Relevance and Management

BWXT's conventional health and safety program is designed to prevent, manage and respond to potential or actual hazards or emergencies in the workplace. The program meets the requirements of *Canada Labour Code* Part II [4] and Canada Occupational Health and Safety regulations [14]. The program's elements are typically developed and managed under the following headings:

- Accident Prevention;
- Occupational Health;
- Safety Communication and Reporting;
- Emergency Response; and,
- Safety Training.

In 2019, a BWXT Medical Workplace Health and Safety Committee was established. The Workplace Health and Safety Committee is comprised of management and employee representatives and is responsible for overseeing the operation of the Hazard Prevention Program and participating in the development of high-level health and safety policies and programs. In addition, the Workplace Health and Safety Committee for monitors operations and recommends improvements to management to help maintain a safe and healthy occupational working environment in each area of responsibility.

The Workplace Health and Safety Committee provides oversight of conventional safety and conducts regular safety inspections.

The BWXT Medical EHS Committee and the Senior Leadership Team set targets each fiscal year in the following areas: Medical treatment incidents, lost time incidents and severity rates, and annually reviews the overall performance of the conventional health and safety program. Conventional health and safety performance is reviewed monthly by senior management and by the applicable health and safety committees.

A program is in place to capture potential accidents through near-miss reporting. Employees are encouraged to report near misses, thus allowing prevention or mitigation of potential incidents.

3.9.2 Past Performance

Reportable conventional health and safety incidents for 2019 to2020 are shown in Table 3. All corrective actions taken as a result of these incidents have been completed.

Table 3: Reportable Conventional Health and Safety Incidents 2019-2020

Year	No. of Lost Time Injuries	No. of Medical Treatment Injures	No. of Minor* Injuries	Incident Rate	Average Schedule 1 Ontario Employer Incident Rate
2019	1	0	1	0.68	2.32
2020	0	2	0	1.11	Information not available at the time of this report

The average Incident Rate for all Schedule 1 Ontario employers is compiled by the Workplace Safety & Insurance Board (WSIB).

Minor Injury: any injury which requires an assessment by a Health Care Professional (HCP) but which does not result in medical treatment (medical treatment includes: certain prescriptions, sutures, other medical care etc…does not include first aid type treatment by the HCP or diagnostic imaging/procedures or prescriptions for over-the-counter medications)*

BWXT Medical was in full compliance with the Canadian Labour Code Part II [4] during this timeframe. All reportable occupational injuries or illnesses were reported to Employment & Social Development Canada (ESDC) and the Ontario WSIB.

3.9.3 Future Plans

BWXT Medical's management team will ensure the scheduling of known strenuous tasks and ensure the tasks have adequate resources. The management team will continue to encourage regular rest breaks for manipulator users. 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.

BWXT Medical is committed to continuous improvement to its conventional health and safety program to prevent, manage and respond to potential or actual hazards or emergencies in the workplace.

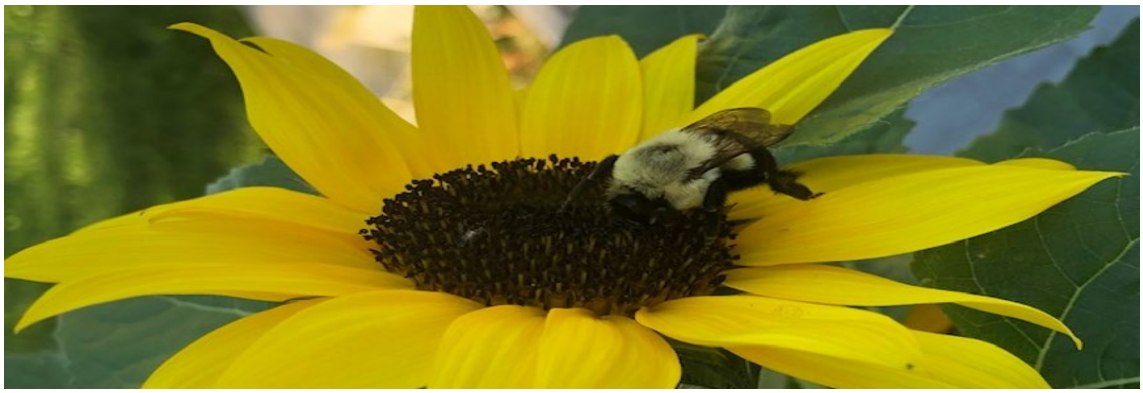
3.9.4 Challenges

Ergonomics related to manipulator use will continue to be a challenge. Historical ergonomic issues have included wrist injuries due to gripping action, elbow injuries due to rotation, and shoulder injuries due to lifting or over-reaching.

3.9.5 Requests

BWXT Medical does not have any requests concerning this SCA at this time.

3.10 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.

3.10.1 Relevance and Management

BWXT Medical's Environmental Protection Program outlines the programs and processes to ensure safety and the application of the ALARA principal specifically related to:

- Airborne effluent;
- Liquid effluent;
- Environmental dosimetry;
- Environmental contamination;
- Hazardous chemical storage and handling; and,

- Waste management and disposal.

BWXT Medical's Environmental Protection Program meets the requirements of:

- CNSC REGDOC 2.9.1 *Environmental Protection Policies, Programs and Procedures* [15]
- CSA N288.1 *Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities* [16]
- CSA N288.4 *Environmental Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills* [17]
- CSA N288.5 *Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills* [18]
- CSA N288.6 *Environmental Risk Assessments at Class 1 Nuclear Facilities and Uranium Mines and Mills* [19]
- CSA N288.8 *Establishing and Implementing Action Levels for Releases to the Environment from Nuclear Facilities* [20]

BWXT Medical's production facilities have been designed and will be operated in a manner to ensure that releases to the environment via air or water emissions are below the limits approved by the CNSC and to prevent radioactive waste or hazardous chemicals being released to municipal garbage or sewer systems.

BWXT Medical's environmental monitoring program will monitor and measure releases to the environment and contaminant concentrations in environmental media (e.g., soil). Limits for radioactive emissions will be determined by the Derived Release Limit (DRL). DRLs were determined for each of the major radioisotopes processed in the facility and subsequently were approved by the CNSC. The DRL considers the critical pathway analyses and the most probable location of highest radiation exposure. The implementation of DRLs ensure that the total dose to a member of the public is less than the annual dose limit of 1 mSv per year.

3.10.2 Airborne Effluent

All production operations are contained within cells, glove boxes and/or fume hoods. Ventilated air from these containment systems is filtered through roughing and HEPA filters and, where appropriate, activated charcoal adsorbers. These systems are designed with redundant fan/motor and filtration units that include pre-filters and primary and secondary filtration units to filter particulates and gaseous airborne effluent. The Nuclear Ventilation System (NVS) has been designed and is maintained to minimize the release of radioisotopes and other hazardous materials to the atmosphere.

The program for monitoring airborne effluent will include qualitative continuous monitoring of process ventilation and stack emissions. This will be performed with the use of in-situ detectors and computerized recording.

Quantitative analysis of effluent will be performed by weekly air sampling of stack emissions using stack cartridges for radioiodines and particulates. If applicable, noble gases will be quantified by in-situ detectors.

Ventilation and stack sampling will be conducted by using particulate and/or activated charcoal filters, depending on the physical and chemical nature of the radionuclide. Radioiodine sampling will involve the use of activated charcoal filter cartridges, and analyses by gamma measurement. Particulates will be sampled by use of cellulose filter papers and analyzed by gamma measurement. If applicable, noble gases will be monitored in real time via detector/Multi-Channel Analyzer (MCA) sampling lines on the ventilation duct.

3.10.3 Liquid Effluent

Radioactive liquid waste will be collected and transported to a licensed radioactive waste management facility. Other waste water which might potentially contain small amounts of radioactive contamination (from emergency showers, personnel wash sinks, water used for routine floor cleaning, etc.) will be collected in holding tanks and then sampled and analyzed against DRLs to ensure that it is in compliance with licence conditions prior to being released to the municipal sanitary sewer.

3.10.4 Environmental Dosimetry

Environmental TLD's have been installed at predetermined locations outside of the facility to monitor ambient radiation levels on an ongoing basis.

Annually, data for the monitoring points will be compared with environmental effluent or other operational data to see if a correlation can be determined. Environmental monitoring data is expected to vary independently of operations at Nordion.

3.10.5 Environmental Sampling

Soil samples will be regularly taken and analyzed from various locations on the Nordion property to test for the presence of radioisotopes and to detect potential soil contamination. Soil sampling is conducted at least every two years.

At least once every two years, sanitary sampling will be conducted to analyze for non-radiological contaminants. Results of the analysis will be compared against municipal by-law limits.

3.10.6 Hazardous Chemical Storage and Handling

Non-radioactive hazardous chemicals used for processing, analytical testing, decontamination, and cleaning purposes are typically used in small quantities and will be handled and disposed of in accordance with company operating procedures and relevant legislation. Any hazardous chemicals that come in contact with radioactive products will be segregated for approved disposal, rather than being disposed of as hazardous chemical waste.

3.10.7 Waste Disposal Program

The radioactive waste management program complies with applicable laws, regulations and licence conditions. Waste diversion programs have been designed and implemented to divert waste below CNSC accepted clearance levels for release through conventional waste methods.

3.10.8 Airborne Effluent

A summary of airborne effluent releases for the Medical Isotopes Operation is provided in Tables 4 and 5. All airborne effluent releases have been well below regulatory limits. Year-over-year, the Ottawa site has met the established EHS targets for airborne releases. The airborne emissions were less than 2% of the DRL. The airborne effluent releases for each year are shown in Table 4 and the emissions expressed as a percentage of the DRL in Table 5.

Table 4: Airborne Releases 2015-2019

Year	I-125 (GBq/year)	I-131 (GBq/year)	Xe-133 (GBq/year)	Xe-135* (GBq/year)	Xe-135m* (GBq/year)	Total % DRL
2015	0.12	0.15	11,916	8,237	10,758	0.07%
2016	0.21	0.35	7,277	4,299	5,421	0.12%
2017	0.0012	0.0008	0	0	0	0.005%
2018	0	0.006	0	0	0	0.006%
2019	0	0	0	0	0	0%
DRL	952	686	6.77E8	1.02E8	6.9E7	N/A
2019 %DRL	0	0	0	0	0	NA
Regulatory Limit	100%	100%	100%	n/a	n/a	100%

* No action levels established for these isotopes.

GBq = Gigabecquerel

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

The following table provides a summary of the air emissions expressed as a total percentage of the Derived Release Limit (DRL) per year from 2015 to 2019.

Table 5: Air Emissions (% DRL/year), 2015 – 2019

Year	I-125	I-131	Xe-133	Xe-135	Xe-135m	Total %DRL
2015	0.01%	0.01%	0.03%	0.16%	0.36%	0.57%
2016	0.004%	0.009%	0.012%	0.056%	0.118%	0.20%
2017	0.00002	0.00002	0	0	0	0.004%
2018	0	0.0009	0	0	0	0.009%
2019	0	0	0	0	0	0%
Regulatory Limit	100%	100%	100%	100%	100%	100%

In November, 2016, production of Mo-99, I-125, I-131 and Xe-133 ceased. Therefore, radioxenon releases also ceased in November 2016. The facility continued to receive I-131 to maintain equipment functionality, but its releases have since become negligible. I-125, with its longer half-life, was still present in some waste and the NVS, but its releases have become negligible as well. Taking into account current and anticipated future operations in the short term, the releases of noble gases and volatile radionuclides such as radioiodines are expected to be negligible. Airborne

emissions are predominantly in the form of particulate matter, which is removed by multiple stages of filtration in the NVS. Particulates are sampled using filter paper, which is analyzed by gamma spectroscopy and other measurement techniques on a weekly basis. Routine releases of particulates have shown to be below detection limits. Therefore, there is no radiological risk associated with airborne emissions.

3.10.8.1 Liquid Effluent

The liquid effluent releases in GBq/yr for the Medical Isotopes Operation for each year from 2015 to 2019 are shown in Table 6.

Table 6: Liquid Effluent Releases (GBq/yr) 2015-2019

Year	Liters	β<1MeV	β>1MeV	I-125	I-131	Mo-99
2015	590,570	0.191	0.044	0.111	0.006	0.06
2016	680,559	0.222	0.051	0.144	0.006	0.052
2017	661,376	0.212	0.048	0.145	0.006	0.049
2018	713,224	0.243	0.055	0.146	0.007	0.055
2019	576,800	0.162	0.038	0.063	0.004	0.036

Table 7 provides a summary of the liquid effluent releases expressed as a total percentage of the Derived Release Limit (DRL) per year from 2015 to 2019. All liquid effluent releases have been well below regulatory limits. Year-over-year, the Medical Isotope Operation has met the established EHS targets for liquid releases.

Table 7: Liquid Releases (% DRL/year), 2015 – 2019

DRL (GBq/yr)	β<1MeV*	β>1MeV*	I-125	I-131	Mo-99	Total %DRL
	7,780	105,000	14,700	10,800	467,000	
2015	2.46E-03	4.19E-05	7.55E-04	5.56E-05	1.28E-05	3.33E-3
2016	2.78E-02	1.38E-04	1.22E-02	1.53E-03	4.79E-04	4.21E-2
2017	3.21E-04	2.29E-05	1.97E-04	2.56E-05	4.36E-06	5.71E-4
2018	3.18E-02	1.56E-04	1.22E-02	1.75E-03	5.35E-04	4.64E-2
2019	2.13E-02	1.07E-04	5.30E-03	1.14E-03	3.51E-04	2.81E-2
Reg. Limit	100%	100%	100%	100%	100%	100%

* The DRL for strontium-90 (Sr-90) is used for β<1MeV and the DRL for yttrium-90 (Y-90) is used for β>1MeV. DRLs are required for only the major isotopes. The majority of the recorded releases are the minimum detectable activities being conservatively reported as real values instead of using zero. As a result, this number is proportional to volumes released.

Liquid effluent releases measured at the Medical Isotopes delay tanks (before release) closely follow the number of litres dumped to the sanitary sewer. This is due to the conservative practice of reporting the limit of detection value instead of a “zero” when the measurement assay detects nothing.

3.10.9 Future Plans

BWXT Medical will continue to assess potential environmental releases as production increases and new radioisotopes are processed. Since most, if not all, releases to the environment are expected to be below detection limits, BWXT Medical will consider additional statistical methods or reporting alternatives to present releases more accurately, and remove over-conservatism.

3.10.10 Challenges

BWXT Medical does not anticipate any challenges related to environmental protection.

3.10.11 Requests

BWXT Medical does not have any requests concerning this SCA.

3.11 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.

3.11.1 Relevance and Management

3.11.1.1 Emergency Preparedness Program

Emergency response planning is required to reduce or mitigate operational impacts and potential environmental, health and safety impacts that may occur in the event of an emergency. BWXT Medical’s Emergency Response Program describes the organization and methods to prepare for, respond to and recover from emergencies, and has been developed based on the requirements of CNSC REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response* [21], Version 2, February 2016.

BWXT Medical will retain ultimate responsibility for emergency preparedness for the NMPF. Under the lease agreement with Nordion, there is a joint emergency response plan established between Nordion and BWXT Medical. Currently, BWXT Medical employees have been trained on the Nordion emergency response program and comprise much of the response team.

The Emergency Response Program describes the responsibilities assigned to various personnel and functions to ensure that proper planning, training and equipment are maintained to manage and respond to emergencies. It documents the methods used to respond to emergencies and to ensure the timely notification of, and coordination with, off-site agencies and organizations that may be affected by such events or requested to provide assistance to supplement the emergency organization.

Under the program, Emergency Response Plans (ERPs) have been developed to respond to various types of emergency situations, including on-site and off-site emergencies that describe the actions to be taken to minimize the health and environmental hazards, which may result from fires, explosions, release of hazardous materials, or other emergencies. Depending on the nature and scale of an emergency, the appropriate ERP is activated. The ERPs outline steps to be taken to notify surrounding community and businesses in the event of an emergency which could impact the local community.

The ERPs will be routinely reviewed, updated, and tested in the form of drills, table top training exercises and full-scale evacuation exercises. A schedule of drills and exercises will be maintained to ensure testing and exercises are conducted regularly. All employees are trained on established fire prevention measures, emergency situation responses, emergency evacuation routes and their responsibilities. Awareness training is conducted during new employee orientation and refreshed through response drills. Emergency responders are provided with the level of training necessary to allow them to effectively perform their designated functions.

Work instructions describe the development of drill and exercise scenarios, drill objectives, assignment of competent drill observers, and critique drill performance. Drills that involve activation of the Emergency Organization are conducted at least annually. An evacuation drill is also conducted annually and is evaluated for adequacy of alarms, evacuation routes and time taken for evacuation. Triennially, a full-scale exercise is conducted. The offsite emergency response organizations necessary to mitigate the consequences of the exercise scenarios are invited to participate in these exercises. Testing of the Emergency Response Contact List will be performed annually to ensure accuracy of off-hour contact information listed, to determine availability of personnel, and to estimate response times.

An Emergency Response Planning Committee will be established with Nordion and will meet on a regular basis to discuss and assess emergency planning needs, to plan emergency response exercises and drills to test existing Emergency Response Plans and as necessary, to review the emergency response plans for suitability and effectiveness. In addition, emergency response procedures will be regularly reviewed and revised as necessary, immediately following the occurrence of an incident, accident or emergency situation.

BWXT Medical will work in partnership with Nordion and the local fire and police departments to ensure safe and appropriate response to potential emergency situations. BWXT Medical will ensure there are regular orientation sessions to the local fire and police departments to familiarize them with the facility and to discuss how to work together in an emergency situation. BWXT Medical will ensure local emergency response organizations are invited to participate in emergency response drills at the site to demonstrate and test how these types of emergencies would be managed. Where possible, emergency response drills will be attended by the local fire department, hazardous materials representatives and paramedics who will participate as exercise players, allowing all players to improve interoperability of response.

Meetings with local hospitals will be conducted to strengthen BWXT Medical's relationship with the community and to optimize rapid, safe care of casualties.

3.11.1.2 Fire Protection Program

The primary goals of BWXT Medical's Fire Protection Program are to minimize the risk of radiological and hazardous material releases resulting from fire; protect facility occupants from death or injury due to fire; minimize economic loss resulting from fire damage to structures, equipment and inventories; and, minimize the impact of radioactive or hazardous material on the environment as a result of fire. The program outlines key fire protection requirements intended to reduce the risk of fire at the facility. BWXT Medical will retain ultimate responsibility for the fire protection program for the NMPF. Under the lease, Nordion will be responsible for providing fire protection systems in the NMPF.

The Fire Protection program has been developed based on the requirements of CSA N393-13, "*Fire Protection for Facilities that Process, Handle, or Store Radioactive Substances*" [7]. This standard specifies the minimum fire protection requirements for the design, construction, commissioning, operation, and decommissioning of facilities that process, handle, or store nuclear substances, including structures, systems and components, and other hazardous substances that directly relate to the nuclear substances being regulated. A Fire Hazard Analysis compliant with CSA N393-13, "*Fire Protection for Facilities that Process, Handle, or Store Radioactive Substances*" has been accepted by the CNSC. The Fire Protection program describes the systems and resources available to prevent and detect fire and to minimize impact from a fire event and consist of the following key fire and life safety elements:

- Inspection and Maintenance;
- Fire Protection Assessment;
- Fire Protection;
- Housekeeping;
- Minimization of Combustibles;
- Ignition Source Control;
- Impairment;
- Design for the Prevention and Mitigation of Fires;
- Training;
- Outside Coordination; and,
- Program Assessment.

The fire protection program outlines the commitment to:

- Maintain a Fire Hazard Analysis;
- Ensure the design, analysis, and operation of facilities are planned and controlled;
- Manage changes that could impact fire protection to minimize potential impacts;
- Ensure BWXT Medical operates, maintains, tests, and inspects the facility in accordance with applicable codes and requirements;
- Ensure impairments to fire protection systems are managed in a manner to minimize the duration of equipment outages and that they are pre-planned wherever feasible;
- Ensure impaired equipment is identified, tagged, and tracked and appropriate personnel are notified;
- Ensure areas are kept clear of debris and the movement and storage of flammable and combustible materials is controlled; and,
- Establish and regularly test Fire Safety Plans.

Fire protection systems are inspected and tested in accordance with the *National Fire Code of Canada* [10] following an established schedule. An annual third-party review and internal self-assessments are conducted and identified continuous improvements are tracked to completion.

3.11.2 Future Plans

BWXT Medical is committed to continuous improvement of its Emergency Management Program and Fire Protection Program. The development of a joint ERP for the Nordion site, inclusive of the BWXT Medical and Nordion Class IB facilities will build on the comprehensive plans currently in place under which BWXT Medical employees have been trained and fill key roles. Continued close cooperation of both BWXT Medical and Nordion will ensure CNSC requirements are met for both Class IB licences.

3.11.3 Challenges

BWXT Medical does not anticipate any challenges with regard to emergency management and fire protection.

3.11.4 Requests

BWXT Medical does not have any requests concerning this SCA at this time.

3.12 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 decommissioning planning.

3.12.1 Relevance and Management

BWXT Medical's Waste Management Program addresses the management of radioactive, hazardous and non-hazardous wastes generated on-site, including the management and disposal methods for that waste. This program ensures compliance with the *Nuclear Safety and Control Act* [1], the *Environmental Protection Act* [22] and the *Transportation of Dangerous Goods Regulations* [23]. Radioactive and hazardous wastes generated in the NMPF are well characterized and are managed according to detailed operating procedures.

Radioactive wastes are managed in such a way as to ensure that they do not give rise to any unnecessary radiation exposures or unacceptable effects on the environment. Any risks which arise in the management of radioactive wastes are kept ALARA. Radioactive solid wastes generated from manufacturing are accumulated in designated, controlled areas. The Waste Management Program ensures that all radioactive waste disposals are conducted in accordance with the Nuclear Safety and Control Act, associated regulations and facility operating licence conditions.

BWXT Medical has established a Preliminary Decommissioning Plan (PDP) for the medical isotopes facility and has submitted a proposed Financial Guarantee to the CNSC. These items are in accordance with CNSC Regulatory Guide G-206 *Financial Guarantees for the Decommissioning of Licensed Activities* [24], CNSC Regulatory Guide G-219 *Decommissioning Planning for Licensed Activities* [25] and CSA N294-09 *Decommissioning of Facilities Containing Nuclear Substances* [26].

3.12.2 Waste from the Active Area

Waste from the Active Area is categorized into four main waste types: routine waste, liquid waste, non-routine waste, and divertible waste. Routine waste is waste generated from production processes that is routinely shipped to approved external radioactive waste management facilities. This waste has been characterized into repositories, or "Waste Blocks." Low-level liquid waste is collected separately and routinely shipped to an approved radioactive liquid waste receptor. Radioactive waste that has not been characterized into a waste block or is not low-level liquid waste is considered non-routine radioactive waste. Non-routine radioactive waste is evaluated for conventional waste disposal or packaged for shipment to a licensed radioactive waste management facility. Waste generated within the Active Area that meets CNSC's unconditional clearance levels is separated from solid active waste and is disposed of by conventional waste disposal methods, such as a landfill. Whereas, solid active waste generated in the Active Area is sent to licensed radioactive waste facilities.

Radioactive waste from other radioisotope licensees will not be transferred to BWXT Medical for subsequent disposal.

3.12.3 Waste Management

BWXT Medical will manage its radioactive wastes in a manner that ensures conformance with the regulatory objectives, requirements, and guidelines of the CNSC, as well as the waste acceptance requirements of radioactive waste receivers.

The production facilities have been designed and will be operated to prevent radioactive waste from being released to municipal garbage or sewer systems and to ensure that releases to the environment via air or water emissions are within limits approved by the CNSC. All radioactive waste that is generated through production operations will be collected and sent to an approved radioactive waste management facility.

There are designated space and processes to store and segregate radioactive waste that is generated in production operations. Primary long term decay storage areas are located in the Medical Isotopes active shipping and receiving area. If needed, additional space for long term storage of divertible waste exists in the KRMF facility. Space is also designated for storage of containers and management of waste being prepared for shipment to external waste management facilities.

3.12.4 Waste Minimization

To continuously improve performance and to implement the principle of pollution prevention, BWXT Medical will regularly monitor waste and establish objectives and targets for continuous improvement.

BWXT Medical will encourage and promote techniques that reduce waste in all areas of operation. The Active Area waste diversion program within the NMPF has successfully diverted waste from disposal to a licensed radioactive waste management facility to regular landfill through segregation at the source and the use of sensitive monitoring equipment for verification that the segregated waste is below the unconditional clearance levels prescribed in CNSC regulations.

Waste that does not meet the unconditional clearance levels may be stored for decay and subsequently re-monitored or sent to a separate licensed radioactive waste management facility. Hazardous and biological materials will be diverted to separate waste streams prior to segregation at source of the solid waste.

3.12.5 Non-radioactive Chemical Waste

Non-radioactive chemical waste is consolidated in designated cabinets in the shipping areas. Non-radioactive chemicals are primarily used in the quality control labs for analyses and testing, in the Radiopharmaceutical wing for decontaminating and disinfecting laboratories, and as carrier solutions for radioactive product. Non-radioactive chemical waste is inventoried on log-sheets. Waste chemicals are then picked up by a licensed waste disposal company for treatment and/or disposal.

3.12.6 Non-Hazardous Waste

A program is in place for the management of non-hazardous waste in the Non-Active Areas of the facility to divert waste such as plastics, metals, paper, cardboard, and organics from landfill. Annually, BWXT Medical will conduct a waste audit of non-hazardous waste to determine diversion program performance.

EHS targets will be set to reduce non-hazardous waste sent to landfill. Initiatives to meet these targets include reducing waste, raising awareness of existing recycling programs and exploring further opportunities to divert waste as feasible.

3.12.7 Decommissioning Plan

The CNSC has accepted BWXT Medical's Preliminary Decommissioning Plan (PDP) and cost estimate for decommissioning the facility. This was submitted as part of the licence application. The PDP meets the criteria of CNSC Regulatory Guides G-219, Decommissioning Planning for Licensed Activities [25], and G-206, Financial Guarantees for the Decommissioning of Licensed Activities [24], as well as CSA Group standard N294-09, Decommissioning of facilities containing nuclear substances [26]. CNSC staff have confirmed that BWXT Medical's proposed financial guarantee instruments are acceptable and meet the expectations set out in G-206.

Details of the financial guarantee are explained in section 4.3.

3.12.8 Future Plans

As BWXT Medical incorporates waste management for new medical isotope products there will be no intentional releases from the process to the sanitary sewer system. Radioactive and hazardous waste associated with new processes will meet the acceptance guidelines of our waste service providers. Radioactive waste will be disposed of to licensed waste management facilities.

3.12.9 Challenges

The limitations as to what the waste service providers will and will not accept will limit BWXT Medical's potential waste diversion activities. BWXT Medical will work with the waste service providers to achieve waste diversion objectives.

3.12.10 Requests

BWXT Medical does not have any requests concerning this SCA at this time.

3.13 Security

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

3.13.1 Relevance and Management

The Security Program outlines the systems, processes and responsibilities for performing security operations with the objective of maintaining safe and secure facilities. The Security Program meets the requirements of the *Nuclear Security* Regulations, SOR/2000-209[5] and is compliant with REGDOC 2.12.3, Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material [27]. BWXT Medical will retain ultimate responsibility for security for the NMPF. Under the lease, Nordion will provide physical security.

3.13.2 Future Plans

BWXT Medical plans to continuously assess threats and risks and make security improvements as these evolve or change.

3.13.3 Challenges

BWXT Medical does not anticipate any challenges at this time.

3.13.4 Requests

BWXT Medical does not have any requests concerning this SCA.

3.14 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 Canadian/International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

3.14.1 Relevance and Management

The program for management of safeguarded material meets the requirements of Nuclear Safety and Control Act [1], General Nuclear Safety and Control Regulations SOR/2000-202 [28], Nuclear Non-Proliferation Import and Export Control Regulations SOR/2000-210 [29] and regulatory document REGDOC-2.13, “Safeguards and Nuclear Material Accountancy” [30].

The type of safeguarded nuclear material that BWXT Medical uses includes depleted uranium, enriched uranium, natural uranium, plutonium, and thorium. The material is in the form of check sources and standards, and shipping containers with depleted uranium as shielding.

3.14.2 Future Plans

As part of the implementation of the BWXT Medical safeguards program, BWXT Medical will apply to the CNSC to become a Material Balance Area (MBA) separate from Nordion. Timing will be determined by the Safeguards Division of the CNSC.

3.14.3 Challenges

BWXT Medical does not anticipate any challenges with regard to implementation of the program for management of safeguarded material.

3.14.4 Requests

BWXT Medical does not have any requests concerning this SCA.

3.15 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.

3.15.1 Relevance and Management

BWXT Medical's Packaging and Transport Program applies to the design, production, use, inspection, maintenance and repair of packages, and the preparation, consigning, handling, loading, carriage, storage during transport, receipt at final destination, and unloading of packages. It applies to various types of packages including Type A, Type B, and Excepted packages. The content of the program addresses regulatory requirements listed in the CNSC *Packaging and Transportation of Nuclear Substances Regulations* SOR/2015-145 [31], Transport Canada *Transportation of Dangerous Goods Regulations* [23], IAEA Regulations for the Safe Transport of Radioactive Material [32], US Department of Transportation 49 CFR [33], and US Nuclear Regulatory Commission 10 CFR part 71 [34].

The Packaging and Transportation Program includes the following elements:

- Design;
- Testing/Assessment/Documentation;
- Regulatory Approvals;
- Manufacturing/Procurement;
- Inspection/Maintenance;
- Loading/Packaging;
- Shipment;
- Customer Use of Packages;
- Return Shipment;
- Decommissioning of Transport Packages;
- Security;
- Safety;
- Package Quality; and,
- Regulatory Oversight.

BWXT Medical maintains a transport package quality plan which describes how the quality assurance requirements for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of radioactive material (RAM) transport packages are achieved. The plan identifies the activities, responsibilities, and actions necessary to ensure that all regulatory, customer, and internal quality assurance program requirements are met.

BWXT Medical is a registered user of the transport packages required for shipments associated with the medical isotopes business.

BWXT Medical will routinely ship radioactive material in Type A and Type B packages (See Figures 8 to 10). Shipments of BWXT Medical's products are made via road and air.

Figure 8: Example of the Components of Type A Transport Package

Note: The inside of the package also contains a Styrofoam insert which surrounds and stabilizes the pot during shipment.

Figure 9: Example of Exterior of Typical Type A Transport Package

Figure 10: Example of Type B Transport Package

3.15.2 Future Plans

BWXT Medical will continue to develop and advance its Packaging and Transport of Radioactive Materials Program.

3.15.3 Challenges

BWXT Medical does not anticipate any challenges related to this SCA.

3.15.4 Requests

BWXT Medical does not have any requests concerning this SCA.

4.0 Other Matters of Regulatory Interest

4.1 Aboriginal Engagement

BWXT in Canada has been a member of the Canadian Council for Aboriginal Business (CCAB) since 2017 and is participating in the CCAB's Progressive Aboriginal Relations (PAR) program at the Committed level.

BWXT Canada developed an Indigenous Relations Committee, made up of employees from across Canada, which is responsible for the maturation of the PAR program through development and execution of the four PAR drivers. The four PAR drivers are; Leadership Actions, Employment, Business Development, and Community Relationships. The committee and members of executive leadership have been trained in both CCAB's PAR program as well as Indigenous cultural awareness. A Canada-wide company policy for Indigenous Relations was developed in 2017 which is publicly available on BWXT Medical's website.

BWXT Medical has identified its Communities of Interest (COI) for the Kanata site. The committee will use the PAR program framework to guide meaningful engagement with these communities.

The Communities of Interest (COI) for BWXT Medical are as follows:

- Algonquins of Ontario which consists of ten Algonquin communities: Algonquins of Pikwàkanagàn First Nation, Antoine, Kijicho Manito Madaouskarini (Bancroft), Bonnechere, Greater Golden Lake, Mattawa/North Bay, Ottawa, Shabot Obaadjiwan, Snimikobi and Whitney and Area.
- Métis Nation of Ontario – Ottawa Region Métis Council
- Algonquin Anishinabeg Nation Tribal Council (AANTC) which is comprised of the Kebaowek First Nation, Nation Anishnabe du Lac Simon, Abitibiwinni, Kitigan Zibi, Long Point (Winneway), Kitcisakik, Wahgoshig, Algonquins of Barriere Lake (Mitchikanibikok), Timiskaming first Nation, and Wolf Lake First Nation.

BWXT Medical will use the following methods to meaningfully engage with its COI's:

- Letters/electronic updates
- Meetings and tours
- Phone calls
- Invitations to events

BWXT Medical's approach is to continue engaging our COI's regularly by letter mail, email, phone calls and meetings to ensure materials and information is readily available. These materials may include community newsletters, invitations to events, requests for meetings, information about regulatory meetings and hearings and/or other events. BWXT Medical wants to ensure our COI's are kept informed about our business and licence application and to establish a point-of-contact should they have questions or concerns.

After establishing our COI's, BWXT Medical had the opportunity to participate in face-to-face meetings with many of its COI's throughout 2019. These meetings were held in conjunction with Ontario Power Generation, our partner for irradiation services related to planned licensed activities.

BWXT Medical has committed to sharing licence application information with its COI's to ensure the communities are informed of the process and how they may participate. Through letters, emails, phone calls and meeting requests, BWXT Medical will make this information available and work to engage with the communities.

After the licence hearing, BWXT Medical plans to continue this outreach to establish and maintain meaningful engagement and relationships with our COI's, while learning more about their communities in the process.

4.2 Cost Recovery

The CNSC recovers the cost of regulating from applicants and licensees through the CNSC Cost Recovery Fees Regulations [35]. BWXT Medical is in good standing of cost recovery. Associated fees for the licence application have been submitted.

BWXT Medical is current on its cost recovery payments to the CNSC.

4.3 Financial Guarantee

CNSC staff have confirmed that BWXT Medical's proposed financial guarantee instruments are acceptable and meet the expectations set out in G-206, *Financial Guarantees for the Decommissioning of Licensed Activities* [24].

The financial guarantee amount is $10,540,000. BWXT Medical has requested that the financial guarantee instrument be a combination of Surety Bond and Letter of Credit, with the first $2,600,000 being satisfied by a Letter of Credit. The remaining obligation would then be satisfied by a Performance Surety Bond. Draft forms of both instrument types were provided to CNSC Staff on October 16, 2019. BWXT Medical is committed to institute the financial guarantee as directed by the CNSC.

4.4 Other Regulatory Approvals

BWXT Medical has applied for an Environmental Compliance Approval (ECA) from the Ministry of the Environment, Conservation and Parks (MECP) for air emissions and noise arising from facility operations.

BWXT Medical has a licence and registration from the USA that authorizes radioactive material distribution. BWXT Medical is a CNSC registered user for all transport package certificates used in Canada. BWXT Medical has obtained validations and endorsements of Transport Package designs it owns from countries in which our Type B packages are used.

BWXT Medical is registered with the Ministry of Environment as a Hazardous Waste Generator. This registration allows for the disposal of non-radioactive hazardous waste.

BWXT Medical performs microbiology testing of Radiopharmaceutical/medical device products and is registered under the Human Pathogens and Toxins Act [36] through the Public Health Agency of Canada. Additionally, BWXT Medical has secured a Human Pathogen Import Permit which allows the importation of biological material required to support microbiology testing.

4.5 Public Information Program

BWXT Medical has developed a Public Information and Disclosure Program and Indigenous Engagement (PIDPIE) in accordance with CNSC REGDOC-3.2.1 "Public Information and Disclosure" [37]. The purpose of the PIDPIE is to provide the strategy and methodologies to be employed for public communications, information distribution and feedback, and how these activities will be managed.

BWXT Medical is committed to communicating and engaging with the communities in which it operates in a timely, transparent and meaningful way. BWXT Medical recognizes that the most effective way to build and sustain public trust is to maintain environmental excellence while fostering an atmosphere of openness and transparency with stakeholders and other interested parties. This requires a demonstrated commitment to operating in accordance with the highest environment, health and safety standards, while at the same time sharing information concerning anticipated effects on the environment, and health and safety of persons that may result from BWXT Medical's activity.

The communications objectives of BWXT Medical's PIDPIE are to:

- Improve the level of awareness and understanding among stakeholders about BWXT Medical's licensed operations, activities, products and services;
- Provide information on the anticipated effects to the environment and on human health and safety, of the licensed activity to stakeholders and persons living in the vicinity of the site;
- Foster dialogue with stakeholders that will assist BWXT Medical in determining the information needs and preferred methods for information sharing;
- Build and maintain a relationship of trust with local residents and stakeholders;
- Provide meaningful opportunities for community members to discuss/share issues and relay concerns related to the Ottawa facility;
- Provide opportunities for community and stakeholder representatives to visit and tour the facility.

4.5.1 Target Audiences

BWXT Medical has selected its target audience of the Public Information and Disclosure Program and Indigenous Engagement (PIDPIE) primarily based on proximity to the licensed facility. This audience is selected by determining the general vicinity that may reasonably anticipate effects (albeit well within or below legal limits) to the environment and the health and safety of persons that may result from the licensed activity. In addition to this group, BWXT Medical selects target audiences based on their specific role in the community and determines whether information about our operations would be of interest. BWXT Medical also includes any person who indicates interest in staying informed. Local Indigenous communities and local elected officials at all three levels of government are included as part of the target audience. In addition, BWXT Medical includes the local health unit, local schools, local first responders, community leaders and community associations in proximity to the site. Annually, the designated list of addresses for communications materials is reviewed for currency.

4.5.2 Communication Tactics

BWXT Medical plans to use a variety of communications tactics to reach a broad spectrum within the target audience and communicate a range of relevant topics to the different stakeholders, Indigenous communities and members of the public.

Some examples include sharing information in regular email updates, including important details in community newsletters and other mailings to indicate an important dates or key information, hosting and participating in community events, sharing information on BWXT's corporate social media channels and posting key information on BWXT Medical's website.

4.5.3 Website, Email and Toll Free Telephone Number

BWXT Medical has a dedicated website (www.medical.bwxt.com), email (isotopequestions@bwxt.com) and toll-free telephone number (1.833.657.4565) for members of the public to contact the company.

The website provides information about the company's operations and activities that can be accessed by members of the public and other key stakeholders 24/7. Additionally, the phone line and email is available 24/7 and monitored daily.

4.5.4 Social Media

BWXT Medical leverages BWXT's social media channels which include Twitter, Linked-In, YouTube and Facebook to share information about company activities. Social media channels have been used to create awareness of the licence application and BWXT Medical's products and services.

4.5.5 Community, Volunteerism and Investment

BWXT's Canada operations have a program called BWXT Volunteer Strong. Through this program all employees have the opportunity to help build stronger communities for those that live and work in them and can volunteer time and expertise to local causes that are important to the communities in areas such as:

- Education
- Health & Wellbeing
- Arts & Culture
- Environment
- Indigenous Relations

In addition to providing volunteer hours, BWXT Medical looks forward to supporting a range of community-based groups/initiatives that help improve community life in three key areas through charitable giving: community and cultural, charitable and health care support, education and vocational support.

4.5.6 Public Disclosure Protocol

BWXT Medical has a Public Disclosure Protocol with the objectives of providing information on the licensed activities to persons living near the site, fostering public awareness, and providing the channels for community members to share issues and concerns related to the licensed facility.

The Public Disclosure Protocol describes how BWXT Medical communicates with the target audience. Based on this protocol, BWXT Medical commits to:

- Consulting with stakeholders to determine the type of information, and method for information sharing regarding this Public Disclosure Protocol;
- Maintaining two-way communication channels with the target audience to understand and address comments, questions and concerns;
- Providing reporting on its website within 48 hours of unusual operational events with the potential for offsite consequences;
- Providing timely reporting on its website within 48 hours of environmental events that trigger notification of the CNSC under Section 29 of the General Nuclear Safety and Control Regulations [28];
- Providing information to the target audience through BWXT Medical's website and/or other Public Information Program activities, about significant operational changes or expansions that require an environmental assessment or amendments to the facility licence;
- Posting environmental monitoring results (relevant sections of Annual Compliance Reports) on its website;
- Posting any transport incidents reportable under the CNSC Packaging & Transport of Nuclear Substances Regulations [31];
- Posting planned and unplanned significant interruptions of facility operations resulting in significant disruption of customer isotope supply;
- Posting this Public Disclosure Protocol on the BWXT Medical website.

Any proposed changes to the Public Disclosure Protocol are reviewed and approved prior to implementation.

BWXT Medical's Public Disclosure protocol does not prescribe the release of sensitive information, such as security related information and trade secrets or scientific, technical, commercial, financial or labour relations information.

4.6 Additional/Other matters

4.6.1 Import/Export

BWXT Medical routinely imports and exports nuclear and nuclear-related dual-use items as part of its operations. These transactions are governed by BWXT Medical's Import and Export Controls Program. The Import and Export Controls Program meets the regulatory requirements of the CNSC, as defined in the Nuclear Safety and Control Act (NSCA)[1] and the associated Nuclear Non-proliferation Import and Export Control Regulations[29], and of Global Affairs Canada (GAC), as defined in Canada's Export and Import Permits Act[38] and associated regulations.

BWXT Medical has applied for a general Export License from the CNSC to permit the export of nuclear substances with atomic numbers 3-87. When necessary, BWXT Medical obtains individual export approvals from the CNSC and/or GAC following the processes outlined in BWXT Medical's Import and Export Controls Program. As applicable, BWXT Medical uses the GAC General Export Permits (GEP-43 and/or GEP-44. GEP-43 and GEP-44 are only used in conjunction with a CNSC export license.

5.0 CONCLUSIONS

As discussed in this CMD, BWXT Medical has a management system that meets all applicable regulatory requirements and addresses all CNSC safety and control areas. This Management System is based on the established Nordion Management System for Safety. The Management System is comprised of programs, procedures and training to protect employees, the environment and our communities against environmental, health and safety hazards.

BWXT Medical is committed to continuous improvement of its Management System and programs. BWXT Medical expects to maintain radiation exposures well below dose limits, and keep environmental emissions and public doses at small fractions of regulatory limits.

The licence application, supplemental information related to the application, and this written submission demonstrate that BWXT Medical is qualified to undertake the licensed activities and that adequate provisions will be made, for the protection of the environment, employees and the public.

6.0 REFERENCES

Table 8: Reference Documents

Reference	Title
[1]	Nuclear Safety and Control Act
[2]	CSA N286-12, Management System Requirements for Nuclear Facilities
[3]	REGDOC-2.2.2 (2016), Personnel Training, Version 2
[4]	Canada Labour Code II
[5]	SOR/2000-209, Nuclear Security Regulations
[6]	REGDOC-3.1.2 (2018), Reporting Requirements, Volume I:Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills
[7]	CSA N393-13, Fire Protection for Facilities that Process, Handle or Store Nuclear Substances.
[8]	CSA B51-14, Boiler, Pressure Vessel and Pressure Piping Code
[9]	NBC-2015, National Building Code 2015
[10]	NFC-2015, National Fire Code 2015
[11]	SOR/2000-203, CNSC Radiation Protection Regulations
[12]	G-129, CNSC Guidance Document, Keeping Radiation Exposures and Doses “As Low As Reasonably Achievable”
[13]	G-228 (2001), Developing and Using Action Levels
[14]	Canada Occupational Health and Safety Regulations
[15]	REGDOC 2.9.1(2017), CNSC Environmental Protection Policies, Programs and Procedures
[16]	CSA N288.1-14, Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluent for Normal Operation of Nuclear Facilities
[17]	CSA N288.4-10, Environmental Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills
[18]	CSA N288.5-11, Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills
[19]	CSA N288.6-12, Environmental Risk Assessment at Class 1 Nuclear Facilities and Uranium Mines and Mills

Reference	Title
[20]	CSA N288.8-17, Establishing and Implementing Action Levels for Releases to the Environment from Nuclear Facilities
[21]	REGDOC 2.10.1(2017), Nuclear Emergency Preparedness and Response
[22]	Environmental Protection Act
[23]	Transportation of Dangerous Goods
[24]	G-206 (2000), CNSC Regulatory Guide. Financial Guarantees for the Decommissioning of Licenced Activities
[25]	G-219 (2000), Decommissioning Planning for Licensed Activities
[26]	CSA N294-09, Decommissioning of Facilities Containing Nuclear Substances
[27]	REGDOC 2.12.3 (2013), Security of Nuclear Substances: Sealed Sources and Category I, II, and III Nuclear Substances
[28]	SOR/2000-202, General Nuclear Safety and Control Regulations
[29]	SOR/2000-210, Nuclear Non-Proliferation Import and Export Control Regulations
[30]	REGDOC 2.13.1 (2018), Safeguards and Nuclear Material Accountancy
[31]	SOR/2015-145, CNSC Regulation: Packaging and Transport of Nuclear Substances Regulations
[32]	IAEA Regulations for the Safe Transport of Radioactive Material (2018)
[33]	US Department of Transport 49 CFR
[34]	US Nuclear Regulatory Commission 10 CFR Part 71
[35]	SOR/2003-212, CNSC Nuclear Safety Commission Cost Recovery Fees Regulations
[36]	Human Pathogens and Toxins Act
[37]	REGDOC 3.2.1 (2018), Public Information and Disclosure
[38]	Export and Import Permits Act

Glossary

AECL	Atomic Energy of Canada Ltd.
ALARA	As Low As Reasonably Achievable
AMU	Atomic mass unit
Bq	Becquerel
CAD	Charcoal Adsorption Devices
CAPA	Corrective Action Preventative Action
CCAB	Canadian Council for Aboriginal Business
CF	Change Form
CNSC	Canadian Nuclear Safety Commission
COI	Communities of Interest
CRA	Canada Revenue Agency
CSA	Canadian Standards Association
DOT	Department of Transportation
DRL	Derived Release Limit
EHS	Environment, Health and Safety
EMS	Environmental Management System
EOC	Emergency On Call
EQMS	Electronic Quality Management System
ER	Emergency Response
ERP	Emergency Response Plans
ESDC	Employment and Social Development Canada
FSAR	Final Safety Analysis Report
GAC	Global Affairs Canada
GBq	Gigabecquerel
GEP	General Export Permit
HAZMAT	Hazardous Materials
HEGS	High Energy Gamma Source
HEPA	High Efficiency Particulate Air
I-125	Iodine-125
I-131	Iodine-131
IAEA	International Atomic Energy Agency
In-111	Indium-111
KOB	Kanata Operations Building
KRMF	Kanata Radiopharmaceutical Manufacturing Facility
LCH	Licence Conditions Handbook
MBA	Material Balance Area
MCA	Multi Channel Analyzer
MECP	Ministry of the Environment, Conservation and Parks
MeV	Mega electron-volt
Mo-99	Molybdenum-99
Mrem	Millirem
mSv	MilliSievert
NEW	Nuclear Energy Worker
NMPF	Nuclear Medicine Production Facility
NRU	National Research Universal
NSCA	Nuclear Safety and Control Act
NVS	Nuclear Ventilation System
OPEX	Operating Experience
OSLD	Optically Stimulated Luminescent Dosimeter
PAR	Progressive Aboriginal Relations
PDP	Preliminary Decommissioning Plan
PIDPIE	Public Information & Disclosure Program and Indigenous Engagement
PPE	Personal Protective Equipment

QA	Quality Assurance
RAM	Radioactive Material
RIR	Radiation Incident Report
RP	Radiation Protection
SAT	Systematic Approach to Training
TLD	Personnel Dosimeter
SCA	Safety and Control Area
WSIB	Workplace Safety Insurance Board
Sr-90	Strontium-90
TI	Transportation Index
TLD	Thermo-Luminescent Dosimeter (Personnel Dosimeter)
WSIB	Workplace Safety and Insurance Board
Xe-133	Xenon-133
Xe-135	Xenon-135
Xe-135m	Xenon-135metastable (short lived)
Y-90	Yttrium -90